**This Zoom Transcript has not been edited for content and grammar**

**Day 1 Part 1**

93

01:42:45.260 --> 01:43:11.450

Wasatch-1: alright welcome everyone. Thank you for making the trip in and being here for today, and thank you to all the virtual folks on with us today as well. My name is Eric Marshall. I'm the executive director of the partnership for Dscsa governance. If you are not familiar. Pdg, is a public private partnership with FDA, dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the Us.

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01:43:11.450 --> 01:43:18.049

Wasatch-1: You can learn more about Pdg. By visiting our website and our Pdg blueprint for interoperability at Dscsa governance org

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01:43:18.392 --> 01:43:36.179

Wasatch-1: we are super excited to be Co. Hosting this meeting here today with FDA. This is an opportunity for public and private stakeholders to come together and support their continued implementation of the Dsa systems and processes. Over the next 2 days you'll hear from trade associations, industry members, and other stakeholders

96

01:43:36.190 --> 01:43:41.070

Wasatch-1: as well as others, as we seek to better understand the current state of Dscsa stabilization.

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01:43:41.650 --> 01:43:49.819

Wasatch-1: We encourage you to engage openly and constructively in this dialogue as we all work toward our shared goal of supply, chain security and patient safety.

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01:43:50.970 --> 01:44:02.059

Wasatch-1: Please do note that this meeting is being recorded. A video recording transcript and written summary will be posted to the Pdg website and emailed to all attendees in the coming weeks

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01:44:02.540 --> 01:44:18.310

Wasatch-1: before we jump into the real substance. I want to do a couple of quick housekeeping items for those of you who are in person. If you've not been with us in this case before. You'll note that the restrooms are outside of the suite. Women's restrooms are in the near hallway, men's restrooms in the far hallway, down past the elevator bank.

100

01:44:18.572 --> 01:44:39.020

Wasatch-1: If you need to step out and need quiet space at any point. There are a couple of phone booths just outside of the room. You can also check at the front desk at any point for extra space or anything else that you might need. And finally, there are drinks. There's a couple of hiding fridges under the 2 big TV screens feel free to help themselves to that break as well.

101

01:44:40.147 --> 01:44:45.692

Wasatch-1: For our virtual participants. I want to give a particular thank you for joining us and being with us online.

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01:44:46.560 --> 01:45:03.920

Wasatch-1: from the beginning, we we really sought to make sure that this is a meeting that was open and accessible to as many stakeholders from as many sizes and backgrounds as possible. And so your participation virtually is critical. Here we're gonna seek to make your experience as equivalent to being in the room as possible.

103

01:45:04.250 --> 01:45:22.019

Wasatch-1: you are automatically muted. If at any point we open it up to public comment or conversation. You can feel free to use the raise hand function, and we'll bring you off mute. However, we'll do most of our audience engagement and question answer through Slider, which some of you may be familiar with, and we'll run through it second, with a couple of example questions.

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01:45:22.020 --> 01:45:39.719

Wasatch-1: But that should be a good opportunity for everyone in room and on screen to do. QA. And participate in the audience engagement. Please do use that. QA. Function throughout our sessions. Even if you don't have a question, it has an upvote option where you can help us bring the most popular questions to the top of that list.

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01:45:40.450 --> 01:46:04.830

Wasatch-1: Also, please note, if you're online with us, virtually, there is a different zoom link for each day. So the zoom link you are logged into today is not the same one to use. Tomorrow you should have separate invites, but it is a different link tomorrow. Please do note that finally, if you have any technical challenges during the the session feel free to use the QA function in the Zoom app or email admin at members Dscsa governance org

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01:46:08.713 --> 01:46:37.610

Wasatch-1: before we jump in. I do. Wanna give just a big thank you to our steering committee, the agenda. The content here over the next 2 days was jointly developed by FDA and Pdg. I won't run you through the full list of names. You can see them on the screen here, but it's a big. Thank you to a number of folks from FDA and our Pdg. Board for helping develop the content and agenda here for the next 2 days as I often say, with these everything that goes well. The next 2 days credit goes to these folks in the effort they put into this anything that doesn't go

107

01:46:37.970 --> 01:46:39.230

Wasatch-1: free to talk to me about

108

01:46:42.180 --> 01:46:58.749

Wasatch-1: Also, I think folks have hopefully seen the agenda, but just a quick rundown of what we'll cover here the next 2 days we'll do a little bit of landscaping today among FDA and Pdg. And then most of the conversation today will really manufacture the wholesaler section of the supply chain.

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01:46:58.920 --> 01:47:10.989

Wasatch-1: Tomorrow we will turn much more of our focus to the wholesaler to dispenser section of the supply chain and some wrap up conversations and reactions later in the day from State Regulators and Dr. Vermont and myself.

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01:47:15.350 --> 01:47:39.589

Wasatch-1: as I mentioned we're gonna use the slide oh, function or app that. Many of you have maybe used to do audience engagement, and again, the QA. For our panels throughout this meeting. And so with that we want to do just a couple of questions here to get things started and going. So 1st question fairly easy. One, what is the Dsc. If you're in person or online, you can scan the QR code.

111

01:47:39.590 --> 01:47:49.430

Wasatch-1: If you have the app, it may open an app, but it should just pop up the browser with the question available there, John, when I click through to the result, see if people are starting to figure it out there.

112

01:47:50.000 --> 01:47:51.450

Wasatch-1: Oh, wow! Everybody got right.

113

01:47:52.020 --> 01:47:56.089

Wasatch-1: I thought we'd have at least a few comedians there, and there we go.

114

01:47:58.730 --> 01:48:00.369

Wasatch-1: Okay.

115

01:48:00.756 --> 01:48:02.830

Wasatch-1: I'll just try to be closer here.

116

01:48:10.070 --> 01:48:16.449

Wasatch-1: Alright. We'll get on to a couple of more serious ones here to start off the conversation, John, if you want to flip to the next one.

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01:48:16.770 --> 01:48:24.589

Wasatch-1: So this is a little bit more of a serious question. Which of the following activities the stabilization period allowed your organization to focus on?

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01:49:12.010 --> 01:49:41.709

Wasatch-1: I see more eyes turning back up toward me so not a big surprise here, right? I think everybody is using these for a lot of these purposes. And not a lot of folks saying they were completely ready last November. Right? And I think that's telling of the conversation that we're gonna have here over the next couple of days where the focus will be right, a lot of improvement that we've seen and dated connections data starting to flow. But a lot of work still to be done on the data quality side. Right? I think that's gonna be a big theme that we hear over the next 2 days.

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01:49:42.590 --> 01:49:49.330

Wasatch-1: We want to flip to the next one. We just have one more here just again to get folks comfortable with using this here over the next couple of sessions.

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01:49:49.590 --> 01:50:02.980

Wasatch-1: Which of the following, do you believe is the greatest barrier to stabilization? So a little bit of the flip side of how you've been using it? What what remains the big barrier in us getting to stabilization here over the remaining stabilization period

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01:50:35.270 --> 01:50:55.970

Wasatch-1: again, not surprising that we see a little bit of everything here but a heavy emphasis. Right? I think folks who've been in some of these conversations over the past year the past several months, right? Data data. There's a big emphasis on that right now, and a big point of emphasis. So thank you again. Main point. There was. Just get folks comfortable using the app again. We'll use this for the QA. Throughout. So please do keep that

122

01:50:56.080 --> 01:51:18.220

Wasatch-1: move into the panels. With that I want to formally open the meeting by inviting Jacqueline Corgan Karai to provide introductory marks on behalf of FDA. Dr. Corgan Karai is the principal Deputy Center Director and FDA Center for drug evaluation and research more commonly known as cedar. And we're super happy to have her here today. With us. Please join me in welcoming Dr. Corgan. Correct.

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01:51:24.550 --> 01:51:28.130

Wasatch-1: I have to bring this down. Can you hear me in the back? Okay, great.

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01:51:28.150 --> 01:51:38.609

Wasatch-1: So thank you. Thank you for coming here this afternoon for those online. We're really excited about this meeting. This is our 1st day of a two-day meeting in which we really want to engage on

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01:51:38.720 --> 01:51:40.950

Wasatch-1: Dsa before I start

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01:51:41.400 --> 01:51:42.070

Wasatch-1: organizers

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01:51:43.830 --> 01:52:07.800

Wasatch-1: governance. This is a great venue. Thank you for hosting us and for partnering with us on this important, and I think the way we've incorporated our virtual participants will allow for maximum participation. I also want to recognize FDA's Dse team. They put a lot of work and dedication into this, as many of you know, if you've ever done a public meeting, it looks easier than it is.

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01:52:08.310 --> 01:52:15.790

Wasatch-1: So I really want to, and thank also of our speakers and panelists who are going to come here and share their experiences and really

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01:52:16.190 --> 01:52:19.579

Wasatch-1: going. But most of all, I want everyone to participate here.

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01:52:19.660 --> 01:52:30.100

Wasatch-1: I was just very interested to see the slide. Poll, and still see 25% answered. That regulatory uncertainty was part of the issue. And so we want to solve that problem

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01:52:30.110 --> 01:52:32.060

Wasatch-1: over the next.

132

01:52:32.120 --> 01:52:34.190

Wasatch-1: the end of the stabilization period.

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01:52:34.330 --> 01:52:41.559

Wasatch-1: I know you all know that over the last decades us supply chain is increasingly complex. It really reaches beyond our work.

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01:52:41.840 --> 01:52:52.480

Wasatch-1: and there's a lot of threats to the supply chain integrity, counterfeiting cargo, theft and introduction. Unfortunately, of unimproved and substandard drugs that can cause patient harm.

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01:52:52.880 --> 01:53:10.710

Wasatch-1: So we really need to protect our supply chain. And as the agency continues Dsa implementation in the next decade our public health mission remains constant to protect consumers from harmful and unsafe drugs. And I know you share that vision and dedication with us.

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01:53:10.870 --> 01:53:18.339

Wasatch-1: So we've made considerable progress in securing the supply chain. But of course there's still work to be done. And that's why we're here today.

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01:53:18.450 --> 01:53:32.539

Wasatch-1: This is really a meeting for industry, FDA and others to tell us about. How is it going? How is that implementation progress? Where are you in the stabilization period? We're now about midway through that period.

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01:53:32.970 --> 01:53:40.590

Wasatch-1: As you know, it was about it last summer that we said we were going to do this one year stabilization period, because we did recognize that the

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01:53:41.510 --> 01:53:54.270

Wasatch-1: and more work to be done for you to troubleshoot and implement and mature your interoperable electronic system and processes. So that ends on November 27.th I'm sure it's all in your calendars

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01:53:54.530 --> 01:53:58.500

Wasatch-1: we do expect at that time you'll be ready to to

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01:53:58.540 --> 01:54:02.650

Wasatch-1: use your validated interoperable system and processes to manage

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01:54:02.720 --> 01:54:15.520

Wasatch-1: products and data ensure, continue continuity of the supply chain and product availability to patients. I will emphasize. We are not going to extend the stabilization period beyond November

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01:54:16.350 --> 01:54:25.909

Wasatch-1: now we did gather a lot of feedback. I know most of you will. You'll hear a little bit about the docket, and that we recently reopened the docket to get additional feedback

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01:54:26.280 --> 01:54:33.920

Wasatch-1: in addition, as an outcome of that feedback. On June 12, th many of you are aware we issued an exception to Small.

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01:54:34.410 --> 01:54:42.759

Wasatch-1: and we're applicable, their trading partners through November 2720, 26. So we have extended their stabilization period again.

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01:54:43.370 --> 01:54:43.800

Wasatch-1: Period!

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01:54:43.970 --> 01:54:47.969

Wasatch-1: Sit back. It's a period to be proactive and and come into

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01:54:49.140 --> 01:55:09.130

Wasatch-1: so a small dispenser for those who are not familiar as a company which owns a dispenser as 25 fewer full time employees, licenses, pharmacists, or qualified as pharmacy technicians, technicians. Now we know that these pharmacies are often located in rural areas or other areas, and we wanted to ensure patient access.

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01:55:09.330 --> 01:55:15.800

Wasatch-1: So it's really our commitment to integrate stakeholder feedback and make sure we're putting patients first.st

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01:55:16.210 --> 01:55:23.550

Wasatch-1: So this 2 year time will stabilize operations and allow them to fully implement drug distribution, and we'll continue to work

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01:55:26.130 --> 01:55:34.099

Wasatch-1: so trading partners that do not qualify for the limited small dispenser exception. And I'm sure that's many of you who are today.

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01:55:34.619 --> 01:55:42.880

Wasatch-1: We you may request a waiver or exception from these requirements, but keep in mind that the agency does expect you to continue

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01:55:43.690 --> 01:55:50.810

Wasatch-1: to meet requirements even after you put that waiver in. We have to look at it. We have to decide whether we can approve it.

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01:55:51.480 --> 01:56:04.980

Wasatch-1: So we have accomplished so much. But we're not really done yet. Right? We're going to transition out of the stabilization period, and it's important to continue to monitor readiness and work collaboratively, as our focus shifts to the path ahead

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01:56:05.030 --> 01:56:07.079

Wasatch-1: after November 2024,

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01:56:07.440 --> 01:56:14.619

Wasatch-1: and, as I said, we reopen that. Rfi, so keep your feedback coming, and and even if there's not an Rfi, we will.

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01:56:14.920 --> 01:56:17.189

Wasatch-1: as we move beyond November

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01:56:17.200 --> 01:56:23.379

Wasatch-1: into December and January to keep telling us what's working? What's not? What advice do you need from us?

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01:56:23.590 --> 01:56:33.049

Wasatch-1: So I applaud all your dedication. I know it's been a lot of work. Obviously we set the standards, but you are sort of tasked with implementing them, and that's probably the hardest work.

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01:56:33.130 --> 01:56:41.769

Wasatch-1: We all want to ensure reliable access to prescription drugs while assuring continued distribution. So thank you again for joining our site. It'd be great

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01:56:41.850 --> 01:56:45.480

Wasatch-1: agenda. And I look forward to these discussions. Thank you.

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01:56:55.650 --> 01:57:03.430

Wasatch-1: So over the last 2 years there's been a lot of discussion, I think, about readiness. How are we coming on? Readiness prepared

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01:57:03.690 --> 01:57:15.660

Wasatch-1: stabilization? Right? We talk a lot about, how are we progressing toward the end goal? I'm not sure there's as consistent and understanding of what does that end goal look like in practical terms out there

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01:57:15.800 --> 01:57:39.360

Wasatch-1: practice. And so that's a big part of the conversation that we want to focus on here over the next couple of days. As well. Yeah, I think most of us would agree that whatever we were at in November of 2,023 probably was not stabilized right? We weren't there yet in November of 2,023, and I think there was broad support and recognition that it was beneficial to have that stabilization period. FDA issued

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01:57:39.692 --> 01:57:50.529

Wasatch-1: at the other end of the spectrum, though I think we also all recognize that even in a really well functioning system, we are never going to get to absolute perfection. Right? There's just too much data.

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01:57:50.530 --> 01:58:15.190

Wasatch-1: too much complexity to accept. Expect absolute perfection down to the individual unit level. With every piece of data. And so that raises the question, kind of then right of where, between those 2 end of the spectrums is stabilized. Right? What does it look like to be stabilized from a practical perspective. And I wanna offer maybe kind of a hypothesis to start the meeting that we may test over the next couple of days to see

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01:58:15.190 --> 01:58:16.609

Wasatch-1: see if this is how

168

01:58:16.610 --> 01:58:24.220

Wasatch-1: thinking about it again, not so much as a position, but as a hypothesis, to see if this is where the conversation goes the next couple of days.

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01:58:24.609 --> 01:58:48.370

Wasatch-1: So, as I said right, FDA issued that stabilization period that ran from last November to this November. But my hypothesis is that stabilization will not be done this November right? Stabilization is something that will continue well beyond November of 2024. You have the stabilization period that affords that regulatory flexibility. But stabilization activities are going to continue

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01:58:48.760 --> 01:59:09.389

Wasatch-1: beyond November of 2024. And even when we get to a well functioning spot, right? There's gonna be a level of continuous improvement that continues over time. And so as I think about the next couple of days. I'm gonna be listening and really watching for what does stabilization mean to people? From the perspective of systems and data starting to flow?

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01:59:09.840 --> 01:59:26.359

Wasatch-1: What does it mean from the perspective of data, quality and data starting to flow across those connections, our ability to have a efficient exception handling processes that allow that product to move in a way that does not disrupt product, access and patient access product.

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01:59:26.520 --> 01:59:54.239

Wasatch-1: What does it look like from a process perspective as people implement their processes, be able to use that data on the back end to actually achieve supply chain security. And what does it look like from a resource perspective, people having the right people with the right expertise to be able to do those activities. And so after that again, just maybe as an initial framework for people to think about. As we have this conversation the next couple of days about what is stabilization going to look like in practical terms on the ground.

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01:59:54.707 --> 02:00:10.539

Wasatch-1: And most importantly, what I think we'll hear is is that it all has to be grounded in collaboration and communication. And so I thank you all for being here to collaborate. We have an opportunity to really move the needle these next couple of days in terms of reaching the line. What that will look like

174

02:00:10.808 --> 02:00:25.549

Wasatch-1: and without a further delay I want to go ahead and turn into our a real substance here of the meeting, and so I'll 1st invite Abu Kundi to present. As many of you know, Abu Kundi is team lead in the office of drug security, integrity and response and Cedars office of compliance

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02:00:25.550 --> 02:00:36.640

Wasatch-1: from here out. We'll just call that oats, since there's a lot of them that we're going to be introducing and today she'll be providing some key takeaways from Da's recent Rfi on implementation of enhanced drug distribution security

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02:00:37.067 --> 02:00:39.989

Wasatch-1: as well as some other Dscsa updates

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02:00:49.960 --> 02:00:50.710

Wasatch-1: down.

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02:00:51.150 --> 02:00:53.719

Wasatch-1: How about right now, is this good? Can you all hear me?

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02:00:53.840 --> 02:00:54.790

Wasatch-1: Okay.

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02:00:55.360 --> 02:00:58.479

Wasatch-1: all right. Well, thank you, Eric. So much for that introduction.

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02:01:00.360 --> 02:01:03.699

Wasatch-1: I'll pause before I get started, and just say that

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02:01:03.900 --> 02:01:05.679

Wasatch-1: this is our

183

02:01:05.760 --> 02:01:08.289

Wasatch-1: I checked this morning. This is our 8th

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02:01:08.490 --> 02:01:10.479

Wasatch-1: Ds. Ussa. Public meeting.

185

02:01:10.700 --> 02:01:12.360

Wasatch-1: Our 1st one was

186

02:01:12.520 --> 02:01:14.329

Wasatch-1: May of 2014.

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02:01:15.380 --> 02:01:23.680

Wasatch-1: So you know, I just want to say, I know we have a lot of virtual attendees, whether you've been to all of those public meetings.

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02:01:23.840 --> 02:01:25.540

Wasatch-1: or this is your first.st

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02:01:26.010 --> 02:01:32.920

Wasatch-1: We're so happy to have your participation. Thank you so much. And I I echo the welcome that you've heard so far.

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02:01:33.290 --> 02:01:34.917

Wasatch-1: And with that.

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02:01:35.490 --> 02:01:39.919

Wasatch-1: enough sentimental dribble. Let's get to brass tacks next slide, please.

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02:01:40.860 --> 02:01:45.610

Wasatch-1: So we do this. In all of our presentations we have a disclaimer.

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02:01:46.037 --> 02:01:49.430

Wasatch-1: This is just a general overview of recent activity.

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02:01:49.470 --> 02:01:51.869

Wasatch-1: It's not intended to be comprehensive.

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02:01:52.430 --> 02:02:04.649

Wasatch-1: It couldn't be unless we had a week plus it doesn't constitute legal advice, and please refer to our guidelines, regulations, and law for specific information. I can.

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02:02:05.630 --> 02:02:06.330

Wasatch-1: That is.

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02:02:07.280 --> 02:02:10.990

Wasatch-1: but fda.gov is always a good place to start with that.

198

02:02:13.520 --> 02:02:14.535

Wasatch-1: Alright!

199

02:02:18.220 --> 02:02:21.869

Wasatch-1: Alright! Is this better? I think it is. I can hear it's much better. Okay.

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02:02:22.070 --> 02:02:22.959

Wasatch-1: all right.

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02:02:24.568 --> 02:02:31.130

Wasatch-1: Request for information. You heard a little bit about this so far, but we we issued a request for information.

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02:02:32.080 --> 02:02:39.159

Wasatch-1: The topic was implementing interoperable systems and processes for enhanced drug distribution security requirements

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02:02:39.630 --> 02:02:53.799

Wasatch-1: under section 5, 82 g. One of the Fd. And C. Act we often call those the enhanced requirements shorthand again open November 20.th It followed the issuance of our compliance policies. In the summer

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02:02:54.010 --> 02:03:10.780

Wasatch-1: we receive 17 comments, and, as Jacqueline noted, we have reopened it, we will post the updated Federal register notice on our Dsa pages. But I'll note that the existing Rfi. That's post online policy pages still guides you to the same docket.

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02:03:11.320 --> 02:03:22.270

Wasatch-1: So, and in consideration of of the public meeting today and tomorrow. That Rfide docket comment period is opened until September 12, th

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02:03:22.300 --> 02:03:24.080

Wasatch-1: 2024,

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02:03:25.220 --> 02:03:27.349

Wasatch-1: and with that next slide, please.

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02:03:31.060 --> 02:03:35.970

Wasatch-1: So this is a list of the questions that that were part of the Rfi.

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02:03:36.310 --> 02:03:44.110

Wasatch-1: And I have a feeling that we're going to in our discussions and panels really revisit some of these in more detail and with updated conversation.

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02:03:44.935 --> 02:03:47.370

Wasatch-1: So I will recap them here.

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02:03:47.640 --> 02:03:57.569

Wasatch-1: How are you using the stabilization period to troubleshoot and mature, secure electronic interoperable system processes for enhanced drug distribution security

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02:03:57.610 --> 02:03:59.740

Wasatch-1: with upstream training partners.

213

02:04:00.130 --> 02:04:08.980

Wasatch-1: And what about troubleshooting and maturing secure electronic interoperable systems and processes for enhanced drug distribution, secure downstream trading partners?

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02:04:09.570 --> 02:04:18.249

Wasatch-1: Question 2. What are the most significant challenges you have overcome? And what strategies did you employ to overcome those challenges?

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02:04:18.860 --> 02:04:24.830

Wasatch-1: Question 3. What aspects of your systems and processes have you successfully operationalized.

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02:04:25.060 --> 02:04:32.049

Wasatch-1: and what are your next steps in your strategy to ensure a successful implementation of enhanced requirements. By November

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02:04:33.240 --> 02:04:34.250

Wasatch-1: 5, please.

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02:04:36.170 --> 02:04:46.439

Wasatch-1: So in looking at these comments, there were a few key themes that that we're hit upon, and again, this is a generalized recap. We can't get

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02:04:46.570 --> 02:04:48.209

Wasatch-1: each one. But generally

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02:04:48.865 --> 02:04:54.320

Wasatch-1: the themes were technical implementation. So troubleshooting data, exchange and quality

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02:04:55.148 --> 02:04:58.500

Wasatch-1: trading partners are working through data quality issues.

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02:04:59.018 --> 02:05:04.720

Wasatch-1: There's still a need for best practices regarding data aggregation and standardizing data.

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02:05:05.627 --> 02:05:12.720

Wasatch-1: and trading partner connections, communications and interdependency. Eric touched on that just now in his his presentation. And and I believe

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02:05:12.730 --> 02:05:15.640

Wasatch-1: we'll be talking more about that in in the coming

225

02:05:16.040 --> 02:05:19.759

Wasatch-1: today and tomorrow. Readiness concerns

226

02:05:19.860 --> 02:05:24.619

Wasatch-1: lack of understanding and or processes to be Dscsa. Compliant

227

02:05:24.750 --> 02:05:28.080

Wasatch-1: costs and resources needed to be compliant.

228

02:05:28.390 --> 02:05:36.589

Wasatch-1: And then we will note that there was a comment on future concerns with regard to the Nbc format

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02:05:37.167 --> 02:05:41.940

Wasatch-1: and potentially how it could affect Ds U.S.A. information exchange

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02:05:43.440 --> 02:05:46.870

Wasatch-1: next slide, please. So we these are other themes that we heard

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02:05:47.060 --> 02:05:54.250

Wasatch-1: more clarity on the wear process that's waivers, exceptions, exemptions. Before the end of the stabilization period. I'll talk a little bit

232

02:05:54.300 --> 02:05:55.419

Wasatch-1: in a second.

233

02:05:55.690 --> 02:06:04.810

Wasatch-1: more stakeholder outreach education and collaboration both generally, and with a focus on how to become compliant via Csa. Requirements

234

02:06:05.420 --> 02:06:10.959

Wasatch-1: and additional guidance on how to confirm the identity and status of an authorized trading partner.

235

02:06:12.010 --> 02:06:22.599

Wasatch-1: So with that I will get into some recent recent activity. We we did post last week our small dispenser exemption. Jacqueline mentioned this.

236

02:06:24.100 --> 02:06:43.289

Wasatch-1: We issued exemptions from certain requirements of section 5, 82 of the Fdn. C. Act. It's pretty much the same requirements that were addressed in our compliance policies to small dispensers, and where applicable their trading partners. That's described in the exemption notification until November 2026.

237

02:06:43.710 --> 02:06:50.960

Wasatch-1: This provides small dispensers additional time to stabilize their operations, to fully implement enhanced requirements, indeed.

238

02:06:52.110 --> 02:07:00.800

Wasatch-1: and a dispenser is considered a small dispenser for the purpose of the exemptions, if, as of November 2720, 24.

239

02:07:00.830 --> 02:07:09.750

Wasatch-1: The corporate entity that owns the dispenser has 25, or fewer full time employees licensed as pharmacist or qualified as pharmacy technicians

240

02:07:10.760 --> 02:07:12.020

Wasatch-1: next slide, please.

241

02:07:12.800 --> 02:07:20.800

Wasatch-1: So with that announcement, we also provided some reminders and additional instruction on

242

02:07:20.840 --> 02:07:31.889

Wasatch-1: submitting waiver and exemption requests so trading partners. And we know that's a good chunk of the supply chain that do not qualify for the small dispenser exemptions, and are unable to meet

243

02:07:31.920 --> 02:07:33.829

Wasatch-1: the enhanced requirements.

244

02:07:34.322 --> 02:07:38.129

Wasatch-1: May request a waiver or exemption from those requirements.

245

02:07:38.532 --> 02:07:45.390

Wasatch-1: Although those requests can be submitted at any time, we recommend that trading partners submit them to us by August

246

02:07:45.590 --> 02:07:46.439

Wasatch-1: this year.

247

02:07:46.780 --> 02:07:50.510

Wasatch-1: We cannot guarantee that we will grant or deny

248

02:07:50.650 --> 02:07:53.600

Wasatch-1: the request, but we're we're gonna try

249

02:07:54.547 --> 02:08:00.360

Wasatch-1: and a trading partner's obligation to comply with and enhanced requirements by November

250

02:08:00.380 --> 02:08:14.970

Wasatch-1: will not be paused or extended upon submission. A request while we're while we're reviewing your request, and our our response is pending the agency expects the trading partner to continue their efforts to meet the requirements

251

02:08:14.980 --> 02:08:18.030

Wasatch-1: until FDA has approved or denied the request.

252

02:08:19.400 --> 02:08:20.270

Wasatch-1: Okay.

253

02:08:21.070 --> 02:08:32.489

Wasatch-1: next slide, please. So normally. I quickly touch on this, but I know that there are a lot of new folks into in in the virtually attending. So I do want to take a moment to say that

254

02:08:33.038 --> 02:08:37.719

Wasatch-1: we have, FDA maintains a number of Dscsa Web pages.

255

02:08:37.750 --> 02:08:47.669

Wasatch-1: And if you're still getting your arms around Dsa, we really encourage you to go and visit it. It has a law. It's more than the 20 guidances we've issued

256

02:08:47.780 --> 02:08:49.599

Wasatch-1: links to information about

257

02:08:49.670 --> 02:08:56.250

Wasatch-1: all of the past 8 public meetings. We've had webinars outreach materials.

258

02:08:56.680 --> 02:09:07.869

Wasatch-1: It's a very good resource to learn more about the law, and then I'll specifically call out our we have a lawn policy pages with all of our regulatory documents.

259

02:09:08.534 --> 02:09:14.409

Wasatch-1: Links to regulations or proposed Regs guidance. Rfis. It's all there.

260

02:09:14.759 --> 02:09:26.939

Wasatch-1: And as I noted at the top. The link to the reopened Rfi. We'll post that on our landing page soon. But the docket link to the existing Rfi will take you

261

02:09:27.268 --> 02:09:28.610

Wasatch-1: and period as well. So

262

02:09:29.390 --> 02:09:42.360

Wasatch-1: with that I'm going to turn it over to Matt. He's ready. So Matt Price is the chair of Pdg's Board of Directors and the co-lead Pdg's Interoperability Committee.

263

02:09:42.420 --> 02:09:50.040

Wasatch-1: and he's going to share Pdg's perspectives on learnings and insights that they've gathered on the progress made during civilization period.

264

02:09:53.180 --> 02:09:57.316

Wasatch-1: I don't know if you want to use a mic stand. I was too short for this.

265

02:09:58.160 --> 02:10:00.000

Wasatch-1: Yeah, let's think of a

266

02:10:03.010 --> 02:10:16.700

Wasatch-1: so I thought it was either coincidental or it was ironic that we come here grappling with 2 key questions that parents around the country approaching summer break are grappling with as they plan out the road trips.

267

02:10:17.170 --> 02:10:18.589

Wasatch-1: Are we there yet?

268

02:10:18.910 --> 02:10:21.020

Wasatch-1: And how much farther

269

02:10:21.370 --> 02:10:36.109

Wasatch-1: the we find ourselves asking essentially the same thing, we get to the midway point of the stabilization period of this midway checkpoint. So where are we? And how much farther do we have to go. And that's what we're gonna consider today, we're gonna start with this

270

02:10:36.110 --> 02:10:51.930

Wasatch-1: conceptual representation of where we find ourselves. And this is this is based on the dis diffusion of innovations theory, the adoption curve when we're doing something new and we're implementing something new. And it largely applies to what we're doing

271

02:10:52.040 --> 02:11:00.560

Wasatch-1: for Dscsa. When you think about what I'll say. 4 key elements of Dscsa, at least from the Pdg blueprint stand.

272

02:11:00.810 --> 02:11:10.890

Wasatch-1: we have Ti exchange transactional information, exchange that data move for every transaction we have verification we have tracing.

273

02:11:10.900 --> 02:11:19.660

Wasatch-1: we have credentialing, and the reality is, all 4 of those find themselves at a different point on this curve, going from left to right

274

02:11:19.960 --> 02:11:45.889

Wasatch-1: to add complexity. Different sectors find themselves at different points on this curve in each of those areas to make it even more complex organizations within those sectors find themselves in different points, and to make it even more complex, some of our organizations find ourselves at different points on that curve. But the reality is interoperability is only operability.

275

02:11:46.040 --> 02:11:50.429

Wasatch-1: If all we care about is ourselves right, we have to do this

276

02:11:50.510 --> 02:12:12.880

Wasatch-1: together. Which is painful but true, we have to figure out a way. So we're gonna consider some things today, just from from really 2 sources, one, the Interoperability Committee itself from Pdg. We have had since the beginning of the stabilization period. We have monthly update meetings, but we transition the 1st part of meetings

277

02:12:12.880 --> 02:12:42.860

Wasatch-1: to a report out from each sector from different entities within those sectors specific to Pdg membership, though, and and we're gonna share some some output from that. There are some slides that have exact numbers, and I'm gonna ask you to ignore the numbers. When you consider the limitation of the the very narrow scope of who is responding to these. But think about it in terms of that adoption curve and ask the question, does it seem like we're moving from lower left

278

02:12:42.990 --> 02:12:51.259

Wasatch-1: to Upper right in these last 6 months, so that we contemplate the next 6 months that we have so just a few disclaimers to, that

279

02:12:51.540 --> 02:13:13.510

Wasatch-1: their summaries from a limited number of members only Pdg members were were part of this initial report out, and that we asked different individuals to share each month. So it's not even necessarily a checkpoint from exact individuals. This is the progress we made in this this month, and then, and so on, and so forth.

280

02:13:13.540 --> 02:13:30.930

Wasatch-1: and that these figures are intended to demonstrate qualitative progressions, not quantitative representations, and especially of the entire industry. So just please keep that in mind as we go through, because the reality is, this does seem like it's going in and out a little bit

281

02:13:33.670 --> 02:13:49.089

Wasatch-1: things. The reality is this is a a progression that it's it's something that takes takes time, and happens over time and not just boom all at once. And we're stabilized.

282

02:13:49.420 --> 02:13:56.469

Wasatch-1: Let's see. So yeah, we can go to the next slide. So these are, these are broken out by those sectors. And we're just going to give a

283

02:13:56.750 --> 02:14:24.290

Wasatch-1: to show that progression from lower left to upper right in each of the sectors for Pdg. Members at the start of stabilization as an example, manufacturers who shared offered that they were approximately 80 to 90% connected, or had those connections established with their downstream trading partners. Most recent updates, we have had those, some of those very ones report to being close to a hundred percent

284

02:14:24.290 --> 02:14:26.819

Wasatch-1: of establishing those connections.

285

02:14:26.900 --> 02:14:27.910

Wasatch-1: However.

286

02:14:28.280 --> 02:14:34.160

Wasatch-1: those are connections. Keep in mind the ability to transmit data, but not necessarily

287

02:14:34.240 --> 02:14:56.019

Wasatch-1: the the the ability to every single transaction, every single product, be passing along that debt, see that reflected in some of the other slides that we consider for P for Pdg wholesalers initially estimated, about 9 75 to 90% connections with upstream trading partners

288

02:14:56.330 --> 02:15:16.689

Wasatch-1: and not receiving Epsis data that is, live for every one of those transactions, or for every one of those trading partners. More recently, whereas we don't have quantitative numbers to demonstrate this. Generally speaking, the reports that we've gotten is has been an increase in that piece of the the actual data

289

02:15:16.690 --> 02:15:38.800

Wasatch-1: being transmitted for all purchase orders and product. So about 70% purchase orders, 65% of product. And the and the J generally, the biggest takeaway from our vantage point is those numbers seem to be increasing each month. So good news through stabilization. Next slide dispensers at the start of stabilization.

290

02:15:38.900 --> 02:15:51.859

Wasatch-1: not seeing much else's data. Not surprising right? So, but but starting to see it more, and it really being a mixed bag with regard to how complete that data is. And then

291

02:15:52.030 --> 02:16:02.629

Wasatch-1: also encouragingly, receiving reports from their major distributors that they're really committed to it. They're working on it, and they expect that to be happening soon.

292

02:16:02.980 --> 02:16:21.249

Wasatch-1: So we we jump forward now about 6 months concerns have been voiced that some are still struggling with Dscsa, especially smaller dispensers. I think you'll probably hear some of this, as we go through the panel discussions we have over the next 2 days, and struggling with reality.

293

02:16:21.380 --> 02:16:28.660

Wasatch-1: limited bandwidth and competing priorities. Improvements in onboarding were reported

294

02:16:28.990 --> 02:16:58.949

Wasatch-1: the establishing of those connections and then data slowly increasing along the way, and then issues with master data data inconsistency, and then at least a perceived lack of implementation progress, especially with smaller dispensers. And I think that's reflective, right in what have seen what the FDA is obviously seen with with a decision that they've made recently with regard to those small entities. Okay, next slide.

295

02:16:59.150 --> 02:17:16.330

Wasatch-1: And then solution providers, interesting things. We didn't have a lot from the beginning, we're especially focused on trading partners. But here's some notes from some of the most recent meetings that we've had with solution providers definitely seeing an increased number of companies exchanging data.

296

02:17:16.360 --> 02:17:19.800

Wasatch-1: That's good, right? As we progress through stabilization.

297

02:17:20.280 --> 02:17:21.860

Wasatch-1: Not as good

298

02:17:22.110 --> 02:17:27.830

Wasatch-1: overall quality of data, a bit. Poor opportunities for improvement

299

02:17:28.224 --> 02:17:50.300

Wasatch-1: another one exception, handling and management top of mind for a lot of us in this space, because we're already seeing and experiencing and and trying to resolve those exceptions, and we're not full blown yet, right when that when when that fire hose opens up, are we gonna be able to handle the output? And so that's been on top of mind. As as was reported.

300

02:17:50.450 --> 02:18:05.609

Wasatch-1: there were some reports of slower rate of onboarding and goal lives, and this was especially not too long after the stabilization period started like like proverbial feet were being taken off the gas pedal.

301

02:18:05.850 --> 02:18:13.040

Wasatch-1: But it seems like that has been improving. And then we thought this was interesting 1 1 that came out from our last

302

02:18:13.139 --> 02:18:21.600

Wasatch-1: meeting, our our last update solution, Provider commented that they've observed that onboarding generally goes well

303

02:18:21.930 --> 02:18:28.730

Wasatch-1: when the entities are adhering to the blueprint right? And that makes sense interoperability. We have to operate

304

02:18:28.920 --> 02:18:45.629

Wasatch-1: together with each other. So we have to speak the same language. We have to translate in the same methods and fashions. And so these are just some of those takeaways from the the implementation. Progress then, and now, at least from the perspective of the Pdg Interoperability Committee.

305

02:18:46.030 --> 02:18:52.930

Wasatch-1: Alright. Next slide. Now we get into the survey results. These are this is the survey that

306

02:18:53.040 --> 02:18:58.940

Wasatch-1: all of those who registered for this conference or this public meeting completed

307

02:18:59.520 --> 02:19:24.239

Wasatch-1: prior to coming here today. Just a few things to note there were 136 trading partners who registered for this meeting, and there were some multiple individuals from the same organizations. And so what we did as part of this data is, get rid of duplications. So we didn't have one entity who had lots of people responding and

308

02:19:24.280 --> 02:19:40.816

Wasatch-1: conflating the numbers and to the harm of another organization with just one. So we we got rid of those duplications. These are high level takeaways from the survey I have, I think, maybe, what? 10 more minutes or so.

309

02:19:41.830 --> 02:19:43.660

Wasatch-1: 15 or 20. Okay.

310

02:19:43.879 --> 02:19:53.920

Wasatch-1: I'm going to apologize in advance because we're going to blast through these slides. But here's here's the the assurance that I'll give you. There's going to be a much

311

02:19:54.070 --> 02:20:09.860

Wasatch-1: more detailed, quite frankly, a much better summary of the results of this survey that Pdg. Will be publishing and will be at at the very least posting on our website. I'm guessing, probably announcing that when that's ready, I encourage you to really

312

02:20:10.120 --> 02:20:12.640

Wasatch-1: take a look at it, because

313

02:20:12.930 --> 02:20:18.699

Wasatch-1: there are a lot of numbers that are given. What we want to make sure that everybody understands is what they're seeing

314

02:20:19.300 --> 02:20:25.459

Wasatch-1: and what they're not seeing. What you're not seeing is a complete representation of all of industry.

315

02:20:25.650 --> 02:20:27.330

Wasatch-1: What you are seeing

316

02:20:27.540 --> 02:20:36.829

Wasatch-1: is are the responses from 136 different organizations or, yeah, organizations

317

02:20:37.110 --> 02:20:38.100

Wasatch-1: that

318

02:20:38.510 --> 02:20:49.559

Wasatch-1: chose to respond, that are probably here at the table because they maybe have, may have been actively involved in this. It doesn't necessarily. In fact, it doesn't represent

319

02:20:49.840 --> 02:21:14.470

Wasatch-1: the feedback from all those who didn't respond. So I just say that because as we go through this, you're gonna see numbers and percentages. Keep in mind what it is, a number or a percentage representing. So these these represent those respondents, the different sectors. They come from lots of manufacturers and pharmacies, wholesale distributors, as we would expect, we we appreciate it.

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02:21:14.470 --> 02:21:21.200

Wasatch-1: having some repackature and reverse distributor and third-party logistic provider responses as well. So these are the numbers

321

02:21:21.240 --> 02:21:27.690

Wasatch-1: again, these slides would be available, too, if you want to take a closer look after. But if we want to go to the next slide.

322

02:21:28.260 --> 02:21:35.340

Wasatch-1: This is on a scale of one to 5 5 being, I am so competent, one being

323

02:21:35.570 --> 02:21:39.150

Wasatch-1: Lord have mercy, I am not confident at all.

324

02:21:39.210 --> 02:21:53.299

Wasatch-1: But these were these were responses to to various questions, the 1st one, how confident are you that unit level, tracing systems and processes of trading partners you purchase from

325

02:21:53.330 --> 02:22:08.419

Wasatch-1: will be stabilized by November. So obviously we would expect the manufacturer is not purchasing, so they're not gonna answer that one. But when you look at this you have varying degrees, and it tends to slide down farther away. You get from the manufacturer.

326

02:22:09.070 --> 02:22:20.269

Wasatch-1: In. In many of these you'll see that the second one that your organization's your organization's unit level tracing systems and processes will be stabilized by November.

327

02:22:20.690 --> 02:22:48.580

Wasatch-1: Again, you have leaning toward really competent, not absolutely, but making progress toward that. And then the last one on this side, that unit level, tracing systems of trading partners you sell to will be stabilized, and you see those numbers come down even more you. You'll see that bump and repackages at 4.3, 3. But remember how many repackages did we have to respond?

328

02:22:49.890 --> 02:23:00.639

Wasatch-1: Just what? 3 to 5, maybe. So, just just keep that in mind, as you see. Look, look at the individual sector, but not necessarily. An absolute comparison.

329

02:23:00.910 --> 02:23:02.649

Wasatch-1: Okay, next slide, please.

330

02:23:03.110 --> 02:23:10.469

Wasatch-1: So this one, when purchasing product from approximately what percentage of your suppliers?

331

02:23:10.480 --> 02:23:21.040

Wasatch-1: Are you routinely receiving complete serialized data? And and this side just to show? So this is the the bars themselves are the percentage of those responding

332

02:23:21.250 --> 02:23:32.349

Wasatch-1: to that that question that way. But the scale off to the side is so, for example, repackager 67% of the repackages. So I think it's 3. So 2 of 3

333

02:23:32.460 --> 02:23:38.729

Wasatch-1: said that they are. They're approximating 95 to a hundred percent

334

02:23:38.770 --> 02:23:45.539

Wasatch-1: of their suppliers are routinely providing them that data does that make sense.

335

02:23:45.880 --> 02:24:12.709

Wasatch-1: So just just kind of think through that. Because I had to wrap really wrap my head double percentizing. Some of these was difficult. But then you'll see, as you get into wholesale distributors. You see some of that dropping down, especially when you think about the number of suppliers that a wholesale distributor or a pharmacy will have that when you go that scale to what? What is the percentage of those that are sending you

336

02:24:12.770 --> 02:24:20.190

Wasatch-1: data? It it drops like this. And so I guess the takeaway from the slide, like many of these slides, is, we still have work to do

337

02:24:20.530 --> 02:24:22.789

Wasatch-1: like like we're working toward

338

02:24:23.150 --> 02:24:30.050

Wasatch-1: stabilization. But we're not stabilized. And we still have a lot to do in the next 6 months. Okay, next slide.

339

02:24:30.650 --> 02:24:39.480

Wasatch-1: So this is this has to do with the product. So we have some suppliers, but not all that are providing that data. What about for the product? Because what we've heard is.

340

02:24:39.560 --> 02:24:43.030

Wasatch-1: there are different levels or degrees of phase in

341

02:24:43.170 --> 02:25:08.869

Wasatch-1: even with trading partners. So you may be getting, I may be getting data for one product from an upstream trading partner, but the 99 other I'm getting, not yet. And and so that's that's what this is really representing here. It shows that percentage of the different sectors for repackagers, wholesale distributors, and pharmacies. So it shows that there is still a fairly significant amount of product

342

02:25:09.120 --> 02:25:13.350

Wasatch-1: that we're not receiving that data for yet, and it it would make sense.

343

02:25:13.540 --> 02:25:19.550

Wasatch-1: especially for the pharmacy to be receiving less, because if if the wholesale distributors are not yet.

344

02:25:19.590 --> 02:25:26.609

Wasatch-1: and the concept of pseudo commissioning hasn't been fully implemented yet for all products at the wholesale district.

345

02:25:26.690 --> 02:25:30.379

Wasatch-1: You can see that. Drop off or understand that going to pharmacies

346

02:25:30.540 --> 02:25:32.460

Wasatch-1: all right next slide, please.

347

02:25:32.980 --> 02:25:39.609

Wasatch-1: So this question, are you actively assessing the quality and accuracy of serialized data?

348

02:25:40.000 --> 02:26:07.939

Wasatch-1: No means naughty? No, no means or red red means? No. And so we see, even even with those different entities within the supply chain from repackages, distributors, different types of pharmacies. There are different degrees of confirmation of that quality and accuracy when it comes in which which is really a big deal. Right? We're keeping virtual and physical worlds in sync. That's that's a goal of

349

02:26:07.940 --> 02:26:19.480

Wasatch-1: Dsca. Are we confirming that? Especially as we get start getting lots of product that now is is experiencing something it never did before aggregation.

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02:26:19.630 --> 02:26:26.119

Wasatch-1: And so that's key for us to all. Work together interoperably, to keep physical and virtual and sane.

351

02:26:26.350 --> 02:26:28.779

Wasatch-1: Next slide, please.

352

02:26:28.800 --> 02:26:36.829

Wasatch-1: So to approximately what percent of your customers? Are you routinely providing complete serialized data?

353

02:26:37.570 --> 02:26:47.810

Wasatch-1: So look at this. It would make sense that manufacturers would be really, really amping up. So we have what we have about 80%

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02:26:48.140 --> 02:26:49.390

Wasatch-1: that are

355

02:26:49.890 --> 02:27:00.149

Wasatch-1: sending to 80% of their downstream trading partners, that is, customers or wholesale distributors, wholesale distributors.

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02:27:00.670 --> 02:27:08.669

Wasatch-1: Not as much right. We have about an equal 80 to 84% who are receiving it from less than 40%

357

02:27:08.720 --> 02:27:25.700

Wasatch-1: of their customers. And so it's just interesting to see, because we also have a lot to ramp up to do in the in the last 6 months from a wholesale distributor standpoint to be sending that data out consistently, routinely and completely as well.

358

02:27:26.110 --> 02:27:28.129

Wasatch-1: Next slide, please.

359

02:27:28.360 --> 02:27:36.039

Wasatch-1: So for approximately, what percent of product you sell are you routinely providing complete serialized data?

360

02:27:36.180 --> 02:27:51.510

Wasatch-1: And we see similar right to that last slide, the amount of product that's going out. So we have in this slide 60% of the manufacturers who responded, said that they are providing that for 95 to 100% of their product

361

02:27:51.770 --> 02:27:53.539

Wasatch-1: really good to see right

362

02:27:53.690 --> 02:27:56.279

Wasatch-1: with wholesale distributors.

363

02:27:56.290 --> 02:28:01.880

Wasatch-1: Wholesale distributors have a little bit of a different take on it with about

364

02:28:02.210 --> 02:28:07.399

Wasatch-1: 75. What? Yeah, about 75% who are saying that they receive it

365

02:28:07.750 --> 02:28:20.669

Wasatch-1: blah from less than 40. And so why? Why is that? Again, think back to what this represents, what it doesn't represent? It represents those manufacturers who responded to this survey, who quite frankly.

366

02:28:20.980 --> 02:28:24.819

Wasatch-1: have been at lots of these tables for the last 10 years.

367

02:28:25.340 --> 02:28:45.000

Wasatch-1: These these wholesale distributors and I speak for a wholesale distributor. We we buy from other entities other than just those at the table. So you can see. Don't just look at the numbers. What do the numbers tell you? They're they're insights. They're not absolute. And so these these numbers from the survey continue to reflect that

368

02:28:45.510 --> 02:28:53.119

Wasatch-1: okay, next slide, are you actively assessing the quality and accuracy of serialized data that you send.

369

02:28:53.790 --> 02:29:07.170

Wasatch-1: So manufacturers of 8.7 7% said no. The vast majority said, yes, the handful of of repackagers and 3rd party solution. Providers said yes, overwhelmingly.

370

02:29:07.320 --> 02:29:21.929

Wasatch-1: Remember, they can all fit on my one hand, though how many different ones responded to the survey, and then wholesale distributors, you know, about 40, 40, no, 40%, no 60%. Yes, that may also.

371

02:29:22.415 --> 02:29:33.089

Wasatch-1: can. Encapsulate the fact that not all data is being received for all products and from all suppliers. But just to give you a feel for the the respondents.

372

02:29:33.310 --> 02:29:34.940

Wasatch-1: all right. Next slide.

373

02:29:37.830 --> 02:29:45.230

Wasatch-1: Do you have interoperable electronic systems and processes to verify product identifiers.

374

02:29:46.820 --> 02:30:00.148

Wasatch-1: I was a bit surprised to see how much red was on this. But I mean for for some pharmacies, you know, you know, maybe we can. We can understand that there's still 23% wholesale distributors.

375

02:30:01.170 --> 02:30:15.170

Wasatch-1: my personal opinion a little bit concerning we? We need to. We need to have those bars the farther up the supply chain as green as we possibly can, especially because a lot of us who responded are actively engaged. So

376

02:30:15.743 --> 02:30:19.176

Wasatch-1: that's the number. Those are the numbers for verification.

377

02:30:19.700 --> 02:30:23.350

Wasatch-1: And then I think, what? How many more slides do we have?

378

02:30:23.750 --> 02:30:25.490

Wasatch-1: Okay, next slide

379

02:30:27.400 --> 02:30:35.199

Wasatch-1: do you have? It's cut off. Do you have interoperable electronic systems and processes to all facilitate the gap information

380

02:30:35.200 --> 02:30:58.499

Wasatch-1: tracing, how? How able are you to to capture the data that's needed to to represent that products, virtual supply chain. This shows the the answers to that. So we still have some in just about all cases, with the exception of chain pharmacies, as reported here, that are still saying no, but largely

381

02:30:58.500 --> 02:31:10.950

Wasatch-1: making a lot of improvements in that that area and the ability to create that virtual or collection of popcorn that trails from dispenser back to manufacturer

382

02:31:11.280 --> 02:31:12.480

Wasatch-1: next slide.

383

02:31:14.420 --> 02:31:30.730

Wasatch-1: So what do you believe is the biggest risk to your organization's ability to stabilize its systems and processes for unit level tracking. And so there were. There were several fields and questions on the survey that were really free text. And so

384

02:31:30.730 --> 02:31:46.629

Wasatch-1: what the data analysts did was take those and identify key themes. And so these were some of the key themes that were identified for manufacturers. Lack of feedback. And I think that's something that we have heard I know in Pdg. And in other venues, too, that

385

02:31:46.750 --> 02:31:51.549

Wasatch-1: that manufacturers are sending data, but they're receiving no feedback

386

02:31:51.800 --> 02:32:01.969

Wasatch-1: back. And I know, for example, like Arthy Nagaraj, Mike Mazer are a couple that have said that even the little bit of data that or feedback they get back

387

02:32:01.980 --> 02:32:11.840

Wasatch-1: has been super valuable, super helpful to them. And so we think about that in these next 6 months, the more we can do it, even if it's just on a limited basis.

388

02:32:11.870 --> 02:32:16.390

Wasatch-1: the better off we we are probably all going to be by sharing that

389

02:32:16.590 --> 02:32:26.480

Wasatch-1: also. Management of exceptions is a big risk as highlighted there. Many concerns with the availability of resources.

390

02:32:26.720 --> 02:32:34.910

Wasatch-1: and many indicated that they don't foresee risks. So we we published those because they were submitted

391

02:32:35.030 --> 02:32:36.800

Wasatch-1: wholesale distributors.

392

02:32:37.990 --> 02:32:46.590

Wasatch-1: the amount of data flowing from manufacturers that was a predominant concern the readiness for all of that

393

02:32:46.790 --> 02:33:11.070

Wasatch-1: and and then several noted that it's it's limited to a small number of manufacturers, but it exists nonetheless, and then dispensers a predominant concern among chains and hospitals that upstream trading partners, or upstream readiness of their suppliers, and then concern about data quality that they're receiving

394

02:33:11.440 --> 02:33:22.759

Wasatch-1: and independent pharmacies much more focused on competing business priorities. Again, some of the risks, the challenges that are faced by these different sectors next slide.

395

02:33:22.830 --> 02:33:39.490

Wasatch-1: What do you believe is the biggest risk to the industry's ability to stabilize its systems and processes for unit tracing again industry's ability, the top 3 in purple. These were the ones that resonated the most. We got the most

396

02:33:39.490 --> 02:33:55.060

Wasatch-1: responses that that fed into these things, uncertainty of their requirements, regulatory regulatory clarity, and trading partner, understanding. That was one of the themes that bubbled up to the top trading partner. Readiness.

397

02:33:55.190 --> 02:33:56.660

Wasatch-1: That was another one.

398

02:33:57.070 --> 02:34:08.249

Wasatch-1: Data, quality and exceptions. Those really represented the top 3 at least from the respondents to this survey, and some of the other things are noted there. Master data.

399

02:34:08.749 --> 02:34:19.539

Wasatch-1: approaches and methods for data exchange risk to patient access, and then time and resources that are needed to support this whole thing from start to finish.

400

02:34:20.090 --> 02:34:21.560

Wasatch-1: Next slide.

401

02:34:22.150 --> 02:34:26.980

Wasatch-1: What is the most important or beneficial action. The industry needs to take

402

02:34:27.130 --> 02:34:31.150

Wasatch-1: to stabilize systems and processes for unit level. Tracing

403

02:34:31.200 --> 02:34:33.489

Wasatch-1: again, look at the top. 3

404

02:34:33.530 --> 02:34:38.109

Wasatch-1: increased standardization of data exchange practices

405

02:34:38.790 --> 02:34:56.730

Wasatch-1: the a key to interoperability. Right? So that that's something that is very important and and beneficial. Obviously, increase downstream trader downstream, trading partner feedback on data quality received

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02:34:56.910 --> 02:35:00.489

Wasatch-1: and then test and improve data quality.

407

02:35:00.580 --> 02:35:20.570

Wasatch-1: Again, things that we need to do actions and steps that we need to take in these, especially next 6 months, and then you'll see some of the things on there. I won't read them all to you, but reasonably makes sense right that we would, we would expect these things to come back in responses and next slide.

408

02:35:20.680 --> 02:35:43.099

Wasatch-1: what is the most important beneficial action regulators need to take to stabilize systems and process just to clarify. This is not a question about regulatory actions. It's about actions that we're asking regulators, or we think regulators need to take, and I'm not gonna explain this one. The 1st 2

409

02:35:43.960 --> 02:35:49.569

Wasatch-1: start enforcing or auditing no more delays, followed by extend the stabilization period

410

02:35:51.030 --> 02:36:08.319

Wasatch-1: for the record. These were not my answers, but so these, these are the top things, and then more or clear guidance and willingness to answer questions, and and I would say probably is, and especially for those who haven't been. It's some of these tables that we have been at some of us, for

411

02:36:08.460 --> 02:36:18.589

Wasatch-1: I mean, Marianne. We've been for here for what? 2,008, 2,009 ish, basically. So yeah, some of those ones that are newer to these tables.

412

02:36:18.640 --> 02:36:20.779

Wasatch-1: And I think that's the last

413

02:36:21.600 --> 02:36:23.550

Wasatch-1: slide. So

414

02:36:23.730 --> 02:36:24.950

Wasatch-1: am I out of time.

415

02:36:25.630 --> 02:36:27.189

Wasatch-1: How much more time do I have?

416

02:36:28.430 --> 02:36:29.600

Wasatch-1: We're going against you on.

417

02:36:29.840 --> 02:36:31.780

Wasatch-1: Okay? So

418

02:36:32.030 --> 02:36:38.749

Wasatch-1: that, said I, I don't have any more slides to share, and we can open these to questions about any of this

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02:36:39.190 --> 02:36:50.419

Wasatch-1: again, like, I said, there will be a much deeper dive when it comes to the report that's that's written to share the results from this survey. But remember the the whole goal.

420

02:36:50.490 --> 02:36:58.760

Wasatch-1: The focus is that adoption curve? And are we moving in the right direction? Are we stagnant? And we're staying in the same place?

421

02:36:59.195 --> 02:37:09.579

Wasatch-1: Because we really don't have the luxury of time and ability to do that? Or are we reasonably making our way up to the upper right corner of that adoption, curve

422

02:37:09.660 --> 02:37:13.960

Wasatch-1: individually and collectively in the spirit of interoperability.

423

02:37:14.200 --> 02:37:15.020

Wasatch-1: So

424

02:37:15.190 --> 02:37:17.229

Wasatch-1: any questions, are we good?

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02:37:19.610 --> 02:37:23.556

Wasatch-1: Good! I suck the all the oxygen out of the room. Thank you.

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02:37:24.570 --> 02:37:25.880

Wasatch-1: Oh, thank you.

427

02:37:29.910 --> 02:37:56.730

Wasatch-1: So now we are gonna start transitioning into panel discussions our next couple of panels will seek to provide a broad perspective on stabilization across each sector, as we hear from trade associations with E within each sector, and our 1st panel is gonna focus on manufacturer perspectives as provided by several manufacturer trade associations. And so with that.

428

02:37:56.790 --> 02:38:11.570

Wasatch-1: I'd like to welcome our panelists, including Lisette Shields, regulatory counsel and FDA's office of drug security integrity and response, who will serve as the moderator of that session. Let's welcome, Lisa.

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02:38:16.890 --> 02:38:20.869

Wasatch-1: Thank you, Matt, I think. Do we have Gillian and Gil? Hi, Gillian.

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02:38:21.530 --> 02:38:24.709

Wasatch-1: if you wanna walk on up here and set up one of these seats.

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02:38:25.000 --> 02:38:27.649

Wasatch-1: And there's mics right there. Can everybody hear me? Okay.

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02:38:28.000 --> 02:38:29.070

Wasatch-1: okay.

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02:38:29.180 --> 02:38:48.289

Wasatch-1: thank you, Matt, for the introduction and welcome to those in the room and also in our virtual environment for attending this panel session. I am very happy today to be serving as your moderator for today, and as Matt had shared. The purpose of this panel session is to provide a broad perspective of the state of stabilization among the manufacturer.

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02:38:49.260 --> 02:38:58.429

Wasatch-1: So today we're very fortunate to have 4 wonderful panelists representing the manufacturer sector very excited to introduce them. For today

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02:38:58.490 --> 02:39:04.690

Wasatch-1: today we have Gillian Buckley from the pharmaceutical research and manufacturers of America.

436

02:39:04.810 --> 02:39:20.160

Wasatch-1: We have Alyssa Flores, who is one of our virtual panelists for today, from the biotechnology innovation organization. We also have Scott Kuzner from the Association for accessible medicines, and our 4th panelist is

437

02:39:20.940 --> 02:39:46.750

Wasatch-1: Gil Ross than Gil, who is also in person from the Pharma and Bio Pharma Outsourcing Association. Thank you so much for attending today, and also thank you for our virtual panelists for today. So to get us started for today, this panel session will be broken up into 2 parts. The 1st part, we will allow our panelists to provide a their perspective on the state of stabilization. All 4 of our panelists represent the manufacturer.

438

02:39:47.222 --> 02:40:16.310

Wasatch-1: The second part, we will transition over to A. QA. Session among our audience members, both in person and online. And I'd like to encourage all of you to use the QR code on this screen to submit your questions throughout this entire time. That'll help us easily transition over from the panel list presentations right into our QA. Session. So without further delay, I'd like to introduce Gillian Buckley to be our 1st presenter.

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02:40:16.530 --> 02:40:21.209

Wasatch-1: Thank you. We have both the great chiefs. Yeah, that's amazing. Gotcha.

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02:40:30.850 --> 02:40:37.559

Wasatch-1: Good morning. Good afternoon. My name is Gillian Buckley. I'm a senior director in science and regulatory

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02:40:37.920 --> 02:40:43.510

Wasatch-1: advocacy, and I'll be presenting feedback on the implementation of the Scsa

442

02:40:45.860 --> 02:41:13.969

Wasatch-1: alright. So I'm going over. Okay. Thank you. By way of introduction, Pharma represents the country's leading innovative bio pharmaceutical research which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2,000 pharma member companies have invested more than 1.2 trillion dollars in the search for new treatments and cures.

443

02:41:13.990 --> 02:41:19.700

Wasatch-1: including 100.8 billion dollars in 2022 alone.

444

02:41:20.380 --> 02:41:21.080

Wasatch-1: It's okay.

445

02:41:22.928 --> 02:41:30.731

Wasatch-1: Can I have the next as background. A common concern among Pharma members is that Dscsa

446

02:41:31.470 --> 02:41:34.839

Wasatch-1: preparedness is uneven across trading partners.

447

02:41:35.410 --> 02:41:45.659

Wasatch-1: The Dsa has interoperability requirements that depend on collaboration, communication, and alignment among trading partners.

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02:41:45.830 --> 02:41:48.550

Wasatch-1: Communication here referring to both

449

02:41:48.690 --> 02:41:53.180

Wasatch-1: downstream communication as from manufacturers to distributors

450

02:41:53.320 --> 02:41:59.660

Wasatch-1: and upstream communication as from dispensers to distributors or manufacturers.

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02:41:59.790 --> 02:42:10.770

Wasatch-1: and if the downstream partners are not receiving data from further upstream that will delay their ability to stabilize their systems. During the allocated time

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02:42:11.890 --> 02:42:16.910

Wasatch-1: Pharma members have used the 1st half of the stabilization period

453

02:42:16.950 --> 02:42:24.320

Wasatch-1: to work with trading partners, to develop systems and processes to meet the Dsa requirements.

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02:42:24.420 --> 02:42:26.220

Wasatch-1: These include

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02:42:26.550 --> 02:42:32.830

Wasatch-1: working with downstream partners to identify and correct problems with ethics, data sharing

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02:42:33.200 --> 02:42:38.729

Wasatch-1: and generally supporting trading partners to jointly implement Dsc.

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02:42:40.410 --> 02:42:47.749

Wasatch-1: Well, Pharma members report that they have systems and processes in place to meet the Sesa requirements.

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02:42:47.890 --> 02:43:02.620

Wasatch-1: They also report that some trading partners may not have the same level of readiness. For example, members have reported that not all trading partners are providing feedback on the competitiveness of data, exchange

459

02:43:03.770 --> 02:43:09.769

Wasatch-1: and data exchange being critical to develop all parties Dscsa systems.

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02:43:11.100 --> 02:43:29.319

Wasatch-1: We understand that not all partners are aware of how to manage data discrepancies, meaning that even if the technical solution may exist, the trading partner has not had sufficient experience with the process to execute it, or to handle inquiries from other trading partners.

461

02:43:30.100 --> 02:43:38.709

Wasatch-1: or, finally, in a position not all trading partners are in a position to accept serialized data at the package level.

462

02:43:39.894 --> 02:43:42.329

Wasatch-1: So can I have the next slide, please?

463

02:43:44.322 --> 02:43:45.710

Wasatch-1: As we know.

464

02:43:46.540 --> 02:43:53.640

Wasatch-1: there's limited time about 5 months left for all trading partners to prepare for Dscf.

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02:43:54.450 --> 02:44:05.010

Wasatch-1: In this time Pharma encourages FDA to promote readiness. Specifically, we would see this to mean that FDA should urge all trading partners

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02:44:05.050 --> 02:44:11.250

Wasatch-1: to use their remaining time to enhance collaboration and enable seamless data exchange

467

02:44:11.990 --> 02:44:16.649

Wasatch-1: for trading partners. This means having systems and processes

468

02:44:16.720 --> 02:44:18.320

Wasatch-1: for interoperable

469

02:44:18.400 --> 02:44:26.659

Wasatch-1: serialized data exchange and a process to provide feedback on the completeness of data exchanged.

470

02:44:27.790 --> 02:44:37.090

Wasatch-1: Trading partners need to establish a process to reconcile a physical product with its electronics, epics, data.

471

02:44:37.140 --> 02:44:44.350

Wasatch-1: and there's also a need to promptly notify manufacturers of data gaps and to collaborate on their correction.

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02:44:44.630 --> 02:44:59.009

Wasatch-1: And lastly, to ensure all downstream trading partners adopt these measures to achieve a stable system at scale, and in thinking about scale, it's important to consider

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02:44:59.300 --> 02:45:06.449

Wasatch-1: the resources required to handle inquiries from manufacturers and the resources required to correct

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02:45:06.500 --> 02:45:11.790

Wasatch-1: problems with data exchange and the resources needed to develop mature systems.

475

02:45:12.730 --> 02:45:18.799

Wasatch-1: Also, since trading partners should exchange serialized data at the package level

476

02:45:19.680 --> 02:45:22.049

Wasatch-1: during the stabilization period.

477

02:45:22.090 --> 02:45:33.960

Wasatch-1: We ask that FDA continue to highlight data aggregation as an essential tool for daily operations and use of the epic standard for data exchange.

478

02:45:34.720 --> 02:45:36.129

Wasatch-1: Next slide, please.

479

02:45:39.790 --> 02:45:47.330

Wasatch-1: Pharma, member companies believe that there will continue to be problems after the end of the stabilization period.

480

02:45:47.730 --> 02:45:52.700

Wasatch-1: Therefore, pharmace supports continued monitoring and risk-based enforcement.

481

02:45:53.840 --> 02:46:03.390

Wasatch-1: Briefly, we encourage the agency to continue to monitor implementation of Dscsa systems and processes for the remainder of the stabilization period.

482

02:46:03.990 --> 02:46:10.270

Wasatch-1: We ask that FDA publicly reinforce its risk-based approach to enforcement of Dsc.

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02:46:10.980 --> 02:46:16.379

Wasatch-1: There may continue to be a high volume of relatively minor errors. After

484

02:46:16.470 --> 02:46:22.660

Wasatch-1: November of 2024, and all parties will need some flexibility to handle these errors.

485

02:46:23.190 --> 02:46:33.860

Wasatch-1: A risk based approach to enforcement could help avoid a potential unintended effect of aggregating drug shortages or affecting patients at the pharmacy.

486

02:46:34.670 --> 02:46:35.980

Wasatch-1: For this reason

487

02:46:36.040 --> 02:46:43.430

Wasatch-1: Pharma further encourages FDA. To provide clarity on the process for waivers, exceptions, and exemptions.

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02:46:44.170 --> 02:46:53.039

Wasatch-1: Members appreciate the recent guidance on lease. They also expect a high volume of requests for waivers, exceptions, and exemptions

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02:46:53.920 --> 02:46:55.359

Wasatch-1: after the deadline

490

02:46:55.440 --> 02:47:00.590

Wasatch-1: and inability to respond to this volume of requests could disrupt the supply chain.

491

02:47:01.455 --> 02:47:16.779

Wasatch-1: They predict that FDA could be inundated with requests for Wes, and may need to allow trading partners to rely on submitted requests to allow for continued transactions while requests are brought, are pending with FDA

492

02:47:17.600 --> 02:47:18.430

Wasatch-1: next slide.

493

02:47:20.450 --> 02:47:29.329

Wasatch-1: Lastly, there'll be continued need for education and outreach Pharma supports the Dscsa portal on Cedar Nextgen

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02:47:29.360 --> 02:47:32.300

Wasatch-1: and its goal of facilitating communication.

495

02:47:33.189 --> 02:47:33.960

Wasatch-1: Among

496

02:47:34.550 --> 02:47:40.410

Wasatch-1: trading partners and FDA, when there's a recall or suspicion of an illegitimate product.

497

02:47:40.700 --> 02:47:47.210

Wasatch-1: With thanks to the agency for the useful published FAQ. On the portal and the reference guidance.

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02:47:47.350 --> 02:47:57.039

Wasatch-1: We would also acknowledge FDA's plan to publish a step-by-step tutorial on how to use the portal, which would be very helpful across supply chain partners.

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02:47:57.230 --> 02:48:06.900

Wasatch-1: So finally, we encourage FDA to issue this tutorial and to take further effort. Efforts to build competency among all supply chain partners.

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02:48:07.340 --> 02:48:12.260

Wasatch-1: And my last point involves verifying authorized trading partner status

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02:48:13.080 --> 02:48:19.139

Wasatch-1: Pharma members want to comply with the short turnaround time that Dsa gives

502

02:48:19.190 --> 02:48:22.940

Wasatch-1: to respond to requests from authorized trading partners.

503

02:48:23.060 --> 02:48:29.609

Wasatch-1: But we note that the authorization of indirect trading partners may be particularly difficult to discern.

504

02:48:30.655 --> 02:48:40.010

Wasatch-1: Pharma encourages FDA to provide guidance on how to verify the identity of authorized training partners under the food, drug and cosmetics.

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02:48:41.230 --> 02:48:42.310

Wasatch-1: that's all. Thank you.

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02:48:48.760 --> 02:48:52.339

Wasatch-1: Thank you so much, Jillian. You can come on over and sit back down if you'd like

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02:48:53.232 --> 02:48:55.909

Wasatch-1: our next presenter will be Alyssa, Florence.

508

02:48:57.910 --> 02:49:22.516

E'Lissa Flores: Hi, everybody! I am Lisa Flores. I am a director in the science and regulatory affairs at the Biotech Innovation Organization, also known as bio. If you're not familiar with bio we're the large. We're the world's largest Associ Advocacy Association representing biotech companies, state groups, academic and research Institutes across the Us. And 30 plus countries.

509

02:49:23.467 --> 02:49:42.229

E'Lissa Flores: So my presentation is very, very brief, and thank you so much. Gillian, for your presentation. So while our manufacturing committee doesn't have an official consensus update or position on this topic. The such the Smes we engage with have already engaged with

510

02:49:42.370 --> 02:49:54.970

E'Lissa Flores: Pharma and bio heavily like they heavily, you know, align with Pharma's presentation today, especially the outreach and so that's a very quick update I have for you all, but I wanted to, just, you know.

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02:49:55.030 --> 02:50:00.670

E'Lissa Flores: Say that there, if unofficially align with Bio's statements, so thank you for having me.

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02:50:03.390 --> 02:50:04.719

Wasatch-1: Thank you so much, Alyssa.

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02:50:04.770 --> 02:50:08.909

Wasatch-1: I am going to now. Turn it over to Scott Kuzner, who's going to share a few words.

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02:50:10.630 --> 02:50:12.767

Scott Kuzner: Alright. Thank you. Everyone. And

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02:50:13.710 --> 02:50:37.940

Scott Kuzner: I'm Scott Koosner, Senior Director of Sciences and Regulatory Affairs at the Association for Accessible Medicines. Am I'm filling in today for Brian Rezak, who ordinarily leads our efforts for Dscsa. He leads our working group. But I'm also a part of that as a staff member. So I know fairly well but definitely big shoes here to fill since Brian's been involved with Dscsa since it's inception.

516

02:50:38.532 --> 02:50:39.829

Scott Kuzner: Next slide, please.

517

02:50:41.704 --> 02:50:58.770

Scott Kuzner: So am for those of you. You're probably familiar with us, but if you're not we represent generic and biosimar medicines in the Us. Generic and bios. Similar products account for 90% of annual Us. Unit volume, but only 17 and a half percent of expenditures.

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02:50:59.831 --> 02:51:16.659

Scott Kuzner: Our members. Investment in Dscsa has been considerable. Our working group meets often. And we we're discussing this on a very frequent basis and following what's going on. Through these discussions we've learned that our members each, have complex ecosystems that are involved in all this

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02:51:17.500 --> 02:51:20.570

Scott Kuzner: and with respect to Dscsa.

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02:51:20.680 --> 02:51:33.159

Scott Kuzner: this level of unit volume up portends a similar share of data, exchange, enhanced verification, tracing activity, and so forth. That will go even beyond November 27, th 2024.

521

02:51:33.490 --> 02:51:35.039

Scott Kuzner: So next slide.

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02:51:36.250 --> 02:51:41.350

Scott Kuzner: So FDA and Pdg, actually back one more slide.

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02:51:41.860 --> 02:51:42.780

Scott Kuzner: There we go.

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02:51:45.160 --> 02:52:08.450

Scott Kuzner: appears to be a slide missing. But that's okay. So FDA, and Pdg provided some issues and questions that they like trade associations to address at this meeting. I'm gonna try to convey our members opinions to you on these topics. From our recent discussions. I'll know that these discussions with our members occurred prior to the release of FDA's policy on enforcement discretion for small dispensers last week.

525

02:52:09.280 --> 02:52:36.810

Scott Kuzner: So sort of 3 purposes of today's presentation are, gonna be 1st we wanna share the perspective of Am and its members regarding the implementation of the Dscsa data exchange requirements for November 2024. Secondly, we wanna share some trends on what Am and its members are seen during the data stabilization period. And 3, rd offer some brief recommendations to the FDA regarding preparations for November 2024.

526

02:52:37.163 --> 02:52:50.359

Scott Kuzner: So with enforcement discretion and the data stabilization period. Just a quick note that this has been in effect for 297 days. It has a hundred 63 to go until we get to November 27.th So

527

02:52:50.550 --> 02:52:53.759

Scott Kuzner: we say all that. Just to say that we're 2 thirds of the way

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02:52:53.900 --> 02:52:56.879

Scott Kuzner: through the data stabilization period today.

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02:52:56.900 --> 02:52:58.549

Scott Kuzner: Next slide, please.

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02:53:00.701 --> 02:53:07.209

Scott Kuzner: So what does this mean to Am and its members for Dscsa systems and processes to be stabilized?

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02:53:07.653 --> 02:53:10.200

Scott Kuzner: In terms of the perspective of our

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02:53:10.210 --> 02:53:33.559

Scott Kuzner: am manufacturers. Some of our members have expressed that for manufacturers our central task and stabilization has been to transmit our unit level data as part of our transaction information to our trade partners. And from that perspective of our survey for respondents, most of our members are near nearing, sending all Ti with unit level information.

533

02:53:33.870 --> 02:53:40.810

Scott Kuzner: One of our members expressed a view of the meaning of the stabilization. This way. We have the quote here on the screen.

534

02:53:40.880 --> 02:53:55.840

Scott Kuzner: To be stabilized would mean that we have reliable systems and processes to confidently exchange data with all trade partners and have trade partners receive all of it with a clear process for the resolution of data discrepancies.

535

02:53:56.030 --> 02:54:15.880

Scott Kuzner: So it's important to remember that in addition to complying with our requirements to include the requisite unit level data in all Ti to do this accurately, companies must integrate their Dscs a data into everyday systems and processes. For example, a few weeks ago our working group

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02:54:16.219 --> 02:54:33.860

Scott Kuzner: At Am. Hosted a meeting for employees of member companies dealing with data optimization how to improve data accuracy as we begin to receive information on discrepancies back from downstream companies. One of our goals for that meeting was to invite as many of the people within our member companies

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02:54:33.870 --> 02:54:42.369

Scott Kuzner: who have not been as involved with Dscsa implementation to become familiar with these efforts, and how they relate to their own responsibilities.

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02:54:42.450 --> 02:54:49.926

Scott Kuzner: The objective of this was to full is to learn how to fully integrate Dsc data into everyday business.

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02:54:50.340 --> 02:54:53.240

Scott Kuzner: and we believe that this is going to be an ongoing process.

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02:54:53.690 --> 02:55:03.770

Scott Kuzner: And so in doing so, we intend to move steadily towards the goal of achieving consistently higher integrity and accuracy of the Dsc data.

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02:55:04.160 --> 02:55:11.919

Scott Kuzner: Some of our members express the opinion that the Go live itself. Will tell us how stabilized we actually are in terms of quality.

542

02:55:13.126 --> 02:55:14.459

Scott Kuzner: Next slide.

543

02:55:17.653 --> 02:55:18.460

Scott Kuzner: so with

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02:55:18.810 --> 02:55:21.930

Scott Kuzner: tracking the stabilization progress.

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02:55:22.880 --> 02:55:26.760

Scott Kuzner: you know, in terms of the percent of onboarded trade partners for data exchange.

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02:55:26.780 --> 02:55:34.190

Scott Kuzner: This is where am started with trying to understand how far along our member companies were. And obviously.

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02:55:34.200 --> 02:55:48.839

Scott Kuzner: if you have not onboarded trade partners for data exchange, then you aren't gonna have exchanging, you won't be exchanging unit level data with them, at least not epcis data. As a stabilization

548

02:55:49.090 --> 02:56:06.559

Scott Kuzner: period has gone on. We believe a more meaningful way of measuring readiness is an estimating the percent of total transaction volumes where unit level data is sent in transactional information. The goal, of course, at go live, or before is 100%

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02:56:06.992 --> 02:56:23.359

Scott Kuzner: of transactions for all companies. Now, ultimately, Dsc. Success will depend on the integrity and accuracy of the data the trade partners exchange. So couple of questions that come to mind. That are really important for this are, you know one.

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02:56:23.410 --> 02:56:29.579

Scott Kuzner: What is the data error rate today? And 2. What will the data error rate be on November 28.th

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02:56:29.890 --> 02:56:35.500

Scott Kuzner: And the answer to both of those today is that we don't know yet what the error rates are.

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02:56:35.999 --> 02:56:54.160

Scott Kuzner: Because this kind of information is not yet been available during the stabilization period. Most reporting on data from trade partners has been about whether or not the unit data was included in the Ti and not on the accuracy of the data reflecting the physical products that are being shipped.

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02:56:54.564 --> 02:56:58.830

Scott Kuzner: Although we believe the accuracy of the data will begin to be available soon.

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02:56:58.870 --> 02:57:09.200

Scott Kuzner: The ability to discover and resolve data. Discrepancies between the data and physical products is key to character is is a key characteristic of stabilization.

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02:57:09.608 --> 02:57:31.510

Scott Kuzner: Putting this in context for the 4.5 billion units per year. That means that even a 2% error rate means 90 million data discrepancies will occur each year. A 5% error rate means that, you know, 225 million of these discrepancies will occur each year. So just just some numbers to put this in perspective when we're talking about error rates.

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02:57:32.000 --> 02:57:57.960

Scott Kuzner: So we bring this up because the quality and accuracy of the data once known may require our members to pivot quickly, to adjust their resources and staff differently, depending on the number of reported discrepancies and resulting investigations. So what will happen to otherwise good product with incorrect Ti unit level data after November 27th

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02:57:58.560 --> 02:58:07.310

Scott Kuzner: am, is consistently maintained over the years that data error rates may never reach a perfect level meaning stabilization will be an ongoing process.

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02:58:07.975 --> 02:58:28.234

Scott Kuzner: S, you know, to summarize some of the general comments our members provided their perspectives on. You know how stabilization is progressing. Generally. Most of them believe that we're not, you know, there yet as an industry. But there has been some good progress made during the data stabilization period, as much higher volumes of products

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02:58:28.650 --> 02:58:34.290

Scott Kuzner: are transacted with unit level data included in the Ti. Then, even a few months ago.

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02:58:34.988 --> 02:58:47.880

Scott Kuzner: additionally, the enforcement discretion period has enabled many of our members to sell through the non aggregated products that were in our distribution centers through 2023 and we thank FDA for that opportunity

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02:58:48.020 --> 02:58:49.369

Scott Kuzner: next slide.

562

02:58:51.493 --> 02:59:01.310

Scott Kuzner: So we wanted to include the general thinking our members have used to delineate and plan for the discovery and resolution of the data discrepancies.

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02:59:02.780 --> 02:59:15.041

Scott Kuzner: you know, we've asked, are these discoveries before the 1st change of ownership within our ecosystem by us? This also acknowledges that our members ecosystems may include contract manufacturers

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02:59:15.470 --> 02:59:23.200

Scott Kuzner: who could be serializing and aggregating our products, and 3 pls to make the data association between the units

565

02:59:23.230 --> 02:59:25.789

Scott Kuzner: in a transaction and that shipment

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02:59:26.289 --> 02:59:35.589

Scott Kuzner: minimizing any errors or issues in these processes, especially recurring issues, is key to minimizing the data discrepancies downstream.

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02:59:37.140 --> 02:59:43.989

Scott Kuzner: in terms of the question, are these discovered after the 1st change of ownership by another part partner

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02:59:44.470 --> 02:59:55.344

Scott Kuzner: we believe that reporting on these discrepancies between trade partners should contain standardized elements included in prompt communications to allow faster, more efficient investigations.

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02:59:56.020 --> 03:00:04.300

Scott Kuzner: In addition to unit information, this should be include a delivery number or po number to identify a specific transaction

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03:00:05.290 --> 03:00:06.630

Scott Kuzner: next slide, please.

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03:00:08.700 --> 03:00:10.100

Scott Kuzner: So in terms of

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03:00:10.150 --> 03:00:17.218

Scott Kuzner: demographics characteristics of trade partners not yet on boarder for unit level data exchange.

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03:00:17.720 --> 03:00:28.950

Scott Kuzner: our members did not cite any sector although a lack of contact is reported to occur more in smaller companies, with fewer people and fewer it resources.

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03:00:29.392 --> 03:00:36.459

Scott Kuzner: Our members have been surprised that scorecarding results are as different from one trade partner to trade partner

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03:00:36.640 --> 03:00:38.800

Scott Kuzner: as they have been so far

576

03:00:39.010 --> 03:00:56.379

Scott Kuzner: given that the systems and processes they use to generate and send data to different trade partners are the same. Our members stated that one trade partner does not reflect another. In a similar business or sector. Companies are performing differently and stabilization from one to another.

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03:00:56.925 --> 03:00:59.050

Scott Kuzner: Next slide, please. And I believe we're getting

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03:00:59.320 --> 03:01:02.420

Scott Kuzner: towards our last slide of the presentation.

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03:01:03.116 --> 03:01:22.809

Scott Kuzner: So we had a few recommendations for FDA between now and November 27th first, st I just wanna state am supports. Pdsa's recommendation that FDA provide written communication to all trade partners within each sector of the Us. Supply chain. We recommend that this communication should list the 2023

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03:01:22.840 --> 03:01:40.689

Scott Kuzner: Dsca. Unit level requirements, this that the sector must achieve. It should also list the penalties for trade partners who do not comply. Our second recommendation is that we believe the FDA should prepare for a possible increase of waiver exceptions. Exemption requests

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03:01:40.920 --> 03:01:50.810

Scott Kuzner: that we need to be answered by the 27th of November. Industry should file any WE requests involving go live to FDA as early as possible.

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03:01:51.070 --> 03:01:57.170

Scott Kuzner: and, thirdly, some of our members are considering having a final date on Board trade partners.

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03:01:57.200 --> 03:02:11.109

Scott Kuzner: after which their Ti data would be placed in a data portal to be made available to these trade partners until they're going to be on board using epcis and in this state would be determined by the individual company as trade partners.

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03:02:11.560 --> 03:02:22.239

Scott Kuzner: Yeah, I'll cut myself off there, if you like. There's a trial tree. Keep it in the firewalls. But we wanna thank Fd. A. And Pdg. For holding this public meeting and for the opportunity to present today. Thanks.

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03:02:29.690 --> 03:02:32.180

Wasatch-1: Thank you so much, Scott. Gil.

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03:02:32.480 --> 03:02:34.130

Wasatch-1: the floor is yours

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03:02:34.370 --> 03:02:35.140

Wasatch-1: like up there.

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03:02:38.800 --> 03:02:40.640

Wasatch-1: Howdy? Can everybody hear me? Okay.

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03:02:41.250 --> 03:03:00.419

Wasatch-1: good. My name's Gil Roth. I run a trade association called the Pharma and Biofarma Outsourcing Association, and I have no slides. Sorry. Our group represents contract manufacturing organizations development services companies and companies that are providing packaging services for their customers.

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03:03:00.500 --> 03:03:04.899

Wasatch-1: I want to thank Pdg. And FDA for inviting us to to speak today.

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03:03:04.990 --> 03:03:11.819

Wasatch-1: Cdmos are usually overlooked in a lot of manufacturing and distribution, related issues. And

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03:03:12.240 --> 03:03:23.240

Wasatch-1: well, to that end. We're not actually officially trading partners in Dscsa. So I'm gonna have a bit of perspective than our partners here in the Association world.

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03:03:23.350 --> 03:03:38.210

Wasatch-1: I do want to talk a little about the CD Mo. Sector and our group. We're founded in 2,014 by me, we have about 40 CD. Mo. Member companies, about 20 something affiliate members which are companies that provide goods and services to our sector.

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03:03:38.910 --> 03:03:45.069

Wasatch-1: Our companies manufacture and help development services for drug companies don't know how

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03:03:45.250 --> 03:03:58.790

Wasatch-1: familiar everybody is with this part of the space. But our companies handle large and small molecule products, generic and innovator. Some of our members are global multinationals, others are single site facilities.

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03:03:58.900 --> 03:04:04.820

Wasatch-1: Most of them are pure play Cdmos, which is to say, they don't own any drugs of their own.

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03:04:04.830 --> 03:04:20.339

Wasatch-1: Others are part of larger pharma companies like Pfizer Center, one which is one of our members. They're part of Pfizer, but they do manufacturing for other companies. So it's really an ecosystem that touches about 40% of all doses distributed in the US.

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03:04:20.980 --> 03:04:34.410

Wasatch-1: But again, we're not actually a trading partner under Dsc, so what our members are doing is providing manufacturing and packaging and serialization services for a lot of the other companies and parties in this room.

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03:04:34.880 --> 03:04:41.989

Wasatch-1: but to that extent we do not have full transparency into our customers, queries and what they

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03:04:42.000 --> 03:04:45.430

Wasatch-1: for right now, how they're responding to exceptions, etc.

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03:04:45.570 --> 03:04:51.909

Wasatch-1: It's only in instances where they have to contact the CD Mo. To reconcile an issue that we would know how things are going.

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03:04:52.808 --> 03:04:57.599

Wasatch-1: I reached out to our 40 member companies. Not a lot of them

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03:04:57.950 --> 03:05:16.069

Wasatch-1: had much to say about the stabilization period. I'll I'll be blunt. One of them put it this way. The biggest observation we've noted is that it appears some of our clients which is to say, the actual license holders of trust have just begun. Looking at their data for the 1st time. Recently

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03:05:16.180 --> 03:05:26.749

Wasatch-1: a small but noticeable increase in comments and questions has started to occur. But for us it's been a small spike in support needs and otherwise it's generally been a non-event for us.

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03:05:26.940 --> 03:05:34.069

Wasatch-1: and that jives with a few other companies that wrote back. Basically, I forwarded this quote. Most of them said, Yeah, that kind of captures where we are

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03:05:34.400 --> 03:05:43.800

Wasatch-1: not seeing an awful lot, but getting the impression that while we've been serializing and sending the data to companies, large and small, all of our our customers.

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03:05:45.200 --> 03:05:58.220

Wasatch-1: either the customers have not been assessing the data necessarily, or it has not been fed downstream, as some of our previous speakers mentioned, including the survey from Pdg. That went into

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03:05:58.390 --> 03:06:03.070

Wasatch-1: how this data quality is being assessed. So another

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03:06:03.230 --> 03:06:15.139

Wasatch-1: member that actually sent back a full response got back, saying, they're also not seeing issues. But they did want to comment on the 3 lead points that were meant to be answered here in terms of what stabilization is going to mean.

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03:06:15.460 --> 03:06:23.110

Wasatch-1: For that 1st question. In your view, what does it mean for interoperable Dscs, a systems and processes to be stabilized? They wrote.

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03:06:23.230 --> 03:06:37.329

Wasatch-1: stabilizing the implementation of the Scsa means investing in and maintaining mature it. Infrastructure as well as deploying best practices to ensure the data received, held and provided is accurate and secure.

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03:06:38.020 --> 03:06:54.870

Wasatch-1: How do they feel stabilizations, progressing demographics, etc. They said. Dsc, systems and processes can be considered stabilized as we've talked about here. The majority of organizations find a way to be compliant with Dscsa through their standard procedures.

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03:06:55.350 --> 03:07:03.620

Wasatch-1: The longer procedures in place, and the more consistency a company can demonstrate, the more stable they'd be considered. And this includes exception. Handling.

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03:07:03.900 --> 03:07:13.959

Wasatch-1: They think stabilization is progressing well from this CD Mo. Perspective, and that the majority of their customers have a pretty good understanding of Dscsa and how to implement it.

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03:07:14.440 --> 03:07:18.950

Wasatch-1: As far as potential actions, industry, or regulators need to promptly take.

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03:07:19.610 --> 03:07:30.440

Wasatch-1: I know FDA never likes hearing this. But we do believe it would be somewhat helpful if Regulators could publish additional information that would somewhat more concise to ease in the interpretations of regulations.

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03:07:30.510 --> 03:07:50.109

Wasatch-1: One specific area that could be of significant support would be the implementation of universal data standards and protocols for electronic data exchange across the entire supply chain. This would reduce errors, and in addition, the industry as a whole should increase training to improve compliance and the overall knowledge base within the supply chain.

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03:07:51.030 --> 03:08:04.589

Wasatch-1: and we have one other member. As I mentioned, we have affiliates, and those are companies that provide goods and services to the Cdmos sector, and one of our affiliates is actually in the room with us today. A gentleman named Carl Axura from I'm gonna say, global pharmaceutical consulting

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03:08:05.540 --> 03:08:20.204

Wasatch-1: advisor. And Carl sent over a couple of comments, he will add more during the QA. Session as he is want to do. But one of Carl's big concerns is that quality agreements between the license holder and the CD. Mo.

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03:08:20.550 --> 03:08:29.300

Wasatch-1: May not be. They exist in every Cdmo relationship with a customer, but they may not be up to date when it comes to

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03:08:29.650 --> 03:08:53.840

Wasatch-1: well, as he puts it, they may not reflect alignment of Dscsa data, data, handling systems and processes. And this is particularly important for that timeline for responding to queries that come up the supply chain. Because keep in mind the Cdmos don't get those queries directly they have to go upstream to the manufacturer and the manufacturer, if they can't figure it out on their side, are going to reach out to the Cdmos.

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03:08:54.030 --> 03:08:57.770

Wasatch-1: We know there's a time deadline for responding to these things.

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03:08:57.920 --> 03:09:03.200

Wasatch-1: But the quality agreement between customer and CD Mo. May not reflect that, and

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03:09:04.150 --> 03:09:12.440

Wasatch-1: that could create problems when it comes to the CD. Mo. Responding in a timely manner that allows the manufacturer to respond in a timely manner further down the supply chain.

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03:09:12.720 --> 03:09:18.450

Wasatch-1: and again Carl can expand on this from some of his own experiences with customers and the Cdmos they work with.

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03:09:18.590 --> 03:09:28.260

Wasatch-1: But he also added that customers and Cdm. Should build out their data accessibility systems and processes and stress test them. During the stabilization period.

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03:09:28.270 --> 03:09:37.480

Wasatch-1: We brought this up with our serialization working group that 1st came together in 2, 1516, as we were in that implementation phase for manufacturers.

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03:09:38.000 --> 03:09:40.370

Wasatch-1: that working group they

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03:09:40.470 --> 03:09:43.190

Wasatch-1: push back to customers, saying, Hey, you should

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03:09:43.300 --> 03:09:52.430

Wasatch-1: kind of test the data that we're sending. And and we know everybody's got different levels of resources. And maybe some of their second 3rd tier customer size

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03:09:52.980 --> 03:09:59.700

Wasatch-1: either doesn't have the resources to do this or doesn't know what stress testing would really entail from a CD Mo perspective. We can't.

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03:10:00.100 --> 03:10:02.560

Wasatch-1: We can't push this forward.

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03:10:03.840 --> 03:10:19.619

Wasatch-1: The phrase I came up with when we 1st started this association 10 years ago, was Cdmos. Don't drive the bus, but the bus doesn't go anywhere without us, so we can't be the ones telling you how to be compliant on that part of the supply chain.

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03:10:19.740 --> 03:10:22.780

Wasatch-1: But the actual trading partners do need to.

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03:10:22.820 --> 03:10:31.159

Wasatch-1: If they find issues with data quality that, you know traces back to the Cdmos, feed it to us so that we're able to to update these things more.

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03:10:31.750 --> 03:10:44.250

Wasatch-1: A few of Carl's other comments, which I will include here were that customers seemed happy just to know that the CD. Mo. Could pass data to the Data Repository like a tracing Rfx. L. Syst, etc.

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03:10:44.460 --> 03:10:45.250

Wasatch-1: and that

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03:10:45.490 --> 03:10:48.020

Wasatch-1: as such the

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03:10:48.420 --> 03:11:01.329

Wasatch-1: customer, the manufacturer, may have kind of stayed on the sidelines while the Cdmos Tech team talked with the solution provider may not have been involved and really understood what was going on when it came to serialization and data.

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03:11:01.680 --> 03:11:02.940

Wasatch-1: And until

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03:11:03.040 --> 03:11:09.900

Wasatch-1: downstream testing of live data to wholesalers occurred, Cdmos customers didn't really have to look too deeply into the data

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03:11:10.240 --> 03:11:13.939

Wasatch-1: leading to potential problems as we get through this last phase.

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03:11:14.961 --> 03:11:26.529

Wasatch-1: and as I mentioned, the second and 3rd tier customer side may not be resourced well enough to really get this as opposed to some of those larger companies in the Pdg survey that are really

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03:11:26.780 --> 03:11:31.050

Wasatch-1: driving the degree of of sophistication when it comes to serialization.

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03:11:32.340 --> 03:11:57.940

Wasatch-1: That's what I've got. I'm looking forward to bringing back observations and questions to our members. I will say should have said in advance, I am not the technical guy. So I know questions are gonna start showing up in that slide. Oh, thing! If I have to say I'm sorry I can't answer that. Please bear with me, but I will bring those questions back to our members, and I hope be able to get some information back to you guys. So Gil Roth, Pbo. Thank you very much for your time.

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03:12:04.270 --> 03:12:16.599

Wasatch-1: Thank you so much, Gil. So at this point in this panel session, we are going to start transitioning over to our QA. So we are going to start collecting questions from our audience members, both in person and online.

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03:12:16.980 --> 03:12:24.383

Wasatch-1: before, as we start collecting those and those questions start trickling in. I do have a question for each of our 4 panelists. I'm sorry.

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03:12:26.580 --> 03:12:33.490

Wasatch-1: Our 1st question for each of our panelists. And I'm just gonna run down the line is what are some reoccurring questions that

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03:12:33.510 --> 03:12:44.399

Wasatch-1: you have seen and addressed in these past ones during the stabilization period, and because, Julian, you were our 1st presenter, you had the longest break. I will. I will ask you first.st

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03:12:45.445 --> 03:12:48.810

Wasatch-1: I'm not sure. Yes, yeah. There we go sit on here.

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03:12:49.520 --> 03:12:52.542

Wasatch-1: I actually have not been at farming for

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03:12:52.940 --> 03:12:56.900

Wasatch-1: more for about 6 weeks, so I have a feeling I,

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03:12:56.980 --> 03:13:03.929

Wasatch-1: our head of my office is here, and you might have a better sense of what's been happening over the last

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03:13:04.160 --> 03:13:06.760

Wasatch-1: stabilization period of the kinds of questions.

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03:13:08.450 --> 03:13:10.700

Wasatch-1: Oh, sure you can come on. I'm here.

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03:13:15.216 --> 03:13:18.143

Wasatch-1: Yeah, have a seat. We have plenty of room up here.

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03:13:22.230 --> 03:13:29.416

Wasatch-1: Yeah, I think nothing really different than all we offer today. I think it's

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03:13:30.220 --> 03:13:32.340

Wasatch-1: you know, all around.

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03:13:34.310 --> 03:13:43.310

Wasatch-1: you know, waivers, exemptions, data how to comply. And I think one of the things we hear the most often

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03:13:43.590 --> 03:13:51.700

Wasatch-1: like, if you know, downstream suppliers do not provide us with data. Sometimes it's not easy to

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03:13:51.760 --> 03:13:53.010

Wasatch-1: compelled

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03:13:53.599 --> 03:13:55.799

Wasatch-1: to receive those data.

663

03:13:57.810 --> 03:14:02.589

Wasatch-1: so again, I think it's all around the the data and quality of data.

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03:14:04.120 --> 03:14:09.639

Wasatch-1: Thanks, Lucy. The data, exchange and quality seems to be a reoccurring thing. Appreciate that insight.

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03:14:09.690 --> 03:14:11.990

Wasatch-1: Gail. Do you have any additional thoughts, Dad?

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03:14:12.100 --> 03:14:13.990

Wasatch-1: I'll say from our side

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03:14:14.110 --> 03:14:16.438

Wasatch-1: the concern was that

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03:14:18.610 --> 03:14:26.169

Wasatch-1: that the the supply chain would be circumvented, and we would start getting verification requests from people who are not our customer.

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03:14:26.710 --> 03:14:29.733

Wasatch-1: because, historically, Pre Dsa

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03:14:30.960 --> 03:14:37.120

Wasatch-1: people would figure out who the contract manufacturer was sometimes, and if their child's medication went into shortage, they would.

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03:14:37.340 --> 03:14:47.399

Wasatch-1: through hook and crook, figure out that the CD. Mo. Was actually making it, and call us as though we could somehow manufacture something that our license not telling us to do so. That was a

672

03:14:47.440 --> 03:14:56.719

Wasatch-1: concern. I asked a number of our members. Are you getting any queries. You know that that circumvent your customers and to date none. And that's that's

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03:14:57.280 --> 03:15:06.630

Wasatch-1: important to them is to make sure that you know again, we're not the trading partner. We have one authorized partner we're supposed to be communicating with, and that doesn't seem to be a problem. So far, everybody's

674

03:15:06.890 --> 03:15:11.729

Wasatch-1: in tune with, you know the role we play. So yeah, well, that's great to hear.

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03:15:12.150 --> 03:15:19.489

Wasatch-1: I'd also like to. I'd also like to turn it over to our online panelists. What about Scott, Scott? Do you have anything additional to add.

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03:15:19.830 --> 03:15:30.349

Scott Kuzner: Sure I think some of the common things we've heard, whatever a little bit of my presentation are, you know questions about the demographics. So the trading partners are we seeing any trends there

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03:15:30.570 --> 03:15:39.429

Scott Kuzner: like I mentioned, it was more of a the the smaller companies with fewer resources and staff. A lot of our discussions. We, you know.

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03:15:39.540 --> 03:15:49.839

Scott Kuzner: folks have asked, when will all of the UN serialized data make its way out of the supply chain? You know, for example, what's sitting around? What surprises might might we find

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03:15:50.160 --> 03:15:57.870

Scott Kuzner: later? And then? You know, the 3rd thing is sort of more of a comment. Slash question, which is

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03:15:58.261 --> 03:16:12.180

Scott Kuzner: we won't really know some of these open, ended questions until November 2024 comes here. And so we're asking ourselves, you know. What is it? We're gonna learn at that point that that anyone might have overlooked. And all of this

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03:16:12.410 --> 03:16:14.409

Scott Kuzner: I think those are some of the

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03:16:14.570 --> 03:16:18.279

Scott Kuzner: 3 3 common areas that we heard often from our our members.

683

03:16:19.280 --> 03:16:21.720

Wasatch-1: Sure. Thanks, Scott. And what about you, Alyssa?

684

03:16:22.270 --> 03:16:31.260

E'Lissa Flores: Yeah, I think the number one thing that I've heard is more transparency around the waivers and more clarity that is needed surrounding that.

685

03:16:33.030 --> 03:16:53.280

Wasatch-1: Thank you. Thank you for your thoughts. We will now turn it over to the questions and queue Zack! What's in what's in queue for us right now. Thank you very much. So I'll be handling a lot of our audience. QA. Questions over the next couple of days. And just one disclaimer that we'll make before we jump into pulling questions off of slide. Oh.

686

03:16:53.510 --> 03:17:13.360

Wasatch-1: from this QA. Bot is to really keep the questions focused on the panelists and the industry that they're representing at the time. So we have a lot of questions that are getting out voted that are more, either the FDA or for dispensers or wholesalers. And because we have so much expertise appear right now from the manor manufacturing sector.

687

03:17:13.480 --> 03:17:24.419

Wasatch-1: we really wanna focus on those the FDA will have opportunities to answer questions at a couple of global panels over the next couple of days, and they have reopened their Rfi

688

03:17:24.570 --> 03:17:38.900

Wasatch-1: in addition to the numerous panels that we're going to have on dispensers and wholesalers of the next couple of days. So if you see, question. The most uploaded questions for this one are mostly directed at the FDA or dispensers. So when I start pulling them, and they're not the most

689

03:17:39.070 --> 03:17:49.560

Wasatch-1: upvoted ones. That's why we are choosing a few that are a little further down, just because we wanna focus on questions that are more for manufacturers. Right now during this panel, and that goes

690

03:17:50.090 --> 03:17:55.280

Wasatch-1: true for all of the panels going forward. So the 1st question that we have

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03:17:55.420 --> 03:18:04.179

Wasatch-1: and this is an anonymous question that came in during this presentation was, why do manufacturers need feedback to know how they are?

692

03:18:04.240 --> 03:18:11.829

Wasatch-1: Well, they are doing sending epcis files? Did they not inspect shipments to confirm that they have captured the serials.

693

03:18:12.400 --> 03:18:19.370

Wasatch-1: Thanks for that question. Now, Jillian, you had spoken about Epc in your presentation. So, Lucy or Gillian, would you like to

694

03:18:19.910 --> 03:18:20.840

Wasatch-1: question off?

695

03:18:24.350 --> 03:18:38.640

Wasatch-1: Could you repeat that question again? Zach? Yeah. So why do manufacturers need feedback to know how well they are doing sending epcis data towards the top. So you everyone can see the question written.

696

03:18:42.700 --> 03:18:49.480

Wasatch-1: I have to admit I'm not. Neither do you know why that comes to technical implementation?

697

03:18:51.630 --> 03:18:52.610

Wasatch-1: so

698

03:18:53.770 --> 03:19:05.760

Wasatch-1: that's quite all right. Yeah, is there anyone? Yeah, is there anybody else on the panel, or, okay, go ahead in our audience?

699

03:19:14.060 --> 03:19:24.289

Wasatch-1: Good afternoon. It's Mike Naser with the Pfizer pharmaceuticals. We've been at this for quite some time exchanging data for the past 2 years, and it's really sometimes it's a black hole.

700

03:19:24.390 --> 03:19:50.570

Wasatch-1: When I successfully send a file, my system shows that file was successfully sent. There is acknowledgement that that file was received, but yet I'm starting to get data where that serial number is missing and downstream systems. So there's an opportunity to collaborate. It's both on the manufacturer and on the distributor side, because there are issues downstream that sometimes that file will not successfully process in their system. You know. Maybe that G. 10 is not set up. Maybe that location. Maybe there's an issue with the file format.

701

03:19:50.570 --> 03:20:08.119

Wasatch-1: I don't know that as a manufacturer. So it's that mechanism that feedback mechanism that allows us that root cause analysis, you know, to kind of really stabilize that system and process and correct that issue. If it's affecting me, it might be affecting another manufacturer as well. So that's why you know, manufacturers constantly ask.

702

03:20:08.250 --> 03:20:21.029

Wasatch-1: looking for feedback on the quality of the data we're sending as you consume that data. Are you able to consume it? Are you able to use it and generate for your outbound trading partners? Because there is a lot to learn, you know, in terms of this is really complex. This is really hard.

703

03:20:21.060 --> 03:20:28.269

Wasatch-1: So yeah, as much feedback as we can get prior to November is really going to help you fully stabilize this into processes. So thank you.

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03:20:29.670 --> 03:20:40.730

Wasatch-1: Thanks so much for that comment. It, that really resonates to me. I think it was Eric or Matt, who had made a comment about you can have the connections being operational. But if they're not interoperable.

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03:20:41.260 --> 03:20:49.410

Wasatch-1: you know, you're you're really halfway there. So that that was a really great comment. I appreciate that insight. Does anybody else have anything additional to add to that

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03:20:50.550 --> 03:20:54.851

Wasatch-1: on our panel, or even in the audience? If you have more of that, it expertise

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03:21:00.190 --> 03:21:17.930

Wasatch-1: and a consultant. But I was with Gideon Award as before. So, to add to Mike's 1, we did so much of exception handling with the Hda. And all those are big, you know. Communication back to my distributors to manufacturers. Not because most of the manufacturers.

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03:21:18.340 --> 03:21:28.060

Wasatch-1: it was. It's through Cmos or through 3 Prs, so the exceptions doesn't. That might be a discrepancy between physically handling as well as with the data.

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03:21:28.200 --> 03:21:37.730

Wasatch-1: Right, Carlos. Yeah. So because of that, we need the feedback so that the gap can be reduced so that distributors are not holding the products because they're going to quarantine the products.

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03:21:38.450 --> 03:21:42.179

Wasatch-1: Thank you. Appreciate your opinion. Looks like you have somebody else.

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03:21:45.660 --> 03:21:51.179

Wasatch-1: Hi! I'm Louise Cloud with Gilead sciences, and you know, one of the challenges is that

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03:21:52.460 --> 03:22:04.980

Wasatch-1: we send data out. And and the large distributors have actually been pretty good about giving us a report card saying you're doing well in terms of providing us information that works for us. But the concern is some of the other partners

713

03:22:05.400 --> 03:22:11.129

Wasatch-1: back to Echo. What Pfizer said. You know they receive the information, and we hear nothing. But what we don't want is

714

03:22:11.340 --> 03:22:12.430

Wasatch-1: October.

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03:22:12.520 --> 03:22:41.020

Wasatch-1: November. Somebody wakes up and says, Guess what? It doesn't work for me, for fill in the blank reason. The vast majority of the reasons seem to be master data issues create problems. That's everything from the Gln associated with it. Duplicate glens, G, 10 issues, etc. And so then what happens if you're a manufacturer, your order goes on. Hold. Your order gets kicked back. We have to resolve data problems and resolving data. Problems that are master data related are fairly easy.

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03:22:41.130 --> 03:22:55.330

Wasatch-1: But resolving data, once it becomes transactional information is really hard. And so that's where we don't want to be is in a place where we've executed a transaction product has been shipped. Serialization information is wrong and correcting

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03:22:55.330 --> 03:23:23.449

Wasatch-1: a technical epcis file with a zillion serial numbers in it is actually quite difficult. And it's technically invasive. And so that puts us in a really bad position. And it takes a long time to do that, and there's a lot of effort associated with it. So the better we know that our trading partners are really working well, there can receive the information they're transacting the information. And that data quality will be higher. And we won't be in a position where we're really really close to the deadline and and having to correct something that's difficult to correct.

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03:23:23.960 --> 03:23:33.699

Wasatch-1: Right? Thank you for that insight. I mean, at the end of the day. It's all. Also, you know, we have the it components to this. But at the end of the day we also have to think about the patients and the public health concerns associated with that.

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03:23:33.730 --> 03:23:35.670

Wasatch-1: So let's move on to the next question.

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03:23:36.090 --> 03:23:45.621

Wasatch-1: One person online who's raises the end? If John can turn on his microphone. I think, Dave Mason, so Ed is hand raised this whole time so we can.

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03:23:57.180 --> 03:24:00.520

Wasatch-1: You should be good to go. Speak, Dave, if you can unmute.

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03:24:01.270 --> 03:24:02.699

David Mason: Okay. Can you hear me now?

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03:24:03.210 --> 03:24:04.340

Wasatch-1: Yes, we can hear you.

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03:24:04.340 --> 03:24:05.106

David Mason: Okay, sorry.

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03:24:05.560 --> 03:24:14.849

David Mason: So to stay Mason from Nevada. So I want to. I would just want to bring up why, it's important, even if it's Epcs or email, or a portal.

726

03:24:14.870 --> 03:24:20.600

David Mason: It's all about the data. And we've been getting data from our distributors. Outbound data. And what we found out is

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03:24:20.740 --> 03:24:26.389

David Mason: we have about a 1% aggregation error. What's that mean? It means for every 1 million units we ship.

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03:24:26.430 --> 03:24:32.770

David Mason: That's 10,000 units that are going to sit on somebody's dock or be quarantined and can't move past the patient.

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03:24:33.060 --> 03:24:37.740

David Mason: So what that allows us to do is is to dig down into the data and actually find

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03:24:37.900 --> 03:24:45.430

David Mason: that our supply sites actually have process issues that we can correct before November to reduce the percentage and reduce

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03:24:45.510 --> 03:24:51.949

David Mason: product that could sit on a dock and not to get to patients which we all care about. So that's why it's very important to get that data.

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03:24:52.180 --> 03:24:53.310

David Mason: Thank you, Eric.

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03:24:55.320 --> 03:25:24.380

Wasatch-1: Thank you so much for that comment. Are we ready to move on to the next question. Yes, we are okay. Great. So John is just put it back up there. So there's an In industry perception that small generic Pharma companies are less prepared for the Dscsa implementation. So either any of the panelists have any comments on this question, or, of course, if anyone here in the in person, audience, or the virtual audience has any comments on that feel free to raise your hand virtually.

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03:25:25.290 --> 03:25:27.229

Wasatch-1: since this is about generics.

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03:25:27.820 --> 03:25:31.420

Wasatch-1: Scott, would you like to comment on this.

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03:25:33.070 --> 03:25:43.379

Scott Kuzner: Sure I'll I'll just I mean I'll I'll briefly comment. What I said in my presentation is, it's you know, we haven't heard from everyone. So it's kind of hard to answer that

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03:25:43.540 --> 03:25:46.620

Scott Kuzner: question. But when we look at trends

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03:25:47.430 --> 03:25:56.840

Scott Kuzner: about the types, that that is sort of what what we're seeing is that some of the entities may be less prepared. But again, it's it's really hard to say.

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03:25:58.420 --> 03:25:58.890

Scott Kuzner: Help.

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03:25:58.890 --> 03:26:01.870

Wasatch-1: Thank you. Scott. Does anybody else have any insight.

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03:26:02.200 --> 03:26:04.939

E'Lissa Flores: And then in here really quick cause.

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03:26:05.190 --> 03:26:05.690

Wasatch-1: Go ahead!

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03:26:05.690 --> 03:26:20.850

E'Lissa Flores: Presents the smaller organizations as well. But just wanted to say, like, you know, my guess, maybe, is capacity, but on resources. But I can relay this question to our members to get specific feedback as well.

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03:26:23.290 --> 03:26:25.020

Wasatch-1: Thanks so much, Alissa and Scott.

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03:26:25.260 --> 03:26:28.629

Wasatch-1: Would anybody else care to comment on this question?

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03:26:28.840 --> 03:26:30.699

Wasatch-1: Well enough, sure, go ahead.

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03:26:34.320 --> 03:26:37.000

Wasatch-1: and if you could also introduce yourself as well. Thank you.

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03:26:37.380 --> 03:26:43.039

Wasatch-1: Thank you. Month to Moroni, and with clerks to consulting in a previous life, actually worked for a generic company, and

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03:26:43.080 --> 03:26:55.450

Wasatch-1: at that time I don't think this is really changed too much. A lot of it was the business case, for how do you roll in the costs for being compliant which are not insignificant. How do you pass that along

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03:26:55.810 --> 03:26:57.519

Wasatch-1: supply chain? So

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03:26:57.560 --> 03:26:59.200

Wasatch-1: probably not a

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03:26:59.250 --> 03:27:18.100

Wasatch-1: a full like picture of what the influences were. But that was definitely something that particularly working with contract manufacturers and downs partners is who's gonna pay for for the compliance, you know, in terms of hardware software process. You know, implementations building out an organization. So that was definitely cost pressure was a big one.

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03:27:18.240 --> 03:27:20.540

Wasatch-1: Sure. Thank you for that. That feedback.

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03:27:21.400 --> 03:27:23.429

Wasatch-1: Okay, let's move on to the next question.

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03:27:24.090 --> 03:27:40.269

Wasatch-1: The next one that we have is, aside from feedback from downstream trading partners. What are some ways that manufacturers can proactively scrutinize their data to ensure good data. Quality is moving downstream. And again, John has it has it up there for us for you to read as well.

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03:27:40.910 --> 03:27:43.940

Wasatch-1: Thank you. Now, we've spoken quite a bit about data quality

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03:27:44.020 --> 03:27:55.420

Wasatch-1: issues. And I know that a lot of insight and comments have been shared. Does anybody have anything additional, either from our panel or audience? Members? That they'd like to share about this question.

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03:28:00.420 --> 03:28:01.687

Wasatch-1: Don't be shy.

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03:28:02.760 --> 03:28:03.910

Wasatch-1: sure. Thank you.

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03:28:08.130 --> 03:28:30.200

Wasatch-1: Priya Gopal again. So we have to implement, you know, checks and balances, basically. And you know, actually did a good ground job with most of the manufacturers and distributors on these exceptions especially. That's number One and number 2 working with the partners. Right? The timeframe. Someone raised about the quality agreements.

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03:28:30.370 --> 03:28:38.019

Wasatch-1: Your extended partners, I would say those are the second one which is important. So the time time is very critical. You don't want our product, warranty

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03:28:38.130 --> 03:28:41.169

Wasatch-1: and shortage of supply. That's the

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03:28:41.490 --> 03:28:42.540

Wasatch-1: those are the 2

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03:28:43.330 --> 03:28:50.610

Wasatch-1: right, especially right now, with 6 months being out, this is a very critical time, the stabilization period. So thank you. We have another question that looks like

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03:28:55.640 --> 03:29:01.164

Wasatch-1: I'm sitting behind distributors, and I keep telling me to stand up.

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03:29:02.140 --> 03:29:30.989

Wasatch-1: It's Mike with Pfizer again. This is a this is a great question, and you know, I know manufacturers have been looking long and hard, I really, you know, tweaking their systems and processes. I mean, this is, this is really a new kind of paradigm shift in the past. Yeah, we had to be active to the Ndc. Recently. It's to the lot. So we have to pick the right lock right in to see. Now we have to pick the right lock, the right Indc. And the right serial number. It's the the level of complexity significant. So your systems and processes have to kind of evolve

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03:29:31.060 --> 03:29:44.700

Wasatch-1: some of the things we've done internally, you know. Certainly a validation checks as as that data comes into your system doing validation checks as you're picking the product, you know, certainly checks and balances in your system before you. Pgi, before you start. Seeing that data, you do a reconciliation.

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03:29:44.700 --> 03:30:04.289

Wasatch-1: The quantity picked versus the number serial number scanned other organizations, you know, in terms of outbound. We have a lot of systems. Even within our own system, we have multiple systems in which data flows through delivery being picked goes from our customer service organization goes out to the warehouse, goes from the warehouse to another system, ultimately to be transmitted to customers.

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03:30:04.290 --> 03:30:25.290

Wasatch-1: You have a lot of interfaces, and we've seen gaps and interfaces where those files will fail, having systems to monitor and having people responsible to monitor, to be as proactive as possible. The last thing I want is a physical product showing up at a distributor or dispenser without the data, because that product will be quarantined and I'll get the call my goal is to resolve that issue before it becomes a problem.

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03:30:25.580 --> 03:30:31.059

Wasatch-1: So I would think most manufacturers are kind of looking at it that way as well and trying to be as proactive as possible.

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03:30:33.160 --> 03:30:43.799

Wasatch-1: Thank you for your insight. I'm sure that we can all take that, you know. Take away that that information as a learning. Let's move on to our next question.

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03:30:43.960 --> 03:30:49.184

Wasatch-1: Well, unmute Stephanie L. Byrne, who's been? Had her hand raised for for quite a while.

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03:30:50.050 --> 03:31:10.740

Stephanie L Byrne: Hi! I I am an independent consultant who primarily works with virtual manufacturers. But I can say that part of the challenge I'm seeing in the ability to proactively scrutinize data for the manufacturers is the difference in adherence to standards across different solution providers. So, for example.

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03:31:11.165 --> 03:31:23.089

Stephanie L Byrne: you may be able to successfully send a file as a manufacturer from something like trace link where everything looks successful. But if you're sending it to

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03:31:23.210 --> 03:31:47.870

Stephanie L Byrne: Cardinal, who's using investigator to check against the letter of the epcis standard for every line in that file you could still have failures due to date and time stamps or glenn Sglen formats things like that. So I think that is part of, you know. A another wholesale distributor is checking the biz point and repoint locations

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03:31:47.870 --> 03:32:00.210

Stephanie L Byrne: for every commissioning and aggregation event in the file, and they want to maintain the master data for every Cmo that you're working with. When, from the manufacturer's point of view. It's like you don't really

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03:32:00.766 --> 03:32:21.279

Stephanie L Byrne: have the right to that information. But it's part of the epci standard. So that is a big part of the challenge that I'm seeing right now in terms of data issues and the inability to be proactive and scrutinizing the data because what is acceptable in one system may be unacceptable in the receiving system.

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03:32:24.410 --> 03:32:25.740

Wasatch-1: And for your points.

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03:32:25.830 --> 03:32:29.509

Wasatch-1: really appreciate that information. Do we have any other comments online

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03:32:29.970 --> 03:32:52.170

Wasatch-1: ready to move on the next one? Okay. So the next one came in from Michael Morone, and his question was to comment on the level of preparedness felt by manufacturers for managing the transfer of Dscsa responsibilities resulting from licensing changes, such as acquisitions, divestitures, etc. And so it's it's up there at the top. If we have any

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03:32:52.200 --> 03:32:56.639

Wasatch-1: any panelists or any audience members that would like to comment on that

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03:32:57.130 --> 03:32:59.750

Wasatch-1: anybody from the panel like to comment on this question.

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03:33:01.810 --> 03:33:03.902

Wasatch-1: I shouldn't. But

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03:33:05.200 --> 03:33:12.379

Wasatch-1: the Cdmos sector is largely driven by private equity investment, and that means you generally have 3 to 5 years to

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03:33:12.630 --> 03:33:29.329

Wasatch-1: sell that CD Mo. Merge it with somebody else. And as a point of fact, I started Pbo A in 2014, with 12 founding members, and within 4 years 7 of them had been acquired, and 8 fell through, as of now

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03:33:29.410 --> 03:33:35.279

Wasatch-1: 2 of them are still standing as the original companies that that actually joined, and one of them was a

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03:33:35.400 --> 03:33:41.200

Wasatch-1: small, sterile fill finish company that just sold majority investment to a private equity firm.

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03:33:41.650 --> 03:33:43.239

Wasatch-1: So this is something that

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03:33:43.460 --> 03:33:50.320

Wasatch-1: I don't know the ins and outs of, but from your side, as those of you who are the license holders who work with Cdmos.

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03:33:50.520 --> 03:34:01.219

Wasatch-1: It is incumbent on you to make sure you understand what those changes are going to potentially be like to make sure that when you're working with Cdmos on this, that if they merge with a larger company.

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03:34:01.450 --> 03:34:15.089

Wasatch-1: those systems are going to stay will take compatible, or at least those practices are going to stay in place. So this is just a reality. The CD Mo. Sector. This is what I fell into 25 years ago, and and you know, figured I'd share it with

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03:34:15.740 --> 03:34:21.270

Wasatch-1: thanks so much, Gil. Anybody else, either from our panel or in the audience who'd like to comment on this question.

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03:34:22.890 --> 03:34:23.600

Wasatch-1: Sure.

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03:34:28.710 --> 03:34:48.659

Wasatch-1: Hello, Mike row with 2 labs. We do, Dscsa consulting. I have several manufacturer clients that have gone through acquisitions, divestitures, either on on both ends of the spectrum. And I would say that these events highlight the lack of interoperability in this in the supply chain, in terms of

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03:34:48.670 --> 03:34:58.399

Wasatch-1: something like historical data, and taking that and importing it into your system, should in theory be something that is seamless. Given interoperability. It's been anything but

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03:34:58.730 --> 03:35:09.389

Wasatch-1: so I think anytime there's an acquisition or divestiture. It creates a flurry of activity. I usually say, if you've done one of them, you've done one of them. So that's my 2 cents on that topic.

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03:35:10.680 --> 03:35:13.289

Wasatch-1: Thank you for that information. Do. We have one more.

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03:35:17.153 --> 03:35:21.949

Wasatch-1: I know there are other manufacturers in the world.

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03:35:22.230 --> 03:35:27.600

Wasatch-1: and I know we we all go through mergers and acquisitions. It's it's it's it's what our industry does.

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03:35:27.640 --> 03:35:48.529

Wasatch-1: But I mean, you have to have a project team. I mean that project team. And and typically in the past, you know, there wasn't a serialization component to it. There has to be a serialization component. And it's not just us. It's it's global serialization. So it's the EU Fmd, it's all the other global mandates. It's it's really highly complex, and you have to kind of meet those requirements in each of those, each of those markets.

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03:35:48.530 --> 03:35:58.749

Wasatch-1: Certainly in the Us. You know, you have your Dscsa responsibilities. It's that transaction information. 6 years you have to be able to, you know, manage and and integrate that data into your system's verification.

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03:35:58.770 --> 03:36:20.430

Wasatch-1: Being able to update. You know the Vrs, the route G tennis, you know, you know, to your repository in tracing requests the 39 elevens. I mean, you have. Digital yeah, folks, you have business folks. You have your serialization. It's 1 of those things that you you know as part of emergent acquisition. Everybody's concerned about. Okay water processing. Send your orders here. Charge back. Send your orders here, returns orders here.

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03:36:20.430 --> 03:36:36.859

Wasatch-1: It's now about serialization. We have a serialization inquiry that comes to the new manufacture of the acquiring company, and the last thing I'll put out there, and I know Tracy from Gs. One's in the room. Gcps, don't do what Pfizer has done over the last 30 years. As part of our acquisitions. We never moved our Gcps

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03:36:36.860 --> 03:36:59.060

Wasatch-1: from the acquired company over to Gs. One. So when I look at a Gcp. We acquired from acquired from a company 20 years ago. It's being used by a food nutritionist. It's somewhere in Chicago. We when we bought pharmacy up, John about 20 years ago. So we're working with Gs one to get that Gcp with Pfizer. But those are those are critical things that have to happen. You have to be proactive in management mergers and stack positions and divestitures.

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03:37:00.400 --> 03:37:08.099

Wasatch-1: I'll add that Pfizer is one of the companies that acquired one of our founders. By the way, hospital? So yeah, it's and it was right in the middle of serialization.

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03:37:08.170 --> 03:37:09.570

Wasatch-1: Yup.

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03:37:11.750 --> 03:37:17.460

Wasatch-1: thanks so much for your perspective. Do we have any other final thoughts on this question before we move on to the next one.

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03:37:17.600 --> 03:37:19.540

Wasatch-1: either online or in person.

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03:37:19.710 --> 03:37:22.500

Wasatch-1: Think we have one online person.

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03:37:23.090 --> 03:37:24.499

Wasatch-1: you know, unmuting.

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03:37:26.400 --> 03:37:27.629

David Mason: Can you hear me?

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03:37:30.930 --> 03:37:32.120

David Mason: Can you hear me?

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03:37:33.240 --> 03:37:35.010

Wasatch-1: Yeah, you're you're good to go, Dave.

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03:37:35.010 --> 03:37:48.480

David Mason: Okay. So Steve Mason again, i i i wanna add, because I've done a lot of divestitures and acquisitions. And one thing I'm going to add, it starts actually, when your legal department and your M. And A. Department

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03:37:48.570 --> 03:37:59.440

David Mason: is looking at a merger or acquisition and making sure that they're well trained and understanding of Dscsa and sterilization. Because if they're not.

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03:37:59.630 --> 03:38:06.790

David Mason: and this is what I I had lessons learned. We we I put together a training for them so they can ask the right questions. So we can.

817

03:38:07.270 --> 03:38:14.203

David Mason: We can provide the right information. So there's always I have what's called a best practice, so I'll give you best practice, and I know

818

03:38:14.520 --> 03:38:18.249

David Mason: There was a mic that was on there. But one of the things

819

03:38:18.470 --> 03:38:21.080

David Mason: I talk about is we talk about Vrs.

820

03:38:21.200 --> 03:38:29.580

David Mason: If it's still in our, in our, in our Gt, in our Gcp, we kind of make a best practice. We'll continue to monitor through a Tsa

821

03:38:29.630 --> 03:38:46.109

David Mason: the verification request until they move, and we have certain things like, how quick can they move their labeling? How quick can they move to their Gcp. Or vice versa. So I think it really starts because it's so complex with your legal and M. And a department, and making sure you have a good

822

03:38:46.190 --> 03:38:53.799

David Mason: understanding and a good contract with that. So you're not at the last minute, or even

823

03:38:54.385 --> 03:38:57.969

David Mason: making everything complex. Because if you if you don't understand it.

824

03:38:57.990 --> 03:39:01.359

David Mason: it becomes too complex to manage, is my opinion.

825

03:39:01.370 --> 03:39:13.559

David Mason: So I think there's really what industry should do is kind of put some best practices together of M. And A's that some people have learned, because I think that would be make it more effective.

826

03:39:14.190 --> 03:39:15.909

David Mason: Thank you, Eric and team.

827

03:39:16.670 --> 03:39:27.380

Wasatch-1: That's a really good point, you know, with the systems and processes in place, the training, the sops and the documentation is a very important component to all of that. So something really important to think about.

828

03:39:28.230 --> 03:39:50.370

Wasatch-1: are we ready for the next question? Yeah, I think think we're quickly running out of time for this session. But we can do one last question. That's kind of a good summation. We're gonna change it a little bit from what John just put up on the screen. So the question is written is, how can industry? And we're just gonna assume the manufacturing industry can better engage and involve dispensers. And then we're also just gonna add distributors as well.

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03:39:51.560 --> 03:39:55.039

Wasatch-1: Is there anybody on the panel who'd like to take a stab at this question?

830

03:40:00.220 --> 03:40:00.950

Wasatch-1: You know.

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03:40:02.180 --> 03:40:04.970

Wasatch-1: Jillian, did you have some thoughts? Oh, I was, oh.

832

03:40:07.510 --> 03:40:14.170

Wasatch-1: okay. Anybody in the audience have any insight to share about this question

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03:40:14.810 --> 03:40:16.580

Wasatch-1: in person or online.

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03:40:21.070 --> 03:40:23.379

Wasatch-1: Do we have any audience members online? Zach.

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03:40:24.870 --> 03:40:25.600

Wasatch-1: okay.

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03:40:26.630 --> 03:40:28.300

Wasatch-1: we have. We have one back there.

837

03:40:28.690 --> 03:40:29.700

Wasatch-1: Thank you.

838

03:40:33.960 --> 03:40:51.340

Wasatch-1: Hi, this is Vid Roger. And with Genentech, I could share some of the ways we've engaged with the dispensers, our dispensers as well as the dispenser community broader than ours. So we've we have less than a hundred entities to engage with. So for us.

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03:40:51.390 --> 03:41:11.549

Wasatch-1: you know, the one on one engagement was our sort of strategy to really get the dispensers to the table to engage with us to educate them, and also let me leveraged our field folks as a way to bring more engagement with the dispensers on Dsc. So when we went live.

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03:41:11.650 --> 03:41:18.540

Wasatch-1: whether it was through portal or directly sending Apcis, we were able to establish that as of last November.

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03:41:18.770 --> 03:41:44.590

Wasatch-1: what we also did was to partner with Gpo group purchasing organizations to do webinars, educational panels, and so on, as a way to bring generate more awareness. And the member participation when we have had these types of web have been pretty impressive, we've had at least a 70 to 80% representation in terms of participation from these dispatch community, and

842

03:41:44.590 --> 03:41:53.779

Wasatch-1: what they're asking for is support and help in ways that manufacturers or wholesale upstream suppliers can do to help them. So really

843

03:41:53.870 --> 03:41:57.480

Wasatch-1: continuing to do that, I think will will be important.

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03:41:58.180 --> 03:42:01.879

Wasatch-1: Thank you. Really appreciate that insight, and I know that we're at time.

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03:42:01.980 --> 03:42:05.970

Wasatch-1: And well, do you have a you? Wanna add one more thing.

846

03:42:06.490 --> 03:42:13.030

Wasatch-1: This will be our last comment. That Carla Tatur this is kind of this comment is on behalf of Nobel Pharmal.

847

03:42:13.190 --> 03:42:20.530

Wasatch-1: So Nobel Pharma was a rare disease company that came from Japan set up a subsidiary in the Us.

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03:42:20.610 --> 03:42:37.890

Wasatch-1: And we got approval for a rare disease drug, and we built our structure to ship direct to pharmacies, to specialty pharmacies. And that's a very successful model in the rare disease space. So the rare disease companies oftentimes are dealing directly with specialty pharmacies.

849

03:42:37.980 --> 03:42:42.079

Wasatch-1: And I, I said this at an Hda meeting before Covid

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03:42:42.100 --> 03:42:51.570

Wasatch-1: is especially pharmacies, are a unique opportunity to work directly with a pharmacy as a manufacturer, and one of my partners is Dave Brown at Walgreens.

851

03:42:52.280 --> 03:42:54.970

Wasatch-1: So we, you know we were able to

852

03:42:55.250 --> 03:43:01.069

Wasatch-1: through direct shipments, and I know some of the big Pharma's are doing some of that direct business as well.

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03:43:01.890 --> 03:43:03.439

Wasatch-1: Thanks so much for your comment.

854

03:43:03.530 --> 03:43:26.880

Wasatch-1: So that is our last question for this session. I would like to thank all 4 of our panelists and Lucy, thank you for being our honorary panelists for today also appreciate our audience members, because without your questions we would not have had such an engaging discussion for today. And with that, and I also look forward to engaging with all of you over the next 2 days during this public meeting. So with that, I'm going to turn it over to Eric

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03:43:26.890 --> 03:43:46.910

Wasatch-1: to continue on this session. Oh, well, I'll be very brief, but we are gonna take a short break here. So we've got about 30 min folks can try to be back just a couple of minutes before 3, so we can start promptly at 3. There are some snacks just outside there feel free to make yourselves at home. Grab drinks, and take 30 min to to refresh

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04:13:23.800 --> 04:13:26.760

Wasatch-1: started if folks can wander back in.

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04:13:27.830 --> 04:13:50.210

Wasatch-1: So we talked to and heard from the manufacturers. We're Gonna turn to the wholesaler sector next and 1st hear from the wholesaler associations, and then from that we'll roll into an industry panel of individual trading partners focused on that manufacturer wholesaler exchange. So first, st we'll kick it off with the wholesaler association panel facilitated by Sarah Keller from FDA.

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04:13:51.290 --> 04:13:55.270

Wasatch-1: Thank you very much. I hope. You can all hear me in the back of the room.

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04:13:56.190 --> 04:13:57.510

Wasatch-1: Yes, thumbs up

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04:13:58.000 --> 04:14:08.990

Wasatch-1: fantastic. Thank you. My name is Sarah Keller. I am actually a regulatory counsel. I'm someone who's graciously awarded me with an Mdm. Ph, but I'm not one of those. I'm actually a JD.

861

04:14:09.358 --> 04:14:23.009

Wasatch-1: I work with the office of drug security and security and response at the office of Compliance at Cedar, at the FDA. You've seen a couple of my colleagues here already speaking, and I work with them.

862

04:14:23.010 --> 04:14:45.909

Wasatch-1: So today our purpose for this panel is going to this panel is going to provide a broad perspective on the state of stabilization among wholesale distributors. We have 2 amazing panelists from the wholesale sector, wholesale distributor sector, and they will be sharing their perspective on industry. Industry, progress toward stabilizations.

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04:14:45.910 --> 04:15:09.580

Wasatch-1: and the actions that all stakeholders can take support. The continued progress. Like our previous panel. We will do a short presentation from each panelist, and then that will be followed by a Q&A session. Like what the set did with our previous panel. So I would like to introduce Liz Gallano from Hda and Christina Levoy from Haida. He's welcome.

864

04:15:09.680 --> 04:15:12.339

Wasatch-1: So I think, Liz, you're up first.st

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04:15:21.680 --> 04:15:22.500

Wasatch-1: Okay.

866

04:15:22.790 --> 04:15:28.080

Wasatch-1: hopefully, you guys can hear me just hold it. Okay, no problem. Can everybody hear me in the back?

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04:15:28.380 --> 04:15:50.960

Wasatch-1: Great thanks, Sarah. So much for that nice introduction. I don't have slides. I'm just gonna make some remarks. Some of you have heard some of this before. So bear with me. My name is Liz Galina, and I am general counsel at Hda, and healthcare distribution alliance. Who are not familiar with us.

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04:15:51.703 --> 04:16:14.739

Wasatch-1: We represent the pharmaceut pharmaceutical wholesalers. We have 38 distributor members. But we also have, manufacturer Allied members about 150 or so as well as service provider members, and then, most recently, we also have the pharmaceutical

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04:16:15.255 --> 04:16:31.219

Wasatch-1: Pcsc pharmaceutical Cargo security coalition and we also just recently launched the Vrs Provider Network which is made up of both service providers and users so, and really more

870

04:16:31.440 --> 04:16:34.515

Wasatch-1: part of this Dsa space

871

04:16:35.590 --> 04:16:48.459

Wasatch-1: our members purchase pharmaceutical products, our distributor members purchase pharmaceutical products from over 1,500 manufacturers. We move about 10 million products daily.

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04:16:48.900 --> 04:16:57.210

Wasatch-1: and serve about 330,000 dispenser sites. Just to give you an idea. That's 38 companies do all of them.

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04:16:59.210 --> 04:17:06.390

Wasatch-1: I'm very proud of the work that we've done at Hda. Over the years on Dscsa, both leading up to it and

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04:17:06.450 --> 04:17:26.379

Wasatch-1: trying to get the legislation passed, and then now for the last. What? 10, almost 11 years working on implementation with our members, our members work diligently around the flock to get this working within their 4 walls, and we meet as an association? At least weekly

875

04:17:27.147 --> 04:17:48.619

Wasatch-1: on working out problems that are common to our distributor members, as well as various work groups and other things that we lead up on our manufacturer side, such as bar code work, groups and exceptions, handling guidelines and things that come up, that we see as gaps that need to be filled

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04:17:48.820 --> 04:17:55.649

Wasatch-1: for the industry and for the supply chain at large. One of the things that

877

04:17:55.930 --> 04:18:00.559

Wasatch-1: we were asked is, you know, what does stabilization mean?

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04:18:01.091 --> 04:18:04.390

Wasatch-1: Given the complexity, the volume of products.

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04:18:05.500 --> 04:18:06.100

Wasatch-1: the

880

04:18:06.520 --> 04:18:29.730

Wasatch-1: wide variation of supply chain partners in each sector, even. I think it's difficult. It probably means different things for each sector, for distributors, I think. And somebody had that had this up there, and one of the other presentations. It really is sort of to receive complete, accurate, accurate, timely data

881

04:18:29.940 --> 04:18:39.969

Wasatch-1: from all supply and in for all NDCS. From all suppliers, and to work through data errors to get to that point where we're only working on some errors we're only working on.

882

04:18:40.290 --> 04:18:42.170

Wasatch-1: We're not just trying to

883

04:18:42.310 --> 04:18:49.589

Wasatch-1: obtain data Exchange, where a lot of our numbers still are. I know the numbers have been

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04:18:49.670 --> 04:18:56.239

Wasatch-1: positive trending and that's sort of across the board, or for the majority.

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04:18:56.684 --> 04:19:03.789

Wasatch-1: That we're seeing in terms of volume, potentially. But there is still, I would say, across our membership.

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04:19:03.840 --> 04:19:08.700

Wasatch-1: we would say, I would say, I'm hearing about 10 to 20%

887

04:19:09.470 --> 04:19:24.610

Wasatch-1: is still outstanding in terms of coming from suppliers or manufacturers rather to distributors in terms of those that are sending full and accurate data consistently for all product lines. There's still that piece that's outstanding.

888

04:19:24.660 --> 04:19:26.310

Wasatch-1: And of that piece

889

04:19:27.025 --> 04:19:36.190

Wasatch-1: I think it's very difficult to know exactly what that volume is, we don't know. It might be the small company with one product. It might be a big company.

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04:19:36.800 --> 04:19:41.300

Wasatch-1: half their products, it might be. There is a lot of variation

891

04:19:41.937 --> 04:20:08.162

Wasatch-1: across the board, and I don't know that there's necessarily any way to measure that accurately across all distributors. And and that goes for large and small, our smallest members are having the same issues that our largest members are having, and vice versa, just maybe on a different scale. And so I just wanted to. You know, we have a wide variety of companies.

892

04:20:08.930 --> 04:20:11.589

Wasatch-1: our smaller members are are mostly

893

04:20:11.680 --> 04:20:35.470

Wasatch-1: regional, privately held, some specialty, some all generics. Some sort of niche. Some are pharmacy co-ops, so they are technically owned by their pharmacy members. But all in all, they're all experiencing the same issues across the board. So if that helps sort of understand where the distributor sector is

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04:20:40.550 --> 04:20:45.321

Wasatch-1: the one thing, 1st of all, I wanna say, thank you to the FDA.

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04:20:45.710 --> 04:20:51.990

Wasatch-1: The thing that I think gets buried a little bit in the guidance or the announcement that you just released

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04:20:53.880 --> 04:21:00.100

Wasatch-1: is the lifting of the stabilization period. Everybody sort of saw it initially and said.

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04:21:00.510 --> 04:21:26.069

Wasatch-1: Hey, you know small dispensers are going to have an exemption, you know, for the next 2 years, but sort of in there, obviously, which you all mentioned this morning or earlier today, was the the fact that the stabilization period will be lifted. Hda has actually advocated for that, consistently, in part because one of the problems that we do have with some

898

04:21:26.915 --> 04:21:45.220

Wasatch-1: both downstream and upstream trading partners is that they were viewing November 27, th not as the end to stabilization period, but as their compliance date, and so they may have connections with distributors, but they were not sending data until that compliance

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04:21:45.520 --> 04:21:51.029

Wasatch-1: or they're testing. But they're not going into full production with their data exchange.

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04:21:51.290 --> 04:21:54.950

Wasatch-1: And that's problematic for distributors. The more time

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04:21:55.090 --> 04:22:05.780

Wasatch-1: that that takes the less and the less I guess I should say the reverse way, the less time that distributors have to work out those problems before November 27, th

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04:22:05.870 --> 04:22:08.199

Wasatch-1: the worse off it is because

903

04:22:08.420 --> 04:22:17.650

Wasatch-1: we're honestly afraid that all of those who haven't acted previously will sort of release the floodgates

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04:22:17.690 --> 04:22:23.950

Wasatch-1: and start working on November 27, which causing bottlenecks, causing

905

04:22:24.559 --> 04:22:29.390

Wasatch-1: quarantining of products, causing data errors that we haven't addressed before.

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04:22:29.700 --> 04:22:39.079

Wasatch-1: And so that's a very big challenge for the distributor community. The other issue that we have is, you know, and this is sort of, I think.

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04:22:39.090 --> 04:22:45.370

Wasatch-1: understood by the distributors not always understood by the rest of the supply chain. But if, for instance.

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04:22:46.202 --> 04:22:48.579

Wasatch-1: you receive product

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04:22:48.740 --> 04:22:53.340

Wasatch-1: and you don't see the serialized data by November 27, th

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04:22:53.420 --> 04:23:00.460

Wasatch-1: we are viewing that as distributors cannot purchase that product. That means that product gets quarantined on their receiving doc

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04:23:00.590 --> 04:23:03.110

Wasatch-1: until the data can arrive.

912

04:23:03.651 --> 04:23:08.780

Wasatch-1: If it gets sent back to a manufacturer is most likely going to be destroyed.

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04:23:09.385 --> 04:23:13.660

Wasatch-1: It will most likely not be eligible for Resale

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04:23:14.283 --> 04:23:15.050

Wasatch-1: if it

915

04:23:15.440 --> 04:23:32.650

Wasatch-1: sits on the loading, on the receiving dog, it most likely will potentially cause backups to other products coming in to the to that same receiving dog. So these are just things that we think about that our members think about in terms of the practical effects

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04:23:33.111 --> 04:23:41.239

Wasatch-1: of lags. You know those that are lagging behind in their efforts and so lifting the stabilization period.

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04:23:41.320 --> 04:23:44.119

Wasatch-1: but really making it firm.

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04:23:44.380 --> 04:23:53.919

Wasatch-1: making that message firm to those manufacturers who have intacted, or even to those manufacturers who've sort of partially acted. I think that's really

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04:23:54.287 --> 04:24:14.280

Wasatch-1: encouraging for us, but we want to keep pushing that message. The ones of you who are in this room, most of you on the phone, and lots of our manufacturer and partners that we work with on our work groups. And via Pvg and pbsa, you're not the necessarily the ones we're concerned about. You guys are the greatest ones that are

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04:24:14.760 --> 04:24:17.299

Wasatch-1: working through errors working through problems.

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04:24:17.650 --> 04:24:27.070

Wasatch-1: And that will continue. It's the ones that we don't know about the one offs or the ones who have taken the position that November 27th is not

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04:24:28.340 --> 04:24:30.830

Wasatch-1: you know it's not the deadline, or is.

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04:24:30.930 --> 04:24:37.420

Wasatch-1: you know, the deadline, and and there shouldn't be anything to be done before then. Those are the the concerning

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04:24:38.430 --> 04:24:40.050

Wasatch-1: actors upstream

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04:24:40.770 --> 04:24:42.680

Wasatch-1: in terms of the

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04:24:44.170 --> 04:24:47.440

Wasatch-1: in terms of the dispenser community.

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04:24:48.494 --> 04:24:58.029

Wasatch-1: One of the things that we have consistently done is try to support our dispenser partners. So I think it's encouraging that the

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04:24:58.110 --> 04:25:16.210

Wasatch-1: latest announcement came out to help small dispensers in particular. That may not be ready. However, I think there's a lot sort of be examined here. Still, we are seeing again that variability and readiness across the dispenser community. And I'm not just talking about small

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04:25:16.250 --> 04:25:29.660

Wasatch-1: talking about large health systems, hospitals, other areas where you know, maybe even big chains, other areas where you know, they won't be affected by the small dispenser exemption at all

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04:25:30.332 --> 04:25:38.440

Wasatch-1: the other the other thing to kind of note. And this is really more, for FDA is so far, in our 1st analysis.

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04:25:38.810 --> 04:25:41.040

Wasatch-1: we don't necessarily see.

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04:25:41.050 --> 04:25:44.509

Wasatch-1: the small dispenser exemption is changing anything

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04:25:44.570 --> 04:25:47.340

Wasatch-1: for the way distributors are doing business.

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04:25:47.811 --> 04:26:15.598

Wasatch-1: It will most likely just continue. We'll put their data on a portal, or we'll you know, continue to send them what they're getting now. It's not going to really relieve us of anything, and it's not going to change anything in terms of how we're doing business. The one thing there is some question about some technical things. That we can get into later, just in terms of interpretation of some of the language, and also

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04:26:16.300 --> 04:26:21.699

Wasatch-1: you know how it, how it impacts, if at all, any specific requirements.

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04:26:24.400 --> 04:26:33.100

Wasatch-1: And I think that's actually pretty much it for my remarks, and I'm going to pass it on to Christina from Haida.

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04:26:33.430 --> 04:26:36.009

Wasatch-1: And then we're going to do Q. And a after that.

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04:26:38.150 --> 04:26:38.820

Wasatch-1: Thank you.

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04:26:52.110 --> 04:26:54.119

Wasatch-1: Alright. Can you guys hear me?

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04:26:54.610 --> 04:26:55.380

Wasatch-1: Alright?

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04:26:55.520 --> 04:27:05.129

Wasatch-1: Thank you so much. Well, just a little bit more background like Sarah said. I'm Christine Olivoy from Haida. We are the Health Industry Distributors Association.

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04:27:05.701 --> 04:27:14.609

Wasatch-1: and although our acronym looks very similar to Hgas, just to make it really easy for everyone to put us on a panel together.

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04:27:14.710 --> 04:27:30.360

Wasatch-1: The main difference between the 2, although we do have some members in common is that Haida members are primary medical products, distributors. So we're talking about delivering medical products, everything from gauze gloves, Ppe diagnostic lab tests, capital equipment.

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04:27:30.840 --> 04:27:45.370

Wasatch-1: So while pharmaceuticals are not the primary product of high end numbers many pharmaceuticals that are utilized by providers like vaccines, Iv solutions, anesthetics. They're gonna move through the Med search supply chain.

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04:27:45.570 --> 04:27:52.020

Wasatch-1: So it is a small percentage percentage of our members. Total sales. We're talking maybe 5 to 15%.

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04:27:52.320 --> 04:28:01.319

Wasatch-1: The pharmaceutical product portfolio is really essential for medsurge distributors to support customer needs, and to be competitive in the market.

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04:28:01.690 --> 04:28:02.630

Wasatch-1: So.

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04:28:03.310 --> 04:28:11.460

Wasatch-1: and getting ready for this meeting, like so many of you, we decided the best thing to do would be to take a snapshot of our membership, and where our members are

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04:28:11.510 --> 04:28:13.760

Wasatch-1: in their readiness for

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04:28:14.220 --> 04:28:17.070

Wasatch-1: November 27.th So we did a survey.

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04:28:17.520 --> 04:28:22.329

Wasatch-1: It was a relatively informal survey about 8 to 10 questions and

952

04:28:22.410 --> 04:28:29.380

Wasatch-1: where we are on Dscsa implementation and the stabilization period. As we're passing that midpoint.

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04:28:29.762 --> 04:28:38.470

Wasatch-1: So we asked our distributor members, and just a little bit of a snapshot of what the respondents looked like. The markets that were served by respondents.

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04:28:38.500 --> 04:28:43.559

Wasatch-1: They varied, but most of them were physicians offices. That was a little over 90%

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04:28:43.830 --> 04:28:46.650

Wasatch-1: hospitals and health systems, a little over 80%

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04:28:47.289 --> 04:28:53.689

Wasatch-1: ambulatory surgical centers, just over 50%. And then some laboratory responded about 45%,

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04:28:54.378 --> 04:29:03.789

Wasatch-1: and the company side skewed a little bit more mid to smaller. About 2 thirds of the respondents had less than 200 employees at there

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04:29:04.540 --> 04:29:13.659

Wasatch-1: companies. So the 1st question, as we pass the midway point of the stabilization period, how would you rate, your current Dscsa implementation, readiness

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04:29:14.320 --> 04:29:22.329

Wasatch-1: clear as mud. All of the answers centered right around average. Nobody said they were fully ready, and nobody said they were completely

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04:29:22.380 --> 04:29:23.490

Wasatch-1: in trouble.

961

04:29:23.750 --> 04:29:25.110

Wasatch-1: not going to be able to do it.

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04:29:25.120 --> 04:29:26.990

Wasatch-1: So right around the midpoint.

963

04:29:27.230 --> 04:29:35.679

Wasatch-1: And then we asked about the progression with authorized trading partners towards stabilization, and I think the results. Without a survey we probably could have

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04:29:35.730 --> 04:29:42.760

Wasatch-1: inferred these from anecdotal and just hearing back from our regulatory work group and conversations we have with members, but

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04:29:42.860 --> 04:29:46.779

Wasatch-1: the large branded manufacturers. The response was generally

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04:29:48.240 --> 04:29:54.990

Wasatch-1: smaller manufacturers that relied heavily on contract manufacturing organizations average to fair

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04:29:55.710 --> 04:30:00.229

Wasatch-1: dispensers with less than 6 locations, fair to very poor.

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04:30:00.330 --> 04:30:04.670

Wasatch-1: and dispensers with more than 6 locations, fair or slightly above fare.

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04:30:06.000 --> 04:30:11.099

Wasatch-1: So then, we just had the kind of an open question, and a lot of these comments, I think, are things we've heard already.

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04:30:11.485 --> 04:30:22.220

Wasatch-1: So I think you know comfort in company kind of situations. But we just said, open-ended Lee, what actions do you believe the industry or regulators need to take to support stabilization

971

04:30:22.660 --> 04:30:27.100

Wasatch-1: and shocking to know when most of the comments came around. Data?

972

04:30:27.871 --> 04:30:43.120

Wasatch-1: These are just obviously not going to be attributed to anyone, but essentially that you know, as far as distributors, they're looking for manufacturers to be sending all of the data for their products. The data is flowing, but sometimes it's incomplete. Sometimes it's late, sometimes there are errors.

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04:30:43.170 --> 04:30:49.969

Wasatch-1: And just like, Liz said. Like this, the folks that are on the phone and are in this room like we're, you know, everyone is doing.

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04:30:50.170 --> 04:30:57.819

Wasatch-1: We're the good. Those are the good actors. We're trying to do everything right. And it's the. It's the smaller guys that everyone's kind of. You know.

975

04:30:58.020 --> 04:31:00.290

Wasatch-1: everyone's trying to do the right thing, but

976

04:31:00.670 --> 04:31:15.059

Wasatch-1: you know that's like kind of why, we were very encouraged seeing the you know, the additional time with the waivers and exemptions, option, education and communication, whether it's customers or with dispensers both small and large.

977

04:31:15.598 --> 04:31:32.189

Wasatch-1: And again, communication from manufacturers to distributors. I mean, it's a chain, right? You know we have to keep everything moving in a circle. There were some folks that said to delay this. You know the stabilization or increase the stabilization period. Again, more time would be necessary.

978

04:31:32.270 --> 04:31:44.250

Wasatch-1: or that think that this should be phased in, and tears or stages. But we actually have respondents that says that we need to keep this process moving forward, and that they, you know, we'll be ready for November 27th if everyone else is ready for November 27.th

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04:31:45.190 --> 04:31:46.150

Wasatch-1: So

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04:31:46.590 --> 04:31:52.049

Wasatch-1: we asked, just generally, Are you receiving, you know, data from your manufacturing partners.

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04:31:52.130 --> 04:31:59.470

Wasatch-1: the actual percentage of suppliers that varied all over the place? People said 20%. They said 80%

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04:31:59.570 --> 04:32:06.300

Wasatch-1: right around 50%. But in general it was about 3 force of respondents said they were getting some sort, but there was

983

04:32:06.310 --> 04:32:08.769

Wasatch-1: almost 25% that said they weren't getting any

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04:32:10.770 --> 04:32:16.359

Wasatch-1: shocking to no one downstream. Readiness is a big concern for almost two-thirds of our respondents.

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04:32:17.077 --> 04:32:25.160

Wasatch-1: And then again we said, kind of a broad question, what were some other areas of concern? And this is from the survey, but also kind of anecdotally that we've from our work groups

986

04:32:25.330 --> 04:32:27.405

Wasatch-1: throughout the last couple years.

987

04:32:28.000 --> 04:32:46.859

Wasatch-1: obviously supply chain disruptions. We're trying to make sure that medical products can get from where they're manufactured, you know, on a ship to the port of Long Beach, on A, you know rail onto a truck to a hospital in the middle of Topeka. So any type of supply chain disruptions means that the

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04:32:47.020 --> 04:32:53.209

Wasatch-1: you know, the patients, the vulnerable populations that need those products that need those medicines aren't going to get them

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04:32:54.790 --> 04:33:02.069

Wasatch-1: concern with smaller dispensers, especially sometimes for our smaller members, too, that the cost of implementing these kind of things

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04:33:02.370 --> 04:33:05.138

Wasatch-1: trying to have this Dsc, readiness.

991

04:33:06.470 --> 04:33:12.809

Wasatch-1: you know that was a concern as well. And then again, we've heard this already. Data, accuracy and completeness.

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04:33:13.960 --> 04:33:15.920

Wasatch-1: So the final question we asked.

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04:33:16.119 --> 04:33:24.150

Wasatch-1: are you fully ready to implement your Dsa requirements when the stabilization period is going to end? On November 27, th

994

04:33:24.430 --> 04:33:28.100

Wasatch-1: 3 fourths said No, and 25% said

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04:33:28.220 --> 04:33:29.290

Wasatch-1: they thought they were

996

04:33:31.070 --> 04:33:39.199

Wasatch-1: fingers crossed right? So anyway, again, we're really pleased with, you know, the FDA announcement for those small dispensers, and the fact that there is

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04:33:39.340 --> 04:33:59.909

Wasatch-1: an exemption or a waiver option to apply. We will, of course, you know, keep feeding that information to our membership, and for those that think they need to apply for that. We wanna make sure we emphasize to do it as soon as possible. And overall we really, you know Haida has always been appreciative of FDA's willingness to work with industry, to make sure that we don't have

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04:34:00.130 --> 04:34:03.179

Wasatch-1: those delays or those disruptions in the supply chain.

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04:34:04.162 --> 04:34:05.669

Wasatch-1: So with that

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04:34:05.830 --> 04:34:08.979

Wasatch-1: I think I'm done, and we'll head back over to Sarah.

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04:34:10.439 --> 04:34:30.339

Wasatch-1: Thank you so much. Liz and Christina. Thank you for your remarks. So we are going to move on to the audience participation portion of this panel. If you haven't done so. You could either use the QR. Code, or you could join cido.com and use the number to submit your questions online. We also encourage you.

1002

04:34:30.340 --> 04:34:41.457

Wasatch-1: Raise your hand. If you have a question for us. We also we. And we'd like to invite our online participants, our virtual participants, to either submit your question or raise your hand virtually so we can.

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04:34:42.570 --> 04:34:46.140

Wasatch-1: So I'm going to start off with a question for Liz.

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04:34:46.160 --> 04:34:56.200

Wasatch-1: But so Christina mentioned during her remarks that she polled her members about how they felt about specialization. Now that we're about halfway

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04:34:56.360 --> 04:35:05.339

Wasatch-1: halfway through the period. Do you have any anecdotal stories or sort of trends that you can tell us about your members and how they're feeling about where we are.

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04:35:05.810 --> 04:35:14.280

Wasatch-1: Sure. Thanks. And this is, you know, as I said, we meet with our distributor members, probably weekly, if not every other week.

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04:35:14.773 --> 04:35:26.780

Wasatch-1: And so we talk about these things a lot. I think again, our sort of mantra. Since the beginning we were very grateful for the stabilization period when it was announced last August.

1008

04:35:26.800 --> 04:35:28.810

Wasatch-1: I think we have

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04:35:28.880 --> 04:35:47.219

Wasatch-1: been diligently trying to use the time to actually do just that, to stabilize our operations and receipt of data and passing of data and trying to perfect things. I think the challenge is is, this is an interoperable, interdependent

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04:35:47.259 --> 04:35:48.430

Wasatch-1: supply chain.

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04:35:48.680 --> 04:36:04.990

Wasatch-1: So what we do within our what distributors do within their 4 walls is only as good as what they can get from upstream, and and that in turn determines what they can provide downstream. We have consistently, for instance, advocated for a phased approach

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04:36:05.040 --> 04:36:11.290

Wasatch-1: and called for milestones to recommended milestones, because

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04:36:11.790 --> 04:36:41.379

Wasatch-1: you can't really just flip a switch and have everything happen in sync, all at the same time. That said. I think there's been tremendous progress made, at least from our members view. But there are still those gaps that need to be taken care of, and it's those gaps that we worry about the most, because that can, you know, cause a bottleneck that can cause a stop and throughput that can cause a quarantine situation. And so those are the things that worry

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04:36:41.500 --> 04:36:51.950

Wasatch-1: the most. Even it might seem like, it's only a 10% or 20%, you know of of product potentially. And that's sort of anecdotal amount.

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04:36:52.513 --> 04:37:02.439

Wasatch-1: It's still, it's still a worry. So still, thank you. Teamwork. So that's kind of where we are, I think.

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04:37:04.230 --> 04:37:11.519

Wasatch-1: And, Christina, do you have anything else to add to that question about your members kind of outlook or

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04:37:11.840 --> 04:37:13.870

Wasatch-1: attitude at this point in the dosha.

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04:37:13.919 --> 04:37:15.220

Wasatch-1: I think the

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04:37:16.529 --> 04:37:29.680

Wasatch-1: I love that the visual of like the it's the flip, the switch. And in talking I got on the phone with a couple of members leading up to the meeting. Just that, you know, I know, had responded to our our informal survey. And I just, you know, just

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04:37:29.910 --> 04:37:33.660

Wasatch-1: Yup, just to flush this out a little bit more, and I had someone say

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04:37:33.890 --> 04:37:35.990

Wasatch-1: that they had felt

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04:37:36.169 --> 04:37:38.750

Wasatch-1: and getting ready, that it was a lot of hurry up

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04:37:39.040 --> 04:37:40.070

Wasatch-1: just to wait.

1024

04:37:41.070 --> 04:37:41.439

Wasatch-1: And

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04:37:41.840 --> 04:37:49.849

Wasatch-1: they were kind of like, all right, we're gonna do it. Let's do it. That being said, what happens at, you know. 12 0. 1, on November 28.th And

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04:37:49.860 --> 04:37:54.220

Wasatch-1: because it is, I find it hard to, you know, to to see how

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04:37:54.529 --> 04:37:59.609

Wasatch-1: the you know going from one day to another. How that you flip that switch right like that. And the idea of

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04:37:59.770 --> 04:38:15.959

Wasatch-1: should you know phases or phased in or tiered? Yeah, it seems like, you know, if you had started kind of one way, and then the chain all stays connected. But yeah, I agree with that. And I think that really resonated with a lot of our members is that you know, as ready as they are trying to be and have been

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04:38:16.493 --> 04:38:17.419

Wasatch-1: when the

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04:38:18.050 --> 04:38:21.600

Wasatch-1: switch is flipped. What does that? What does enforcement actually look like?

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04:38:23.710 --> 04:38:27.619

Wasatch-1: Do you have any other comments from the audience or online?

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04:38:29.619 --> 04:38:31.260

Wasatch-1: I think there's someone in the back.

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04:38:41.730 --> 04:38:48.986

Wasatch-1: Hi! My name's Ria ria Chao. I'm the CEO of Alice Pedia. Alice Peddia has over a thousand

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04:38:49.619 --> 04:39:02.810

Wasatch-1: customers. That's trading partners who are trading partners in the pharmaceutical industry. So I I do want to bring to everyone's attention this small dispenser waiver program

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04:39:02.840 --> 04:39:06.889

Wasatch-1: to have impact on a lot of our small distributors.

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04:39:07.150 --> 04:39:13.839

Wasatch-1: I know larger distributors. There's virtually no impact, because larger distributors do have

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04:39:13.990 --> 04:39:18.389

Wasatch-1: a lot tracing capabilities such as Asn

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04:39:18.650 --> 04:39:24.279

Wasatch-1: and and Epcs for package tracing on the on the package level.

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04:39:24.490 --> 04:39:28.250

Wasatch-1: But for a lot of smaller distributors, that's not true.

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04:39:28.968 --> 04:39:35.059

Wasatch-1: So a lot of small distributors that they just recently, I would say, in the last 12 months

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04:39:35.500 --> 04:39:53.570

Wasatch-1: are implementing epcis. So at this point we are actually advising them that not only they may need the Epcs capabilities, but also Asn capabilities. So there are 2 issues here. One is they. This is something that they don't have, and they need to have.

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04:39:53.830 --> 04:39:55.390

Wasatch-1: And then, second.

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04:39:55.970 --> 04:39:59.829

Wasatch-1: to get connected on the Asn level.

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04:40:00.090 --> 04:40:06.279

Wasatch-1: It's very, very hard nowadays, just because everyone is focused on Epcs connections.

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04:40:06.490 --> 04:40:12.839

Wasatch-1: And typically those connections are not well in the same. So I just want to bring it to everyone's attention that

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04:40:14.360 --> 04:40:18.169

Wasatch-1: they are a lot of our customers who are very concerned.

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04:40:21.790 --> 04:40:25.799

Wasatch-1: Thank you for your comment. Do we have any online comments at this point

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04:40:26.190 --> 04:40:32.040

Wasatch-1: we do have a Dave Mason with his hand raised, and then we'll get to the audience questions that are up on your screens.

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04:40:32.970 --> 04:40:34.539

David Mason: Alright, Eric! Can you hear me?

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04:40:35.360 --> 04:40:37.269

Wasatch-1: Yeah, you're you're good to go, Dave.

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04:40:37.270 --> 04:40:42.069

David Mason: Okay, I just wanna make sure. So I have a comment. Here we keep talking about epcis.

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04:40:42.290 --> 04:40:53.489

David Mason: and we keep talking about that. But now we're going from a distributor to a lot of dispensers, and in the regulation it talks about wholesalers can be the service provider or the dispenser.

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04:40:53.670 --> 04:40:59.479

David Mason: and when I'm dealing with dispensers, I'm not sending you Pcs. Most of these are portal customers.

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04:40:59.540 --> 04:41:13.490

David Mason: Who can? Who can pull the file or get the information from the portal. So I think we need when we're talking when we're going down. The supply chain. Epcs is very prevalent between manufacturers and distributors.

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04:41:13.650 --> 04:41:18.320

David Mason: But there seems to be this misconception that the the Spencer's

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04:41:18.390 --> 04:41:23.499

David Mason: have to have Epcs which they don't. It says in the regulation email

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04:41:23.650 --> 04:41:24.690

David Mason: portal.

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04:41:24.870 --> 04:41:37.349

David Mason: or as 2 or as 2 connection, and I think it needs to be very clear to the dispensers, because a lot of them just don't understand that part of their regulation. So if the team up there could

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04:41:38.260 --> 04:41:44.570

David Mason: clarify some of that. It would be great Liz. And I don't. I'm sorry I don't know the other person's name. I know Liz.

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04:41:44.840 --> 04:41:49.019

David Mason: so it would be great if he would clarify that to help the dispenser community.

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04:41:51.261 --> 04:42:01.380

Wasatch-1: I was never here. So there's been a request for clarification from Liz directly. Liz, do you have any comments?

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04:42:02.147 --> 04:42:15.999

Wasatch-1: When this is really, I guess you know, it's not just me. I'm not a technical person exactly but I believe that that is that my understanding comports with Dave's understanding, and that

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04:42:16.200 --> 04:42:22.729

Wasatch-1: for the most part, when you are talking about independent pharmacy or small dispensers.

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04:42:22.860 --> 04:42:27.310

Wasatch-1: the wholesalers are able, if they choose to

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04:42:27.500 --> 04:42:34.580

Wasatch-1: provide, or, you know, sort of provide that service, and many are doing that as providing the data

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04:42:34.710 --> 04:42:36.170

Wasatch-1: on a portal

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04:42:36.736 --> 04:42:40.559

Wasatch-1: which is not necessarily Epc, areas. However.

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04:42:41.150 --> 04:42:47.190

Wasatch-1: again, it depends on variability. So I don't know, Ria, what your smaller

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04:42:47.380 --> 04:42:51.150

Wasatch-1: customer you know what smaller customers you're talking about, but

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04:42:51.470 --> 04:43:06.290

Wasatch-1: I don't know that we've necessarily seen that at least not with an Hda. We haven't seen a challenge with as going downstream or with lot level information going downstream. Distributors should be doing today.

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04:43:06.985 --> 04:43:08.910

Wasatch-1: And so that's, you know.

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04:43:08.950 --> 04:43:25.510

Wasatch-1: maybe something to explore. But and then in turn for the smaller dispensers, I think our members are pretty confident that they are getting what they need now. It's really the bigger ones that probably have have bigger issues.

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04:43:26.500 --> 04:43:32.700

Wasatch-1: you know, large chains, hospital systems, etc. That will receive probably epcis information.

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04:43:33.630 --> 04:43:38.030

Wasatch-1: Okay, thank you for that. I think we can go ahead and move on to our

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04:43:38.130 --> 04:43:44.359

Wasatch-1: question. We do have one more hand raised. This this question, Pam Forster, if you wanna

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04:43:44.550 --> 04:43:49.819

Wasatch-1: think she she lowered her hand right as we we went to that. But go ahead, Jim, if you have a have a comment.

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04:43:51.690 --> 04:44:12.692

Pam Forster: Thanks, Eric. I just wanna caution with saying that dispensers can utilize distributor or manufacturers portals, because if they order from multiple wholesalers or multiple manufacturers for the same type of product, or if they transfer product externally to a non own entity.

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04:44:13.140 --> 04:44:19.410

Pam Forster: are the wholesaler portals and the manufacturers portal set up to take those into consideration.

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04:44:22.120 --> 04:44:30.299

Wasatch-1: Yeah, as far as I know, they are not set up that way to take that into consideration. And so if you have multiple support multiple suppliers, you know.

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04:44:30.460 --> 04:44:41.829

Wasatch-1: probably would have to go on to multiple portals. I do think there are, and I don't know how many specific ones there are. But I know that there are a couple of software providers

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04:44:41.890 --> 04:44:50.700

Wasatch-1: that are specifically targeting this issue, and they're specifically marketing to either smaller distributors and or small

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04:44:50.990 --> 04:44:55.919

Wasatch-1: dispensers to try and provide a solution.

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04:44:56.329 --> 04:45:11.469

Wasatch-1: That sort of is sort of a 1 stop shop where you go in, and then all your data gets funneled to that one solution, and Carl is nodding at me. So I know it's true. But I don't, you know again, that's not

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04:45:11.480 --> 04:45:18.610

Wasatch-1: sort of universal. So to your point, that's a very real issue. If you're buying for multiple suppliers.

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04:45:19.250 --> 04:45:25.420

Wasatch-1: Does anyone have a comment about this? This question about multiple suppliers I see I had raised in the back.

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04:45:25.840 --> 04:45:28.953

Wasatch-1: It's Rian. I think

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04:45:34.450 --> 04:45:47.649

Wasatch-1: this is Ria real chow from Lspedia. I do want to comment on small independent dispensers, and they can have multiple locations. So it's not. Some may may think.

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04:45:47.690 --> 04:45:50.259

Wasatch-1: You know, it's 1 store, I mean 25

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04:45:50.270 --> 04:45:53.800

Wasatch-1: pharmacists plus technicians, technicians.

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04:45:53.840 --> 04:46:00.050

Wasatch-1: They can manage 1015 stores. That's that's not small in in your thinking.

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04:46:00.565 --> 04:46:17.680

Wasatch-1: Also these. They are very proactive, small dispensers, independent dispensers that they don't want to be deprived of the data. They see the value in data, they use the value for their daily operations. They shave

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04:46:17.810 --> 04:46:22.589

Wasatch-1: 4 HA day by utilizing the data versus paper receiving.

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04:46:22.650 --> 04:46:28.379

Wasatch-1: So I think as a community, we shouldn't just say, Oh, you guys can go to the portal.

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04:46:28.470 --> 04:46:44.059

Wasatch-1: It is not a effective process for them. They also run a very challenging business nowadays, so for them to shave a few hours every day at every store level is huge benefit to them. So we should be thinking, how can we help them?

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04:46:47.606 --> 04:46:53.300

Wasatch-1: Thank you for that perspective. I think we are going to move on to the next question.

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04:46:53.860 --> 04:47:22.989

Wasatch-1: Yes, so thank you all for sending in all these great audience questions. So the 1st one that has been the most up voter that we'll go with is what will wholesalers do with product that they don't receive epcis data for this kind of segues nicely from our Epcs. Data discussion beforehand? The second part of the question is, will there be an exception in which they will ship such product to dispensers? I think that's more focused towards the FDA, so we can focus most of the distributors. Answer

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04:47:22.990 --> 04:47:35.489

Wasatch-1: 1st half of this question, we start with the panel and then move on to the audio. Either Liz or Christina. Do you have any perspective on this question? Or should I go 1st and take a crack at it?

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04:47:37.191 --> 04:47:45.750

Wasatch-1: So currently, we're in the stabilization period. So currently, it depends on the distributor and the distributor supplier

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04:47:45.850 --> 04:47:48.599

Wasatch-1: relationship. I know some distributors are

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04:47:48.820 --> 04:47:51.730

Wasatch-1: setting timelines for their

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04:47:51.920 --> 04:48:04.720

Wasatch-1: manufacturers so that they can get product in production with epcis data exchange. And so they may be pushing. That you know well, before November 27th

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04:48:05.880 --> 04:48:13.650

Wasatch-1: November the 27th is really the big question. And that is, you know, essentially, if you receive

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04:48:13.940 --> 04:48:32.779

Wasatch-1: product and you don't receive the data for it, if it's an exception, and it goes through like, you know, there's a glitch, and this is like a manufacturer. You normally receive product. For what have you? Then you can stop the product and and work through that exceptions. Pro process.

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04:48:33.140 --> 04:48:50.340

Wasatch-1: If it's product that is not capable of having epcis data shipped with, you know, exchanged with it. Then that product would have to be quarantined under the law. Essentially, that product cannot be received or purchased by that distributor under the law.

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04:48:50.360 --> 04:48:51.939

Wasatch-1: and therefore can't

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04:48:51.980 --> 04:48:55.720

Wasatch-1: move forward unless there is a we.

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04:48:55.770 --> 04:49:01.539

Wasatch-1: If that manufacturer has a waiver, exception or exemption for that product, then

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04:49:01.630 --> 04:49:05.889

Wasatch-1: hopefully, the distributor knows about it, and it could move forward.

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04:49:06.810 --> 04:49:11.119

Wasatch-1: Yeah. And just to kind of build off it, Liz said, I think that that's 1 of the things that

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04:49:11.150 --> 04:49:16.329

Wasatch-1: you know. I know. I said my remarks. I think you mentioned it. It's mentioned multiple times, you know this

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04:49:16.440 --> 04:49:21.999

Wasatch-1: recent announcement just last week, with the, you know, opportunity for small dispensers to

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04:49:22.518 --> 04:49:27.720

Wasatch-1: you know, have another 2 years, or then obviously, exemptions. And you know you can apply for them

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04:49:28.710 --> 04:49:50.279

Wasatch-1: really getting that information out and having that clarity just the way you described it. Where it's like, okay, we're in the stabilization period until this date, and when it becomes the 20 November 27.th If there isn't that exemption you can't, and that you don't have the data. You can't. Quarantine can't take it. That's that's what it says. I think that there's still a lot of confusion about that. And I think it's not just

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04:49:50.290 --> 04:49:55.290

Wasatch-1: it. It's not just little guys and independence, you know. I think that I think that so anything moving forward

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04:49:55.550 --> 04:49:57.100

Wasatch-1: to really get

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04:49:57.950 --> 04:50:05.610

Wasatch-1: clarified Faqs, webinars, small meetings like this, town halls. I don't know the best all of the above.

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04:50:05.630 --> 04:50:14.510

Wasatch-1: but I think people have questions, and I think the best that we can do to keep everyone in communication and getting that clarity will go a long way to making this successful.

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04:50:16.040 --> 04:50:20.789

Wasatch-1: Are there any comments from the audience, either in person or virtual?

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04:50:22.040 --> 04:50:22.830

Wasatch-1: We

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04:50:23.090 --> 04:50:24.950

Wasatch-1: I see a hand over there.

1121

04:50:32.280 --> 04:50:36.400

Wasatch-1: Hi! Thanks, Amir. I'll leave from some Cora. I just wanted to add

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04:50:36.410 --> 04:50:39.519

Wasatch-1: a couple of comments on this. You know.

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04:50:39.710 --> 04:50:40.939

Wasatch-1: process of

1124

04:50:41.280 --> 04:50:48.860

Wasatch-1: what happens with when we have product that doesn't have done. Of course there is a big difference, as was mentioned between

1125

04:50:48.900 --> 04:50:55.800

Wasatch-1: prior to November and after November we we have flexibility before November 27.th

1126

04:50:55.860 --> 04:50:58.309

Wasatch-1: After that that flexibility

1127

04:50:58.590 --> 04:51:00.810

Wasatch-1: technically goes away. And

1128

04:51:00.890 --> 04:51:03.360

Wasatch-1: you know, we're very clear about

1129

04:51:03.920 --> 04:51:06.290

Wasatch-1: our process because we have

1130

04:51:06.310 --> 04:51:11.190

Wasatch-1: to have some consistency in our processes for operational reasons

1131

04:51:11.240 --> 04:51:14.050

Wasatch-1: as well as regulatory reasons. So we.

1132

04:51:14.190 --> 04:51:17.480

Wasatch-1: I caution people from thinking that we can handle

1133

04:51:17.940 --> 04:51:22.470

Wasatch-1: too many variations. And you know there are a lot of scenarios. But

1134

04:51:23.140 --> 04:51:31.770

Wasatch-1: our operational folks have to have sops. They have to have processes. Our systems also have to be ready to handle these scenarios. So

1135

04:51:32.020 --> 04:51:39.460

Wasatch-1: to simplify it, products without data will be quarantined in our view. Then we go into this exception handling

1136

04:51:39.490 --> 04:51:43.740

Wasatch-1: process, which was, you know, you'll hear that a lot nowadays, because that is.

1137

04:51:43.800 --> 04:51:47.399

Wasatch-1: you know, that's where a lot of the work is happening right now.

1138

04:51:47.510 --> 04:51:48.939

Wasatch-1: Most of us are

1139

04:51:49.230 --> 04:51:51.620

Wasatch-1: focused on exception handling. Now that

1140

04:51:51.660 --> 04:51:59.119

Wasatch-1: a lot of data is coming in. We're we're seeing exceptions. We can simulate. We could test. We could pretend

1141

04:51:59.230 --> 04:52:04.590

Wasatch-1: it's November already, and and but the plan is after November.

1142

04:52:04.660 --> 04:52:06.180

Wasatch-1: as was mentioned

1143

04:52:06.440 --> 04:52:09.580

Wasatch-1: without a we. We have to quarantine that product.

1144

04:52:09.730 --> 04:52:17.469

Wasatch-1: and we can't tell if it's resolvable or not. Necessarily. We don't. All we know is we? We don't have the data for it.

1145

04:52:17.580 --> 04:52:22.070

Wasatch-1: or the the more scary ones. I can't scan it.

1146

04:52:22.390 --> 04:52:26.619

Wasatch-1: and and that's where it's like, Oh, these all go into an exception handling process.

1147

04:52:26.800 --> 04:52:32.870

Wasatch-1: We work with our trading partners at that point. Whether it can be resolved or not is going to depend on.

1148

04:52:33.430 --> 04:52:37.889

Wasatch-1: you know. The trading partner whether they can help us resolve this or not.

1149

04:52:38.423 --> 04:52:42.140

Wasatch-1: And then, of course, the wes process kicks in

1150

04:52:42.710 --> 04:52:47.040

Wasatch-1: the. I don't know if this question implies this or not, but there is a trend.

**Day 1 Part 2**

1

00:00:00.050 --> 00:00:01.470

In-Person Participant-1: Sure inventory that

2

00:00:01.480 --> 00:00:04.330

In-Person Participant-1: we will have sitting in our warehouse. Probably

3

00:00:04.340 --> 00:00:13.670

In-Person Participant-1: we're trying to reduce that, and I'm sure most distributors are concerned about that we're trying to reduce it by pressuring our trading partners to.

4

00:00:14.080 --> 00:00:14.990

In-Person Participant-1: you know.

5

00:00:15.510 --> 00:00:21.769

In-Person Participant-1: you know. Let let's reduce that gap or eliminate it. We know there probably won't be 0.

6

00:00:22.090 --> 00:00:33.270

In-Person Participant-1: But that's that's the plan is like, let's not wait till November, but come November. We are probably gonna deal with transitional inventory a little differently than any new receipts.

7

00:00:33.670 --> 00:00:37.379

In-Person Participant-1: and I think that's there is a general understanding that

8

00:00:37.640 --> 00:00:38.400

In-Person Participant-1: that's

9

00:00:38.500 --> 00:00:40.170

In-Person Participant-1: part of the transition. So

10

00:00:40.440 --> 00:00:41.220

In-Person Participant-1: thank you.

11

00:00:42.360 --> 00:00:56.860

In-Person Participant-1: So I see a lot of nodding heads. Does anyone have anything else to add to that comment? Or we do have one online from a Josh polio apologies. If I'm mispronouncing that incorrectly. So we we just unmuted Josh, so you guys can start.

12

00:00:57.130 --> 00:00:58.879

Josh Poliakoff: Great can you hear me?

13

00:01:04.519 --> 00:01:06.099

In-Person Participant-1: Ye. Yes, Josh, we can hear you go ahead.

14

00:01:06.100 --> 00:01:11.749

Josh Poliakoff: Okay, perfect. Yeah. Hi, I'm Josh Pollakoff. From health source distributors.

15

00:01:12.270 --> 00:01:35.468

Josh Poliakoff: and had a question regarding the the the T 3 transition to the T 2 and now it's requirement is the transaction information and transaction statement. And I saw that. You know, it has for the the we we like we like was mentioned before. We have a portal where we you know, relay the serialization information to our customers.

16

00:01:36.181 --> 00:01:43.918

Josh Poliakoff: As well as currently the the T 3 and I saw that it said that you know, for these small dispensers.

17

00:01:44.270 --> 00:02:08.569

Josh Poliakoff: you know, they can continue as of now with their with the current process that they're doing with the transaction information, the transaction statement, and I wanted to get clarity on the transaction history as well cause that's something we're we're sun setting as we go to the serialization part. Is there? There are requirement for the transaction history to be provided as well? Or do we now go

18

00:02:08.570 --> 00:02:15.740

Josh Poliakoff: with the, you know? Can we start now with the T 2, and just just relay the transaction information as well as the transaction statement.

19

00:02:18.420 --> 00:02:25.759

In-Person Participant-1: We only have 1 min left for that question, and that question does seem like it actually has more to do with the dispenser side.

20

00:02:26.260 --> 00:02:27.850

In-Person Participant-1: Can I ask

21

00:02:28.320 --> 00:02:33.420

In-Person Participant-1: my FDA colleagues to consider this question for possibly the dispenser panel

22

00:02:35.410 --> 00:02:36.800

In-Person Participant-1: or our panel.

23

00:02:44.090 --> 00:02:50.208

In-Person Participant-1: because we are pretty out of time? And I think it's going to require more than a 10 second answer.

24

00:02:51.590 --> 00:02:52.680

In-Person Participant-1: Haga.

25

00:02:53.410 --> 00:02:57.719

In-Person Participant-1: can we go ahead and kick it to the dispenser panel? The question.

26

00:02:58.570 --> 00:02:59.270

In-Person Participant-1: okay.

27

00:02:59.400 --> 00:03:00.220

In-Person Participant-1: okay.

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00:03:00.717 --> 00:03:23.650

In-Person Participant-1: I think that actually wraps up our session. I'm so sorry for the lack of time at the end. But I really would like to really thank Liz and Christina here today, for their insights and their remarks. And I'd like to thank the audience, both here and online for your participation as well. And actually, Liz is gonna stay up here and lead us in our next discussion.

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00:03:23.790 --> 00:03:24.700

In-Person Participant-1: Mr. Speaker.

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00:03:31.930 --> 00:03:39.130

In-Person Participant-1: they're shuffling. I'm just gonna make 2 real quick announcements. One. I know we've got a lot of questions coming in. Just note we are capturing and cataloging, though.

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00:03:39.220 --> 00:03:50.379

In-Person Participant-1: even if the panelists aren't responding, we are capturing those questions. Second, someone left a laptop on a table out there. So if you left a laptop, it may be on the tables outside of the room.

32

00:03:52.810 --> 00:03:54.049

In-Person Participant-1: Fax, and we found it.

33

00:05:25.160 --> 00:05:29.239

In-Person Participant-1: Can you hear me? Okay? Alright. Thanks everybody.

34

00:05:30.850 --> 00:05:52.130

In-Person Participant-1: So shifting a bit. I'm going to be moderating the next panel. Stabilization of manufacturer to wholesaler data exchange. And I have a great group with me today. They're each. Can I introduce themselves? But I just kind of read off also our our great team here today we have Rt.

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00:05:52.480 --> 00:06:01.830

In-Person Participant-1: Niagara, Santa. From Samothy, Kristin, Mationi from Teva. Marian Nelson from cardinal health and paments from Smith drive

36

00:06:02.340 --> 00:06:03.060

In-Person Participant-1: out.

37

00:06:04.680 --> 00:06:05.650

In-Person Participant-1: So

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00:06:06.210 --> 00:06:24.580

In-Person Participant-1: this is going to be, you know, to hear from each of them about the status of stabilization as it relates to their transactions what they're seeing between manufacturers and distributors thus far through stabilization period in terms of data exchange and some of their

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00:06:25.107 --> 00:06:33.399

In-Person Participant-1: concerns and experiences. And then we're going to have chance for Q&A as well. So

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00:06:33.850 --> 00:06:58.039

In-Person Participant-1: we're going to dig a bit deeper than we have already today. And really understand what these experiences have been recent successes remaining challenges. And then also, just about a little bit about. So we're gonna start with a little bit about their role and organizations. So I will just go ahead and start. Let's start at the end.

41

00:06:59.061 --> 00:07:05.970

In-Person Participant-1: Hi, everyone! I'm Martina Raj. I'm part of the North America supply chain team.

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00:07:06.415 --> 00:07:16.690

In-Person Participant-1: I represent a large manufacturer. We have about 25 sites and Cmos, and we ship out to around 85,000 customers, distributors, and dispensers.

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00:07:18.300 --> 00:07:44.680

In-Person Participant-1: I am Mary Ann Nelson, regulatory manager with cardinal health. So we're a large pharmaceutical wholesale distributor out of Dublin, Ohio, and I've been involved in Dscsa, basically from the beginning. And in fact, my track and trace experience goes back to Florida pedigree and California serialization somewhere around 18 years. So kind of scary when you start adding it up. But happy to be here today

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00:07:49.120 --> 00:07:52.709

In-Person Participant-1: in the room, have that same experience

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00:07:53.810 --> 00:08:05.800

In-Person Participant-1: I am Kristen mationi from Tev pharmaceuticals. Another large manufacturer. I have been part of our Dscsa readiness program for about 3 years, leading the onboarding of suppliers.

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00:08:06.080 --> 00:08:12.360

In-Person Participant-1: our line packaging line and distribution center implementation as well as customer onboarding and support

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00:08:14.180 --> 00:08:21.450

In-Person Participant-1: Pam Clements Smith Drug Company. We are a hostile distributor located in Spartanburg, South Carolina.

48

00:08:21.710 --> 00:08:29.090

In-Person Participant-1: I'm actually a general manager of a distribution center, and I focus also on Dscsa. And I am the lead.

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00:08:30.270 --> 00:08:35.550

In-Person Participant-1: Great. Thank you all for being here, and so we'll see. I don't know who wants to go first, st but

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00:08:36.116 --> 00:08:45.730

In-Person Participant-1: let's start out with for each of you. What are the biggest, maybe successes or improvements you've seen in the last

51

00:08:45.740 --> 00:08:54.479

In-Person Participant-1: 6 to 8 months. Particularly during stabilization. And then what are you seeing as sort of the biggest challenge that that remains.

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00:08:54.780 --> 00:09:14.700

In-Person Participant-1: Do you want to start, Mary Ann? Sure, I'll go ahead. So you know we are seeing much higher engagement from manufacturers, and the numbers are up. And I look at it as Number one. The number of connections established number 2, the percentage of serialized data that we're receiving from manufacturers.

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00:09:14.700 --> 00:09:34.870

In-Person Participant-1: and then number 3. Our ability to assess the accuracy and timeliness of the epcis files that we're receiving. So today, we have established connections with almost all of our 500 plus suppliers. If you look back to last November, that number was about 64%

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00:09:35.254 --> 00:09:56.029

In-Person Participant-1: and today, we're receiving serialized data for approximately 80% of our units last November. This was in the 30 to 40% range. And today, in terms of being able to assess the data accuracy. So this is where you know, we are actually comparing the physical product received with the epcis data.

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00:09:56.050 --> 00:10:16.000

In-Person Participant-1: And we're reconciling approximately 72% of purchase orders. And again, that gives us that ability to report on data accuracy. And last November it was about 10. So a lot. A lot of work has been done and improvement shown. But there's still more that needs to be done. And I think you know one of the key areas.

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00:10:16.000 --> 00:10:31.849

In-Person Participant-1: And what we're focused on right now is being able to report on that data accuracy. Right? Manufacturers want to know. They want feedback. We've heard that a number of times today. And that's a process that's kind of still evolving and and takes time. And we can get into more details a little bit

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00:10:34.190 --> 00:10:50.170

In-Person Participant-1: sure. I think for us, you know, we started shipping aggregated data back in May of 2023, and you know, over the 1st few months. One of the significant improvements was the issue of master data, so that those were the primary

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00:10:50.250 --> 00:10:55.369

In-Person Participant-1: issues that we experienced early on. And we've worked through most of that or

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00:10:55.400 --> 00:11:16.109

In-Person Participant-1: I'm optimistic that we have and then, more recently, I think a huge improvement is getting, you know, from the Big 3 wholesalers reports back for Epcs scorecarding. We're still working through that. But you know I'm very optimistic that now we have the Big 3 providing those scorecards to us.

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00:11:20.570 --> 00:11:30.439

In-Person Participant-1: I see. Progress is on the inbound our, you know, data coming in from our Cmos and manufacturing sites are mostly stable.

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00:11:30.570 --> 00:11:45.994

In-Person Participant-1: This was not the case, you know, even a couple of months or last year. So right now, I can say, like, you're stabilized there. Connections are no longer an issue. Like, if someone reaches out for a connection, it's practically like within a day you can get connected. I have not seen issues there.

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00:11:46.597 --> 00:12:11.490

In-Person Participant-1: I've seen some successes with even claims like we had one where, you know, we were able to resolve a shortage using the serial number, and that was like really incredibly exciting. But that was one case. But it shows a lot of promise. Where I continue to see challenges is the data quality. And I think we've spoken a lot about that. I'd like for better solutions in terms of, you know, business managing

63

00:12:11.794 --> 00:12:27.039

In-Person Participant-1: exceptions and things like that. I don't think we are there yet, because a lot of it is still into spreadsheets, and I don't think we can manage that via spreadsheets and definitely training. I think we spoke a bit about that, too, like across the organization and our customers.

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00:12:31.990 --> 00:12:40.110

In-Person Participant-1: So it's definitely been the inbound side. Standing up our Dcs. We still have one DC left to stand up, which happens next week.

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00:12:40.400 --> 00:12:47.550

In-Person Participant-1: Once we get that DC stood up, we'll actually be able to get a true view of how much data is actually flowing and and is accurate.

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00:12:48.195 --> 00:13:01.859

In-Person Participant-1: We have experienced great. We launched a DC. Last week. It went very, very well. We had very few Arabs. The Arabs that we see are typically surrounded around data. It's bad data that we've received in master data file.

67

00:13:02.020 --> 00:13:10.379

In-Person Participant-1: And that may not be the actual product data that we're receiving. So when you scan the item, as Amir said, the item doesn't scan

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00:13:10.812 --> 00:13:17.240

In-Person Participant-1: so definitely still need to work on data, but as far as implementing and being able to receive, it's going very well.

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00:13:21.640 --> 00:13:29.910

In-Person Participant-1: It really acknowledges, you know, sort of this data gaps or data errors. And also, I think, Rt, you meant mentioned also

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00:13:30.000 --> 00:13:37.249

In-Person Participant-1: the master data problems. And we've been hearing a lot about there like, Do any of you have suggestions for how we can like what

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00:13:37.320 --> 00:13:43.220

In-Person Participant-1: sort of as a best practice, or what seems to be working when you're working those issues out.

72

00:13:46.100 --> 00:13:47.040

In-Person Participant-1: So me

73

00:13:47.340 --> 00:13:55.859

In-Person Participant-1: years back. I was optimistic that we would all have some type of shared database for all of our master data. We're not there yet.

74

00:13:55.920 --> 00:14:06.640

In-Person Participant-1: but I think you know, for us, and that I know this happened with us early on. We had provided spreadsheets, and then we update wholesalers using the Hda form but whether

75

00:14:06.760 --> 00:14:14.859

In-Person Participant-1: it was actually updated in the appropriate systems necessary for them to receive it in their distribution center is another question. But it seems.

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00:14:16.090 --> 00:14:23.999

In-Person Participant-1: And I say this with my fingers crossed, that we're at a point where most of that primary master data product, master data

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00:14:24.080 --> 00:14:27.843

In-Person Participant-1: is in sync between us and our downstream trading partners.

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00:14:28.820 --> 00:14:40.170

In-Person Participant-1: the abbreviated Hda form, I think, is very helpful, because it's it's much shorter. You can easily share that, but I think a lot of it is still happening in spreadsheets. And I don't know that that's the most efficient

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00:14:40.180 --> 00:14:44.890

In-Person Participant-1: way to be sharing with whether you're onboarding a new trading partner.

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00:14:48.080 --> 00:15:05.110

In-Person Participant-1: Yeah, just so one other thing, I mean, we do load the master data into our systems. But we can also take the information from the header of the epcis document. So if it's not there, we have a way to populate that information and be able to receive in that product.

81

00:15:05.538 --> 00:15:24.859

In-Person Participant-1: One other data point I'll mention is, you know, the whole idea of just incorrect file formats where they're not complying with the GS. One standards and we have some software that will check that, you know, and provide feedback to manufacturers immediately on that. So we found that helpful to, you know.

82

00:15:25.360 --> 00:15:27.729

In-Person Participant-1: resolve many of the issues up front.

83

00:15:29.320 --> 00:15:38.460

In-Person Participant-1: Great thanks, Mary Ann. One of the issues that we're seeing us is a little bit off our script. But it within exceptions. And I've heard this

84

00:15:38.889 --> 00:16:02.079

In-Person Participant-1: also on a panel I did last week. Is sort of this data latency issue data coming. And I know this is from the distributor standpoint, at least, data coming after the product comes. Which, then can create a logjam. You know how often, I guess maybe Pam. And then, Marianne, how often are you seeing it?

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00:16:02.330 --> 00:16:07.289

In-Person Participant-1: And then we'll move to the manufacturers and see kind of your thoughts on how we can

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00:16:07.822 --> 00:16:09.550

In-Person Participant-1: address it the best

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00:16:10.273 --> 00:16:24.809

In-Person Participant-1: we definitely get product before we get data. Lots of times. The issue that we have today since we aren't live in all of our Dcs. And we're not doing. A true comparison is so we've received the product and the file shows up.

88

00:16:24.840 --> 00:16:49.979

In-Person Participant-1: and it doesn't match. So when I do a comparison. I can't. I'm not showing my Eps file. My item is active, even though I showed it in my system as received. So we've got to marry those 2 items together, and we've got to stop the product before it actually makes it to my receiving. For so there's definitely work that we have to do on our side, that we've got to know that that file is received for that purchase order.

89

00:16:50.454 --> 00:16:51.990

In-Person Participant-1: And it's gotten much.

90

00:16:54.497 --> 00:17:07.019

In-Person Participant-1: So I think data latency is definitely an issue. So the truck arrives on our dock and we go and unload it, and we go to receive the product in that ecis spot there?

91

00:17:07.403 --> 00:17:29.660

In-Person Participant-1: And then maybe it shows up, you know, an hour, 2 h, sometimes 5 h, sometimes 9 h. Now I have to say that doesn't necessarily mean that the manufacturer didn't send it to us right? Because once it hits our system, it goes through a number of nodes to make it available in our Wms system, our warehouse management system.

92

00:17:29.660 --> 00:17:50.479

In-Person Participant-1: And so we've had to put in monitoring to kind of track it at all those points within our distribution center to try to pinpoint the reason for that latency. You know, I think early on, we automatically just said, Oh, suppliers. We're not getting this from you. And you know, we got feedback that we needed to to understand more before we make a generalization.

93

00:17:53.029 --> 00:18:19.649

In-Person Participant-1: Yeah. So we are definitely seeing a lot of latency issues. One reason that we know of is because the distribution center that ships out to the distributor is like right next door. So they do get the product before they get the data. That's the one that we know of. But there are others. We are definitely seeing a lot of it. I think, like Michael, you did to this before, like there are a lot of interfaces before you know the data gets out of the core system

94

00:18:19.710 --> 00:18:34.329

In-Person Participant-1: into the distributor system. So for us to understand where that latency occurs, like, we almost have to go every system and find that timestamp to figure out what is going on. So we are not quite there yet. It's on our list of things to do.

95

00:18:34.630 --> 00:18:41.439

In-Person Participant-1: and I guess feedback probably helps you there, too. Right?

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00:18:42.870 --> 00:18:43.770

In-Person Participant-1: Great

97

00:18:43.900 --> 00:18:53.100

In-Person Participant-1: Kristen. Did you have anything to add to that one? Okay, great. Okay. So from your almost viewpoint, like, what does stabilization

98

00:18:53.190 --> 00:18:54.490

In-Person Participant-1: look like?

99

00:18:55.610 --> 00:18:57.199

In-Person Participant-1: Is it perfection?

100

00:18:59.580 --> 00:19:09.170

In-Person Participant-1: No, we already heard that. It's not gonna be a perfection. I mean, I think it's it's getting, you know, accurate timely

101

00:19:09.180 --> 00:19:20.810

In-Person Participant-1: data on a consistent basis, so we can act upon it. I think the other piece is to have a way to timely and efficiently

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00:19:20.850 --> 00:19:28.460

In-Person Participant-1: correct errors right until we can do that. You know, we don't have a way to always move that product forward. So that's definitely

103

00:19:28.580 --> 00:19:30.180

In-Person Participant-1: a piece to it

104

00:19:32.280 --> 00:19:52.503

In-Person Participant-1: for me stabilization is like, almost a 3 pronged approach where you have systems, data and processes. So for the most part, data should be flowing. I want to say, like, you know, 100%. If I say that I sent 100% of the data, the distributor should like receive 100, I do expect exceptions like that will continue

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00:19:52.830 --> 00:20:07.350

In-Person Participant-1: But we need systems in place as a business user to be able to resolve those exceptions and even identify that an exception is happening. And same thing for processes like, I expect that across the industry we are aligned on what processes should be.

106

00:20:09.420 --> 00:20:37.219

In-Person Participant-1: Actually, I have. So no, I was just gonna piggyback on what Arthi is saying. I think that define process. So one, we we need accurate data. We need to know that it's getting there. But we need to have standardized processing because various wholesalers want things resolved in various ways. And it's difficult to to quickly understand. Okay, X person wants it this way. Y wants this. But some type of standard across the industry would be helpful.

107

00:20:38.580 --> 00:20:53.309

In-Person Participant-1: And then, Arki, I'm gonna switch to you for a second or back to you. And that sounds can be for Kristen, too. From a manufacturer perspective. I mean, we always focus on manufacturer to wholesaler exchange. But what about what are you seeing differently.

108

00:20:53.350 --> 00:21:00.370

In-Person Participant-1: or what are their challenges when you are doing? A manufacturer to dispenser exchange?

109

00:21:01.230 --> 00:21:09.372

In-Person Participant-1: Yeah. We are connected to about a hundred dispensers right now, and they vary from specialty pharmacies to health systems.

110

00:21:09.890 --> 00:21:34.040

In-Person Participant-1: I I don't have a lot of feedback from dispensers. There is a couple of them who do reach out on an adult basis. There is one particular one, and you know who you are, who is very, very engaged. And we appreciate that because, like what we see with dispensers is like, for example, like, I don't see master data issues with the distributors who are providing feedback like that's very

111

00:21:34.466 --> 00:21:56.550

In-Person Participant-1: with distribute, but dispensers. What I see is, it's the way you know the Po is placed. So there are like all these nuances, like serialization touches, like, you know, yeah, obviously, our Erp system or claims returns like all all across our network. So the way the Po is placed, for example, is what impacts. You know, some of the data not going out so that that feedback is critical.

112

00:21:56.780 --> 00:21:59.060

In-Person Participant-1: I don't have too much of it today.

113

00:21:59.970 --> 00:22:00.750

In-Person Participant-1: Great

114

00:22:01.150 --> 00:22:06.900

In-Person Participant-1: Kristen. No, not much. The over 95% of our volume is going through a distributor. So it's very small.

115

00:22:06.950 --> 00:22:08.160

In-Person Participant-1: very great.

116

00:22:08.330 --> 00:22:14.449

In-Person Participant-1: We have wondering if we should shift to QA. From the audience just given.

117

00:22:15.350 --> 00:22:16.400

In-Person Participant-1: I'm Ralph.

118

00:22:18.170 --> 00:22:25.550

In-Person Participant-1: So yeah, we do have a number of questions that have been coming in while you've been speaking. And obviously, anyone that's here in the in person or online. If you want to

119

00:22:25.660 --> 00:22:35.070

In-Person Participant-1: do the QR code to go back in and add your own question, feel free to so the current top voting. One that we have is how to trading partners handle foreign teams.

120

00:22:35.090 --> 00:22:45.019

In-Person Participant-1: and do you, as any of the panelists have any best practices to share? We can also, of course, open it up to anyone in the audience virtually or here in person as well for this one.

121

00:22:45.820 --> 00:22:46.720

In-Person Participant-1: Thankfully.

122

00:22:49.776 --> 00:22:58.510

In-Person Participant-1: So today, you know, if we get in pallets that we have mismatched Epson, so we basically have product. But no data.

123

00:22:59.090 --> 00:23:11.590

In-Person Participant-1: We've gone live in multiple Dcs, and we've kind of set the standard that technically, that products going into quarantine, and I'm not gonna revert the way that I'm receiving in order to put that product in my system.

124

00:23:11.800 --> 00:23:18.690

In-Person Participant-1: So in some instances it's taking a week or longer to even get a response back from the manufacturer.

125

00:23:18.920 --> 00:23:33.640

In-Person Participant-1: They may or may not have ever seen this themselves. So we're sitting on product and not able to put it to ourselves. So not only that, we have to make the decision. How long do we keep this product before we say

126

00:23:34.000 --> 00:23:36.750

In-Person Participant-1: I'm gonna need you to pick this up or reship.

127

00:23:37.539 --> 00:23:43.379

In-Person Participant-1: This product retransmit your Ep Sas file. But please

128

00:23:43.670 --> 00:23:48.879

In-Person Participant-1: do something with the other one, because if you send me a duplicate. Ssc, that's gonna fail to do

129

00:23:49.341 --> 00:23:59.750

In-Person Participant-1: so it's it's how you handle it. It's how they handle it as it comes into the system. If it's not right, it's gonna sit. And that's today.

130

00:24:00.100 --> 00:24:19.040

In-Person Participant-1: November 27.th I I can't sell it at all without that data. So it's it's very painful to handle. It's very timely. It will affect supply chain and just getting those things like more standardized on how those are handled will help wholesalers and manufacturers greatly.

131

00:24:22.725 --> 00:24:29.050

In-Person Participant-1: So you know, we have a different approach. Right now because of the stabilization period.

132

00:24:29.460 --> 00:24:38.510

In-Person Participant-1: So we are quarantining product. But if we've got a palette, and that all of the product all of the items on that palette are the issue. We're not gonna quarantine

133

00:24:39.280 --> 00:24:56.070

In-Person Participant-1: quarantine a case, so we can log it in our exception system. Provide that feedback to the manufacturer. But we want to let the other product go through, and we're fortunate, you know, that we do have the stabilization period to do that. As Pam is in November, we won't have that anymore. So it's really

134

00:24:56.070 --> 00:25:13.670

In-Person Participant-1: important that we start the process now, and I've heard comments that some manufacturers are waiting to actually even provide the data until November. By doing that we risk not having the time to resolve the issues. Right? So it's it's really important that the data is coming now.

135

00:25:13.730 --> 00:25:17.639

In-Person Participant-1: we can at least simulate to a degree that quarantining process.

136

00:25:17.730 --> 00:25:25.009

In-Person Participant-1: And right now we're we're soliciting feedback right? And then we'll go ahead and release it. Once you've got an acknowledgement from the manufacturer.

137

00:25:25.280 --> 00:25:34.759

In-Person Participant-1: But we're not necessarily having them resend the data in all cases, or necessarily changing the file, be able to provide that data downstream.

138

00:25:35.130 --> 00:25:36.480

In-Person Participant-1: get it initially.

139

00:25:37.370 --> 00:25:43.409

In-Person Participant-1: And I just want to thank you for doing that, because prior to April first, st

140

00:25:43.810 --> 00:25:51.169

In-Person Participant-1: I don't think any of our distributors were actually quarantining anything. And this is an exercise. We're we're

141

00:25:51.350 --> 00:26:01.020

In-Person Participant-1: exercising muscles so that we know post November 27.th What to do? But if I don't have my trading partner quarantining, it

142

00:26:01.530 --> 00:26:26.529

In-Person Participant-1: it doesn't get quite as much escalation within my organization. So you know, for example, if Cardinal sends an email saying, we're quarantined with this product, there's a lot more lot, faster reaction time internally. Then, if it's hey, here's an issue. But don't worry about it. We're just gonna continue to send it downstream. So it's I'm very positive that we are actually getting emails, notifying us that it

143

00:26:26.650 --> 00:26:32.120

In-Person Participant-1: product is getting quarantined because it's not very often. I mean, we're not so far it hasn't been the case.

144

00:26:32.640 --> 00:26:45.309

In-Person Participant-1: Foster, reaction, time or panic. I don't know what it is, but on our side, like in preparation for Ms. November, we are ramping up

145

00:26:45.330 --> 00:26:50.909

In-Person Participant-1: our customer service would be the 1st line of contact for any of those emails coming in.

146

00:26:51.140 --> 00:27:04.900

In-Person Participant-1: And we're also trying to put in like a 24 by 7 support, especially because one of the distributors called out that you know they receive product late at night, or vrs in the morning. So we make sure that we have support.

147

00:27:07.140 --> 00:27:25.997

In-Person Participant-1: Thank you all. I actually have one before we go to a next audience question. I was actually thinking as I was listening to you all. As we're getting. You know, we're past the Halfway mark of the stabilization period, and in the announcement the other day. FDA also noticed

148

00:27:26.380 --> 00:27:33.830

In-Person Participant-1: or notified everybody, you know. If you need a waiver, exception or exemption, you should probably

149

00:27:33.990 --> 00:27:57.479

In-Person Participant-1: get that process moving. What do you like? I guess this is sort of for all of you. Do you have any sort of challenges with respect to your trading partners having we's that you anticipate. And or you know, do you share that what do you think about the the recommendation to apply for these by August first, st

150

00:27:58.440 --> 00:28:06.050

In-Person Participant-1: I I think that's a great recommendation. And one, you know, Cardinal, has been suggesting to our manufacturer trading partners all along that

151

00:28:06.260 --> 00:28:08.049

In-Person Participant-1: can't provide data.

152

00:28:08.300 --> 00:28:38.209

In-Person Participant-1: Use the we process that was in the guidance in in 2,018. Appreciate the FDA, you know. Kind of saying, Hey, you know, do it by this date, so we have the time to respond to it. And so we'll look to the manufacturers to let us know if they did obtain a we? So we can flag that product in our system to not look for that serialized data coming with that, I think challenges is for our downstream trading partners. How do they know about the we?

153

00:28:38.486 --> 00:28:55.889

In-Person Participant-1: And I don't know that we have that process clear. It would be nice if there was a website that said, here are all the We's that have been granted. That everyone can access. But I understand there might be some security concerns about publishing that, you know widespread. So I think that's an area we still need to to work on

154

00:28:58.020 --> 00:29:00.660

In-Person Participant-1: slightly different. Take on the weeds.

155

00:29:01.310 --> 00:29:24.660

In-Person Participant-1: I mean, I I get the I get the point. I mean, if you have one product, let's say, you know, that's not aggregated, or you have an issue, one specific product. It makes sense. You have a V, but what do you do for data? That's not, you know, you have data issues that's not specific to a product like, are we saying, Okay, take these across all products like that doesn't make sense either. So what do we do there?

156

00:29:26.350 --> 00:29:27.350

In-Person Participant-1: Yeah. And I think.

157

00:29:27.760 --> 00:29:28.920

In-Person Participant-1: just for my

158

00:29:29.010 --> 00:29:32.390

In-Person Participant-1: broader distributor perspective. I think we aim

159

00:29:32.440 --> 00:29:49.940

In-Person Participant-1: think about that. I know our members. Some of them, maybe, are not 100, or don't know if they'll be 100 ready in November. And so the question becomes, well, do I apply for a we? And do I apply for something that's data specific, like

160

00:29:50.418 --> 00:30:05.050

In-Person Participant-1: or product, specific or trading partner specific. And so it's, I think there's some challenges that lots of industry partners will sort of have to. What work through in the next month or 2, probably.

161

00:30:10.400 --> 00:30:11.949

In-Person Participant-1: Should we go back to the

162

00:30:12.780 --> 00:30:16.580

In-Person Participant-1: audience? Q. And A. Do we have this from the room? Tim

163

00:30:17.360 --> 00:30:20.780

In-Person Participant-1: Tim Stearns are exceptions, handling and data.

164

00:30:20.840 --> 00:30:23.817

In-Person Participant-1: Guru at Hda.

165

00:30:28.740 --> 00:30:33.389

In-Person Participant-1: My coffee got cold. So I'm gonna talk to wake up. I get.

166

00:30:33.520 --> 00:30:45.590

In-Person Participant-1: I I got up at 4 this morning. I got up at 4 this morning just running on fumes. But to address this issue of informing

167

00:30:45.650 --> 00:31:04.610

In-Person Participant-1: trading partners of of an exemption status. We recently published an updated guide to the Edi 8 32 product catalog. It's it's kind of a 1 of these, the old workforce electronic data interchange way of conveying product information to downstream trading partners.

168

00:31:05.060 --> 00:31:14.879

In-Person Participant-1: And and so we kind of revamped the thing to convey a lot of Dsa information, but the one that's probably of most interest. Here is the exemption staff. So if a

169

00:31:15.345 --> 00:31:26.570

In-Person Participant-1: manufacturer has been granted an exemption, they would convey that information to a wholesale distributor typically using the Hda product shirt form. I think

170

00:31:26.620 --> 00:31:47.699

In-Person Participant-1: that was mentioned earlier. So that's kind of that quick down and dirty form that doesn't have a gazillion pages and and and fields on it like a new product launch that you have to go through the new form, for they then would capture that information in their systems. And and and again, I mean, a lot of this is still in the idea stages, and it always starts with us publishing and implementation guide as a blueprint for how to do it.

171

00:31:47.960 --> 00:31:53.499

In-Person Participant-1: But then, the distributor in theory at least would eventually then

172

00:31:53.520 --> 00:31:58.159

In-Person Participant-1: in their systems, take that Hda product, form, update.

173

00:31:58.440 --> 00:32:09.170

In-Person Participant-1: map it to this. Ed, i. 8, b, 2, transaction and then disseminate it down the dispenser community to inform them of a new exemption status. But I mean it also carries

174

00:32:09.460 --> 00:32:20.079

In-Person Participant-1: up, you know, things like product name dosage, form strength package size all things that's that is listed in the act as far as product specific. Ti, if you will.

175

00:32:20.520 --> 00:32:22.329

In-Person Participant-1: So hopefully, that helps.

176

00:32:36.810 --> 00:32:54.469

In-Person Participant-1: okay, assuming we don't have any other comments in person, or virtually we can move on to the next audience question, which is already highlighted up there in green, which is, how are you adding to the human resources to handle exceptions? What are related? Staffing challenges? To all of these exception issues?

177

00:32:56.010 --> 00:33:06.889

In-Person Participant-1: You wanna go first.st I'll jump in there. You know. So we made some assumptions initially when trying to figure out what we were going to need for our exception. Handling

178

00:33:07.263 --> 00:33:34.519

In-Person Participant-1: staff right? And so we looked at a 1% error rate 15 min per transaction to make that notification and communication. Now that 1% error rate is probably low, right? Because if you think back to 2015, when we started getting as we were at about 8 error rate. But when we put the numbers to an 8% error rate, it ended up that we would have to hire 100,

179

00:33:34.630 --> 00:34:01.290

In-Person Participant-1: and that just is a hard sell when you don't actually have, you know the data behind it? And so right now, we've added approximately 20 people on our exception team, with another 20 scheduled to come on board in the next month or so. And it remains to be seen, you know, whether that's going to be enough. I have my doubts about that. So you know it is concerning, and I think the other piece of it is the

180

00:34:01.640 --> 00:34:27.000

In-Person Participant-1: the quality of the personnel. They have to have some technical expertise. You know, in this room we've been talking epcis and glens and gtens for a very long time, but you know people that are new. It's a foreign language, right? So this really takes patience and training to get people up to speed. And right now we're talking about like the notification piece of it. We're not getting into those

181

00:34:27.000 --> 00:34:46.589

In-Person Participant-1: people who can actually go into the epcis and and do that deciphering of information, and really coming up with. You know what changes need to be done. So yeah, it's a big endeavor. And I'll just also say, you know, when we talk about these vendor score cards going out to 500 plus suppliers every week.

182

00:34:46.639 --> 00:34:53.920

In-Person Participant-1: That is very labor-intensive, and and something, you know, as a wholesaler, I don't think we plan for right. I mean, we know that that people

183

00:34:53.989 --> 00:35:00.120

In-Person Participant-1: important and we're working it. But you know, it's just very challenging to be able to stay up with. With that

184

00:35:01.860 --> 00:35:24.610

In-Person Participant-1: I can add Marianne, completely agree like it's I'm sure it's very intensive, you know, for you guys to send us that report. But even on the manufacturer side, to like dig into that report and really figure out what went wrong takes a lot of time and effort. And today we are getting, you know, this feedback from the Big 3. I don't know what happens to the other, you know. 100

185

00:35:24.610 --> 00:35:44.069

In-Person Participant-1: plus customers for us, you know. One fine day, if they get up and say, Okay, I'm going to provide you feedback. We are not staffed for that. It takes time to ramp up, and it takes time to get people trained to Marianne's point. So that's 1 of the reasons why we ask for feedback, you know sooner rather than later. So we know what to plan for.

186

00:35:45.960 --> 00:36:01.858

In-Person Participant-1: You, plan for staffing, and then not quite have it come to fruition people on our team, and we have it separated into 2. So we have a team for our inbound, and we have a team for coming from downstream trading partners.

187

00:36:02.260 --> 00:36:04.979

In-Person Participant-1: And I was laughing. Earlier

188

00:36:05.430 --> 00:36:33.439

In-Person Participant-1: I had pitched this waving hypercare, and essentially it went for a year and a half, and I think it was our CIO in the meeting was like, Hypercare isn't a year and a half, and I said, I get it not normally, but we have to have this team in place when we go live in our distribution center, and then I don't expect that our downstream trading partners are quite ready yet. So then, 6 months from now I need the team still in place, because we're going to get all this feedback from our downstream trading partners.

189

00:36:33.730 --> 00:36:36.319

In-Person Participant-1: And then you know the deadlines. But

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00:36:36.490 --> 00:36:43.349

In-Person Participant-1: it didn't end up coming to fruition, so we had hired additional resources to support our customer service team.

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00:36:43.400 --> 00:37:10.330

In-Person Participant-1: But we didn't have adequate feedback and didn't have the the need demonstrated need to keep these resources on because we weren't getting feedback from many downstream trading partners. So it's just kind of chicken and egg, you know where you are planning for it. It doesn't come to fruition. But then to turn around, you know, as Archie was saying, if everybody in this room, you know, or on on the the call starts providing us feedback in 2 months

192

00:37:10.410 --> 00:37:16.480

In-Person Participant-1: to be able to onboard and ramp up a team that's trained specifically for these types of issues

193

00:37:16.890 --> 00:37:18.440

In-Person Participant-1: is problematic.

194

00:37:19.360 --> 00:37:20.100

In-Person Participant-1: That's

195

00:37:20.570 --> 00:37:26.089

In-Person Participant-1: so. We've taken the approach approach of, we've kind of split it between operations. And it.

196

00:37:26.598 --> 00:37:35.439

In-Person Participant-1: So ops, does things. It does things. And we're working through the exceptions process so that we can train a person per DC. But

197

00:37:36.020 --> 00:37:40.169

In-Person Participant-1: hoping that a person per DC will be able to manage the exceptions

198

00:37:41.150 --> 00:37:42.376

In-Person Participant-1: that's crashing.

199

00:37:43.190 --> 00:37:44.890

In-Person Participant-1: Can I just ask one.

200

00:37:44.970 --> 00:37:48.150

In-Person Participant-1: maybe favor of everyone who's participating on this?

201

00:37:48.240 --> 00:37:51.340

In-Person Participant-1: I was on a panel a few weeks back and was.

202

00:37:51.520 --> 00:38:11.949

In-Person Participant-1: I don't wanna say complaining, but expressing my concern that we don't get a lot of feedback, so we don't know how well we are actually doing, and 2 consultants who work with distributors came up to me afterwards and said, Hey, just wanna let you know, like everything's going really well, that feedback is crucial. So even if you don't have issues with

203

00:38:12.010 --> 00:38:13.440

In-Person Participant-1: your suppliers.

204

00:38:13.890 --> 00:38:19.030

In-Person Participant-1: I would suggest reaching out and saying, Hey, we've been evaluating your data, or

205

00:38:19.040 --> 00:38:22.950

In-Person Participant-1: if you haven't, but we have been evaluating it, and

206

00:38:23.120 --> 00:38:24.599

In-Person Participant-1: thank you. It looks good.

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00:38:24.660 --> 00:38:29.910

In-Person Participant-1: But any that any of that communication over communication is always preferred.

208

00:38:32.700 --> 00:38:34.612

In-Person Participant-1: Kristen. Thank you.

209

00:38:37.050 --> 00:38:42.899

In-Person Participant-1: What about? And just from your all's perspective? If there's anything that you could

210

00:38:43.570 --> 00:38:54.680

In-Person Participant-1: tell or ask the Regulators for in terms of what would be most helpful to your efforts from your viewpoint right now, what would it be?

211

00:38:58.160 --> 00:39:15.080

In-Person Participant-1: I appreciate the message that stabilization is not going to be extended, because that gives us a little bit of you know, Pump, when we go back to manufacturers to say, Hey, we're not getting this, and there are a few that maybe feel like, Oh, you know, it's

212

00:39:15.370 --> 00:39:39.439

In-Person Participant-1: that can is gonna get kicked right. But that was very clear. So I think that was helpful. You know, I I think, though, it is concerning about all of these exceptions, and how we're gonna handle them, and that we don't have necessarily agreed upon processes fully implemented by all of our service providers that we can use and so

213

00:39:39.490 --> 00:39:40.610

In-Person Participant-1: how are we gonna

214

00:39:41.250 --> 00:39:53.640

In-Person Participant-1: be having an issue with sending product downstream. And certainly none of us wants to affect product availability. So I think, being aware of that and staying close to that is important.

215

00:39:55.580 --> 00:40:01.580

In-Person Participant-1: and I will echo that I I don't want for any further enforcement discretion, because

216

00:40:01.590 --> 00:40:03.550

In-Person Participant-1: we really do. I mean we.

217

00:40:03.600 --> 00:40:17.079

In-Person Participant-1: I think somebody on the last panel, said, Hurry up and wait. We have put so much effort and work into this and getting to this point, and we need to keep moving forward and having that momentum but I know from my perspective.

218

00:40:17.120 --> 00:40:26.609

In-Person Participant-1: working to onboard all of our suppliers and our packaging lines and our distribution center simultaneously, while you know, onboarding and connecting with downstream trading partners.

219

00:40:27.510 --> 00:40:36.590

In-Person Participant-1: It's very overwhelming. And so, if there is any opportunity, you know, I know the announcement for small dispensers came out. But

220

00:40:36.890 --> 00:40:40.519

In-Person Participant-1: any other type of phased approach might be helpful, so that

221

00:40:40.560 --> 00:40:45.360

In-Person Participant-1: manufacturers and distributors can really get to a solid state

222

00:40:45.698 --> 00:41:06.890

In-Person Participant-1: and then focus on further downstream, because I mean we're in a supply chain. I understand. Dsa went across the board, but it it starts at one end and it goes to the other end. And we really need to stabilize each and every one of those nodes in order for all of us, you know, to do what we ultimately want to do is get a patient, a safe product.

223

00:41:09.200 --> 00:41:32.420

In-Person Participant-1: Co. Again the comments that were already said, I appreciate the Regulators engagement. I do understand. You know there is no reason for a trading partner to not be at the table at this point, like everybody should be, you know, working towards stabilizing. But you know, we need like some kind of a fine line where we don't put patient lights at risk like we don't stop product for lack of data.

224

00:41:32.797 --> 00:41:51.200

In-Person Participant-1: I have a little story like my daughter switched doctors, and you know she was trying to get her medication, and as she switched doctors. We couldn't get a renewal for the prescription, and we were going around in circles with, you know, one doctor pointing her to the primary care, and we were going back and forth. We lost 5 days

225

00:41:51.230 --> 00:42:08.076

In-Person Participant-1: and all in my mind, like all I could think of, because that's all we do all day is, Messa. It's like, Oh, my God! Like, if the pharmacy were to tell me, I can't give you this because you don't. I don't have the data like I'd probably lose my mind, even though I'm part of the Ssa. Like I'd lose my mind.

226

00:42:11.490 --> 00:42:17.500

In-Person Participant-1: Sorry. Okay. What? How much time do we have left.

227

00:42:17.530 --> 00:42:18.940

In-Person Participant-1: Do we have 5 min.

228

00:42:19.250 --> 00:42:22.940

In-Person Participant-1: 20 min or so? Always 20 min. Yeah. Oh, okay.

229

00:42:23.150 --> 00:42:24.539

In-Person Participant-1: alright. Let's keep going.

230

00:42:25.750 --> 00:42:26.680

In-Person Participant-1: Sorry.

231

00:42:27.427 --> 00:42:33.450

In-Person Participant-1: Let's see, I don't know we want to take this one. Do we have any other audience? Questions?

232

00:42:34.210 --> 00:42:35.470

In-Person Participant-1: Oh, yes, okay.

233

00:42:45.980 --> 00:42:49.090

In-Person Participant-1: Hi, everybody. I'm Angela Nelson from Cbs health.

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00:42:49.100 --> 00:42:54.619

In-Person Participant-1: And I just want to thank you, Kristen, for mentioning that, because, while I agree.

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00:42:54.650 --> 00:42:55.899

In-Person Participant-1: you know, with

236

00:42:56.490 --> 00:43:25.139

In-Person Participant-1: not keeping this going and going, I do feel like as a downward, you know, trading partner, we need some type of some type of implementation. As for stages, you know, making sure that we've got all the correct data from manufacturers, sailors, so we can do what we do, and to your point, not keep drugs from our patients, because, as a pharmacist myself, and I think I've said this before. It would be horrific if I had that drug in my hand and told the patient.

237

00:43:25.140 --> 00:43:28.100

In-Person Participant-1: I can't give this to you, because I don't have the data.

238

00:43:28.590 --> 00:43:31.619

In-Person Participant-1: which is something we struggle with as a dispenser.

239

00:43:31.670 --> 00:43:56.289

In-Person Participant-1: So while we want to not kick this down the road, we need to do the right things for our patients. And we keep talking about data we talk about, you know, making sure we have accuracy. And you know, we've got to continue to talk about that patient on the other end. So I just thank this panel because I just think that's really important for us to continue to talk about our patient at the end of you know the beginning of this data

240

00:43:56.390 --> 00:43:57.960

In-Person Participant-1: in accuracy.

241

00:44:04.920 --> 00:44:07.169

In-Person Participant-1: Okay, I have another one.

242

00:44:08.160 --> 00:44:26.360

In-Person Participant-1: sample returns. Sample returns verification. We haven't talked about yet. Today I know that we've got some questions, maybe, as they relate to moving forward. Post November 27, th and in light of the dispenser, the small dispenser exemption.

243

00:44:27.212 --> 00:44:28.597

In-Person Participant-1: But how?

244

00:44:30.070 --> 00:44:38.730

In-Person Participant-1: How is it evolving, I guess, from when we started this process? Do you want to start, Marianne? Yes, happy to happy to take this one.

245

00:44:38.730 --> 00:45:00.079

In-Person Participant-1: So you know, one of the questions we get is, is the Vrs still needed? Right? And you know it's true that primary wholesaler distributors like like cardinal health, are going to use the direct-to-replicate data. We get the epcis from the manufacturer. We're going to store that G. 10, serial number lot X-free.

246

00:45:00.290 --> 00:45:27.020

In-Person Participant-1: Nbc, in our databases. So we can do that. Verification for saleable returns is what we're talking about primarily saleable returns. So yeah, we want to do that internally if we can. But if we didn't get epcis for it, and that return is, you know, coming back. And we had no data at that time. We're gonna rely on Irs, the Verification router service. We're gonna have to go back to the manufacturer

247

00:45:27.020 --> 00:45:50.049

In-Person Participant-1: now. We don't have to use the Vrs. It can be a manual process. But the whole point of the lightweight messaging standard was to get a sub second response, right. So you know, sending emails to a verification is not the most efficient. So yes, primary wholesalers are needing it. Secondary wholesalers are going to need it all the time, right? Because they're not getting anything correct from the manufacturer, so

248

00:45:50.050 --> 00:46:15.669

In-Person Participant-1: they are always going to be relying on an alternative source. Going back to the manufacturer to get it, and I think it's also important to remember that that dispenser obligation to verify for suspect and illegitimate product comes back into play in November, not for the small dispensers, but everyone else. It does so, you know. I I say, that the Vrs. I I so I still see a need for it, and if manufacturers aren't going to participate in it.

249

00:46:15.700 --> 00:46:41.329

In-Person Participant-1: then they better be prepared right to get the email to get the phone call and have a way to document that process. Right? So you know, when the request was made and when the response was made, because there is an obligation to respond to a verification request within that 24 h period. So that being said, you know, there there are, I think, still some issues. You know that we're trying to resolve within the the Vrs. So.

250

00:46:41.800 --> 00:46:43.520

In-Person Participant-1: Cardinal, we're we're

251

00:46:43.550 --> 00:46:55.630

In-Person Participant-1: doing cell bore returns in one facility right now. So last in May, we sent about 22,000 requests through the Vrs and you know, about

252

00:46:55.630 --> 00:47:21.949

In-Person Participant-1: 30%. We got no response. So manufacturers not participating. Alright. So that's 1 area. We're gonna have to go back and look at you know. But we got responses from 60 a little bit more than 60 and 92% of those responses all came back positive. Right? So that's great. Put the product back into sale inventory. That's how the process was supposed to work. But 8% came back with a negative

253

00:47:22.050 --> 00:47:35.990

In-Person Participant-1: verification. So that means quarantine, the product, right? We we didn't get a positive. We have to put it in quarantine, and now reach out to the manufacturer to figure out, okay, why did you give me a negative response? And in all of those circumstances.

254

00:47:36.070 --> 00:47:53.690

In-Person Participant-1: The manufacturer came back after analyzing it, and said, Nope, we can give you a positive verification. We we found that information. And so we're spending time, not just the wholesalers time, you know, to send those notifications to quarantine product. It's not available, but manufacturers. Time, too, right? Because you're having to

255

00:47:53.730 --> 00:48:02.299

In-Person Participant-1: do the research for it. So I think you know, we we call these. We coin the term false negatives. And I think that's something that needs to be understood.

256

00:48:02.330 --> 00:48:28.839

In-Person Participant-1: you know, as I said right now, we're doing it in one of our facilities. When we add another 2022 facilities, the volumes gonna go up, and I think it's gonna be a challenge. Last thing I'll just mention on the Brs is, there are some latency issues with that as well. The responses, I think, were designed to be second when it was 1st designed. And you know we are seeing, you know, 5, 8 25 seconds right? And if you think about

257

00:48:28.840 --> 00:48:40.609

In-Person Participant-1: someone at the return good station standing there waiting, waiting, waiting, and not being productive. You know, that's very concerning. So Brs is important. But there's some things that need to be worked out with it

258

00:48:41.720 --> 00:48:43.440

In-Person Participant-1: the same as well.

259

00:48:43.620 --> 00:48:55.669

In-Person Participant-1: We're we're very valuing, based on our repository, our data repository. And then, if we don't have a response, there, there's no data through them back out to the Brs. So it's going to be very important to move several products through.

260

00:48:56.300 --> 00:49:10.640

In-Person Participant-1: and we've seen a downturn in utilization of it. But we do have a lot of these false negatives. And most of them. It's either case, sensitivity issue where the lot isn't entered correctly because it is case sensitive.

261

00:49:10.690 --> 00:49:12.540

In-Person Participant-1: But we've seen a lot of

262

00:49:12.630 --> 00:49:19.489

In-Person Participant-1: it. Seems like the field is concatenated. So people will have people, you know, whoever submitting it might put.

263

00:49:19.550 --> 00:49:48.620

In-Person Participant-1: You know, the xbiri and the lot in the same field. So I don't know exactly how how it's working, but that's a good point. No, and and there is motorship on the distributor as well with our scanning process, because, you know, with the inverted Alpha characters, lowercase uppercase. If the user has taps on on their workstation, the scanner automatically inverts right? And of course, you know, when you go through the Vrs. It is case sensitive, and so that will return a negative.

264

00:49:48.620 --> 00:50:11.589

In-Person Participant-1: And we have seen some of those. I'll just call them weird situations where additional characters are added on to a lot or a serial number. And of course that's going to fail. And you know, when we send out these data. We try to include a picture of the barcode and and the human readable, and you can see what the real lot number is. And then you're like, why did this scan come out that way? So

265

00:50:11.970 --> 00:50:29.430

In-Person Participant-1: you know, we're learning right? Yeah, those yeah, we can figure out. But thank you for that. Yeah, Mary and I loved everything that you said. I hope like more trading partners will be on the Vrs like today. We see less 10. I want to say, like, maybe there are 8 trading partners who are using the Vrs

266

00:50:29.725 --> 00:50:46.289

In-Person Participant-1: I've seen an update this year like last year. In 2023, from the 1st quarter to the second quarter there was a rise, and then it just like declined. But this year I'm you know, just for the 1st 2 quarters I'm seeing like more than 50% increase. And most of it is

267

00:50:52.490 --> 00:51:06.299

In-Person Participant-1: as as you guys were talking. I was just also thinking to myself, you know, from a distributor point of view. I know you know many of you are not distributors, but it just struck me as we're going through all these details. Marianne is

268

00:51:06.740 --> 00:51:20.820

In-Person Participant-1: and and Pam as well. You know one of the things that sort of makes this industry and the supply chain unique and and also sort of is that it's core is really the efficiency that we drive.

269

00:51:21.150 --> 00:51:26.480

In-Person Participant-1: And that's something that I think you're just kind of struck me like. It makes

270

00:51:26.570 --> 00:51:48.740

In-Person Participant-1: good sense to get things to a place where it is efficient, where you don't have that person at the returns station waiting for, you know, 20 seconds, or what have you, whatever it is? To slow things down. We don't have quarantining a product to slow things down like the entire industry really is about

271

00:51:48.750 --> 00:51:59.919

In-Person Participant-1: moving things quickly, doing things the same way efficiently. You know, and as low as cost possible. And it's just struck me as as sort of part of this whole

272

00:52:00.060 --> 00:52:03.629

In-Person Participant-1: is really trying getting to that place right?

273

00:52:04.890 --> 00:52:12.390

In-Person Participant-1: Unless, like post November, it's not just saleable returns anymore. Right? Like verification expands to a lot more use cases.

274

00:52:12.440 --> 00:52:27.899

In-Person Participant-1: So I'm hoping our dispenser colleagues will also join us on the Vrs. Because I don't think as a manufacturer we could support, you know, so many emails coming in and manually looking at the verification. So an automated solution works great

275

00:52:29.550 --> 00:52:30.410

In-Person Participant-1: rapes.

276

00:52:31.540 --> 00:52:45.909

In-Person Participant-1: Audience question. It's been well uploaded next that we can probably get to, which is, how are distributors handling dropship? Pcis. I'll take that one so it just depends on the on the distributor. Right? So

277

00:52:46.020 --> 00:53:07.020

In-Person Participant-1: right now, you know, there is a provision in the law that allows for drop shipment data to be provided by the manufacturer. If the distributor doesn't physically handle it. So in the case of drop shipments, and I think that was made so that when the dispenser got that product, they could use it immediately versus waiting for

278

00:53:07.400 --> 00:53:11.999

In-Person Participant-1: the wholesaler, the manufacturer to build a wholesaler, the wholesaler to build the dispenser.

279

00:53:12.100 --> 00:53:25.019

In-Person Participant-1: So you know, in in the serialized environment? You know, one of the potential solutions is for the manufacturer to send the epcis for the drop shipment

280

00:53:25.120 --> 00:53:36.918

In-Person Participant-1: to the distributor and the distributor to pass that on basically unaltered, either via ecis the end user or make it available on the

281

00:53:38.489 --> 00:53:55.310

In-Person Participant-1: so that is one way, but not all distributors have that way to do it. So one of the challenges in the Pcis is in version 1.2. There's not a flag for drop shipment. It's coming with 1.3, but we're not on one right now, so

282

00:53:55.310 --> 00:54:23.619

In-Person Participant-1: there has to be some logic built in to understand that the sold to is the wholesale distributor and the ship to is the dispenser customer. So I can tell you. For, Cardinal, we don't have that in place right now. So we're looking for the manufacturers to continue to provide some, if you have the ability to send it via ecis direct. Most, I think, are providing it on on a portal. But again I'd say, ask your distributor, you know what they can do.

283

00:54:25.900 --> 00:54:52.159

In-Person Participant-1: See one ramification of this for the dispensers. In some cases we send it through our distributor portal, and in other cases it's direct to the dispenser, and in some cases we might already be a you know the dispenser might already be our customer, and they might say, Hey, we are connected to you. Send us that data directly, so I can see a a scenario where a dispenser might get data from both the distributor and the manufacturer.

284

00:54:52.340 --> 00:54:55.310

In-Person Participant-1: And I guess something is going to fail at some point.

285

00:55:01.170 --> 00:55:12.960

In-Person Participant-1: Okay, so we can move on to the next audience question. So one kind of through line that we've heard a good bit through this panel and other comments is the need for feedback. So for manufacturers, and also

286

00:55:13.170 --> 00:55:22.309

In-Person Participant-1: distributors as well. How many training partners are providing feedback on the quality of your data that you're providing for shipments to your customers right now.

287

00:55:22.440 --> 00:55:26.489

In-Person Participant-1: Those obviously can be ballpark. You don't have to know exactly how many, but

288

00:55:28.320 --> 00:55:30.930

In-Person Participant-1: for the the longest time. One

289

00:55:31.808 --> 00:55:41.180

In-Person Participant-1: just recently. 3. My issue is the quality of that feedback. And when we have questions about the feedback.

290

00:55:41.770 --> 00:55:43.740

In-Person Participant-1: the responsiveness, and

291

00:55:43.820 --> 00:55:49.548

In-Person Participant-1: I don't mean that in a derogatory way at all, because I know it's overwhelming.

292

00:55:49.940 --> 00:55:59.430

In-Person Participant-1: but it's really hard to do anything with that feedback. If we can't have a conversation and understand, is it accurate? Why, if it

293

00:55:59.450 --> 00:56:03.391

In-Person Participant-1: isn't accurate, what can we do to make it more accurate?

294

00:56:04.010 --> 00:56:06.069

In-Person Participant-1: but that's really, I mean, it's

295

00:56:06.600 --> 00:56:17.409

In-Person Participant-1: and I've talked to other colleagues at other manufacturers who aren't even getting what we are getting. So I feel fortunate as one of the larger manufacturers that we are at least getting threes, for.

296

00:56:18.350 --> 00:56:20.900

In-Person Participant-1: you know, on a weekly, by-weekly basis.

297

00:56:22.360 --> 00:56:23.486

In-Person Participant-1: Yeah. Hello,

298

00:56:24.100 --> 00:56:33.950

In-Person Participant-1: We are very grateful to the ones who who do provide us feedback, and I'll take that to nothing at all. So we have one scorecard one

299

00:56:34.400 --> 00:56:57.779

In-Person Participant-1: kind of inconsistent data, and then one accurate data. I think we still we do have like weekly calls with one of the distributors, you know who you are, and I'm incredibly grateful for those weekly calls to help us align. But yeah, we desperately need feedback you know, when we when we started out, like I, I know, we have belabored this point of data quality. But

300

00:56:57.920 --> 00:57:20.009

In-Person Participant-1: I I just want to tell you about, like, you know, our story, like when we report metrics to our upper management. It's almost like we need to have a sanity point of view versus a customer point of view. Like, you know, we might see 100% 90% of data going out. And then when we get feedback from the distributors, it's like shocking, like, you know, there, there's so many things failing.

301

00:57:20.050 --> 00:57:24.380

In-Person Participant-1: And we have no idea, I mean, like some of this feedback has helped us

302

00:57:24.470 --> 00:57:38.230

In-Person Participant-1: put in, like, you know, or at least it's in our roadmap to put in, you know better measures in place, so that we don't send out that which is not okay. But in other cases, like, you know, there is work to be done on both sides. So

303

00:57:38.590 --> 00:57:39.340

In-Person Participant-1: yep.

304

00:57:40.360 --> 00:58:05.839

In-Person Participant-1: Say, you know, as I said before, it's been challenging to provide accurate feedback. You know, we we think we're providing what's good feedback. And then we hear from a manufacturer. And it's like, Oh, okay, let us go back to the drawing board and reconsider that. And we've spent a lot of time. You know, with our with our teams, kind of looking at the measurements and trying to get them as as accurate as possible.

305

00:58:05.840 --> 00:58:25.180

In-Person Participant-1: something as simple as a po number. Right? It has digits in it, and then everyone begins with a C, and the last 3 alphas! Are what distribution center it's going to, and that C and that alpha isn't always appearing. And then so there's not a match on the Po. And so we say we didn't get it. But

306

00:58:25.270 --> 00:58:39.169

In-Person Participant-1: I was there just on the reporting side didn't match. And it's those little things it's complex, right? You don't even think about that until you know someone looks at it and says, Wait a minute. And now you have to go back and rearrange your reporting to reflect that.

307

00:58:40.905 --> 00:58:52.830

In-Person Participant-1: So we're providing information on the inbound. If we've received your Epcs file we've had responses of quit sending me this I'm not ready.

308

00:58:53.622 --> 00:58:55.727

In-Person Participant-1: You're overwhelming me.

309

00:58:56.610 --> 00:59:13.870

In-Person Participant-1: This was the same. Po. Yes, sir, it is. You shipped it to different times. So it's kind of on both sides. We've turned it on. And some people said, Stop! And we've turned it off. And they're like, you're not sending me anything. So we currently have everyone on. So if you're not getting anything kudos to you.

310

00:59:14.070 --> 00:59:21.099

In-Person Participant-1: everything's going well. We are working on. When we implement our next DC, next week we'll start sending out Joel's workaround

311

00:59:21.110 --> 00:59:23.480

In-Person Participant-1: to what's actually being, or safe versus

312

00:59:23.540 --> 00:59:25.349

In-Person Participant-1: a Dp's file. So

313

00:59:26.060 --> 00:59:28.260

In-Person Participant-1: review for mastery, how we

314

00:59:29.119 --> 00:59:51.490

In-Person Participant-1: so for you guys both, I guess, for 1st from the manufacturers, and then distributors are the problems that you are seeing like when you do get that feedback and you? Is it univers like, are they universal for for all the respondents? Or is it really a case by case basis depending on the files?

315

00:59:54.080 --> 00:59:57.410

In-Person Participant-1: I can't really tell you that because we don't have enough data

316

00:59:57.880 --> 01:00:03.110

In-Person Participant-1: to evaluate early on a lot of it was master data issues. So you know.

317

01:00:03.240 --> 01:00:11.490

In-Person Participant-1: we had provided A. G. 10. They were. Still they had the prior, G. 10 loaded, so it didn't add but

318

01:00:12.080 --> 01:00:14.310

In-Person Participant-1: I don't know. I would guess that

319

01:00:14.340 --> 01:00:18.109

In-Person Participant-1: once we start to do the root cause analysis of these issues.

320

01:00:19.050 --> 01:00:22.769

In-Person Participant-1: and we understand the root cause we put in prevention and actions.

321

01:00:23.880 --> 01:00:25.129

In-Person Participant-1: I'm hopeful that

322

01:00:25.480 --> 01:00:27.230

In-Person Participant-1: we'll get to stabilized

323

01:00:28.210 --> 01:00:30.550

In-Person Participant-1: status relatively quickly.

324

01:00:30.570 --> 01:00:31.939

In-Person Participant-1: But I I

325

01:00:32.830 --> 01:00:34.689

In-Person Participant-1: don't have. Yeah.

326

01:00:35.780 --> 01:00:37.149

In-Person Participant-1: Sometimes it's that

327

01:00:37.390 --> 01:00:53.670

In-Person Participant-1: you, as a wholesale or manufacturer, if you're using a 3 PL. The 3 Pm. May still have old product on the shelf. So they're still shipping old product. And we've gotten the new master data. So that's the reason where we load that it doesn't match up all the time.

328

01:00:53.740 --> 01:01:09.240

In-Person Participant-1: So then we get an error because we can't receive it, even though you know that's you're going to be shipping that it's not just currently what you've been shipping. So that may be why, you see some of the errors. But our primary errors are Master Data, Glenn Sglen and Timestamp.

329

01:01:09.430 --> 01:01:27.680

In-Person Participant-1: Those are what typically give us the worst problems, or it's a duplicate. Ssc, so whether the manufacturer may have had an issue, maybe on the initial file coming out to us, and they've resend it, and that Ssc. Fails because it's duplicated. We've seen Ssc. That have nothing on them.

330

01:01:27.850 --> 01:01:31.059

In-Person Participant-1: They send me an Sfcc. But there's no serialized data with it.

331

01:01:31.090 --> 01:01:37.319

In-Person Participant-1: But those are our standard problems coming inbound what the errors are. And then, when we actually receive.

332

01:01:37.677 --> 01:01:50.749

In-Person Participant-1: It's Pi data doesn't match. G, 10 is not loaded. There are occasions when we have a duplicated G 10 in our system which also causes problems. So those are kind of our standards of the problems that we see on the regular.

333

01:01:52.620 --> 01:02:20.340

In-Person Participant-1: Take the feedback very, very seriously. We have daily calls with all of the you know it. Folks from every interface that meets together and looks at looks at this feedback on our side like we try to simplify our architecture, our serialization architecture to reduce interfaces. And that had some setbacks. So we do see some common you know data challenges across the feedback that we are getting

334

01:02:23.860 --> 01:02:26.842

In-Person Participant-1: great. Thanks, you guys. I

335

01:02:28.650 --> 01:02:44.080

In-Person Participant-1: we, I know we have 1 min left. And I'm sort of distracted by the question at the bottom of the screen. Which is, which is, are you still passing pedigrees from providing serialized information? And I think that. I hope that's a big

336

01:02:44.160 --> 01:02:47.590

In-Person Participant-1: no because that was

337

01:02:47.910 --> 01:02:52.829

In-Person Participant-1: repealed. By the Tscsa 10 years ago.

338

01:02:53.325 --> 01:03:02.839

In-Person Participant-1: So anyway, does anybody have any parting thoughts for the audience or the online participants before we sign off

339

01:03:05.450 --> 01:03:09.080

In-Person Participant-1: collaboration communication. I mean, that's how we're gonna

340

01:03:09.310 --> 01:03:10.730

In-Person Participant-1: get to where we need to be.

341

01:03:13.060 --> 01:03:14.530

In-Person Participant-1: If you're not connected.

342

01:03:15.470 --> 01:03:18.109

In-Person Participant-1: please call me. I'll give you my card.

343

01:03:19.380 --> 01:03:21.319

In-Person Participant-1: I still have about 10%.

344

01:03:25.660 --> 01:03:33.899

In-Person Participant-1: All right. Well, thank you so much. I think this is a great panel and appreciate all of your efforts, and I think I hand this over

345

01:03:34.140 --> 01:03:35.230

In-Person Participant-1: to Aaron.

346

01:04:02.200 --> 01:04:09.750

In-Person Participant-1: All right. We've arrived here at our last session, so I'm excited to be joined by Dr. Lever Bois here, and we're going to spend the remainder here

347

01:04:09.750 --> 01:04:36.099

In-Person Participant-1: kind of offering some takeaways trying to organize the conversation from the day, and then we will open it up to questions. So we will again put another QR. Code up concurrent. Continue to encourage folks to submit questions that we'll be happy to take as we finish up wrapping up some some final thoughts here. So at the beginning of the day I I had framed out, and how I was gonna be listening to this question of what is stabilization in 5 dimensions

348

01:04:36.270 --> 01:05:03.550

In-Person Participant-1: systems, data and exceptions, processes, patient access and resources. And so I've just kind of organized what I thought. I've heard you the last few hours in that way. So on the system side, right? I think we we heard a lot about at least a few times this not just following standards, but this consistent application of standards. Right? When you start to get down at that system level to how people are applying standards internally and down at that very detail level.

349

01:05:03.730 --> 01:05:19.999

In-Person Participant-1: and the importance of having that integration across all of your systems within your organization. Right? This came up in that conversation around latency the number of systems that your data flows through and is connected those touch points, and how you integrate that in your organizations.

350

01:05:20.140 --> 01:05:36.330

In-Person Participant-1: that with regard to data and ex and exceptions, right? Probably the thing that we heard most over and over, entirely, unsurprisingly right? I think confidence right? When you get to the point where you have confidence in your data starts to signal what may look like stabilization.

351

01:05:36.360 --> 01:05:59.729

In-Person Participant-1: I like the way somebody put it right at when we're only worrying about exceptions. That will be a good day right in in part, what we've heard to a, you know, recent conversations and kind of came through here today is this sort of this 80 20 rule, as you think about exceptions. Right? I think folks are starting to feel like they've zeroed in on that 80% right? The glen issues the the G 10 issues, the master data pieces

352

01:05:59.910 --> 01:06:08.809

In-Person Participant-1: those pieces where you can fix one issue and resolve it, you know, for a lot of suppliers, a lot of customers, a lot of products, a lot of transactions

353

01:06:09.040 --> 01:06:16.450

In-Person Participant-1: and people starting to now flip to that 20%, right? Those one-off product, specific transaction specific types of exemptions

354

01:06:16.753 --> 01:06:27.229

In-Person Participant-1: starting to look a lot more like like stabilization. The other phrase I heard I think it was Scott Kuzner that I really liked as well right. This notion of consistently higher integrity to your day.

355

01:06:27.300 --> 01:06:34.289

In-Person Participant-1: right in some ways saying continuous improvement in another way. But I think it's a nice application of it to the conversation we've been having.

356

01:06:34.983 --> 01:06:57.100

In-Person Participant-1: I'm gonna hold the process piece. I think we're gonna hear more of that. Probably tomorrow, right? As we start to turn to the pharmacy end of the supply chain. With regard to patient access. Right? It stabilize. What does that look like? Lower quarantines and lower risk of return? Right. I think we heard that that patient risk start to come through. And we start talking about product getting held up in quarantine, and the difficulty working through that.

357

01:06:57.100 --> 01:07:16.150

In-Person Participant-1: or when you hit that point where the product's just gonna go back and and potentially be destroyed so that nobody wants to see as well and then on the resource side, I just continued to be, for lack of a better word, fascinated by the amount of staffing and complexity of the staffing to handle exceptions. Right? You know.

358

01:07:16.150 --> 01:07:32.289

In-Person Participant-1: Mary Ann talked to me about 40 people, and still maybe not being enough to handle exceptions, and so I don't. I don't know what that means for stabilization. I guess it means layoffs down the road when you can start repurposing those customer service people in your account stabilize. I don't know, but I continue to be

359

01:07:32.520 --> 01:07:33.360

In-Person Participant-1: daddy

360

01:07:33.930 --> 01:07:48.429

In-Person Participant-1: fascinating, concerned by the amount of human resource that is needed to work through that complexity of that hiring challenge. And so yeah, those are really kind of the the pieces that that I saw and highlighted in that question. But we I'd love to just get your rep

361

01:07:55.220 --> 01:07:58.600

In-Person Participant-1: process presented today. And those in the audience that have

362

01:07:58.900 --> 01:08:01.670

In-Person Participant-1: participated is is really valuable for us.

363

01:08:37.160 --> 01:08:40.410

In-Person Participant-1: Great. And you need to understand.

364

01:08:51.840 --> 01:09:11.749

In-Person Participant-1: Okay, that's better. You need to take a snack, break and you need to pull the people in the card. Understand what else needs to be done, and I think that idea of what we need to be doing from a communication and collaboration perspective. Mary Ann kind of hit the nail on the head at the end. What do we need to do

365

01:09:12.180 --> 01:09:27.889

In-Person Participant-1: but that snack break provides us with an opportunity to evaluate and monitor our systems and processes, and to make sure that we're coordinating and collaborating as effectively as to to make sure that we're able to get through the stabilization period and get through it together.

366

01:09:27.899 --> 01:09:38.139

In-Person Participant-1: and I say together because we can't do it, you can't do it alone, and we can't do it alone. And as we've been working through the stable period. We've been

367

01:09:38.200 --> 01:09:54.199

In-Person Participant-1: seeking guidance, seeking, input, I should say, so we could make sure that we could provide information out in a timely fashion and convey what the important pieces are from an implementation perspective. I think I'm going in and out, and if I am, just raise your hand

368

01:09:54.994 --> 01:10:07.169

In-Person Participant-1: so a couple of things that I've really heard today. Which I is really is is really important for us is continuing improving education and outreach.

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01:10:07.170 --> 01:10:25.609

In-Person Participant-1: and how we can think through what that means. I think it's really important for us to coalesce around how we can be as creative and innovative. And, Eric, I would love to get your thoughts on what that what you think that means as the lead for the partnership for Dscsa governments.

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01:10:26.670 --> 01:10:49.369

In-Person Participant-1: Yeah. So I think I think you're right with the collaboration engagement piece was absolutely key, and I guess I heard 3 layers of tears of it right one was, and I'll maybe do the 2 easier ones. First, st right? One was within your organization right? Some folks talked about that importance of making sure all parts of your organization are involved and educated in in understanding words here, from

371

01:10:49.370 --> 01:11:17.459

In-Person Participant-1: legal and contracting down to Mba. So we heard that part right? And that's where right? You can really leverage. I think best practices, good practices, engage with your trade associations, forums like Pdg, Gs, one, right, those places where you can get out and do what you're doing today, connecting, engaging with everybody else from the industry. Second, then, is engaging with those trading partners who are out there. You're actively connected and sending and exchanging data with right? We've heard a lot today about

372

01:11:17.720 --> 01:11:39.970

In-Person Participant-1: the the intensity of collaboration needed to move data exchange to stabilized data exchange. Right? And I think part of that is just time and value. Right? I think we're starting to see it, and we're starting to see things move in a much better direction and part of it is a resource challenge, right? We just spent some time talking about it on that last panel, but I I think the

373

01:11:40.200 --> 01:12:10.140

In-Person Participant-1: the the that tier layer that people are most thinking about there, including you. Probably Lee, right, is those people who are not actively engaged in in sending data. Vetting data aren't here today, likely, either. Right? And so how do we reach those people who aren't part of these conversations and start to get the attention and traction. I think you're right. You've gotta get creative. You gotta get strategic some folks offered some ideas on different ways to leverage other business partnerships and reach some of those parts of the supply chain.

374

01:12:10.460 --> 01:12:34.059

In-Person Participant-1: But I guess there's maybe 2 other things that I think we really have to think about, too. One is, how do we make it? A business priority for them? Right? How do we take it from a regulatory need or compliance issue and make it a true business priority for them. And and we heard some of that today, right? When when saleable returns, start to become a challenge for someone because

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01:12:34.140 --> 01:12:44.099

In-Person Participant-1: they didn't have the data and data was off. They can't. Their wholesaler can't verify and say won't take a saleable return right? That starts to become a a business imperative in a business priority for them.

376

01:12:44.170 --> 01:12:51.240

In-Person Participant-1: When it starts to go back, as some folks talked about and and goes into destruction. We start to take good product out of the supply chain.

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01:12:51.657 --> 01:13:12.189

In-Person Participant-1: Yeah, I won't push this line too far, but if it right starts to eventually become a commercial risk and a product access risk, too, right? Or or when start slow starts to get hung up and quarantine. So how do we start to to pivot the conversation from a compliance and regulatory conversation, and start to make it a business priority. For some of those organizations

378

01:13:12.410 --> 01:13:24.503

In-Person Participant-1: emphasizing to that right? It's it's not only dispensers right? I think we a lot of times we automatically fall to. Oh, it's the small dispensers, but I think it it cuts across all parts of the supply chain is part of what we heard here today as well.

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01:13:24.750 --> 01:13:49.400

In-Person Participant-1: and I think we also have to do a better job of of making what making that educational and engaging material more actionable and more simplified. And I know this will come up tomorrow. I see Elisa Bernstein back here, and you've done a great job of talking about this. I still don't know that anybody, myself included right, is quite hit the head. The nail on the head, yet in terms of really conveying it especially to pharmacists.

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01:13:49.440 --> 01:13:52.230

In-Person Participant-1: in a very simple, practical.

381

01:13:52.260 --> 01:13:59.440

In-Person Participant-1: action-oriented kind of way. What they need to do, and I think there's still opportunity for improvement there as well.

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01:13:59.690 --> 01:14:02.865

In-Person Participant-1: I do wonder. And Lee I mentioned in your perspective, I think

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01:14:03.650 --> 01:14:10.780

In-Person Participant-1: 2 sides to your announcement last week, right? With regard to the lifting of the stabilization period for parts of the supply chain, right

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01:14:11.070 --> 01:14:24.800

In-Person Participant-1: does become a momentum, create an action forcing event which is good. I I do worry and wonder for the small dispenser community. And there's a lot of them. Right? Have we made that challenge harder by giving them

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01:14:25.030 --> 01:14:37.659

In-Person Participant-1: some breathing space right? And I think I think that's what we're gonna hear tomorrow is that risk of a lot of folks are gonna turn to other priorities. And so how do we guard against that? How do we keep that pressure on

386

01:14:37.720 --> 01:14:43.060

In-Person Participant-1: recognizing the reason you had to make that move for the sake of access.

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01:14:43.190 --> 01:14:56.759

In-Person Participant-1: Kind of say, I think, that we started the stabilization period as a measure to ensure that trading partners had ample time to ensure that product could move the supply chain while they were implementing Dscsa.

388

01:14:57.030 --> 01:15:11.850

In-Person Participant-1: And the data that we're seeing so far shows that treating partners took advantage of that time. They didn't just stop implementing Csa, sure, there's some that stopped. There's new systems and processes. I'm not gonna disregard that.

389

01:15:12.000 --> 01:15:27.600

In-Person Participant-1: But the vast majority that started engagement in increased their engagement in Ds. U.S.A. They continue down the pathway, and I think that for us to think about it from that perspective. As relates to the small dispensers.

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01:15:27.600 --> 01:15:50.610

In-Person Participant-1: we have an opportunity in this 2 year period to do the exact same thing we did during a stabilization period we can continue to do additional outreach and education. We can work to make sure that they truly understand what's required, and we can bring additional partners to the table. And so I think that's really the opportunity that we're have we have by having that additional time

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01:15:50.750 --> 01:15:59.330

In-Person Participant-1: it can. It can go both ways. There may be some small dispensers that are just like I'm gonna wait till the end. But that's not what we saw during the stabilization period.

392

01:16:00.200 --> 01:16:02.199

In-Person Participant-1: Yeah, I think that's fair.

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01:16:02.840 --> 01:16:09.830

In-Person Participant-1: You know. What are the other questions Lee that I had? Is it something that came up? I forget now who said on the last panel,

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01:16:10.270 --> 01:16:37.409

In-Person Participant-1: that importance of of keeping the patient in mind and doing the right thing for the patient right. One of the questions that comes up over and over is what happens. We'll raise it to you right? What what happens when the pharmacist is there with the product? There's a data question right in in doing right by the patient. I just love your perspective kind of on that frame. Yeah, I think from the FDA perspective, that's always 1st and foremost on our mind. We always think about that before we make any policy decision. So I think that

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01:16:37.410 --> 01:16:47.190

In-Person Participant-1: as we're moving through this period of time, understanding that the patient stays at the forefront from a Dsa perspective. It does it for all of us, our other perspectives.

396

01:16:47.410 --> 01:16:48.080

In-Person Participant-1: But

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01:16:48.190 --> 01:17:08.150

In-Person Participant-1: we we did our initial outreach and education for the stabilization period about ensuring access to patients. And we want to make sure that we continue to keep that going, that we continue to ensure access to patients through the system processes that we have in place and the policy options that we have in front of us.

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01:17:08.390 --> 01:17:14.169

In-Person Participant-1: Yeah. And I think it's fair to know, too, right? Doing the right thing, for the patient doesn't necessarily mean

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01:17:14.440 --> 01:17:18.154

In-Person Participant-1: always hand the product over right? That's 1 of the risks right is.

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01:17:19.407 --> 01:17:42.710

In-Person Participant-1: you have to have that. You have to have the full sop and the set of controls and processes around it right to be able to conclude. I have this product without data. And it's a product I feel good about giving to the patient right? It's it can't just be a I have product, and I'm I guess it must be a data error. Right? There, there's a bar that was raised through the Dsc. For a purpose, and so doing right by the patient

401

01:17:42.710 --> 01:18:00.699

In-Person Participant-1: can have both sides of that coin, too. It can be we. We definitely need to look at both sides of the point. I think something you brought up in terms of the the sops and our OP. Our operations. I think what's really important for us to think through. And and it's something that's come out in almost every one of the presentation or the panel discussions is

402

01:18:01.120 --> 01:18:02.300

In-Person Participant-1: we're not.

403

01:18:02.610 --> 01:18:28.349

In-Person Participant-1: We're not able to think about this independently. We have to think about this in an interdependent manner, and if we're not, then we're probably not gonna make it to the end stage. Those trading partners. How are you thinking about those systems and processes to ensure that you're really establishing those processes with your trading partners, and that there's alignment. And I someone, not. I'm sorry for not having the actual panelists, because I like to do that if I'm gonna amplify a message.

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01:18:28.360 --> 01:18:35.650

In-Person Participant-1: But someone said that we've got to make sure our systems and processes are amplified are are aligned across our trading part

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01:18:35.750 --> 01:18:50.179

In-Person Participant-1: to really ensure that we're effectively moving product. And I think that that's what we'd wanna. Do. We want this effectiveness? We want to ensure efficiency in the system. And you do that by aligning operations, not just internally

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01:18:50.770 --> 01:19:17.380

In-Person Participant-1: with others outside. Yeah. And I think to interconnection and relatedness of the components of the Dsc, too, right? We spend a lot of time today talking about did exchange where the interoperability conversation always goes, but keeping in mind. It's position within that full Dsc kind of suite of tools from atp verification to verification systems, product, identifier verification, traceability as well. Right?

407

01:19:19.240 --> 01:19:22.379

In-Person Participant-1: Other key takeaways from the day. Aye.

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01:19:22.510 --> 01:19:24.620

In-Person Participant-1: I think we've hit all of you.

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01:19:25.450 --> 01:19:29.170

In-Person Participant-1: Okay, have questions started coming in. Zack.

410

01:19:30.530 --> 01:19:31.250

In-Person Participant-1: Oh.

411

01:19:32.716 --> 01:19:33.690

In-Person Participant-1: good morning.

412

01:19:37.520 --> 01:19:40.010

In-Person Participant-1: Just wait. Paper.

413

01:19:41.590 --> 01:19:44.909

In-Person Participant-1: Supriya Kopal. I'm a consultant.

414

01:19:45.476 --> 01:19:47.180

In-Person Participant-1: No. The 27th

415

01:19:47.730 --> 01:19:52.399

In-Person Participant-1: ideal situation, everything great. We all heard the problem statements here.

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01:19:53.580 --> 01:19:55.020

In-Person Participant-1: What does our plan be?

417

01:19:55.650 --> 01:19:58.900

In-Person Participant-1: So I don't, you know, like Kathy alluded.

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01:19:58.930 --> 01:20:03.220

In-Person Participant-1: we don't want shortage. We all that's everyone's goal here.

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01:20:03.600 --> 01:20:13.370

In-Person Participant-1: But is there? Everyone has a process. And to move the drug just by documenting sop, we can move the drug based on the priority of the drugs.

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01:20:13.540 --> 01:20:16.209

In-Person Participant-1: I don't know. I just want to hear from everyone.

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01:20:16.690 --> 01:20:43.700

In-Person Participant-1: So I I think the question you're asking is actually question we would ask of industry, what is the plan? B. What systems and process of have you put into place for exceptions, handling? Where have you gone in terms of asking or seeking out your weir, so is there. Is there a plan in place? Because what we've been on is a very long road trip, and you are developing your map to make sure you get from point A to Point B

422

01:20:43.890 --> 01:21:03.549

In-Person Participant-1: in that point A to Point B, there's planning that happens to ensure that you effectively are able to address the in stage 2. You don't just arrive and jump out of the car, and everything's ready to go. You have to unpack that car you have to make sure people have what they need in the next stage of your trip. That's what that is. That's what the plan B is.

423

01:21:06.790 --> 01:21:07.680

In-Person Participant-1: lists.

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01:21:12.690 --> 01:21:18.689

In-Person Participant-1: Thanks. Yeah, I just have kind of a follow-on question to that which is.

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01:21:18.890 --> 01:21:23.400

In-Person Participant-1: well. 2. It's sort of a 2 part question. Because I think for many

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01:21:23.470 --> 01:21:34.799

In-Person Participant-1: a plan. B is apply for a week, in some cases depending on where you are in your process, right and evaluate. Now is the time to evaluate

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01:21:35.020 --> 01:21:47.100

In-Person Participant-1: kind of what you think you're going to encounter in the next couple of months, and whether you'll need a wee. But I think the challenge the challenge there, I think, for all the companies is that

428

01:21:47.190 --> 01:21:51.690

In-Person Participant-1: you don't want to admit now that you're not going to be ready in 4 months. But if you don't.

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01:21:51.740 --> 01:21:54.780

In-Person Participant-1: if you don't sort of plan ahead, then you're also

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01:21:55.040 --> 01:21:58.310

In-Person Participant-1: going to be behind the 8 ball, and when that when that

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01:21:58.580 --> 01:22:06.730

In-Person Participant-1: time comes the challenge. Also, I think. And maybe this is a unknown is sort of that risk assessment like anything that FDA can

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01:22:07.320 --> 01:22:14.449

In-Person Participant-1: give us as industry in terms of. And maybe it's now maybe now is too early. But in terms of

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01:22:14.740 --> 01:22:28.669

In-Person Participant-1: how Enforcement's going to look and what the expectations can be for those who are making a strong effort. And, you know, continuing along and working through exceptions and working through data

434

01:22:28.750 --> 01:22:30.020

In-Person Participant-1: earnestly.

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01:22:30.526 --> 01:22:32.150

In-Person Participant-1: I think I think

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01:22:32.340 --> 01:22:39.090

In-Person Participant-1: a clue, or you know some signs from FDA in terms of how enforcement will look after November.

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01:22:39.110 --> 01:22:43.169

In-Person Participant-1: I think, would be, would go a long way to to helping

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01:22:43.290 --> 01:22:46.759

In-Person Participant-1: people's comfort, level and and kind of moving things along.

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01:22:48.390 --> 01:23:16.809

In-Person Participant-1: So you said you had 2 questions, and I heard really one I I just wanna make sure like cause. I I'll kind of like weave in what you've said all along. I think that you're right. There's going to be some people who are not ready to acknowledge that they're not ready. That's gonna put them behind the 8 ball. I just wanna say that. 1st and foremost, we've we've specifically indicated that we are looking for people to be proactive in their identification of whether or not we're going to input a request.

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01:23:16.830 --> 01:23:43.619

In-Person Participant-1: And that needs to be something that organizations need to think through critically, so that we have an opportunity to address the products that are the products and programs that are being the the Weas are requested for like any business, it takes time to do the work that's associated with it. We wanna make sure that we are setting ourselves. And I'm not saying this is the FDA. But we're setting ourselves as a totality

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01:23:43.820 --> 01:23:45.869

In-Person Participant-1: up for success because

442

01:23:45.950 --> 01:24:00.430

In-Person Participant-1: it's a the supply. Chains are interconnected. If one organization is potentially not prepared. It could have large ramifications for a lot of others. We wanna make sure that those are all organizations, understand what

443

01:24:00.440 --> 01:24:04.740

In-Person Participant-1: we have in place to to really facilitate supply chain integrity.

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01:24:05.440 --> 01:24:08.179

In-Person Participant-1: patient access to products. Because.

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01:24:08.390 --> 01:24:17.450

In-Person Participant-1: like everyone said, That's our number one, concern is the patient access to products. So we want to make sure that organizations understand?

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01:24:17.640 --> 01:24:20.199

In-Person Participant-1: If I could just add one thing that's not even related.

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01:24:21.038 --> 01:24:36.549

In-Person Participant-1: We have heard in this meeting, and before beginning in like August of last year. Make sure you're out there talking. Make sure you're speaking about what you need and how you're doing what you're going to be doing.

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01:24:36.660 --> 01:24:45.999

In-Person Participant-1: And we understand. And that's why we've been trying to communicate as much as we have. We intend to take a risk based approach in terms of enforcement, our compliance and enforcement

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01:24:46.440 --> 01:25:01.629

In-Person Participant-1: to make sure that we are looking at things that matter most. And so we, I hear you, and will continue continue to communicate with industry. To make sure there's clarity associated with what we're doing.

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01:25:02.900 --> 01:25:07.842

In-Person Participant-1: Good. I'm gonna take one up screen and then we'll come back to the office just to kind of mix it up a little bit.

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01:25:08.770 --> 01:25:17.740

In-Person Participant-1: Do we have one? You've settled on, Zack, or, yes, we'll we'll start off with this 1st one that's the most uploaded. So this one's directed into to the FDA.

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01:25:18.360 --> 01:25:28.719

In-Person Participant-1: So, in light of the FDA's statement earlier about ignored extending the enforcement. The stabilization period is a phased approach, an option.

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01:25:29.000 --> 01:25:53.889

In-Person Participant-1: So I love how the the question has morphed throughout the panels, because it's kind of been in there, and I've been watching it shift, and more and more. It's gotten succinct. Just add a little levity to the to the panel. I. What? What I wanna make sure is that we have heard from stakeholders across the supply chain, and both that there is potential for

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01:25:53.890 --> 01:26:07.939

In-Person Participant-1: potential need for a phased approach. But we've also heard like, Hey, we just need this done, we need this now. And so in evaluating our approach, we've evaluated all comments across. The participants that have been providing us with feedback.

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01:26:08.130 --> 01:26:16.329

In-Person Participant-1: We recognize that there are diverse needs across the supply chain and believe that the approach that we've put out there in terms of

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01:26:16.340 --> 01:26:24.525

In-Person Participant-1: the stabilization period which provided an opportunity for organizations to come pull, to continue to for their programs.

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01:26:25.170 --> 01:26:46.889

In-Person Participant-1: was a good approach, and we continue to believe that the issuance of the small dispenser we're request was, is going to be an approach that brings compliance for Dscsa. So I think, the question is, is it off the table as an option? That's not what we've outlined online? And I would recommend that everyone go online

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01:26:47.460 --> 01:26:56.930

In-Person Participant-1: our newest information that's available to really make it clear about the approach that we're intending to take for Dsa.

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01:26:58.710 --> 01:26:59.400

In-Person Participant-1: 10,

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01:27:00.080 --> 01:27:15.060

In-Person Participant-1: one more Zack before turning out. It's in the room. Yes. So another one kind of in the similar vein, based on the recent announcement is, are the waivers and exception approvals going to be made public for trading partners to know as

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01:27:15.210 --> 01:27:16.569

In-Person Participant-1: waivers and exceptions.

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01:27:17.124 --> 01:27:21.679

In-Person Participant-1: So I think that this one is we typically don't

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01:27:22.076 --> 01:27:35.270

In-Person Participant-1: post public information. There's a lot of reasons why there would be opportunities, for, I think, supply chain incursions if we were beginning to post this publicly across the board. And so we

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01:27:35.370 --> 01:27:59.810

In-Person Participant-1: we are not posting. We approvals in the public domain. But I'll point out that the the infirm, if a waiver, exception or exemption is received, trading partners are responsible for sharing that with other trading partners. So you're you should have that information from your trading partners that are providing you, and you should be able to receive that information from them.

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01:28:02.600 --> 01:28:03.609

In-Person Participant-1: Carl. Go ahead.

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01:28:05.261 --> 01:28:10.900

In-Person Participant-1: I I've been blessed over the years to work on a lot of great therapies, and so

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01:28:10.930 --> 01:28:14.940

In-Person Participant-1: I believe very much that not all therapies are created equal.

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01:28:15.010 --> 01:28:26.169

In-Person Participant-1: We have a list of essential medicines that came out of the pandemic are all those essential medicines currently one 100% ready for compliance

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01:28:26.490 --> 01:28:29.519

In-Person Participant-1: on November 27.th Do we know that

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01:28:29.570 --> 01:28:32.790

In-Person Participant-1: as a starting point you mentioned risk management.

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01:28:33.080 --> 01:28:39.390

In-Person Participant-1: How do you assess risk management? Is it going to be based on therapeutic value?

472

01:28:39.650 --> 01:28:43.569

In-Person Participant-1: Is it going to be the essential medicines have to be a hundred percent.

473

01:28:44.060 --> 01:28:48.400

In-Person Participant-1: Or I guess you give a we if somebody's not ready.

474

01:28:48.840 --> 01:28:53.500

In-Person Participant-1: is that is that kind of standard that you're gonna apply to the risk management.

475

01:28:53.920 --> 01:29:14.160

In-Person Participant-1: So we certainly in risk management certainly weighs in patient access and patient access weaves and medical necessity. I can't speak to whether or not 100 of the products that are on the medical necessity list are ready for Dscsa. There's probably people in this room who have

476

01:29:14.780 --> 01:29:29.989

In-Person Participant-1: products that are on that list, and it would be interesting to hear from them. But honestly, even if we heard from them. It wouldn't give us a really good picture for all of the products that are on that list. Because we know we've got the people that are in this room are most likely to be

477

01:29:30.140 --> 01:29:53.320

In-Person Participant-1: ready. Right? So I I think it would be kind of interesting. From a risk based perspective. Patient access plays a role in in developing what we think of as one of the most a very important factor in ensuring that case, that there's supply chain integrity and and so that we will be weighing that

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01:29:57.290 --> 01:29:59.829

In-Person Participant-1: Zach other questions in the queue.

479

01:29:59.840 --> 01:30:09.739

In-Person Participant-1: Yeah. So we've had Dave Mason, with his hand raised for a little bit. I don't know, Dave, if you have, have a comment. But back from one of your one of the previous discussions.

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01:30:10.040 --> 01:30:10.640

David Mason: I'm here.

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01:30:10.880 --> 01:30:15.689

David Mason: So okay, I have a I have a comment and a question.

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01:30:15.820 --> 01:30:16.890

David Mason: So

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01:30:17.000 --> 01:30:22.180

David Mason: in the manufacturing space from an FDA, we've been heavily FDA regulated, but in the

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01:30:22.290 --> 01:30:26.300

David Mason: in the space of distributors, and especially dispensers.

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01:30:26.320 --> 01:30:32.040

David Mason: they. This, a lot of this is new because they they don't follow the Cfrs. But they follow. The

486

01:30:32.060 --> 01:30:40.989

David Mason: the distributors are good distribution practices. So we keep talking about this risk based approach. And I've been in a lot of industry meetings and everything.

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01:30:41.340 --> 01:30:48.340

David Mason: And I think when you leave the manufacturing space, it's it's kind of confusing and understanding

488

01:30:49.281 --> 01:30:53.149

David Mason: does it from a distributor and dispenser what that means and

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01:30:53.200 --> 01:30:57.330

David Mason: it could. The is the FDA planning on putting out some type of guidance

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01:30:57.400 --> 01:31:06.589

David Mason: for this, because I think it would help, or or some kind of QA. Document, because there's a lot of confusion when you talk with space approach.

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01:31:06.970 --> 01:31:10.870

David Mason: And then, before he answered the question, my other concern is.

492

01:31:11.020 --> 01:31:18.830

David Mason: we keep talk. I want to. I want the product. Get it. Get to the patient, too. But what I'm starting to see is a lot of illicit activities

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01:31:18.900 --> 01:31:21.819

David Mason: down in the supply chain more than usual.

494

01:31:22.240 --> 01:31:33.649

David Mason: So when you talk about this risk-based approach, I think I've heard people down below just say, Oh, if I don't have data, I'm just going to pass it. And I think that should be part of a a risk based approach.

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01:31:34.098 --> 01:31:41.260

David Mason: Anyway, we we should have rules and regulations in place to make sure we're not passing on, even without data

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01:31:41.827 --> 01:31:56.159

David Mason: counterfeit or diverted products and things like that, so that it's kind of inner. So she can talk about the what your plans are, how to communicate this risk based, approach more towards the distributor and dispenser space.

497

01:31:57.080 --> 01:32:01.298

David Mason: Does that make sense? I hope I made sense. I was rambling a little bit.

498

01:32:01.580 --> 01:32:15.969

In-Person Participant-1: So I I think I understand it, and I'll address I think I'll be able to address your point. I you know, I think for years there have been individuals who've been talking about the confidence that we have within the data that's available.

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01:32:16.332 --> 01:32:32.190

In-Person Participant-1: Some of that has is data integrity like, what's the confidence that we have in our communications with our trading partners, and the confidence that we have and the information that's being passed with regulators. And I think what Dave's pointing try pointing out is

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01:32:32.270 --> 01:32:39.429

In-Person Participant-1: the importance of the data that's moving and the value that plays in ensuring supply chain integrity.

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01:32:39.943 --> 01:32:59.779

In-Person Participant-1: From a a guidance perspective. We're not intending to issue a guidance on this. There's a fair amount of information. We believe, that showcases that the level of compliance is necessary, and we'll be looking at the systems and processes that are around organizations to

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01:32:59.780 --> 01:33:17.960

In-Person Participant-1: ensure where we have an opportunity to do compliance and enforcement and where we would go into facilities. And you can imagine that there'll be a number of different things that will weigh into that as we're looking at the information that's submitted for 39, 11.

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01:33:18.410 --> 01:33:34.429

In-Person Participant-1: If you're seeing a listed activity in the supply chain, I just call out. Everyone should be reporting that to the Food and Drug Administration we are more than interested action on things that are listed within the supply chain. So provide us with information as quickly as possible, so we can start to have

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01:33:34.520 --> 01:33:49.107

In-Person Participant-1: actions together to ensure that Dscsa is working as fundamentally as it needs. Yeah. Dave, I I hear you on the need for that type of I'll say direct the guidance

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01:33:49.720 --> 01:34:18.810

In-Person Participant-1: And and I think that goes back to my earlier comments, too, of you know I don't mean this to to mean FDA guidances, but right? I think that continues to frame it in a very compliance centric way, right? And I think what you're getting at, Dave really, is that need for how do we make that practical and actionable for the people who haven't played in that space right? And to me, that's more of a role for trade associations or forms like Pdg. For other places like that, where where we can speak from a less of a regulatory perspective, and more in that practical implementation. Terms, too.

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01:34:18.850 --> 01:34:32.019

In-Person Participant-1: I think another place where that works really well is working with like with at the State level and making sure that we're building collaborations. The way that we need to to ensure that

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01:34:32.020 --> 01:34:55.450

In-Person Participant-1: as we're going out into an enforcement perspective as we're going out into a compliance perspective that the the relationships that we have with the State boards of pharmacy and the relationships that we have at the States with the States in general are gonna really make a big difference. And so I think that it's really important for us to continue to understand. How can, how we can leverage

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01:34:55.710 --> 01:35:09.909

In-Person Participant-1: all participants within the supply chain, those that are working at the local level, those that are, you know, in at the higher level, at the Federal level. And how can we really ensure that we're really, effectively making a difference?

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01:35:12.550 --> 01:35:39.800

In-Person Participant-1: It's okay. If I still a couple of easy ones off the screen. Zack, yeah, go ahead. Maybe I'll hit a couple of easy ones, one existing tools or resources available for those struggling, just getting started. Maybe I point to a few things. One I know, Aba, you pointed in your presentation the FDA's resource page if you're in the dispenser space is a great website Dsc. Pharmacy, Hda, Pbg, many of the pharmacy associations have tried to compile and organize many of the resource

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01:35:39.800 --> 01:35:59.510

In-Person Participant-1: just out there to make sense for a pharmacy. And then, obviously, your trade associations as well. I know one of the other questions was, will all the questions up here be answered? I will not promise that we'll answer every question. We are capturing them, cataloging them, and we'll be doing a written report after the meeting that will try to speak to as many of them as we can.

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01:36:00.740 --> 01:36:30.049

In-Person Participant-1: And then the other one that I saw there that maybe again, on a slightly lighter note, I'll say one of the questions, have we seen instances where Dscsa data is starting to be leveraged and you're welcome to comment on that to the extent you can, Lee, I'll say, yeah. I read a I saw an article a couple of weeks ago in Vanity Fair. Not always. My go to source for Dsc data or infra information insights. But talking about some of the Ozmic issues. And it. I do think it. It painted a nice picture of

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01:36:30.260 --> 01:36:38.330

In-Person Participant-1: what many of us to talk about for a long time, that the Dsca. Is not a magic bullet right? There is no silver bullet for these types of issues. It just

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01:36:38.420 --> 01:36:55.999

In-Person Participant-1: one more tool in the toolkit to to continue to push back about people who are trying to find and be just as creative as as anyone. And so I I thought it was just a good job of putting Dsc in context of how this plays out in reality on the ground.

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01:36:59.180 --> 01:37:08.510

In-Person Participant-1: Were there other audience questions to that? Zack? Yeah, there were. There were a couple that didn't get a ton about both, because they were all similar, and so none of them got the same one. But they all were

515

01:37:08.540 --> 01:37:21.169

In-Person Participant-1: vein of how can trading partners determine if an exemption that they see from another trading partner is legitimate, their their audience questions are wondering if this is the standard form or anything like that.

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01:37:25.160 --> 01:37:33.959

In-Person Participant-1: Well, so there's information provided from the FDA. And I can turn it over to Aba, who can get into the extreme technical details associated with these.

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01:37:34.307 --> 01:37:42.749

In-Person Participant-1: But they should have confidence in the information based on the the singularity of it of it. But, Aba, do you want to weigh in

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01:37:45.020 --> 01:37:46.860

In-Person Participant-1: on the technical details.

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01:37:48.820 --> 01:37:56.710

In-Person Participant-1: It's not a super technical answer, but it goes to a key theme. I mean, as you said, the onus is is.

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01:37:56.780 --> 01:38:05.520

In-Person Participant-1: you know historically, it's on the trading partner, the recipient of the waiver exception or exemption to educate

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01:38:05.630 --> 01:38:12.790

In-Person Participant-1: their trading partners about what's going on. But to the larger question as to the you know the competence in

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01:38:12.930 --> 01:38:16.630

In-Person Participant-1: when you get that information. And you know, do you believe them?

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01:38:17.500 --> 01:38:26.459

In-Person Participant-1: Well, I think that's the secret sauce of Dsa. It's the data. Yes, but it's also you all have to get it to know each other a lot better and trust each other.

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01:38:27.260 --> 01:38:29.770

In-Person Participant-1: Right. Can you all hear me. So

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01:38:30.010 --> 01:38:34.199

In-Person Participant-1: you know I think part of the assessment of believing them is knowing them.

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01:38:34.600 --> 01:38:35.490

In-Person Participant-1: So

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01:38:35.700 --> 01:38:38.179

In-Person Participant-1: that's the best answer I can give on it again, Matt.

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01:38:38.270 --> 01:38:41.730

In-Person Participant-1: not super technical, but definitely holistic.

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01:38:50.670 --> 01:38:59.180

In-Person Participant-1: Let's take one more from this slide. Oh, and then it looks like there's a couple of questions towards the back of the room as well. One more, one more we could do from the audience is

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01:38:59.250 --> 01:39:05.680

In-Person Participant-1: someone mentioned that as they look around the room they can see people who attend basically every single Dsa meeting.

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01:39:05.820 --> 01:39:15.660

In-Person Participant-1: And the question to both Lee and Eric is, how do we get out to a broader audience? To those who aren't in this room or virtually attending on zoom.

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01:39:16.820 --> 01:39:23.820

In-Person Participant-1: Yeah. So we specifically tried to build this meeting out to make sure we were bringing in slightly different parties.

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01:39:23.910 --> 01:39:49.320

In-Person Participant-1: and make sure that we weren't having a barrier to entry by making it just in person that we were really broadening the scope. This is a really well attended public meeting as but at least based on registrations. It was. It was one where we thought that we were able to bring in new stakeholders by by partnering with Pdg. To do the public meeting. I think

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01:39:49.430 --> 01:40:12.360

In-Person Participant-1: the questions a little broader than that, though I think the question is, how can each and every one of us make sure that we're communicating and building stronger relationships with our trading partners, so that our trading partner. The trading partners understand what the requirements are. And then, as the regulatory agency, how do we communicate better? And

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01:40:12.360 --> 01:40:38.490

In-Person Participant-1: FDA continuously determ like evaluates how we're communicating what we need to do. Additionally, what recommendations have come into us. We. We take your recommendation seriously. When someone, when an organization comes to us and a a an a trading partner comes to us and we wanna make sure that we're doing it as creatively and innovatively to ensure that we're deep within the supply chain.

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01:40:39.420 --> 01:40:56.970

In-Person Participant-1: And so I think it's the onus is on each and every one of us to look at what systems and tools we have to communicate. And then how do we build those really strong relationships to ensure that the organizations didn't just receive information from us, but they

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01:40:57.120 --> 01:41:00.500

In-Person Participant-1: solidly understand the value.

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01:41:00.700 --> 01:41:07.400

In-Person Participant-1: but they solidly understand the business proposition behind Dsa, and they solidly understand the the patient health

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01:41:07.934 --> 01:41:17.130

In-Person Participant-1: proposition behind Dsc. And that takes that takes conversations in some time. In some cases, between industry stakeholders.

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01:41:17.594 --> 01:41:47.070

In-Person Participant-1: And from an FDA perspective, it takes us really thinking critically about how we're communicating. So what organizations are we using to amplify our message? And how are we continuing to try to get our reach out water which we are doing continuously. If you have ideas, don't hesitate to bring them forward. We, you know, we really do think through each of our our opportunities. To make sure that we're reaching as deeply within the supply chain as possible. And I know that was really

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01:41:49.090 --> 01:41:54.650

In-Person Participant-1: you hit it. And I'm just gonna start to sound like a broken record. I just we gotta keep making the business

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01:41:54.920 --> 01:41:57.820

In-Person Participant-1: pitch and make it a business priority for them. Yeah.

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01:41:58.910 --> 01:42:00.650

In-Person Participant-1: couple of questions in the vacuum.

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01:42:07.950 --> 01:42:15.579

In-Person Participant-1: Thank you. This is Ria child from Alice Pedia. This is really from practical perspective.

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01:42:16.075 --> 01:42:36.029

In-Person Participant-1: Because I know all our customers is gonna come to us as a solution provider to provide them practical ways to manage. We's. So I want to understand if their submission, if a trading partner submits a we application, are they applying? We on the lot level

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01:42:36.080 --> 01:42:37.880

In-Person Participant-1: or product level

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01:42:37.980 --> 01:42:40.640

In-Person Participant-1: or location level

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01:42:40.690 --> 01:42:50.910

In-Person Participant-1: or entity level, or even like global level. So so just try to get understanding. What is the scope of we.

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01:42:50.950 --> 01:42:53.830

In-Person Participant-1: how limited or unlimited it can be.

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01:42:53.880 --> 01:43:11.660

In-Person Participant-1: Yeah, I think that's on the trading partner to make the determination as to what level they need there, we that's not an FDA to make that determination. So we are relying on the trading partner to come to us and identify what they need their we to be.

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01:43:13.468 --> 01:43:15.621

In-Person Participant-1: It's I was not too

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01:43:16.100 --> 01:43:25.960

In-Person Participant-1: Lisa Schwartz, from the National Community Pharmacist Association, and and still have a lot of concerns, maybe with some of the we

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01:43:26.150 --> 01:43:27.180

In-Person Participant-1: and

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01:43:27.600 --> 01:43:32.120

In-Person Participant-1: and and I'm hearing some some heads behind me nodding. Yeah. Yeah. And

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01:43:32.340 --> 01:43:43.100

In-Person Participant-1: I I need to know. And you don't need to have an answer today, but it should be soon. If I have a pharmacy asking me, How do I know if this we, that this trading partner is giving me

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01:43:43.200 --> 01:43:50.829

In-Person Participant-1: is legitimate. How do I verify that with FDA? Who do I call? And what's their turnaround for getting me that information?

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01:43:52.880 --> 01:43:55.589

In-Person Participant-1: I think you're you're asking for a very specific

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01:43:56.025 --> 01:44:10.110

In-Person Participant-1: point of contact at in the drug supply chain organization to make a verification. If, indeed, someone is potentially working with a trading partner that they don't have confidence in for the We. I think we're trying to indicate is that

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01:44:18.310 --> 01:44:20.110

In-Person Participant-1: no, but this is like the

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01:44:20.725 --> 01:44:29.300

In-Person Participant-1: like trustless system, right? Like. I know you very well, but I still need you like. I need to know that that's a legitimate document that you're handing me

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01:44:30.440 --> 01:44:50.699

In-Person Participant-1: so. I don't believe FDA is going to be verifying every we that we provided from every trading partner that would legitimately stop products removing, so we will be able to like your your trading partner should be providing you with their their fee that has been authorized.

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01:44:51.560 --> 01:45:07.719

In-Person Participant-1: I assume those are issued in some sort of a pretty formalized, pretty, formalized document that's signed. And if someone questions the the document, that's when I think someone would need to reach out to the Food and drug administration. If there is like a hesitancy in terms of that.

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01:45:08.860 --> 01:45:25.799

In-Person Participant-1: I understand the trust but verify process. But this is probably not the time to use the trust, but verify it. So it's developing trust within your organization and then working through other things through other verification measures to determine whether or not there's a risk based reason to verify that we.

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01:45:29.350 --> 01:45:30.804

In-Person Participant-1: Tim, go ahead.

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01:45:31.630 --> 01:45:32.420

In-Person Participant-1: Okay.

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01:45:40.090 --> 01:46:02.409

In-Person Participant-1: Hi, Chris Grant, with Johnson and Johnson and I I gotta say that that response concerns me right? I deal in product security. And we, along with other people in this room, have gone through several years of dealing with supply chain partners who are authorized and licensed, who are doing bad things. And if we're relying on trust, and there's no mechanism to verify.

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01:46:02.500 --> 01:46:12.150

In-Person Participant-1: We've already seen that in the supply chain, and and I don't see any reason. But that won't continue where people who are looking for a good deal are just going to say, here I got a wheat, buy my product.

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01:46:13.390 --> 01:46:39.860

In-Person Participant-1: understand? And that's why I think there needs to be systems and process, and determining whether or not you trust that we, we recognize that there are organizations within the supply chain that may try to take advantage of of of something. So if you believe that you have a we that has been is an inauthentic, we so is taking advantage of FDA's opportunity to provide this

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01:46:39.860 --> 01:46:52.280

In-Person Participant-1: flexibility. The Wes will be rather rather standard. And so you should be able to determine, based on that, whether or not you should trust that we.

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01:46:55.440 --> 01:46:56.330

In-Person Participant-1: Scott?

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01:46:56.690 --> 01:46:57.430

In-Person Participant-1: Nope.

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01:46:57.680 --> 01:47:00.560

In-Person Participant-1: we'll we'll squeeze 2 more in Scott. And then, Elisa.

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01:47:04.330 --> 01:47:07.280

In-Person Participant-1: just to add a little color to the the last comment.

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01:47:08.280 --> 01:47:13.470

In-Person Participant-1: whether we can get to a point where we have some kind of formal documentation for a we or not

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01:47:14.140 --> 01:47:21.350

In-Person Participant-1: is probably not at all that critical, because we don't have any place to look to see if a drug is subject to the Dsa. Or not in the.

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01:47:22.380 --> 01:47:42.770

In-Person Participant-1: That has always been the statement from the FDA that we need to rely on the manufacturer to identify if it's in scope or out of scope. So applying a higher level of rigor to the we doesn't make much sense when somebody could simply say, It's not in scope, and we would accept that as practice it. It's kind of a little bit different way to look at it, but it it puts it into perspective.

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01:47:48.600 --> 01:47:51.460

In-Person Participant-1: Last question to Elisa Bernstein.

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01:47:54.340 --> 01:48:10.320

In-Person Participant-1: Thank you, Elise Bernstein, and actually Scott, you you you got my point out there. You know, in terms of. We've heard today that a lot of the the holdup is dealing with exceptions, and we're gonna hear that tomorrow. But probably

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01:48:10.974 --> 01:48:18.289

In-Person Participant-1: not as much, because sometimes there's not a whole lot of data going down in order to figure out what what's an exception. But

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01:48:18.500 --> 01:48:37.159

In-Person Participant-1: the downstream part between the wholesale and dispensers and the dispensers really need to think about this. So I'm wondering. And you said, when you started this panel, you said, well, we F. FDA needs to think about what are those areas of outreach and education and awareness that we need to focus on? And I don't know. Am I supposed to be pointing this somewhere?

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01:48:38.290 --> 01:48:40.839

In-Person Participant-1: Oh, and and so

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01:48:41.710 --> 01:48:47.589

In-Person Participant-1: I I think what we're hearing is that that A we.

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01:48:47.680 --> 01:48:52.099

In-Person Participant-1: or what is a product under Dscsa. Those

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01:48:52.300 --> 01:49:20.039

In-Person Participant-1: will be considered exceptions in a way, and it may not be the exceptions that we're dealing with now, but those be the exceptions in the future. And maybe this is something that you at FDA can really kind of. Put on your list high in your list of how to work with stakeholders in the supply chain, and trading partners in the supply chain, to to look at those as exceptions, and how to handle those at the different nodes in the supply chain.

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01:49:24.560 --> 01:49:25.340

In-Person Participant-1: Here we go

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01:49:26.860 --> 01:49:51.250

In-Person Participant-1: alright. Well, that wraps up our session and our day. We will be back tomorrow we will begin at 10 Am. Eastern time promptly again. The folks who are on virtually, please remember you will have a different zoom link. It is a different sign on Link tomorrow. If you have any questions about that, please reach out to our team but again we'll start at 10 Am. Promptly tomorrow. So please go

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01:49:51.250 --> 01:50:00.870

In-Person Participant-1: here a little bit in advance. We will focus much more on that wholesaler pharmacy side tomorrow. So thank you, Dr. For wrapping up, and we look forward to kicking off again tomorrow.