Introduction, Background, and Scope

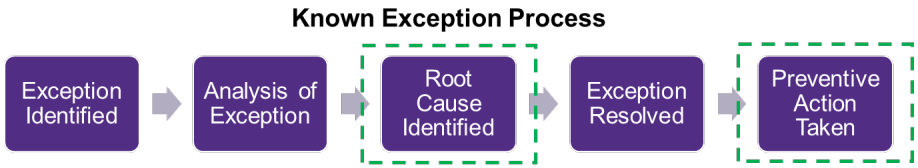
A misalignment exception occurs when there is a misalignment between the physical supply chain and virtual supply chain. There are numerous types of misalignment exceptions, but they generally fall into two categories: "product, no data" and "data, no product." Extensive industry work has been, and continues to be, done to support more efficient handling (identifying, understanding, and resolving) of misalignment exceptions. Less collective industry work has been done to understand the root causes of misalignment exceptions and identify continuous improvement activities to *prevent* misalignment exceptions before they occur. This document is intended fill that gap and aid stakeholders as they evaluate and improve their individual business practices to reduce misalignment exceptions.

Accordingly, this document is specifically and narrowly focused on the *root causes* of misalignment exceptions, not the handling of misalignment exceptions once they occur. Those root causes are rooted in individual business practices—people, processes, and technology. This document is intended purely as an *educational resource* to aid individual companies as they evaluate and improve their business processes; it is *not* intended to establish specific recommendations or best practices. As an educational resource, the root causes and continuous improvement opportunities here are not intended to be exhaustive; they represent the collective experience of many PDG members, but do not purport to represent all experiences.

As stakeholders consider the root causes of misalignment exceptions, it can be helpful to recognize where and how the root cause of a misalignment exception fits into the broader misalignment handling process. From a linear, chronological perspective, the root cause of an exception is the first occurrence in the exceptions process, as shown below.

Linear Exception Process

This process shows the importance of tracking root causes along with monitoring and reporting errors when they occur. By tracking the root cause of errors that are monitored and reported, entities can more efficiently learn how to more frequently prevent misalignment exceptions. However, when evaluating an individual misalignment exception, the root cause can be viewed as the outcome of the analysis of that individual misalignment exception.



Root Causes and Preventive Actions

The table below is intended to help identify and categorize the root causes of misalignment exceptions, including examples of specific individual root causes that can occur. Understanding the landscape of root causes enables a trading partner to evaluate opportunities to reduce or prevent those root causes and prioritize continuous improvement activities they may undertake.

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
1 Human Error			
1.1 Mis-pick/Product Handling Mistake	• Picker scans one package on the shelf but picks a different package • Picker scans 5 packages but only picks 4 packages	Either or both: Product No Data and Data No Product	• Training, for example: ○ Teach "pick what you scan, scan what you pick" ○ Understanding how a mis-pick may present during both picking and packing ○ Understand the cost to the customer • System controls, for example: ○ User interfaces and audio/visual cues for each scan and/or the quantity and/or error ○ Configure systems to trigger error when # of SNs scanned and # of packages picked differ • Process improvements, for example, scanning as close to real-time as possible and segregate during packout

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
1.2 Process Interruption	• Picker is interrupted by a discussion with a supervisor and disrupts scanning process	Either or both: Product No Data and Data No Product	• Process documentation and training on how to limit interruptions and resume post-interruption • System controls, for example: ○ User interfaces and audio/visual cues for each scan and/or the quantity and/or error ○ Warnings, errors, or timeouts based on significant time gaps ○ Configure systems to trigger error when # of SNs scanned and # of packages picked differ
1.3 Data Input Error	• Typographical error in manual data entry	Either or both: Product No Data and Data No Product (most commonly product, no data)	• Training, for example: ○ Train on importance of data accuracy, where mistakes are most common, and the elements where accuracy is most critical • System and process controls, for example: ○ Utilize “performed by” and “checked by” roles ○ Utilize technology to minimize manual data entry ○ System configurations to check formats and reconcile corresponding data
1.4 Logistical Breakdown	• Product loaded on the wrong truck • Product offloaded at the wrong location • Product opened in transit accidentally	Either or both: Product No Data and Data No Product	• Understand, evaluate, and integrate common industry practices for effective handling and distribution, for example: ○ Leverage HDA Guidelines for Bar Coding in the Pharmaceutical Supply Chain and

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			GS1 standards and white papers ○ Track data and trends for how and why these issues are occurring ○ Have systems and processes for quality control of packaging. ○ Double check all logistical information to avoid loading issues when packages are distributed on trucks to distribution centers ○ Have clear demarcation between each of the deliveries ○ Recognize that backorders and exception orders are at higher risk for errors ○ Have detailed and accurate packing lists
1.5 Scanning the Wrong Barcode	• User scans a non-DSCSA barcode and treats it as a DSCSA failure	Either or both: Product No Data and Data No Product	• Training • Follow HDA's Guidelines for Bar Coding in the Pharmaceutical Supply Chain and GS1 standards and white papers when creating and applying labels and barcodes, including proper spacing of barcodes and separation of DSCSA and non-DSCSA barcodes • Strive to minimize the number of barcodes • Consider systems that can confirm the correct type of barcode is being scanned
2 Aggregation/Inference Processes			
2.1 Aggregation Errors	• Incorrect serial number associated with a case		See below

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
2.1.1 Line and Capture Errors	• Incorrectly capture product identifiers being aggregated • Camera misreads or misses an identifier to be associated to a case	Either or both: Product No Data and Data No Product	• Understand, evaluate, and integrate GS1 white paper on aggregation • Minimize human intervention in the process • Avoid assumptions in your process about what is going into a case • Design systems to verify data and product as close to final step as possible • Understand limitations of automated systems and implement appropriate process controls (for example, clearing line in event of a stoppage or error)
2.1.2 Data and System Errors	• Correct identifiers are captured on the line but are not translated to data correctly • Momentary outage so what was physically captured on the line is not captured in the data • System bug associates packages to the incorrect case	Either or both: Product No Data and Data No Product	• Understand, evaluate, and integrate GS1 white paper on aggregation • Minimize human intervention in the process • Improve Training and systems checks. • Ensure system changes are subject to change control processes, thorough testing, and validation
2.1.3 Process Errors	• QA employee pulls product for quality testing without reflecting in aggregation record • Packages are missed in the identifier reading process • Human error in manual case packing	Either or both: Product No Data and Data No Product	• Understand, evaluate, and integrate GS1 white paper on aggregation • Minimize human intervention in the process • Exercise added diligence and caution, including training, when unpacking and repacking (i.e., anytime a sealed case is opened, such as in an internal quality

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			audit)
3 Master Data			
3.1 Missing Master Data	• GTIN or SGLN is not loaded into the ATP's systems or inadvertently deleted	Product, No data	• Training, for example: ○ Train employees on the new TI data elements that core interoperability elements[1] • Process controls, for example: ○ Communicate your master data requirements internally and externally. ○ Ensure your trading partners have clear and current contact information and encourage the use of a DSCSA email address that is not tied to one individual ○ Ensuring all parts of your business *internally* communicate master data changes (GLN, GTIN, etc.) to the appropriate DSCSA contacts, teams, and systems ○ For new products, ensure master data is sent to downstream trading partners before any product is sent

[1] Please review the PDG Blueprint on dscsagovernance.org, specifically Chapter 3 on Page 8, for a discussion and list of core interoperability data elements. PDG Blueprint Link

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			○ Clearly define the process for managing applicable WEEs • New GLNs should be proactively communicated for new locations • Utilize the HDA new product template, and make sure all relevant data elements are included
3.2 Errant Data	• Wrong GTIN is associated with the product • Incorrect GLN associated with a particular location	Data Issue	• See 3.1 • Good Master Data Management Practices ○ Govern master data through clear SOPs in accordance with the regulations and guidelines applicable to your sector. ○ Identify clear point of accountability for master data management ○ Who has access to the data? ○ Can be handled similarly to document control practices. • Cross check to align a single location to a single GLN.
3.2.1 Outdated Data	• An outdated SGLN is still active	Data Issue	• See 3.1 • *Proactively* and *regularly* communicate and align with your customers and suppliers to set the expectation that any master data changes should be communicated in advance.

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			• Incorporate early communication of master data changes into SOPs.
3.2.2 Not timely communicated by/to trading partner	• Manufacturer did not communicate a new GTIN to customers	Data Issue	• See 3.1
3.2.3 Not timely communicated within the trading partner	• Manufacturer communicated a new GTIN to wholesaler, but wholesaler did not communicate to the right people internally	Data Issue	• See 3.1
3.2.4 Duplicate Data	• Multiple GLNs attached to a location	Data Issue	• See 3.1 • If multiple GLNs are assigned to a single location, collaborate with trading partners to ensure those multiple GLNs are being intentionally managed (not an inadvertent duplication of GLNs) (see section 5.16 of GS1 US DSCSA R1.3, GS1 US DSCSA FAQ 2.4.12)

3.3 Incorrectly Formatted Master Data	• SGLN is incorrectly formatted
	• sGTIN is incorrectly formatted
	• Incorrectly formatted NDC (10 vs 11 digit)
		Data Issue	• Follow GS1 implementation guidelines
			  ○ They are covered in the GS1 implementation guides, but also follow FDA guidance on expiration date formatting
			  ○ Have some mechanism that the data has been delivered to the downstream trading partner.
			• Encourage trading partners to proactively monitor data has been successfully sent and received

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
3.3.1 Company Prefix Error	• Company prefix not communicated or not processed correctly • SGLN not recognized as individually licensed	Data Issue	• See 3.2 • Educate teams and trading partners on GCP length and it role in proper SGLN format.
4 File Failures			
4.1 File incorrectly formatted		Data Issue Either or both: Product No Data and Data No Product	• Follow all applicable GS1 standards and guidelines • When using a third-party solution, ensure solution provider is following applicable GS1 standards and guidelines System controls, for example: o Do a robust validation at the outset of shipment o Periodic checks for potential glitches in the solution o Monitor the expiration dates for certificates and coordinating with partners *early and broadly*. Alert your network about nearing expiration dates o Notify your networks of all endpoint changes proactively.
4.1.1 Noncompliance with GS1 standards and guidelines	• Events are out of sequence • Data syntax issues, such as timestamp issues • Incorrectly formatted or missing data	Data Issue Either or both: Product No Data and Data No Product	• See 4.1 • Follow applicable GS1 standards and guidelines, including *Errata for GS1 US Implementation Guideline: Applying GS1*

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
	components		*Standards for DSCSA and Traceability Release 1.2*

4.2 System incorrectly configured		Data Issue
		Either or both:
		Product No Data and
		Data No Product
			• Follow all applicable GS1 standards and guidelines
			• System controls, for example:
			  ○ Do a robust validation at the outset of shipment
			  ○ Periodic checks for potential glitches in the solution

4.2.1 System misconfiguration causes data/message to be generated incorrectly	• Time clocks are not synchronized across internal systems, causing events to be out of sequence	Data Issue Either or both: Product No Data and Data No Product	• See 4.2 • Be alert to misalignment of millisecond field length across systems
4.2.2 System misconfiguration causes data/message to be incorrectly read/interpreted	• Non-unique message identifier due to a split order	Data Issue Either or both: Product No Data and Data No Product	• See 4.2

4.2.3 Solution not routing message correctly/to the correct party	• Router is routing to wrong endpoint
	• The file endpoint is changed but not communicated
		Data Issue
		Either or both:
		Product No Data and
		Data No Product
			• See 4.2
			• System controls, for example:
			  ○ Notify your networks of all endpoint changes proactively
			  ○ Periodically review and validate trading partner information

4.2.4 Certificate issues	• Expired certificates	Data Issue	• See 4.2 • Monitor the expiration dates for certificates and coordinate with trading

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			partners *early and broadly*. Alert your network about nearing expiration dates
4.2.5 Latency and performance issues	• Slow system causes the file to be late • System is down/has unplanned outage	Data Issue Either or both: Product No Data and Data No Product	• See 4.2
4.3 Data batching too infrequently	• Short-distance delivery and product arrives before data	Data Issue Product, No Data	• Evaluate the location of your trading partners and assess the optimal batching frequency for your organization • Evaluate the timing of batching at end-of-day. Time differences can cause issues with proper date of batching
5 Product Issues			
5.1 Product Lost in transit	• The product or package goes missing during the process of being transported from one place to another. This can happen due to various reasons, such as mishandling, misrouting, or unforeseen delays.	Lost Product	• Relationships with carriers can help speed the process of determining why product was lost • Process controls, for example: o Double checking all logistical information to avoid loading issues when packages are distributed on trucks to distribution centers o Per the HDA bar coding guideline, pallet labels should clearly indicate which distribution center they are destined for

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			○ Have clear demarcation between each of the deliveries ○ Have detailed and accurate packing lists
5.1.1 By trading partner	• Internal mismatch in pick and put away process • Unresolved shortage	Lost Product	• See 5.1
5.1.2 By 3PL	• Product misplaced by 3PL	Lost Product	• See 5.1
5.1.3 By carrier	• Product misplaced by carrier	Lost Product	• See 5.1
5.2 Damaged Product		Damaged Product	• Relationships with carriers can help speed the process of determining why product was damaged • Process controls, for example: ○ Validation during product development ○ In-line checks ○ Product packaging quality checks ○ Manage and audit the quality and performance of carriers
5.2.1 Inadequate packaging	• Inadequate grade of cardboard leads to product or barcode being physically damaged	Damaged Product	See 5.2

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
5.2.2 Inadequate labelling	• Pallet label falls off • Case labeled once instead of twice, as expect under HDA guideline	Damaged Product	See 5.2 • Follow HDA best practices for placing multiple labels
5.2.3 Damage before shipment	• Barcode or product is physically damaged • Forklift runs over a case or unit • Case is crushed during pallet shrink wrapping process	Damaged Product	See 5.2
5.2.4 Damage during shipment	• Barcode or product is physically damaged • Corner of case is smashed in movement • Pallet falls over in truck during transit	Damaged Product	See 5.2
5.2.5 Damage after receipt	• Barcode product is physically damaged • Forklift runs over a case or unit • Pallet stacked on a “do not stack” pallet	Damaged Product	See 5.2
6 Other Data Systems			
6.1 Data Systems: Internal System and Connection Issues	• System updates (new code) causes an error (e.g., changes the format of an EPCIS message)	Data issue	• System controls, for example: o Leverage validation practices o Conduct periodic checks for potential glitches in the solution o Monitor the expiration dates for certificates and coordinate with

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			partners *early and broadly*. Alert your network about nearing expiration dates
6.2 Data Systems: External System and Connection Issues	• Certificate failures/expired certificates • Downstream partner's internal system is hacked/compromised	Data issue	• Ensure good communication with all trading partners to handle any external issues • See 6.1
6.3 Data Systems: Third-Party Solution Issues	• Change to a solution provider or their system	Data issue	• See 6.1
6.4 Data Systems: Downtime and bandwidth issues	• Third-party solution is down for maintenance and delays sending of EPCIS file	Data issue Product, no data	• See 6.1 • Ensure planned and unplanned downtime are part of your communication protocols • Promote good communication and coordination with internal and external partners
6.5 Data Systems: Other		Data Issue	• See 6.1
7 Barcode and Scanning			
7.1 Incorrect encoding			
7.1.1 Noncompliance with barcode standards and guidelines	• Expiration date is incorrectly encoded in the 2D • Missing or unnecessary Function 1 and Group Separators create parsing issues • Incorrect Group Separators between quantity and lot when using linear	Packaging and Labelling	• Follow 21 CFR § 201.2., USP ⟨7⟩, GS1 standards and guidelines and HDA barcoding guideline ○ In particular, ensure expiry date formats conform to formats defined in USP ⟨7⟩

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
	barcodes on case		• System and process controls, for example: ○ In process line checks. ○ Utilize barcode grading systems consistent with commercial requirements and relevant standards (e.g., ANSI) ○ Quality check labels before they are sent out, including periodic sample confirmation of printing and reading equipment ○ Monitor and track returns due to barcode issues
7.2 Barcode quality and misapplication	• Barcode too small • Barcode proximity too close • Color contrast inadequate • Poor barcode print quality	Packaging and Labelling	• Follow GS1 standards and guidelines and HDA barcoding guideline • System and process controls, for example: ○ Utilize barcode grading systems to ensure barcode quality meets or exceeds minimum quality required by your commercial agreements at time of application ○ Utilize accepted methods to assess the durability of your barcodes to verify that barcodes will continue to meet minimum quality levels after being subjected to the stresses of shipment

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
			○ Monitor and track returns due to barcode issues ○ Use over-labeling cautiously; If reusing case shippers, ensure old labels/barcodes are rendered entirely unreadable (*see* FDA perspective HERE) ○ If shipping partial cases, ensure sealed case labels/barcodes are rendered entirely unreadable; partial cases should be identified by SSCC per GS1 standards (GS1 US DSCSA FAQ, 2.2.15)
7.3 Incorrect decoding/inability to decode	• Assumes the barcode is accurate and readable, but error in the specific read	Packaging and Labelling	• Validate scanners at set up • Recalibrate all scanners on a pre-set schedule • Ensure scanning equipment is capable of reading poorest barcode quality permitted by applicable commercial agreements
7.3.1 User error	• User misuses the scanner	Packaging and Labelling	• Increased and more frequent user training ○ Include CAPS lock training in particular • Ensure barcode scanning guidelines and training have been updated to reflect DSCSA 2D datamatrix

People/Process/Training/Technology Failure *(Root Cause)*	Example	May Present As	Areas for Continuous Improvement *(Preventive Action)*
7.3.2 Hardware/software setup error	• Scanner was setup with CAPS lock on • Software updates are not current • Scanner appends additional data elements cached from prior scans	Packaging and Labelling	• Validate scanners at set up • Establish process and schedule/interval to recalibrate scanners • Be attuned to challenges and support cost when maintaining multiple brands and models of scanners

Conclusions and Calls to Action

In the course of discussion, PDG identified concrete opportunities to reduce root cause of common misalignment exceptions. Specifically:

- We encourage GS1 to create a best practices document for the management and handling of GLNs.
- We encourage stakeholders to evaluate whether there would be value in created a standardized new location form, similar to HDA's new product form.

Industry stakeholders should prevent misalignment exceptions from happening through further study and tracking of their root causes. We encourage industry leaders to continue to create and share best practice documents that could help stakeholders evaluate and prevent the root causes of misalignment exceptions. We hope stakeholders will use the information included in this document to reduce the number of misalignment exceptions they manage and the number their trading partners manage.