



Partnership for DSCSA Governance

**Advancing Collaborative, Timely Implementation
of DSCSA Interoperability**

Episode 5: Credentialing

Webinar Series (Register at <https://dscsagovernance.org/blueprint/>)

•Webinar Episode 1: DSCSA Overview, Interoperability, & the Role of ATPs

- February 23, 1:00 – 2:00pm ET
- Register [HERE](#).

•Webinar Episode 2: TI/TS Exchange

- March 1, 1:00 – 2:00pm ET
- Register [HERE](#).

•Webinar Episode 3: Verification

- March 9, 1:00 – 2:00pm ET
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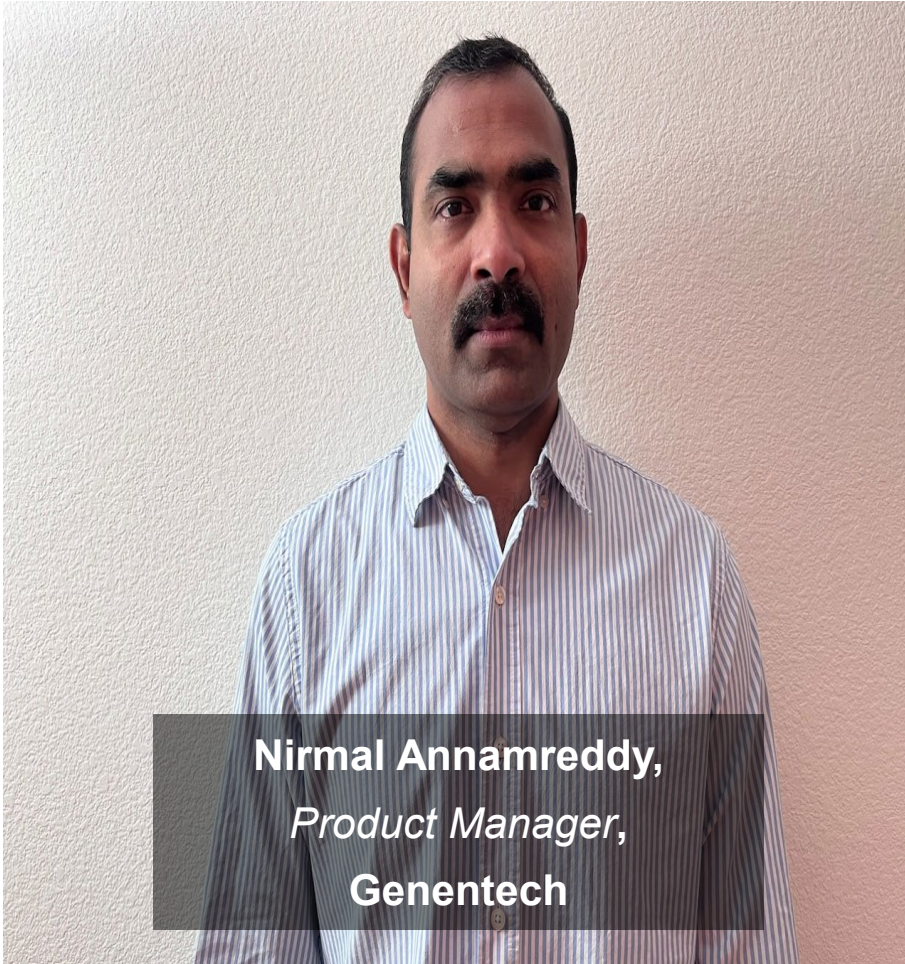
•Webinar Episode 4: Tracing

- March 16, 1:00 – 2:00pm ET
- Register [HERE](#).

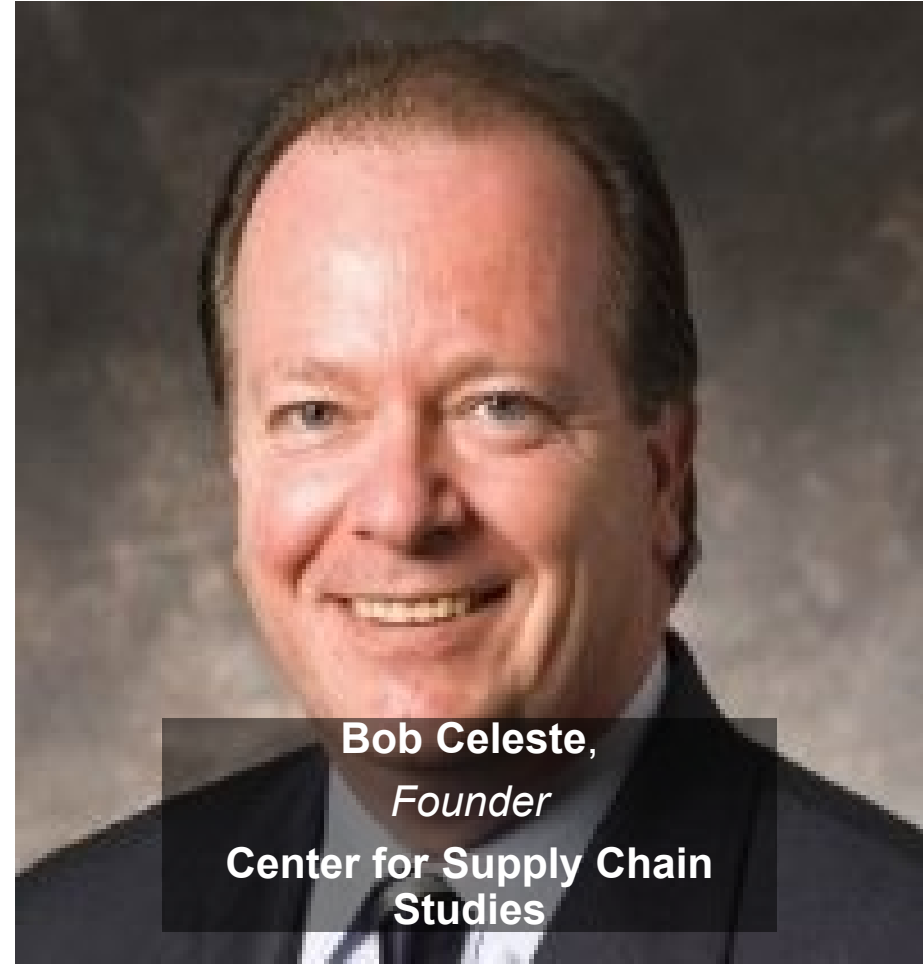
•Webinar Episode 5: Credentialing

- March 23, 1:00 – 2:00pm ET
- Register [HERE](#).

Today's Speakers



Nirmal Annamreddy,
Product Manager,
Genentech



Bob Celeste,
Founder
**Center for Supply Chain
Studies**

The Partnership for DSCSA Governance (PDG)

PDG is a collaborative forum and FDA public-private partnership dedicated to developing, advancing, and sustaining an effective and efficient model for interoperable tracing and verification of prescription pharmaceuticals in the U.S.

www.DSCSAGovernance.org

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**Partnership for DSCSA Governance (PDG)
Foundational Blueprint for 2023 Interoperability**

Chapter 6: DSCSA Credentialing and User Authentication Functional Design

Version 1.0
March 1, 2023

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Key Terminology

Credential is a tool by which an organization can demonstrate that it meets a set of requirements that demonstrate it is authorized, as required by the DSCSA, and identity proofed.

Credentialed means, for a trading partner, having demonstrated both authorized status and identity according to PDG-defined credentialing process.

Authorized means a trading partner is duly licensed or registered, as required by the DSCSA.

Digital Credential is an OCI-specified representation of a W3C Standard Verifiable Credential meeting the business requirements associated with credentialing within the electronic network.

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Credentialing PDG Blueprint

Credentialing is a process—which may be more manual or more automated—used by an organization to demonstrate that it is licensed/registered and is the organization it claims to be.

Why It Matters: The volume of electronic interactions between trading partners in an established commercial relationship will increase in 2023, and credentialing in each trading partner to confirm the identity of each trading partner with which to interact.

Five Things to Know

1. Credentialing is a required part of the tracing process but is not required for exchange (because TI exchange occurs within an established commercial relationship).
2. ATPs may choose to execute the credentialing process by leveraging digital credentials or through alternate processes, such as manual processes that build on KYC/KYS practices.
3. Credentialing processes must validate the trading partner's authorized status (i.e., are they duly licensed/registered) and the trading partner's identity (i.e., are they who they claim to be).
4. A trading partner's credential/authorized status must be reconfirmed on a regular basis, most often on a weekly basis.
5. A trading partner's authorized status must be confirmed using an official data source maintained by the licensing/registration authority.

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Credentialing Methods PDG Blueprint

In an interoperable environment, it is important that trading partners have a shared understanding of the minimum threshold that must be met by a trading partner to be considered authorized and have its identity authenticated. Absent such a threshold, two trading partners may both claim to be authorized and authenticated, but a trading partner who engages with them would have no predictability of what that status actually means. Chapter 1 of the *Blueprint* defines that minimum threshold.

Credentialing Process Required. PDG requires the use of a credentialing process as part of tracing and verification. This process can take numerous forms; the key is that each trading partner has a *sound process* to confirm the authorized status and identify of the other trading partners with which they are interacting.

Credentialing Method Optionality. While digital credentials represent an efficient approach to credentialing, PDG also recognizes the practical reality that their adoption will likely be gradual, particularly given competing demands for November 27, 2023 compliance and the learning and maturation processes that will occur after that date. Therefore, PDG recognizes that trading partners may use alternate processes, including company-specific non-automated processes, to demonstrate the threshold assurances of authorized status and identity in Chapter 1 have been met. PDG is optimistic that trading partners will recognize the efficiency of digital credentials during the early period of compliance and migrate toward their use, but the accommodation of manual processes is important to ensure the PDG-defined EDDS network is inclusive of a critical mass of the industry.

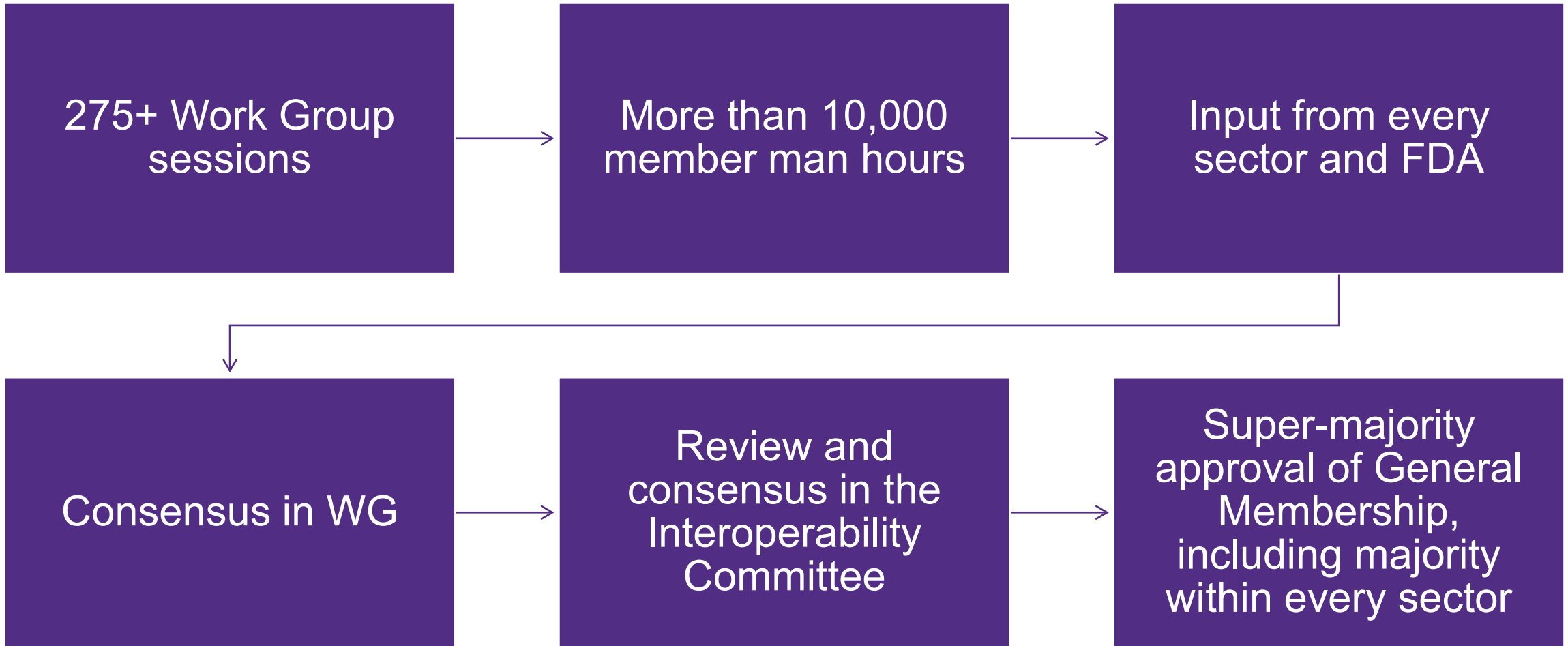
Blueprint Chapter 1 establishes the threshold for determining whether a given trading partner is "authorized" and identity-proofed

↓

Credential: A process is required to **confirm** and **convey** that the threshold in Chapter 1 of the *Blueprint* has been met

↓

Digital Credential Conforming to OCI (Optimal Future State) *Methods* Alternate Processes (e.g., contact the trading partner by phone and ask a series of questions to confirm authorized status and identify)



Chapter 3: TI/TS
Exchange Functional
Design
Published February 2023

Chapter 4: PI Verification
Functional Design
Published February 2023

Chapter 5: Tracing Functional
Design
Published February 2023

Chapter 6: Credentialing and User Authentication
Functional Design
Published March 2023

Chapter 2: Functional Design for Interoperability
Published February 2023

Chapter 1: Compliance and Business Requirements
Published July 2021

Credential: A tool by which an organization can demonstrate that it meets a set of additional requirements, as defined by PDG, to ensure they are a valid trading partner who is both uniquely identified and authorized, as required by the DSCSA.

Credentialed: Having demonstrated both authorized status and identity according to PDG-defined credentialing process.

“**Digital credentials**” refer to W3C Verifiable Credentials as applied to the PDG-defined EDDS network by the OCI Open Specifications.

Credentialing Process and Optionality

Blueprint Chapter 1 establishes the threshold for determining whether a given trading part is “authorized” and identity-proofed



Credential: A process is required to **confirm** and **convey** that the threshold in Chapter 1 of the *Blueprint* has been met



Digital Credential Conforming to
OCI
(*Optimal Future State*)



Alternate Processes
(e.g., contact the trading partner by phone and ask a series of question to confirm authorized status and identify)

DSCSA Definition of Credentialing

“(2) AUTHORIZED.—The term ‘authorized’ means—

“(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

“(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

“(C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and

“(D) in the case of a dispenser, having a valid license under State law.

DSCSA Definition of Credentialing

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

Section 582, as added by section 202, is amended by adding at the end the following:

“(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

“(1) IN GENERAL.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:



State Licensing Status



State License Analysis

Table 3 - State License status and Credential Issuance Requirements

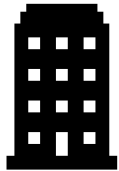
State	Status From State Source	Interpreted Status (Active/Non-Active)
Alabama	Active	Active
	Closed	Non-Active
	Inactive	Non-Active
	Revoked	Non-Active
	Surrendered	Non-Active
Alaska	Active	Active
	Conditioned	Active
	Inactive	Non-Active
	Limited	Active
	Probation	Active
	Suspended	Non-Active
Arizona	Open	Active
	Open - Previous Discipline	Active
	Administrative Hold	Non-Active
	Applied - Awaiting Board Approval	Non-Active
	Approved - Awaiting Inspection	Non-Active
	Archive	Non-Active
	Closed	Non-Active
	Closed - Did Not Renew	Non-Active
	Closed - Did Not Renew + Prev. Discipline	Non-Active



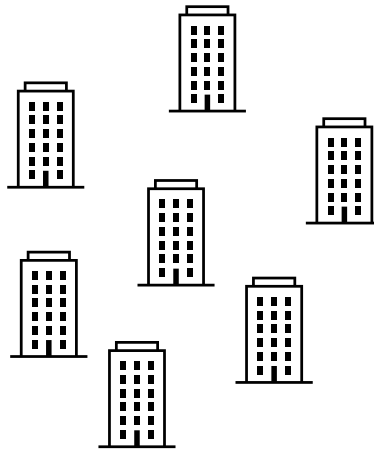
Benefits of the PDG Credentialing Process

Credentialing is a trusted process used to pre-establish and demonstrate the “authorized” status of a trading partner.

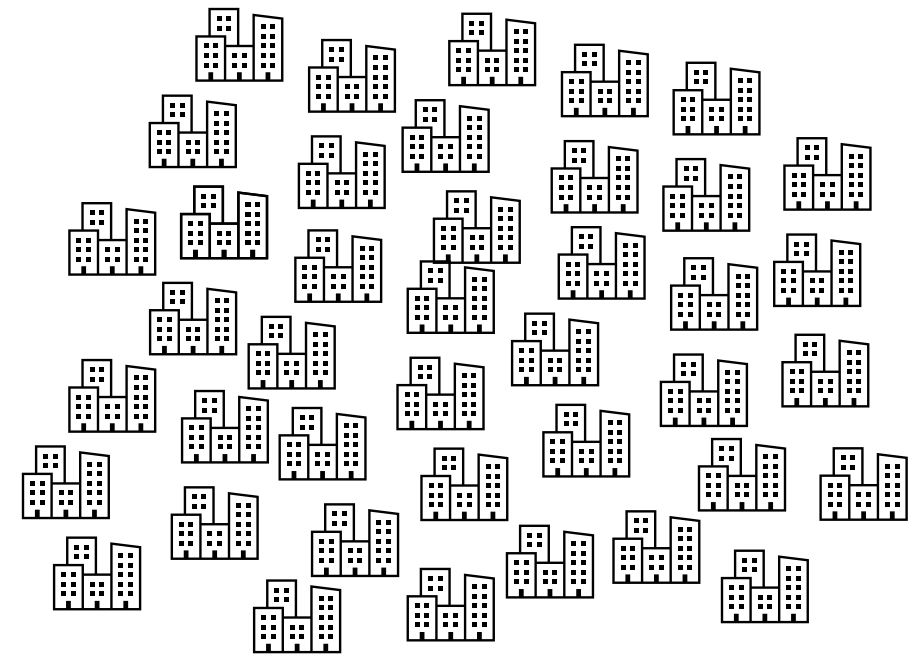
YOU



**YOUR DIRECT TRADING PARTNERS
WITH WHICH YOU HAVE AN
ESTABLISHED RELATIONSHIP**



**YOUR INDIRECT TRADING PARTNERS
WHO MAY ENGAGE WITH YOU FOR
VERIFICATION/TRACING AT ANY TIME**

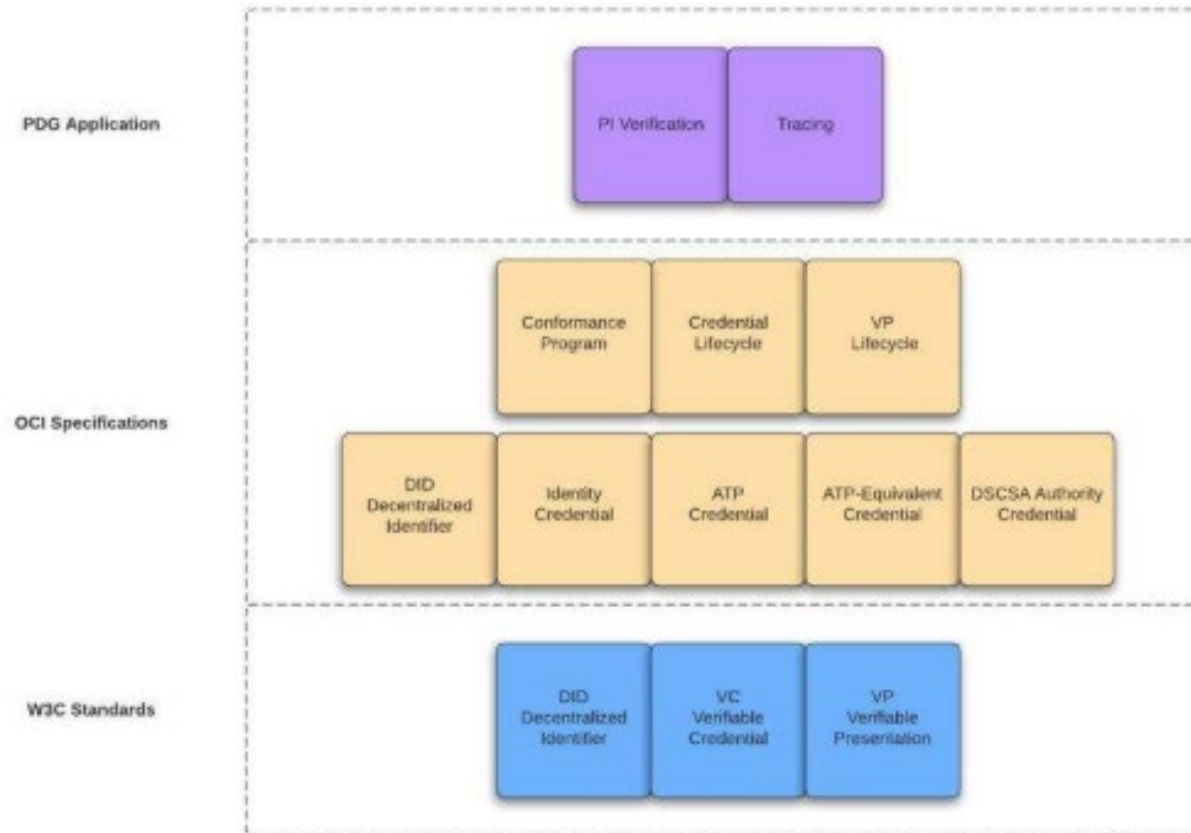


Credentialing Lifecycle

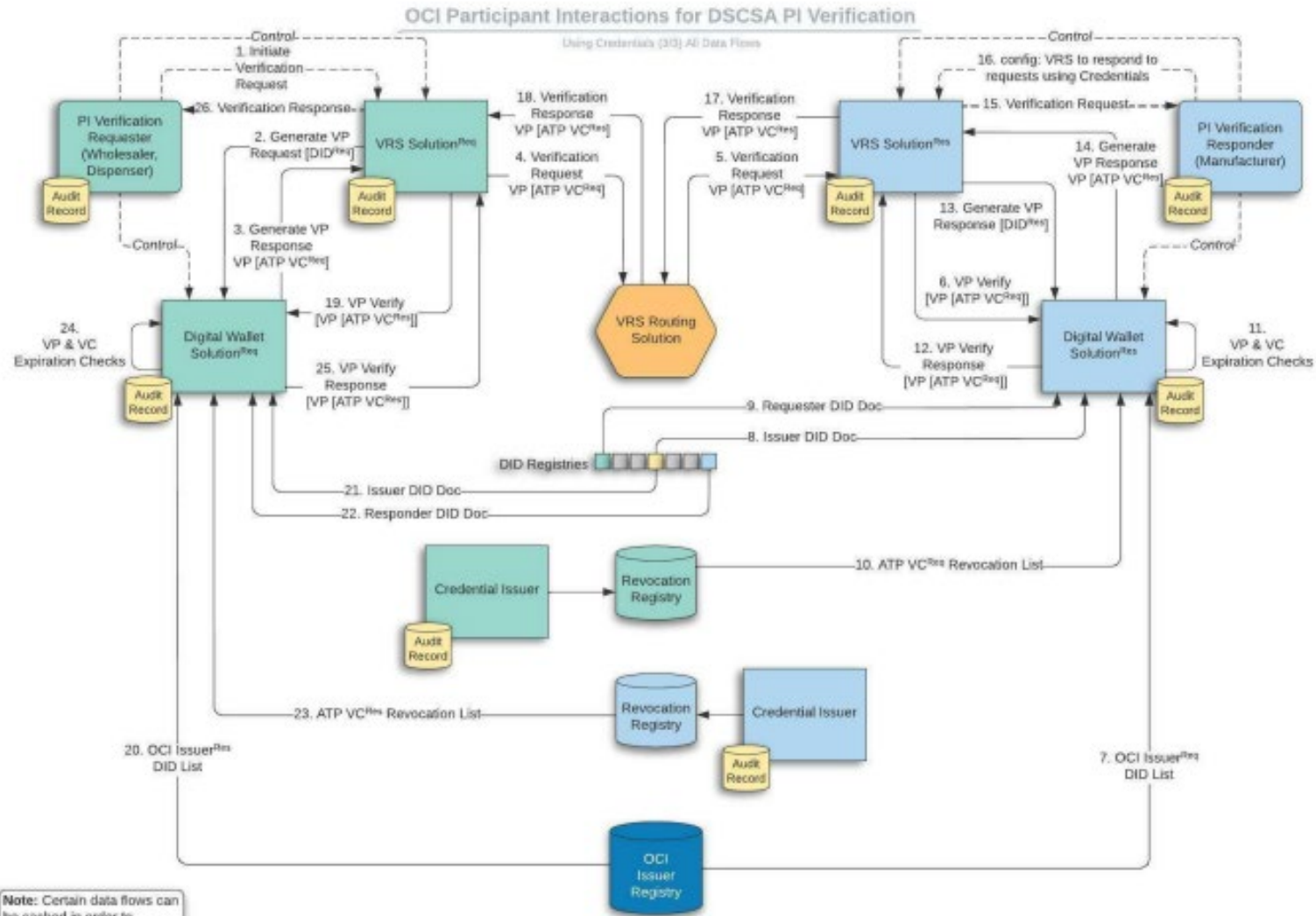
Credential Lifecycle

PDG | November 8, 2022

Using W3C Standard
credentials in the
PDG-defined EDDS network



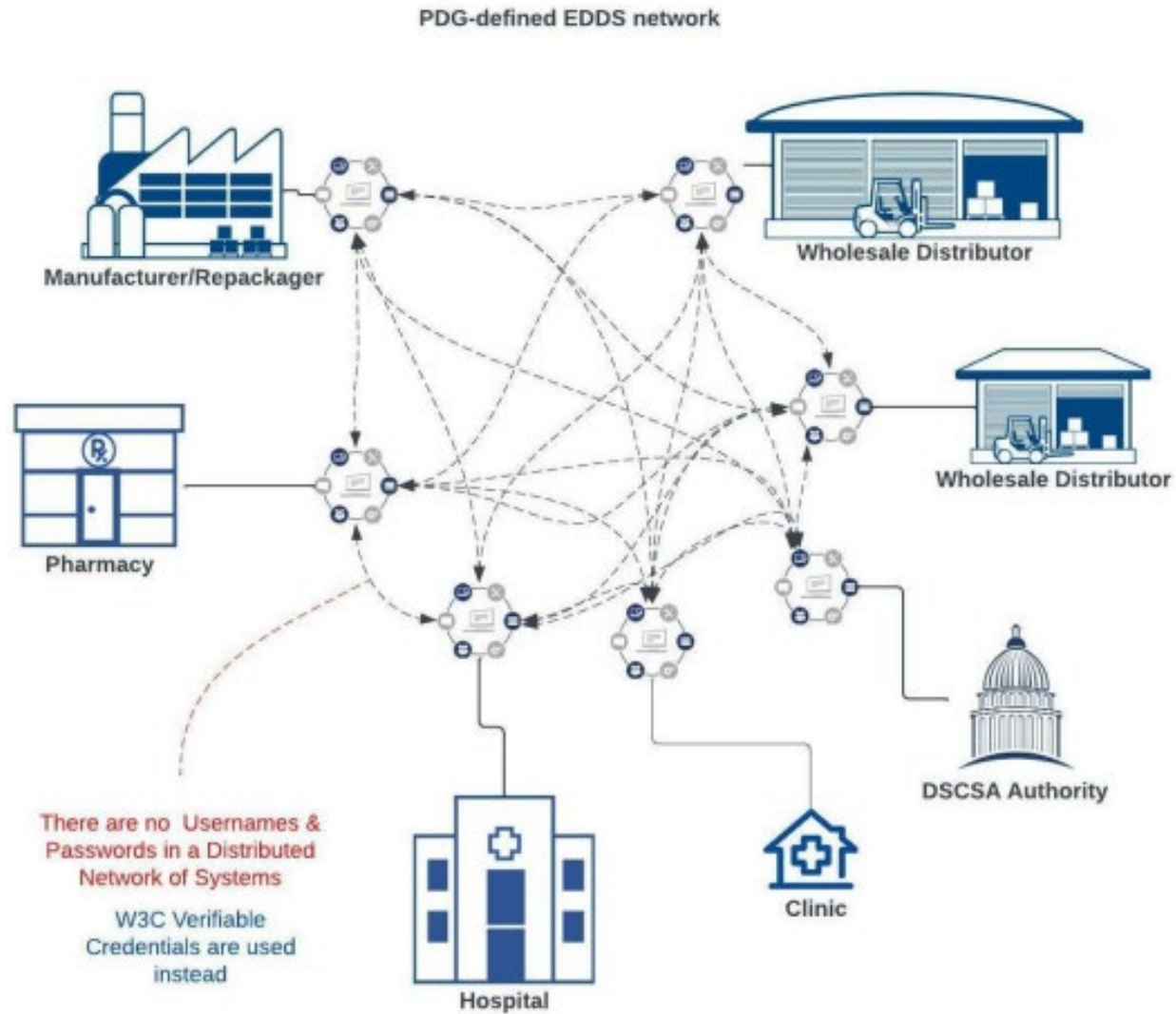
OCI Optimal Process



Note: Certain data flows can be cached in order to improve end-to-end PI Verification performance.

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Credentialing and the EDDS Network



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Questions?

More Information



For additional information and to join:

Visit www.DSCSAgovernance.org

Email admin@members.dscsagovernance.org

