

DSCSA for Dispensers

and their Trading Partners

OCI Credentials: Your Key to the DSCSA Network

November 17, 2022

What is OCI

Open
Credentialing
Initiative

An open **initiative** supporting the pharmaceutical industry in complying with **DSCSA** Authentication and Authorization requirements through Open-Source Credential Specifications



OCI works closely with stakeholders to promote interoperability and DSCSA application

We work with...

- **HDA** to integrate OCI ATP Credentials in PI Verifications processed by VRS
- **GS1 US** to include the optional use of the OCI ATP Header in the GS1 US Guideline for using the Lightweight Messaging Standard for PI Verification
- **PDG** to recognize the OCI architecture as the standard for establishing ATP status in appropriate DSCSA digital transactions
- **AAM** requested to recognize the OCI architecture
- **Trading Partners and Solution Providers** to adopt and onboard
- **FDA** to establish awareness that a solution for the ATP requirement is available and validated by compliance teams



Advantages of OCI Architecture

Every OCI member is committed to adopting and supporting OCI architecture, guidelines, and trust frameworks to support industry collaboration



Efficiency

Verify ATP status instantaneously, with low effort



Interoperability

Share and verify ATP status with any party, with no added friction



Trust

Know-your-ATP through cryptographic resolution and built-in trust



Due diligence

Identify verification carried out in accordance to conformance criteria



Standardization

Global and open standards (GS1 and W3C) ensure no vendor lock-in



Security-by-design

Protect against fraud and malicious actors



Agenda

Description:

In this interactive session the Open Credentialing Initiative (OCI) will introduce the concept and practical application of electronic credentials. Attendees will explore their use in the context of DSCSA and learn how to obtain credentials to enable timely compliance with the DSCSA Authorized Trading Partner (ATP) requirements.

Session Goals:

1. Develop an understanding of the role of credentials
2. Who can help me
3. Why are credentials needed
4. Where to apply the credentials
5. Ease of obtaining/maintaining credentials

DSCSA Challenges

What are Verifiable Credentials?

Why Verifiable Credentials?

Credentials in Action:

How do I get them? / How do I use them?



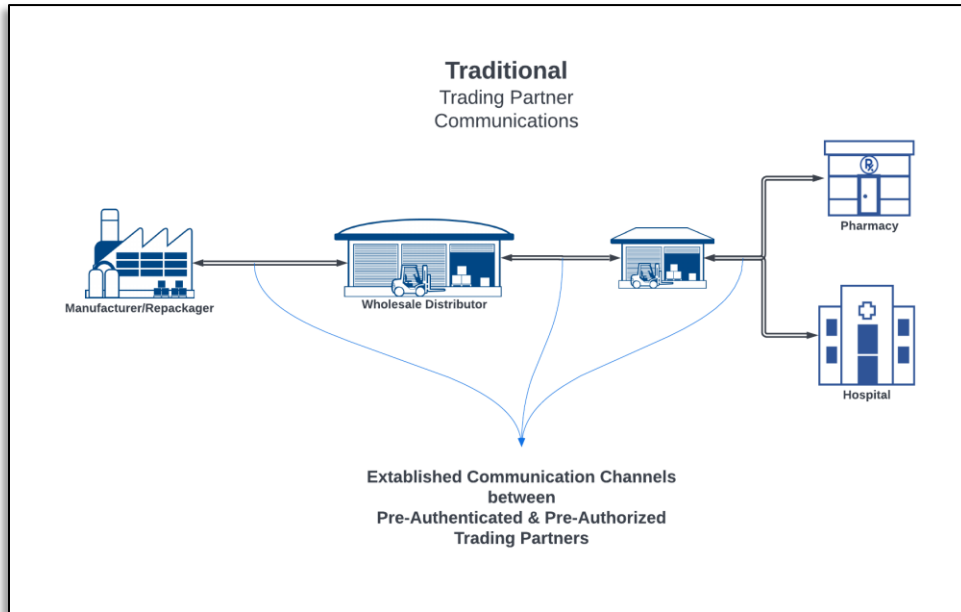


DSCSA Challenges

1. DSCSA Trading Partners

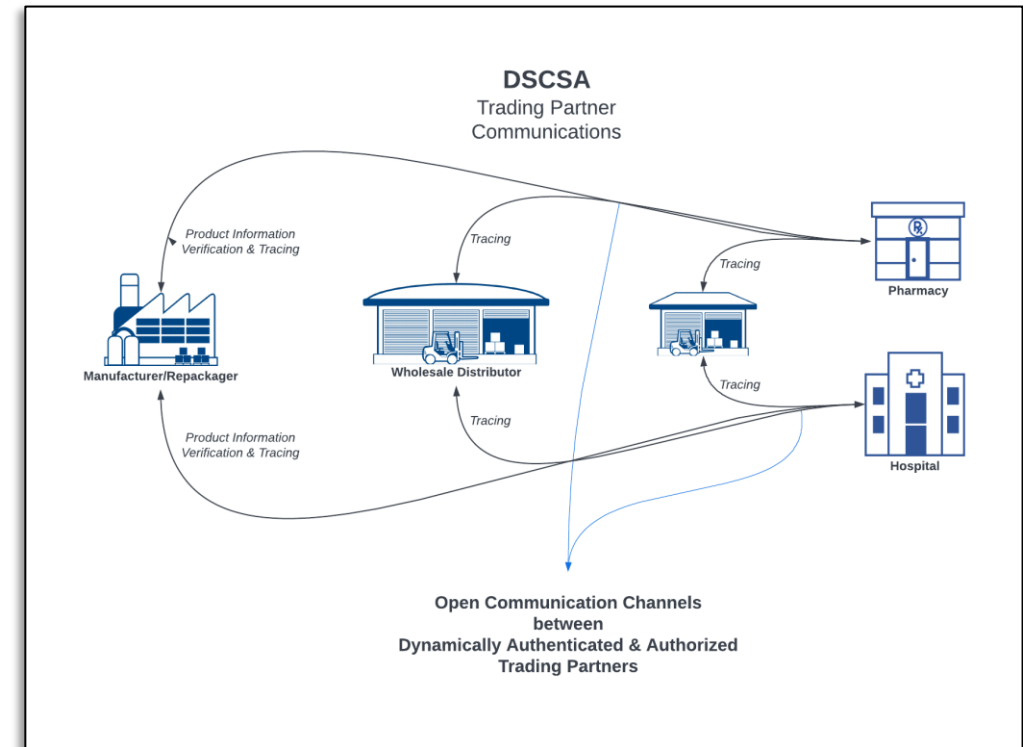
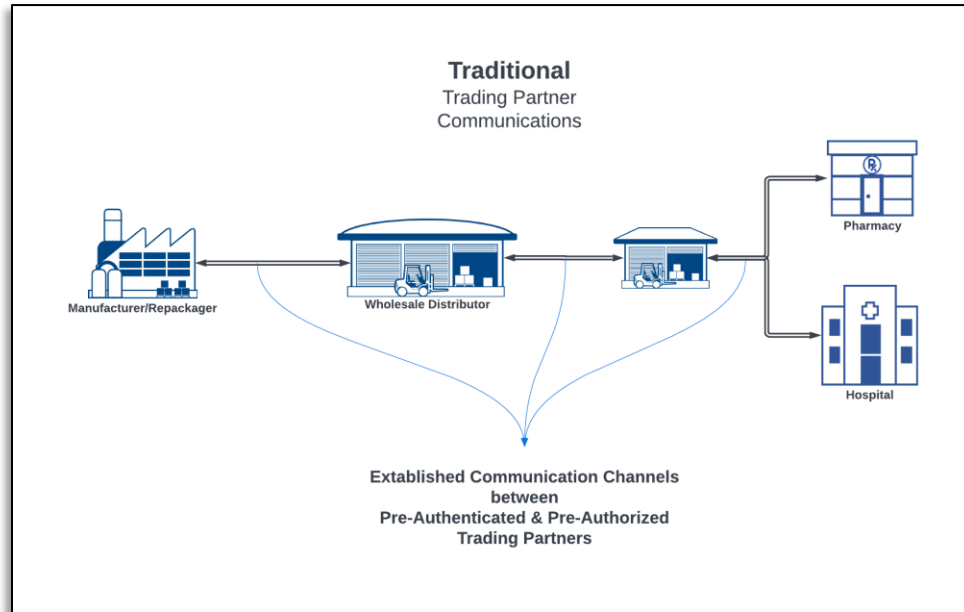
DSCSA Challenges

DSCSA Trading Partners



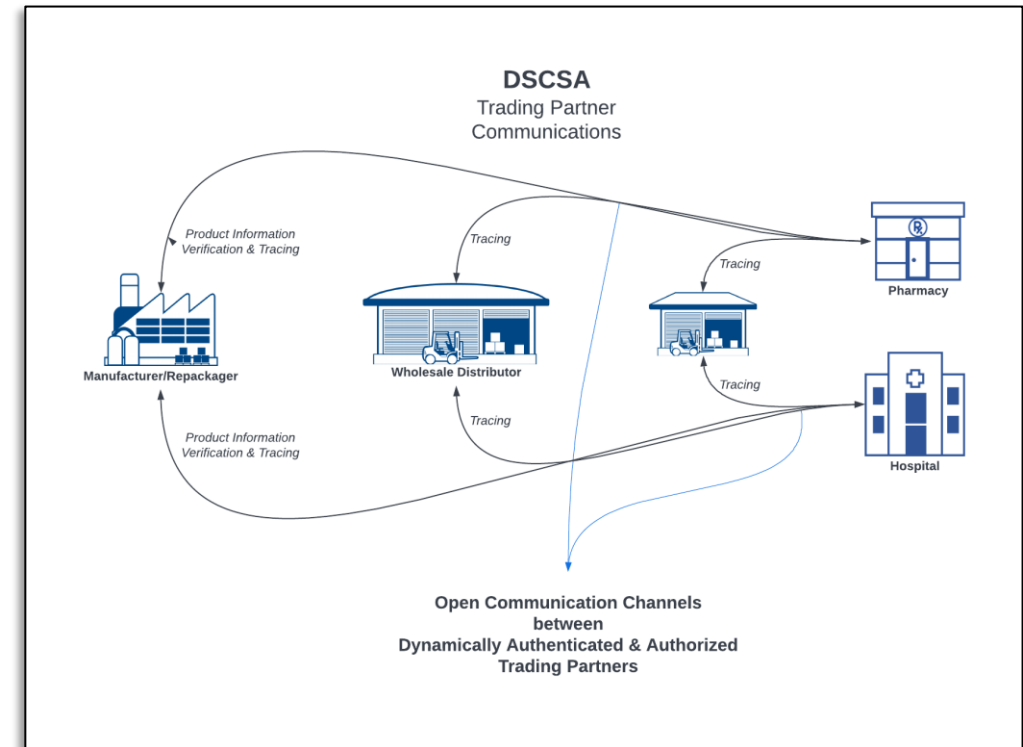
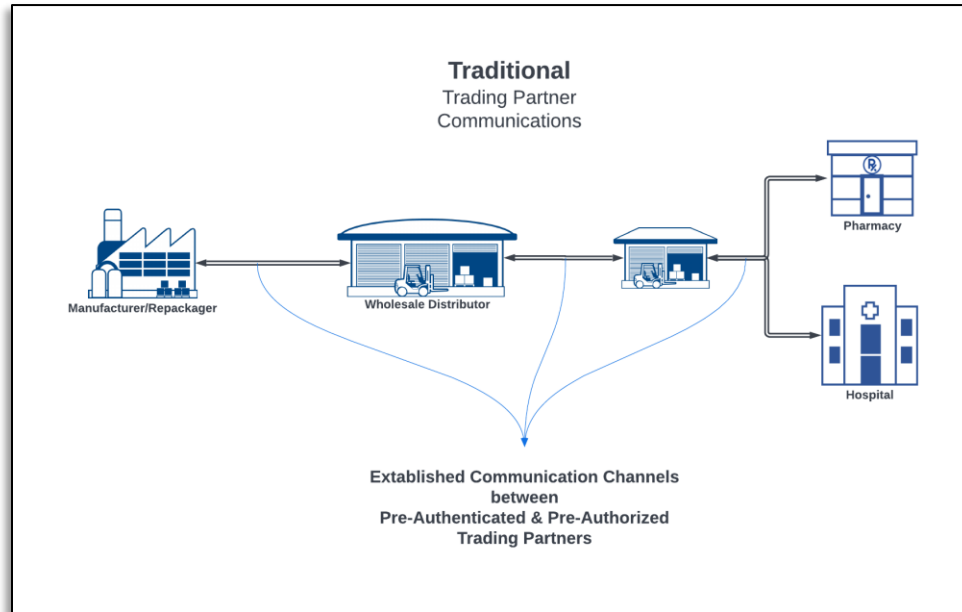
DSCSA Challenges

DSCSA Trading Partners



DSCSA Challenges

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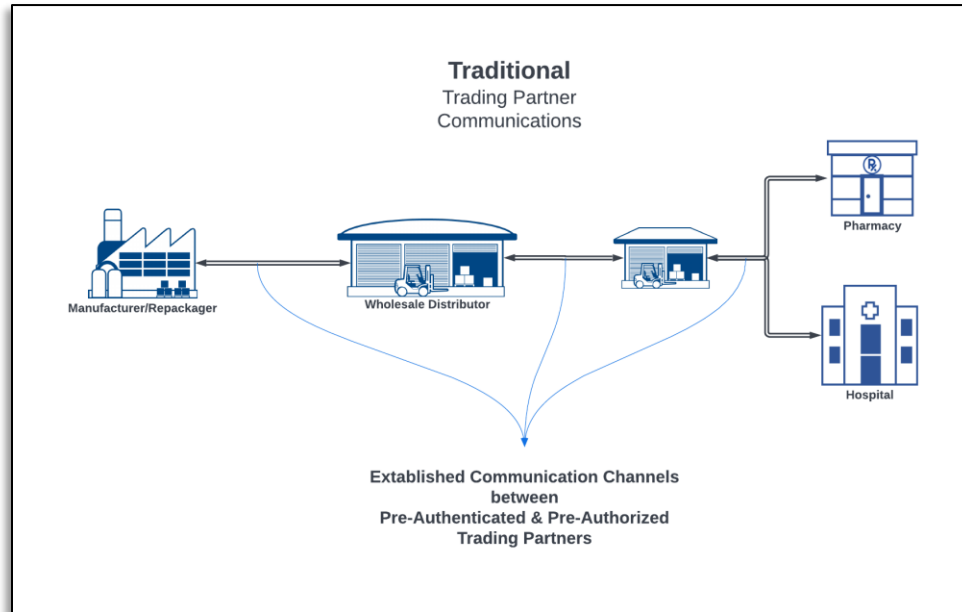


Authentication and Authorization takes place during Onboarding, prior to Transacting

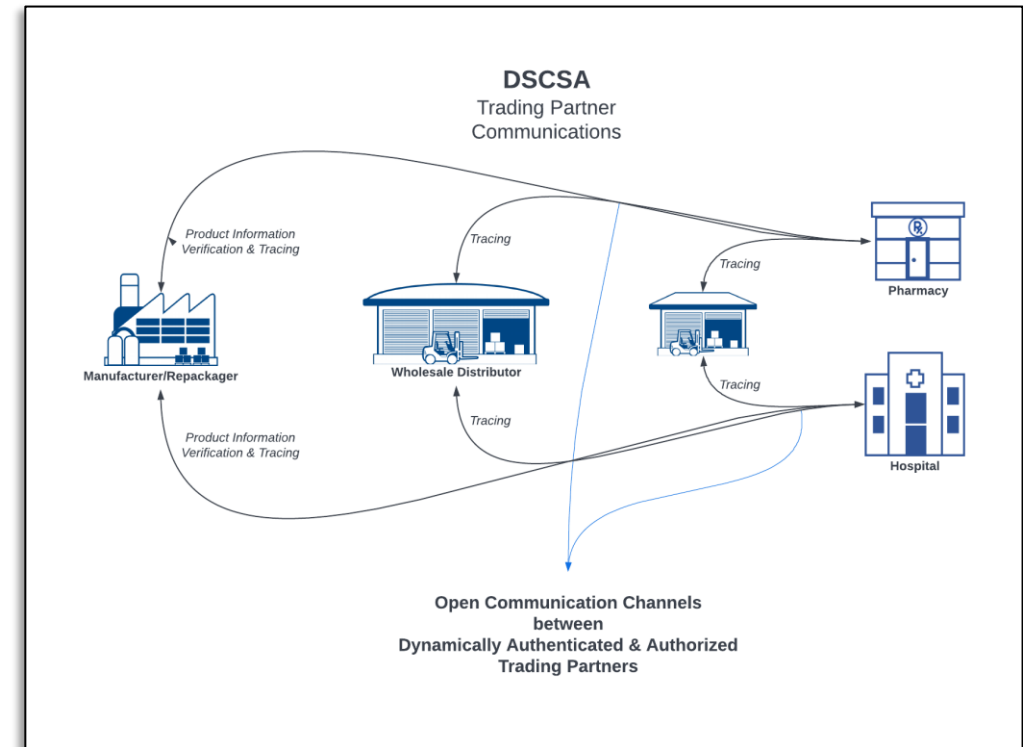


DSCSA Challenges

DSCSA Trading Partners



Authentication and Authorization takes place during Onboarding, prior to Transacting



Authentication and Authorization takes place Dynamically, at the time of Transacting



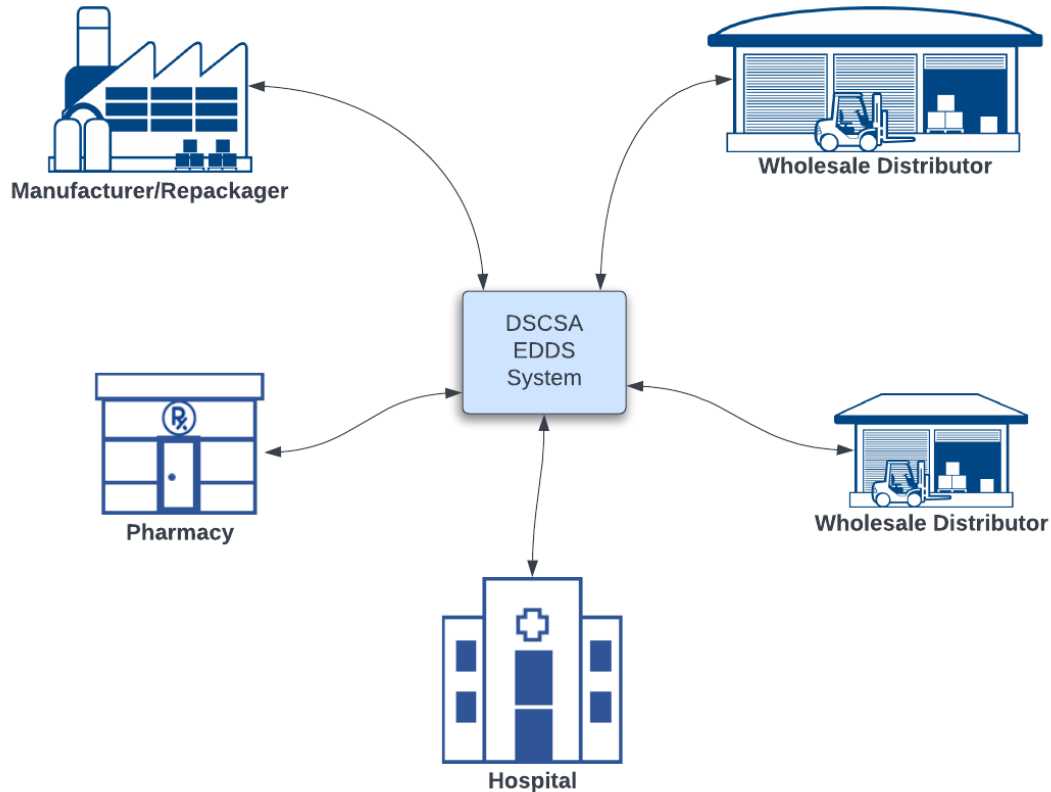


DSCSA Challenges

2. The DSCSA Enhanced Drug Distribution Security System

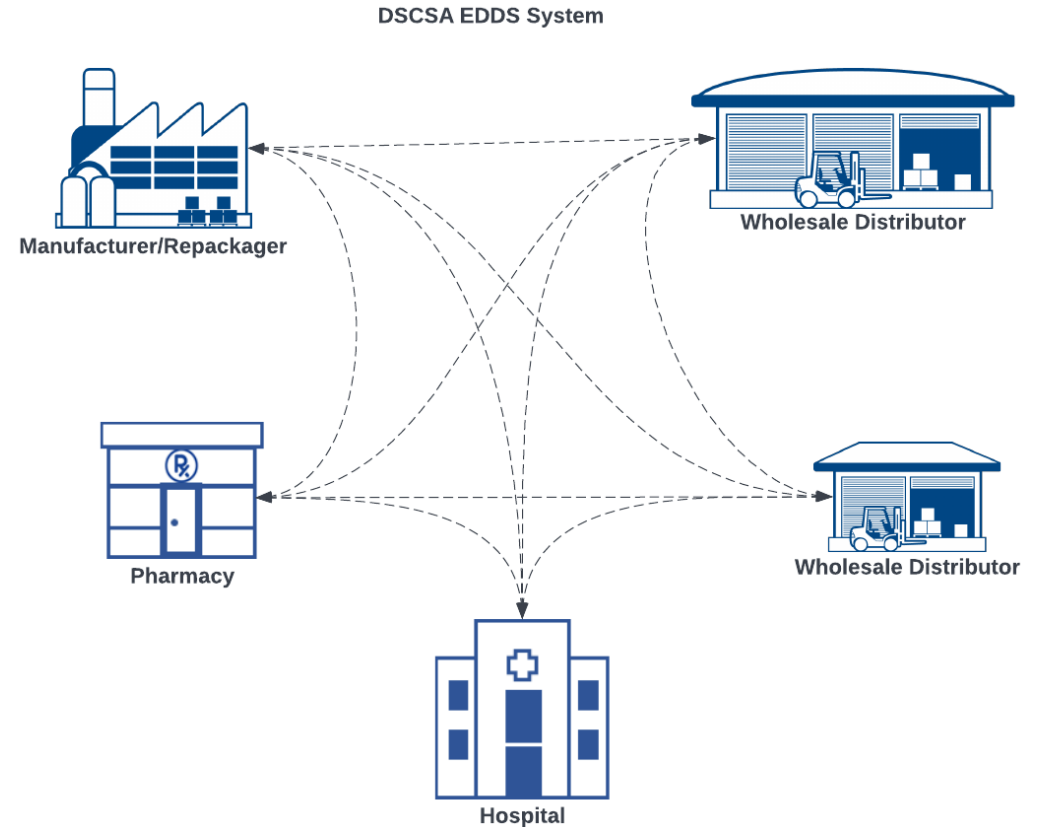
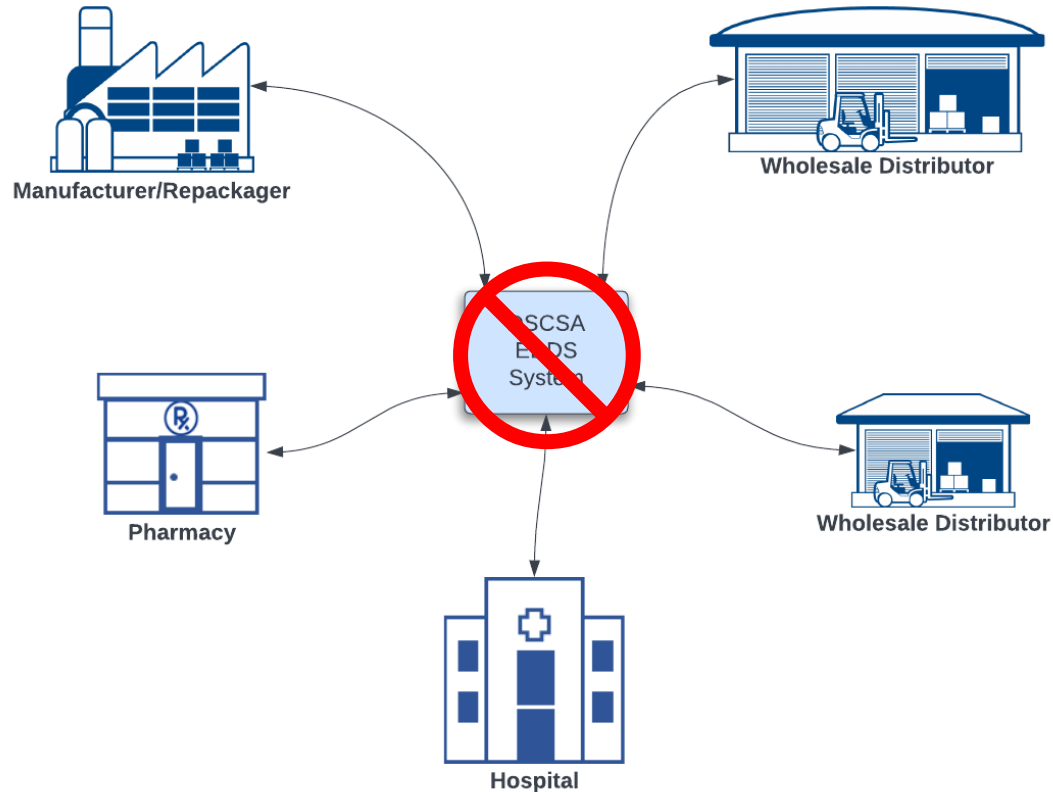
DSCSA Challenges

The DSCSA EDDS System – A highly distributed network of systems



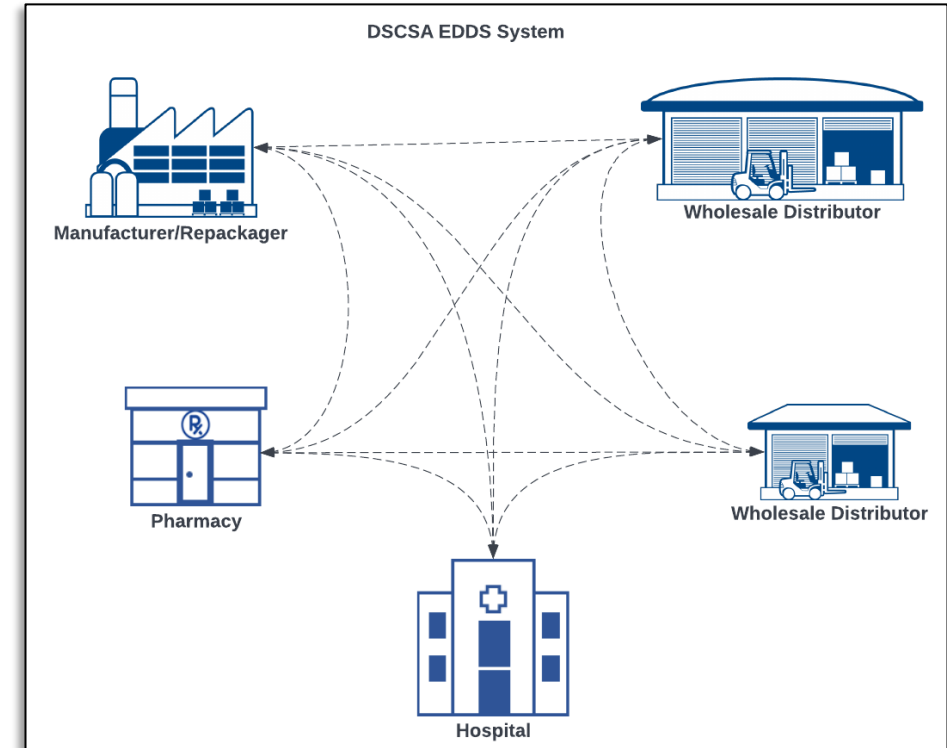
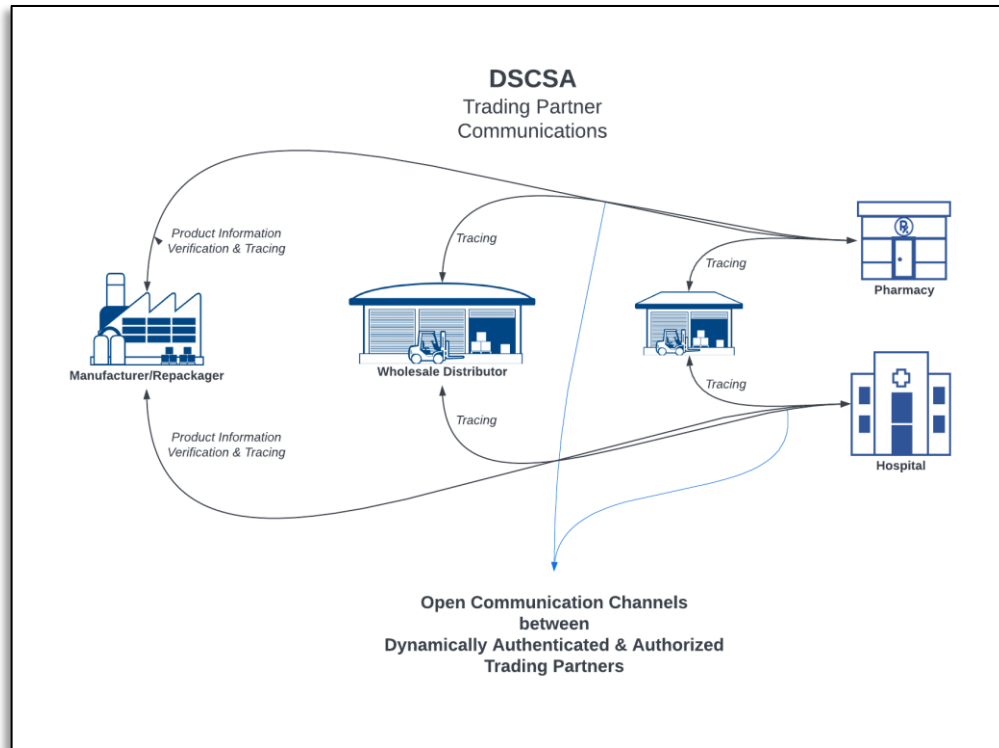
DSCSA Challenges

The DSCSA EDDS System – A highly distributed network of systems



DSCSA Challenges

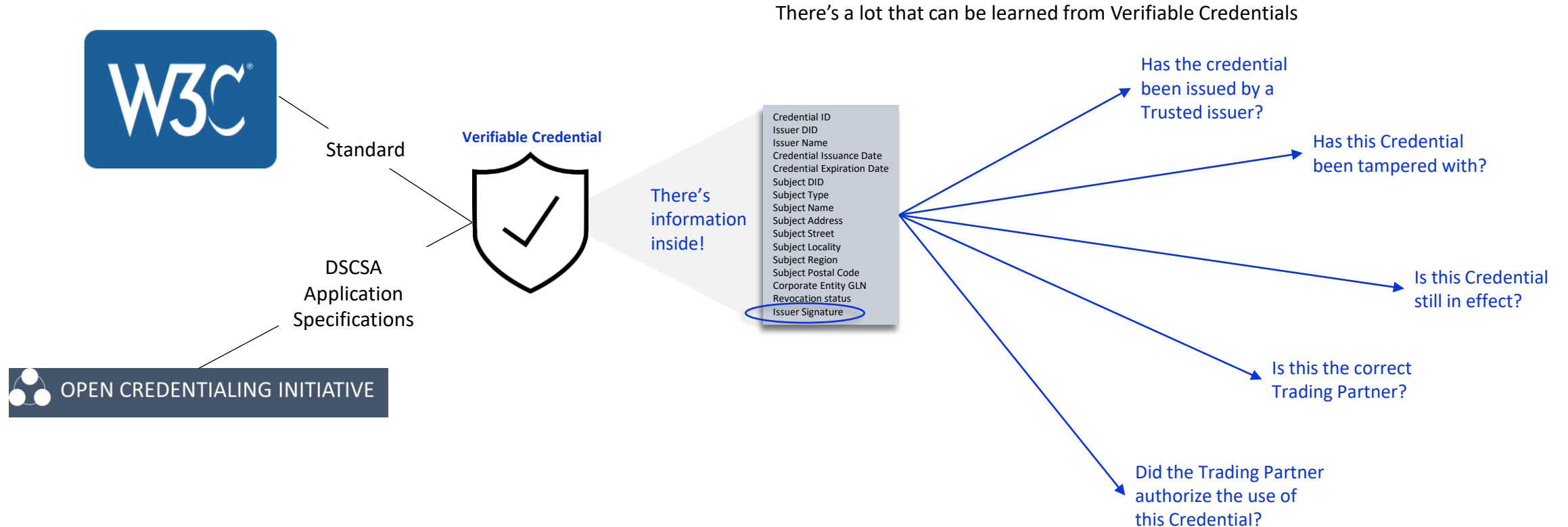
The DSCSA EDDS System – A highly distributed network of systems





What are Verifiable Credentials?

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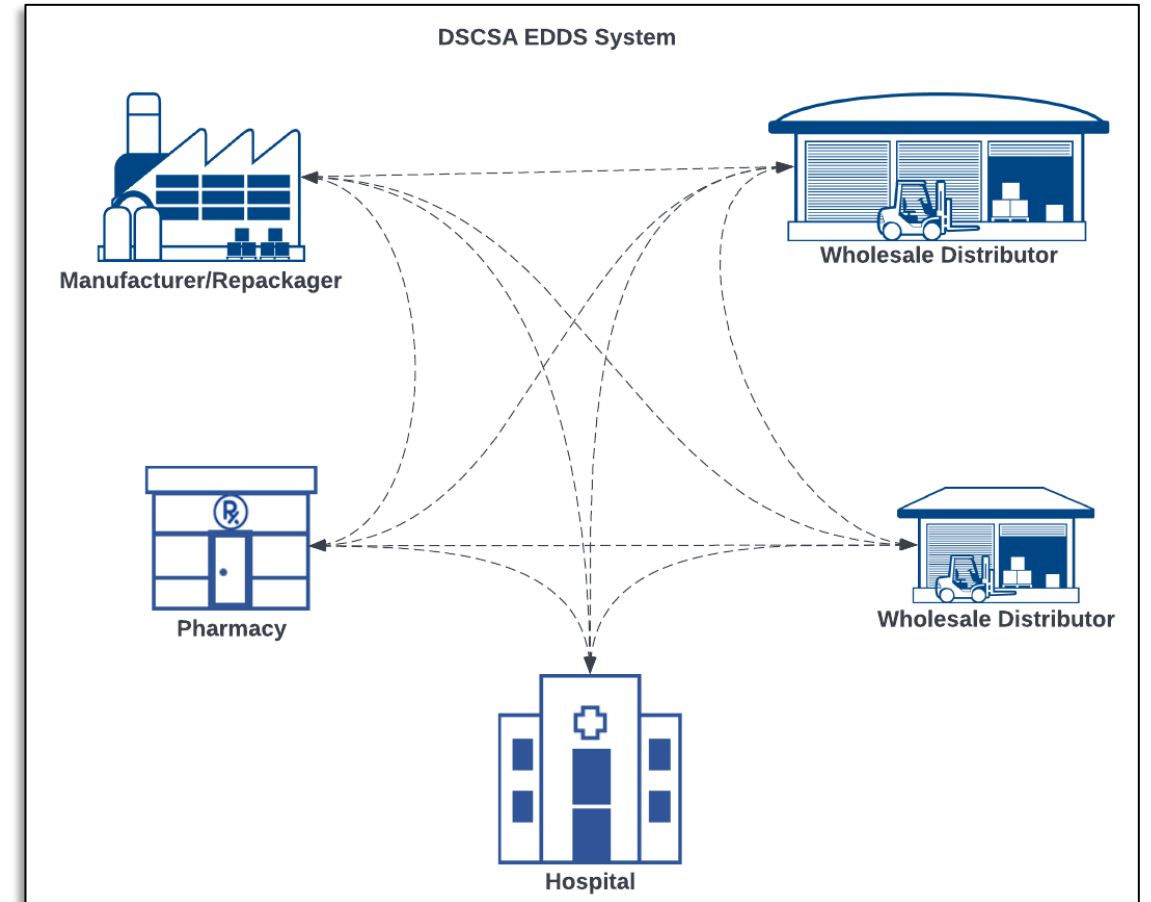




Why Verifiable Credentials?

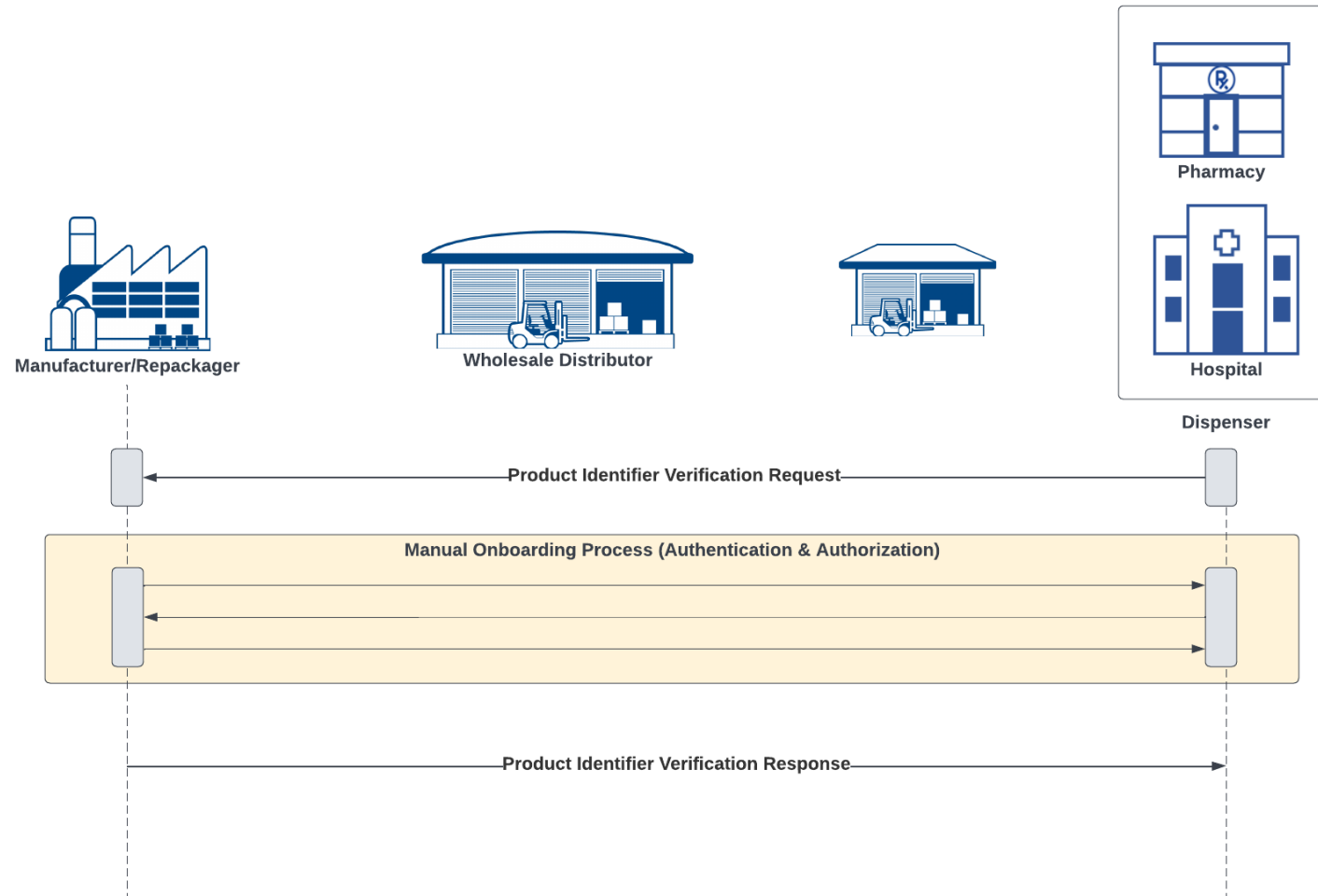
What are Verifiable Credentials?

The DSCSA ATP Verifiable Credential functions like a username and password in the highly distributed DSCSA EDDS System



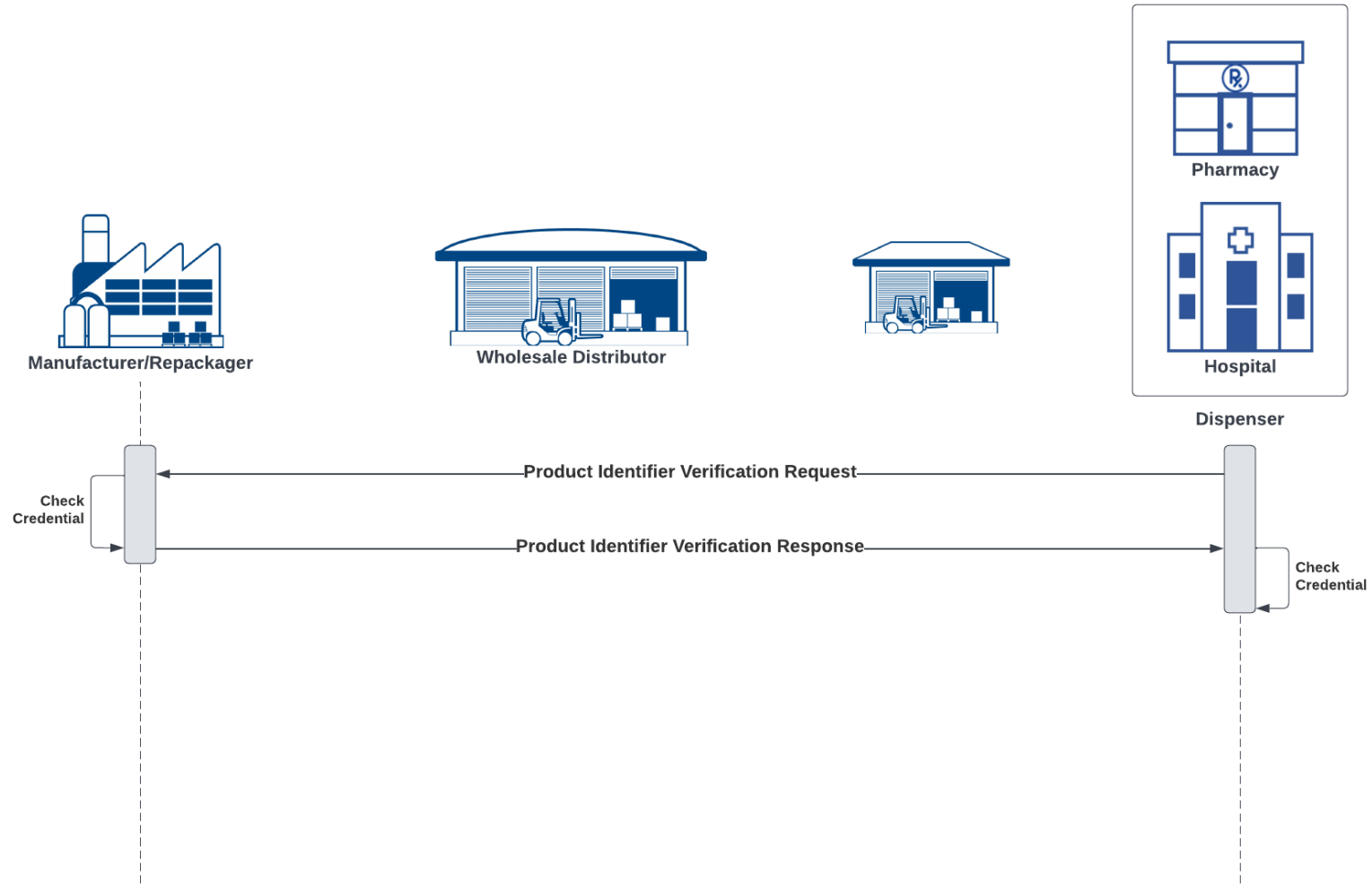
Why Verifiable Credentials?

PI Verification without Credentials



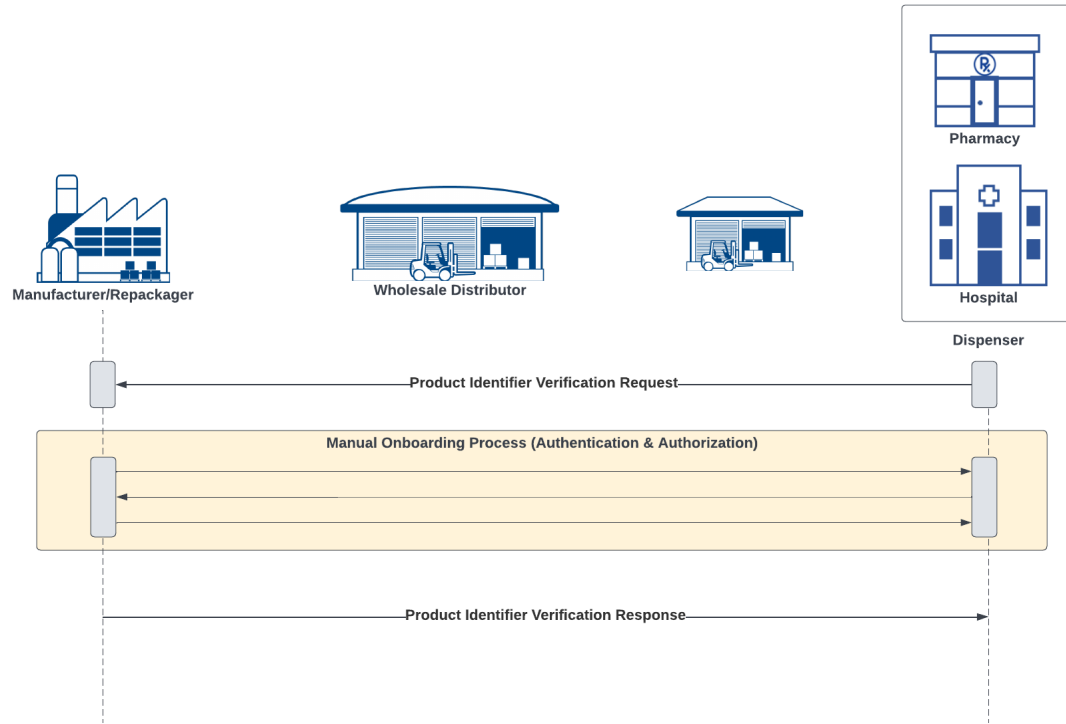
Why Verifiable Credentials?

PI Verification with Credentials

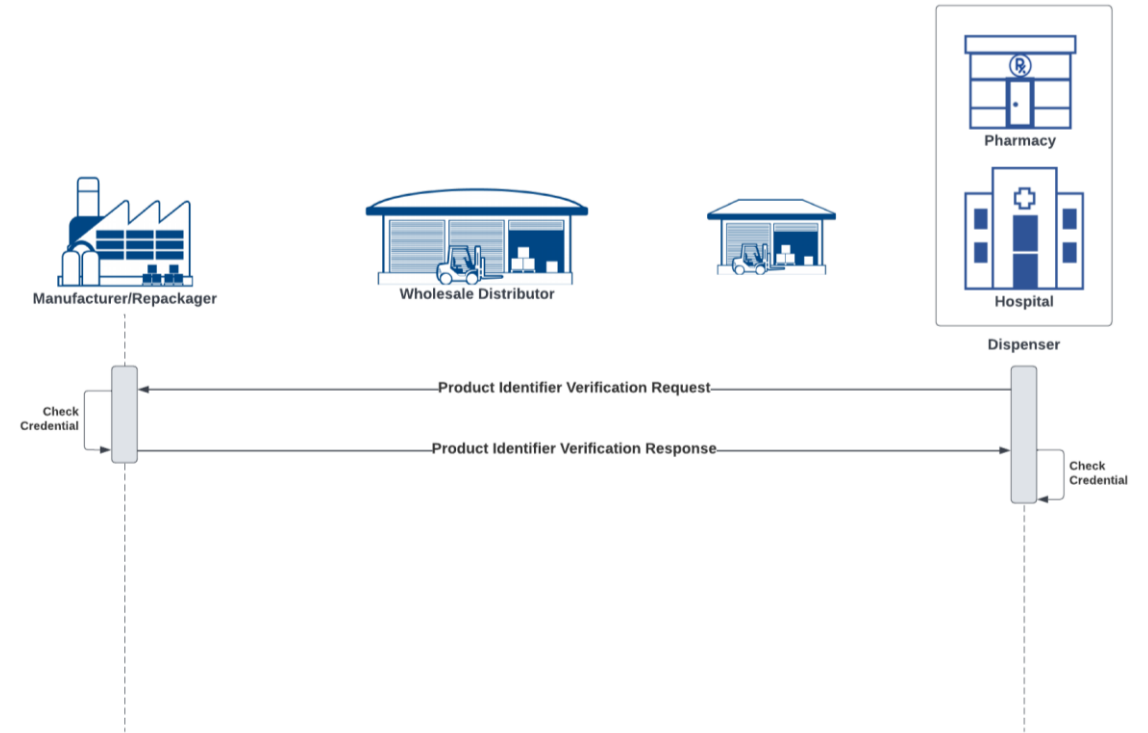


Why Verifiable Credentials?

PI Verification & Credentials



PI Verification without Credentials



PI Verification with Credentials



Why Verifiable Credentials?

Interoperable – ie: credit cards?

Open specifications allow solutions to adopt the same schemas, APIs, etc.

Assurance

Trusting other's credentials, Built on open published standards for identity assurance and security

Security

Cryptographic features

Confidentiality

Issuer is not involved with transactions, wallets limited in transaction data access / separation of duties / mitigate correlation & aggregator of data

Choice

Open specifications allow competing solutions to interoperate within the adopting eco-system

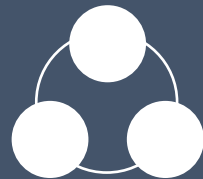
Convenience

Ease of obtaining, using vs manual onboarding processes

Economical

Over manual KYC/KYS or onboarding processes





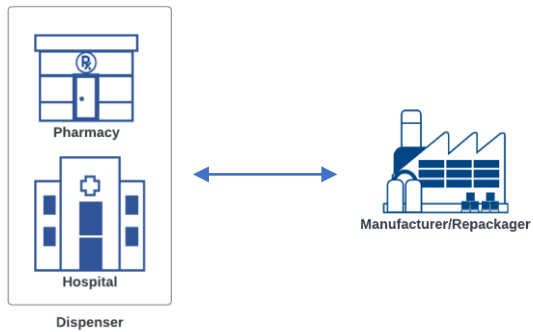
Dramatization

Acquiring and Using
a DSCSA Authorized Trading Partner Credential

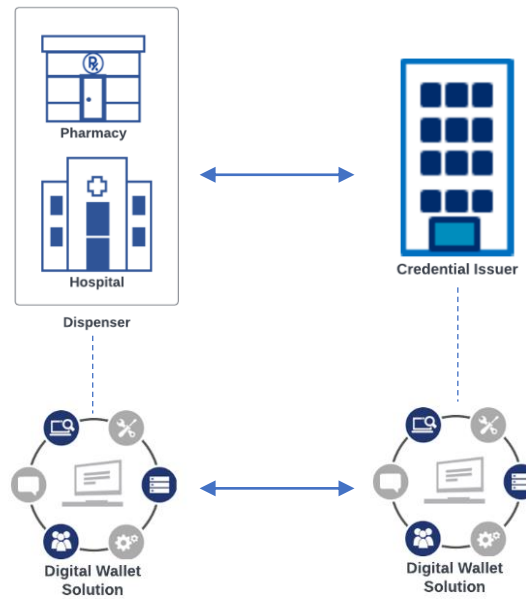
Dramatization

Acquiring and Using the ATP Credential

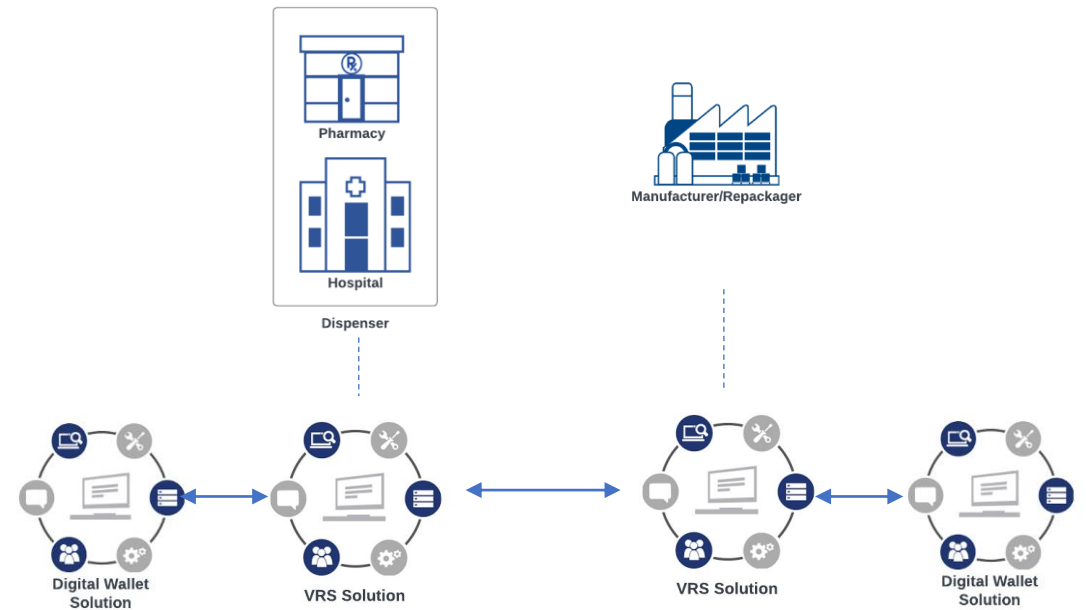
Act 1:
PI Verification Today



Act 2:
Acquiring an ATP Credential



Act 3:
Using an ATP Credential
for PI Verification



Dramatization

Acquiring and Using the ATP Credential

Actors:

VRS:

Manufacturer's VRS: Brittany Santiago, Systech

Dispenser's VRS: Marc Blekkink, Movilitas

Manufacturer:

Chris, Wirrig, Spherity

Dispenser:

Max Peoples, RxScan

Issuer:

David Kessler, Legisym

Wallets:

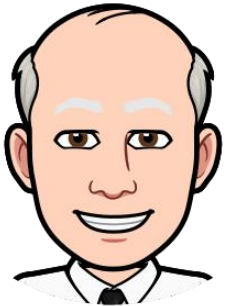
Dispenser's Wallet: Alex Colgan, XATP

Manufacturer's Wallet: Georg Jurgens, Spherity



Dramatization

Acquiring and Using the ATP Credential



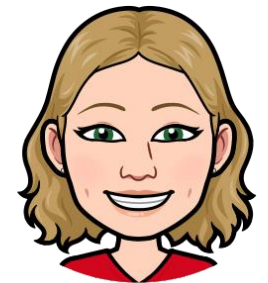
Dispenser



Dispenser's
VRS



Manufacturer's
VRS



Manufacturer



Issuer with
Wallet



Dispenser
Wallet



Manufacturer
Wallet



Act 1: Today

Manual Verification Process



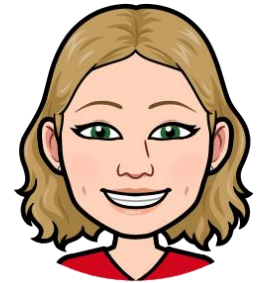
Dispenser



Dispenser's
VRS



Manufacturer's
VRS



Manufacturer



Issuer with
Wallet



Dispenser
Wallet



Manufacturer
Wallet



Act 2: Acquiring a Credential

Your “TSA Precheck” for Interoperability



Dispenser



Dispenser's
VRS



Manufacturer's
VRS



Manufacturer



Issuer with
Wallet



Dispenser
Wallet



Manufacturer
Wallet



Act 3: Using Your Credential!

Compliance in a Few Seconds



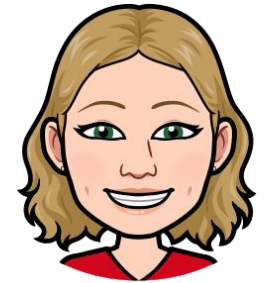
Dispenser



Dispenser's
VRS



Manufacturer's
VRS



Manufacturer



Issuer with
Wallet

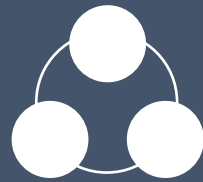


Dispenser
Wallet



Manufacturer
Wallet





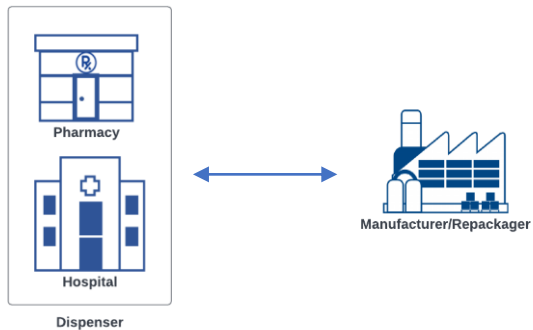
Dramatization - *Discussion*

Acquiring and Using
a DSCSA Authorized Trading Partner Credential

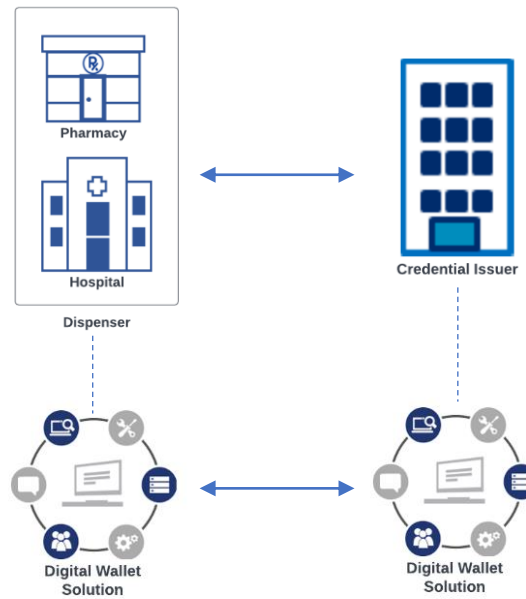
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Acquiring and Using the ATP Credential

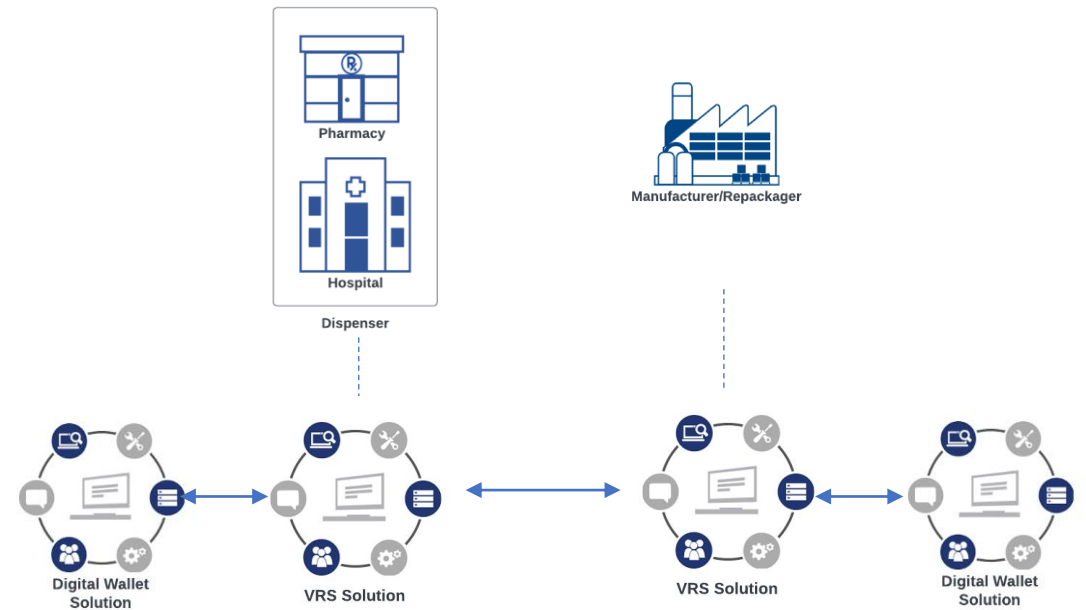
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Questions?