

OPEN CREDENTIALING INITIATIVE

DSCSA

Who Are You Sharing Information With? DSCSA Enhanced Drug Distribution Security system

A P O I N T O F V I E W

PI Verification and Trace records are part of your official record for DSCSA investigations.

It is essential to know to whom you provide information and who provides information to you, along with their ATP status.

FUNDAMENTAL SYSTEM SECURITY DESIGN PRINCIPLES

AUTHENTICATION

The process of verifying the entity that has requested or provided information.

AUTHORIZATION

Verifying whether the authenticated Trading Partner should have access to the requested information or should have provided the information.

DSCSA

- ✓ Identify Entities, at time of digital interaction.
- ✓ Verify their Identity.
- ✓ Verify their Authorization Status (ATP, ATP-Equivalent or DSCSA Authority)

OCI SPECIFICATIONS

APPLYING W3C DIGITAL CREDENTIALS TO DSCSA

ALIGN WITH

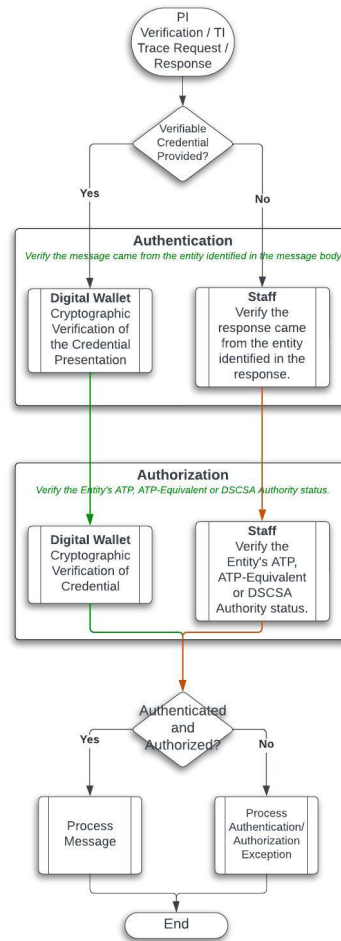
- PDG Foundational Blueprint for 2023 Interoperability
- Verification Routing Service Design for Verification Interoperability
- GS1 US Implementation Guideline for DSCSA Verification of Product Identifiers
- FDA Guidance for Industry Part 11, "Limiting system access to authorized individuals."
- FDA General Principles of Software Validation
- FDA Computer Software Assurance for Production and Quality System Software

THE CHALLENGE

Implementing secure and efficient data exchanges across a complex web of diverse software solutions is challenging for Trading Partners and Solution Providers. Traditional authentication and authorization methods through onboarding procedures suffer from vulnerabilities, delays, and interoperability issues. The industry has turned to the promising world of decentralized identity and verifiable credentials to address these shortcomings.

PREPARE

Enhanced Security, Streamlined Compliance, Interoperability, Improved Efficiency



582(g)(1) of the FD&C Act...
"(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets,..."

Nefarious actors will attempt to pass themselves off as legitimate Trading Partners and Authorities.