[Company] Standard Operating Procedures	
Document Identifier	
Title: Confirming ATP Status and Identity	
Version	
Effective Date	

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish and define the procedures for confirming Authorized Trading Partner (ATP) status and identity to meet the enhanced drug distribution security (EDDS) requirements effective November 27, 2023 under the U.S. Drug Supply Chain Security Act (DSCSA). ATP status and identity confirmation of [Company] and its trading partners, and documentation of these activities in electronic form, are the first steps for enabling the interoperable electronic tracing of a product at the package level.

2. SCOPE

This SOP applies to functions responsible for obtaining credentials that validate [Company]'s ATP status and identity as well as confirmation of ATP status and identity of [Company] trading partners involved in non-exempt prescription drug product transactions within the United States, as part of initiating an interoperable system and annual confirmation of ATP status of all active ATPs thereafter.

3. RESPONSIBILITIES

- **[Name/Department]:** Initiates process to obtain and maintain valid credentials that confirms the ATP Status and Identity of [Company] .
- **[Name/Department]:** Initiates process to confirm ATP Status and Identity of [Company] trading partner(s).
- **[Name/Department]:** Checks ATP Status and Identity of trading partner(s).

4. DEFINITIONS

- **Authorized Trading Partner (ATP):** The DSCSA restricts access to the distribution system for prescription drug products by requiring that trading partners of manufacturers, repackagers, wholesale distributors, third-party logistics providers (3PLs), and dispensers meet the applicable requirements for being ATPs. The DSCSA includes definitions for *authorized* and *trading partner* with respect to these categories. For example: "To be considered an authorized trading partner, a wholesale distributor must have a valid license under State law or section 583 of the FD&C Act, in accordance with section 582(a)(6) of the FD&C Act, comply with the licensure reporting requirements in section 503(e) of the FD&C Act, as amended by DSCSA, and accept or transfer direct ownership of a product from or to a manufacturer, repackager, wholesale distributor, or dispenser."
- **Enhanced Drug Distribution Security (EDDS).** A set of requirements for enhanced drug distribution security at the package level under section 582 of the FD&C Act, as added by the DSCSA. These requirements, commonly known as the "enhanced system," are designed to improve the security of the drug supply chain and went into effect on November 27, 2023.

- **Identity Proofing:** the activity of collecting sufficient evidence to prove the:
  - existence of the organization (i.e. trading partner);
  - identity of the organization;
  - identity of the organization's representative; and
  - authority of the representative to act on behalf of that organization.
- **OCI-Compliant Verifiable Credential:** A digital credential that conforms to the specifications outlined by the World Wide Web Consortium (W3C) and NIST Identity Assurance Level 2, and attests to the ATP status and identity of the credential holder in accordance with Partnership for DSCSA Governance (PDG) Blueprint credentialing requirements.
- **Partnership for DSCSA Governance (PDG).** A public-private partnership between industry and FDA established to define electronic interoperability requirements and guidelines, which are outlined in the Foundational Blueprint for 2023 Interoperability (the "PDG Blueprint").
- **PDG-Defined EDDS Network***:* Systems and processes to support the EDDS in compliance with the PDG Blueprint.

5. PROCEDURE

5.1. Obtain a OCI-compliant verifiable credential for [Company]

5.1.1. Select a vendor that sells OCI-compliant verifiable credential that includes functionality for managing the lifecycle, creation and storage of cryptographic key material in order to manage, present, and validate credentials. This is sometimes referred to as a wallet.

5.1.2. Gather and electronically send relevant documents to validate [Company] ATP status and identity proofing per vendor instructions. The vendor will advise once the credential has been issued.

5.1.3. As applicable, provide existing vendor(s) (e.g. Verification Router Service solution provider) with permissioned access to the wallet in order to check credentials on [Company]'s behalf.

5.1.4. Renew credential prior to expiration. Renewals will usually be on an annual basis for most type of Authorized Trading Partners.

5.2. Initial confirmation of ATP status and Identity for trading partner for interoperable system

5.2.1. Request confirmation of ATP status and identity for a list of active or potential trading partner(s)

This may be conducted via email or through other channels as needed.

5.2.2. Confirm ATP Status and identity of companies listed in the request. Acceptable methods of confirming ATP status and identity are:

- OCI-compliant verifiable credential which includes a third-party check of ATP status and identity proofing per PDG Blueprint requirements.

OR

- **For ATP status,** conduct a manual check of databases for ATP status as outlined on the FDA's website (see Authorized Trading Partner section) AND

- **For identity proofing,** gather documents that prove the existence and identity of the organization, identity of the organization, identity of the organization's representative, and the authority of the representative to act on behalf of the organization.

5.2.3. Document confirmation activities

- Documentation must be signed and dated by the person conducting the confirmation of ATP Status and Identity and be maintained for a minimum of 6 years.

5.2.4. Document retention activities

- Documentation must be maintained for a minimum of 6 years.

6. REFERENCES

- Title II: Drug Quality and Security Act
- FDA, Identifying Trading Partners Under DSCSA, Draft Guidance July 2022
- FDA, Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Guidance for Industry August 2023
- FDA, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs Guidance for Industry December 2023
- FDA, DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs Guidance for Industry
- PDG, Chapter 5: Tracing Architecture Functional Design
- PDG, Chapter 6: DSCSA Credentialing and User Authentication Functional Design
- GS1, US DSCSA Implementation Suite

- OCI, DSCSA Interoperability Profile

7. REVISION HISTORY

Version	Date	Description	Author
1.0	[Date]	Initial Release	[Author's Name]

8. APPROVED FOR RELEASE BY:

Name	Title	Signature	Date