[Company] Standard Operating Procedures	
Document Identifier	
Title:	DSCSA Tracing Requests and Responses
Version	
Effective Date	

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish and define the procedures for enhanced product tracing and gathering of relevant product tracing information to meet the enhanced drug distribution security (EDDS) requirements effective November 27, 2023 under the U.S. Drug Supply Chain Security Act (DSCSA). Documentation of these activities in electronic form are the key steps for enabling the interoperable electronic tracing product at the package level.

2. SCOPE

This SOP applies to functions responsible for initiating and responding to product tracing from Authorities and other Authorized Trading Partners (ATPs) for non-exempt prescription drug products within the United States as part of a secure and interoperable electronic system.

3. RESPONSIBILITIES

- **[Name/Department]:** Responds to and initiates product tracing requests in compliance with the EDDS requirements.
- **[Name/Department]:** Confirms ATP status of product tracing requestors that are not Authorities.

4. DEFINITIONS

- **Authority.** The DSCSA requires prompt responses to certain types of requests for information from the Secretary "or other appropriate Federal or State official." The PDG Blueprint definition of Authority includes FDA, State Licensing Boards, and DEA.

- **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.

- **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 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.

- **PDG-Compliant TI request JSON:** A structured message format for communicating TI and TS for the purposes of initiating a trace request.

- **PDG-Compliant TI response JSON:** A structured message format for communicating TI and TS for the purposes of responding to a trace request.

- **Tracing.** Under the DSCSA, product ownership traces are executed to support suspect, illegitimate, or recalled product investigations or for compliance audits. [Company] may initiate a trace in support of these activities, be required to undertake tracing activity upon request by an appropriate Authority, or may be required to respond to a trace request by another ATP.

- **Transaction Information (TI):** Under the DSCSA, the following information is to be transferred during a change of ownership of non-exempt prescription drug products: "(A) the proprietary or established name or names of the product; (B) the strength and dosage form of the product; (C) the National Drug Code number of the product; (D) the container size; (E) the number of containers; (F) the lot number of the product; (G) the date of the transaction; (H) the date of the shipment, if more than 24 hours after the date of the transaction; (I) the business name and address of the person from whom ownership is being transferred; and (J) the business name and address of the person to whom ownership is being transferred." Beginning on November 27, 2023, transaction information "shall include the product identifier at the package level for each package included in the transaction."

- **Transaction Statement (TS).** Under the DSCSA, each transfer of non-exempt prescription drug products between persons in which a change of ownership occurs is required to include a statement that the entity transferring ownership in a transaction "(A) is authorized as required under the Drug Supply Chain Security Act; (B)

received the product from a person that is authorized as required under the Drug Supply Chain Security Act; (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582; (D) did not knowingly ship a suspect or illegitimate product; (E) had systems and processes in place to comply with verification requirements under section 582; (F) did not knowingly provide false transaction information; and (G) did not knowingly alter the transaction history.

5. PROCEDURE

5.1. Product Tracing Background

Tracing a package(s) is conducted in a series of TI Requests and TI Responses. The types of data that may be requested via the EDDS network include:

- **TI/TS:** All relevant TI/TS information that the request recipient has in its possession.
- **All known owners:** All known owners that the request recipient has in its possession.
- **Last known owner:** Last known owner that the request recipient has in its possession.

In cases where TI data does not tell the full story of the ownership path of a package and other relevant details are available, requesters and responders of product tracing requests should communicate outside of the EDDS system using the contact information provided in the TI Request and TI Response messages.

Tracing requests can come from Authorities and ATPs that are gathering tracing information for purposes of investigating suspect product or assisting an Authority.

5.2. Responding to product tracing request from Authority

5.2.1. Evaluate request. Search the [Company] system of record in order to find the applicable TI and TS related to the product(s) being traced.

5.2.2. Complete the PDG-compliant TI response JSON including the [Company] verifiable credential.

5.2.3. QC TI responses JSON

5.2.4. Send TI response JSON no later than 1 business day, unless otherwise specified by the Authority. For FDA, submit via the DSCSA portal in CDER NextGen. For other Authorities, send as directed in the request.

5.2.5. Maintain all trace messages in electronic format for a minimum of 6 years. Trace messages that are part of an investigation of suspect product should be maintained for a minimum of 6 years after the investigation.

5.3. Responding to product tracing request from another ATP

5.3.1. Confirm ATP status and identity. If ATP status can not be confirmed via verifiable credential, other methods should be employed to confirm ATP status and identity prior to sending a response.

5.3.2. Evaluate request. Search the [Company] system of record in order to find the applicable TI and TS related to the product(s) being traced.

5.3.3. Complete the PDG-compliant TI response JSON including the [Company] verifiable credential.

5.3.4. QC TI response JSON

5.3.5. Send trace response to requester.

5.3.6. Maintain all trace messages in electronic format for a minimum of 6 years. Trace messages that are part of an investigation of suspect product should be maintained for a minimum of 6 years after the investigation.

5.4. Initiating a product tracing request to another ATP

5.4.1. Identify appropriate ATP for to receive a product tracing request

5.4.2. Complete the PDG-compliant TI request JSON including the [Company] verifiable credential.

5.4.3. QC TI request JSON

5.4.4. Send trace request.

5.4.5. Investigation is completed.

5.4.6. Maintain all trace messages in electronic format for a minimum of 6 years. Trace messages that are part of an investigation of suspect product should be maintained for a minimum of 6 years after the investigation.

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, 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