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Warehouse **Department**

**Distribution** **SOP # 0007**

 Revision #1.1

 Implementation Date: March 12 2015

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# Standard Operating Procedure for Product Tracing

## 1. Purpose

On November 27, 2013 President Barack Obama signed the Drug Quality and Security Act (DQSA)1 into law, bringing a successful conclusion to efforts by the industry and consumer groups to create a national pharmaceutical serialization and track and trace regulation, one that eliminates the patchwork of state laws in addition to providing new regulations for compounding pharmacies.

<COMPANY NAME> utilizes the TrackTraceRx solution to meet the demands of the DQSA in particular title II of the DQSA the DSCSA. In order to be DSCSA compliant one must meet the following criteria:

* Track and Receive transactional data at a lot-level such as a Transaction History (TH), Transaction Information (TI) and Transaction Statement (TS). These transactional data are referred to in the industry as a “T3s”.
* Verify transactional data (T3s) against all products shipment received. Quarantine any shipment that are determined missing their respective T3 data or if a product deemed suspect.
* Store T3 data received for a period of at least 6 years from the date of shipment receipt. This includes any exceptions handled within your supply chain.
* Handle any request for verification from any federal organization.

## 2. Scope

Identify the intended audience and /or activities where the SOP may be relevant. Answer these questions, Which specific operations or tasks within an operation will be covered? Who is the SOP written for? Example:

The SOP for Product Tracing is for all employees that deal with the handling of ownership and transferring of ownership of Rx products to other trading partners.

## 3. Prerequisites

Outline information required before proceeding with the listed procedure; for example, worksheets, documents, etc.

## 4. Responsibilities

Identify the personnel that have a primary role in the SOP and describe how their responsibilities relate to this SOP. If necessary, include contact information.

John Doe - Compliance Manager

john@company.com

555-555-5555

## 5. Procedure

**Inbound Procedure**

* Perform Receiving & Receipt of shipment
* Verify Product on Packing Slip
* Login to TrackTraceRx portal
* Query Transaction if ASN was received to match on TrackTraceRx portal.
* etc..

**Outbound Procedure**

* Step 1
* Step 2
* Step 3

**Quarantine Procedure**

* Step 1
* Step 2
* Step 3

**Request For Verification**

* Step 1
* Step 2
* Step 3

## 6. References

List resources that may be useful when performing the procedure; for example, Admin policies, Municipal Code, government standards and other SOPs.

**Title II of the Drug Quality and Security Act**

<http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm>

## 7. Definitions

Identify and define frequently used terms or acronyms. Provide additional and/or relevant information needed to understand this SOP.

Trading Partners - Is the manufacturer, repackager, wholesale distributor and dispenser from who accepts direct ownership of a prescription drug. 3PLs do not take ownership of the product.