



## LifeScience Logistics

<b>Title:</b>	Prescription Drug DSCSA Track/Trace	
<b>Number:</b>	WI 600.03	<b>Rev. Date:</b> 07-NOV-23
<b>Rev. Level:</b>	003	

### 1.0 PURPOSE

The purpose of this document is to outline the Prescription Drug tracking and tracing processes at Life Science Logistics to fulfill the regulatory requirements of the Drug Supply Chain Security Act (DSCSA) for Third-Party Logistics Providers.

### 2.0 SCOPE

This procedure applies to all LSL facilities and vendors who are responsible for shipping, receiving, repackaging, and serialization of drug product received from Contract Manufacturing Organizations for commercial sale.

### 3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
H.R. 3204 (21 U.S.C. 301)	Drug Supply Chain Security Act
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1100	Document Control
WI 600.05	Prescription Drug Receiving
WI 600.06	Prescription Drug Hold and Release
WI 600.07	Prescription Drug Initial Sampling and Laboratory Testing
WI 600.08	Prescription Drug Relabeling Requirements and Process
WI 600.10	Prescription Drug Pick/Pack/Ship
WI 600.15	Prescription Drug Inventory Management

### 4.0 DEFINITIONS

Axway Data Repository	Serialization Information Management System
Canadian product information	Product information provided by the Foreign Seller
Decommission	Formal process to remove or deactivate. For example, remove original data or deactivate current systems.
Product Identifier	A standardized graphic that includes, in both human-readable form and on a machine-readable data carrier (2-



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	<p>dimensional data matrix barcode) that conforms to the standards developed by a widely recognized international standards development organization:</p> <ul style="list-style-type: none"><li>• The standardized numerical identifier,</li><li>• The lot number, and</li><li>• The expiration date of the product.</li></ul>
Product Information	Product Information provided by LifeScience Logistics
Serialization	Application of a unique identifier assigned randomly or sequentially to an item intended to provide a singular reference to a specific product or product package. The serial identifier may be composed of numbers or an alphanumeric character string of fixed or variable length.
SSI	Section 804 Serial Identifier. A unique alphanumeric serial number of up to 20 characters that is assigned and placed on or affixed by the Foreign Seller to each package and homogenous case of the product that the Foreign Seller intends to sell to an Importer. For purposes of the SSI, "package" means the smallest individual saleable unit of product for distribution that is intended by the Foreign Seller for sale to an Importer located in the United States, and "individual saleable unit" means the smallest container of product sold by the Foreign Seller to the Importer.
<u>Standardized Numerical Identifier</u>	<p><u>A set of numbers or characters used to uniquely identify each package or homogenous case. The Standardized Numerical Identifier combines:</u></p> <ul style="list-style-type: none"><li>• <u>The NDC that corresponds to the specific product (including the</u></li></ul>



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	<p><u>particular package configuration);</u>  <u>and</u>  <ul style="list-style-type: none"> <li>• <u>A unique alphanumeric serial number of up to 20 characters.</u></li> </ul></p>
Transaction Record	Refers to the FDA DSCSA requirement to capture drug product and supply network information at each change of ownership. Includes the Transaction History, Transaction Information and Statement as defined in DSCSA.

### 5.0 ABBREVIATIONS/ACRONYMS

BOL	Bill of Lading
CMO	Contract Manufacturing Organization
CQCU	Corporate Quality Control Unit
DSCSA	Drug Supply Chain Security Act
LSL	Life Science Logistics
QA	Quality Assurance
SDS	Safety Data Sheet
SOP	Standard Operating Procedure
WI	Work Instruction

### 6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system. Manages the quarantine, testing and release of the drug product. Maintains quality and security according to DSCSA.
Foreign Seller	Provides drug product for wholesale to LSL for distribution according DSCSA.
Shipping and Receiving	Provides documentation in preparation of shipping and receiving product according to Life Science Logistics procedures.
Vendor/Re-labeler	Responsible for the reserialization and relabeling of the product according to DSCSA and Life Science Logistics requirements.

### 7.0 SERIALIZATION OF DRUG PRODUCT

Overview



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Trainee Printed Name	Trainee Signature	Department	Date

*Trainer: Signature below indicates you have presented training on procedure listed above and confirm all listed employees completed training as defined.*

Document Number / Training Session	Trainer Printed Name (N/A if Self-Training)	Trainer Signature (N/A if Self-Training)