LifeScience Logistics			
Title:	Prescription Drug DSCSA Track and Trace Regulatory Requirements		
Number:	SOP 7005	**Rev. Date:**	26-Oct-2023
Rev. Level:	000		

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
FDA Guidance	Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers
FDA Guidance	DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs
FDA Guidance	Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers; Guidance for Industry; Availability
FDA Guidance	Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs
FDA Guidance	Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act
FDA Guidance	Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification
FDA Guidance	Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs

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10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Read and Understand – Self Training	☐ Read and Exhibit Competency – Trainer Led with Module/Assessment when applicable	☐ Instructor Led – Trainer Led with Module/Assessment when applicable

Procedure Name or Description of Training	Procedure Number	Revision Level

Trainee: Signature and date indicates you have trained and understand this procedure and all associated documents as well as the training module/material listed above.

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