LifeScience Logistics			
Title:	Prescription Drug Returned Merchandise		
Number:	SOP 7003	**Rev. Date:**	15-Nov-2023
Rev. Level:	001		

1.0 PURPOSE

The purpose of this procedure is to describe the process to receive, quarantine, store, and disposition merchandise returned from a Prescription Drug Program customer. This procedure applies to all LSL facilities that warehouse Prescription Drug Program merchandise.

2.0 SCOPE

Merchandise returned to an LSL facility as a result of a recall, market withdrawal, over-shipment, wrong item shipped, Customer complaint, Customer order cancellation or as a free astray are all within scope.

WI 600.11, Prescription Drug Returns, covers undeliverable addresses and free astrays.

Client-specific instructions on handling returns supersede this SOP.

3.0 REFERENCES

21 CFR 210 & 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality System regulation
ISO 13485	Medical Devices – Quality Management Systems
SOP 1003	Recalls, Removals, and Corrections
SOP 1101	Control of Records
SOP 1351	Deviation/CAPA – RX
SOP 1351.01	Deviation Report – RX
SOP 7000	Prescription Drug Destruction of Products
SOP 7003.01	Returned Merchandise Authorization Log
SOP 7003.02	Free Astray Log
WI 600.06	Prescription Drug Hold and Release
WI 600.06.02	Damaged Product Form - RX
WI 600.11	Prescription Drug Returns
WI 600.15	Prescription Drug Inventory Management
WI 600.24	Pharmacovigilance

4.0 DEFINITIONS

Call Tag Number	A unique identifier for an appointment time/date for a common carrier to pick up the materials to be returned to LSL.
Counterfeit	A fraudulent imitation of legitimate merchandise.
Customer	“ship to” location
Customer Return	Merchandise which was shipped from LSL facilities and is sent back to LSL.
Free Astray	Returned materials arriving at LSL without an RMA; also known as a blind return.

Merchandise	Any Client pharmaceutical, medical device, labeling, kits, in-process material, etc. where the Client owns the product and LSL distributes.

Product Complaint	Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device or drug product after Client releases for distribution.
Return Merchandise Authorization (RMA)	Tracking number assigned by WMS for each return
Temperature Sensitive Product	Any product with a label stating a temperature range for storage.

5.0 ABBREVIATIONS/ACRONYMS

3PL	Third Party Logistics
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
DEA	Drug Enforcement Agency
FDA	Food and Drug Administration
FTS	Full Time Supervisor
LSL	Life Science Logistics
PPE	Personal Protective Equipment
QA	Quality Assurance
RMA	Return Merchandise Authorization
SDS	Safety Data Sheet
SISPQ	Safety, Identity, Strength, Purity, Quality
SOP	Standard Operating Procedure
VAWD	Verified-Accredited Wholesale Distributors
WI	Work Instruction
WMS	Warehouse Management System

6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
Customer Service / Functional Owner	Ensure training requirements by position are updated in the Quality Management System to align with tasks listed in each document's revision. Approve documents to meet the purpose of the procedure and meet current revision guidelines.

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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)