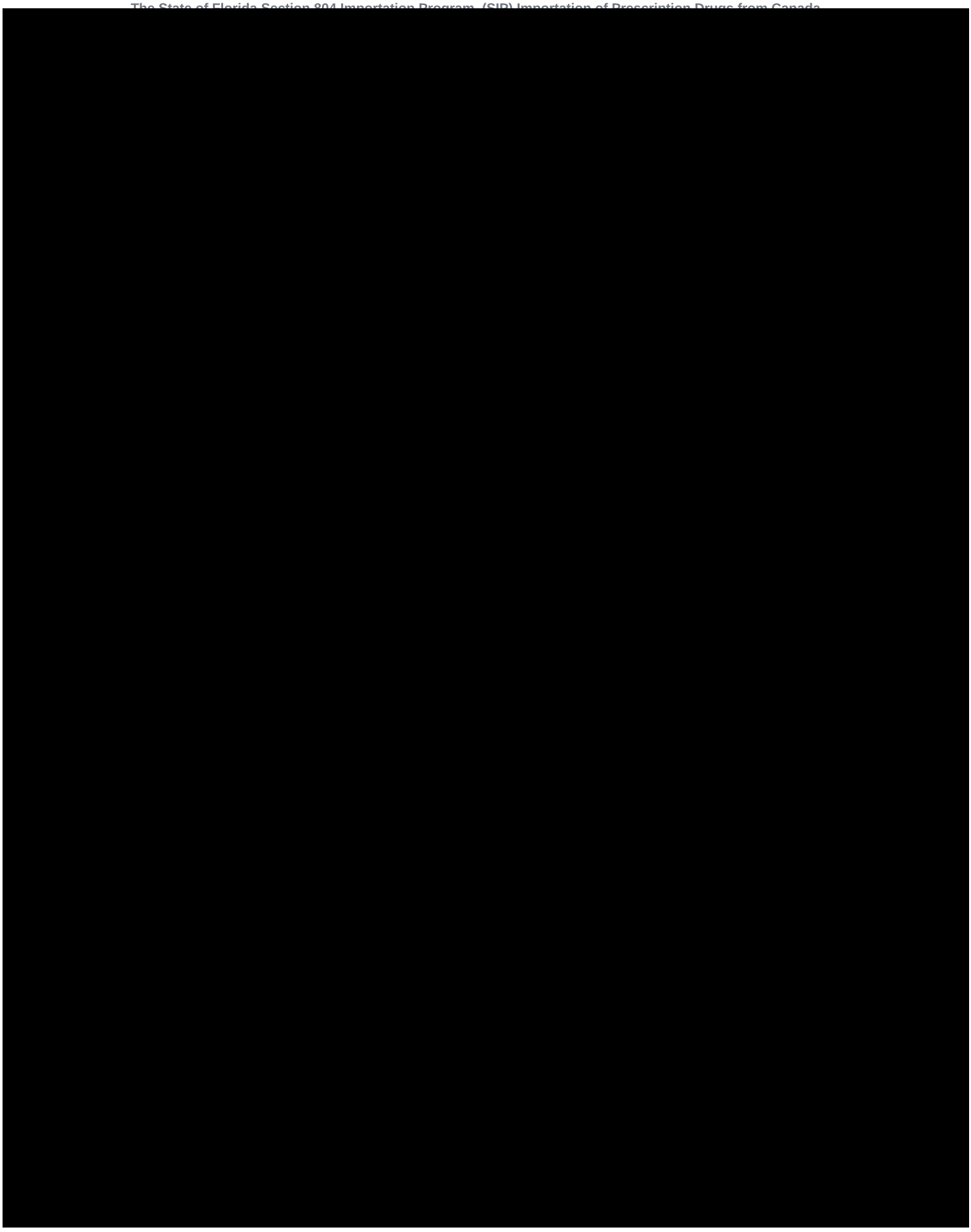
Attachment H: SIP Recall and Return Processes

Prescription Drug Pharmacovigilance, Drug Recall & Return Process Flow

The State of Florida Section 804 Importation Program, (SIP) Importation of Prescription Drugs from Canada



1.0 PURPOSE

The purpose of this procedure is to define the process of conducting recall activities including receiving notification of the decision to recall product, regulatory notification of recall activities, retrieval of recalled product, and/or destruction of recalled products distributed by LifeScience Logistics. Removal and correction activities requested by the Client are also addressed.

2.0 SCOPE

This procedure applies to all LifeScience Logistics Distribution Centers.

3.0 REFERENCES

21 CFR 7	Recalls (Including Product Corrections)
21 CFR 211	Current Good Manufacturing Processes for Finished Pharmaceuticals
21 CFR 803	Medical Device Reporting
21 CFR 806	Medical Devices; Reports of Corrections and Removals
21 CFR 810	Medical Device Recall Authority
ISO 13485	Medical Devices – Quality Management Systems
SOP 1003.01	Recall Log
SOP 1003.02	Recalled Product Management Form
SOP 1003.03	Recall Placard
SOP 1003.04	Recall Report
SOP 1101	Control of Records
SOP 2003	Commercial Returned Merchandise
SOP 4003	Destruction of Product
WI 300.11	SNS Hold, Release and ENR
WI 400.09	Commercial Hold and Release

4.0 DEFINITIONS

Class I Recall	A situation where there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
Class II Recall	A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
Class III Recall	A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences but violate FDA labeling or manufacturing laws.
Client	An organization using the services of LSL based on a contractual agreement.
Consignee	Any person or firm that has received, purchased, or used a device involved in a correction or recall. This does not include lay individuals or patients.
Correction	A repair, modification, adjustment, relabeling, destruction, or inspection of a product without its physical removal to some other location.
Extended, Not Relabeled (ENR)	A product's expiration date has been extended by FDA for emergency response situations but has not been relabeled to reflect the new expiration date. ENR is used as a product type to match Client inventory system.
Importer of Record	Party in whose name the entry is made. For example, a Customs House Broker might make an entry and become the "importer of record" by using his importer ID and bond on behalf of his client, the true "importer of record" is the person or company filing the redelivery bond under Section 802(b) and 536(b) of the FD&C Act [21 U. S. C. 382(b) and 360mm (b)].
Market Withdrawal	The removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation.
Medical Device Report	FDA requirement for medical device manufacturers to report incidents where death or serious injury have occurred or have the potential to occur. As the distributor, LSL is not responsible for reporting, but must maintain records of incidents.
Recall	A voluntary action taken by a firm to correct or remove from the market any product that is in violation of laws administered by the FDA.
Removal	Physical removal of a device or drug from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Safety Alert	Notification to users that the use of a product may, in certain circumstances, pose a risk of substantial harm.
Voluntary Withdrawal	A manufacturer initiated removal from market due to a potential risk to patients.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
ENR	Extended, Not Relabeled
FDA	Food and Drug Administration
IC	Inventory Control
LSL	LifeScience Logistics
MDR	Medical Device Report
OPS	Operations
OTC	Over the Counter
QA	Quality Assurance
RC	Recall Hold
RMA	Returned Merchandise Authorization
SNS	Strategic National Stockpile
SOP	Standard Operating Procedure
WI	Work Instruction

6.0 RESPONSIBILITY

QA/Functional Owner	Maintain this procedure in accordance with the LSL document and data control system. Lead all recall activities. Ensure electronic segregation of recalled product within the LSL warehouse. Perform FDA Notification if applicable. 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.
Operations	Performs physical segregation of recalled product within the LSL warehouse. Attaches Recall Placards to recalled product.
Inventory Control	Provide inventory and distribution records for affected product.

Client Services	Provide a list of Ship-To contact information for all recalled product. Monitor status of recalled product and provide status updates as necessary. For LSL-led recall activities, prepare and mail recall notices and participate in effectiveness checks.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly report any problems or deviations from the procedure to Supervisor or designee.

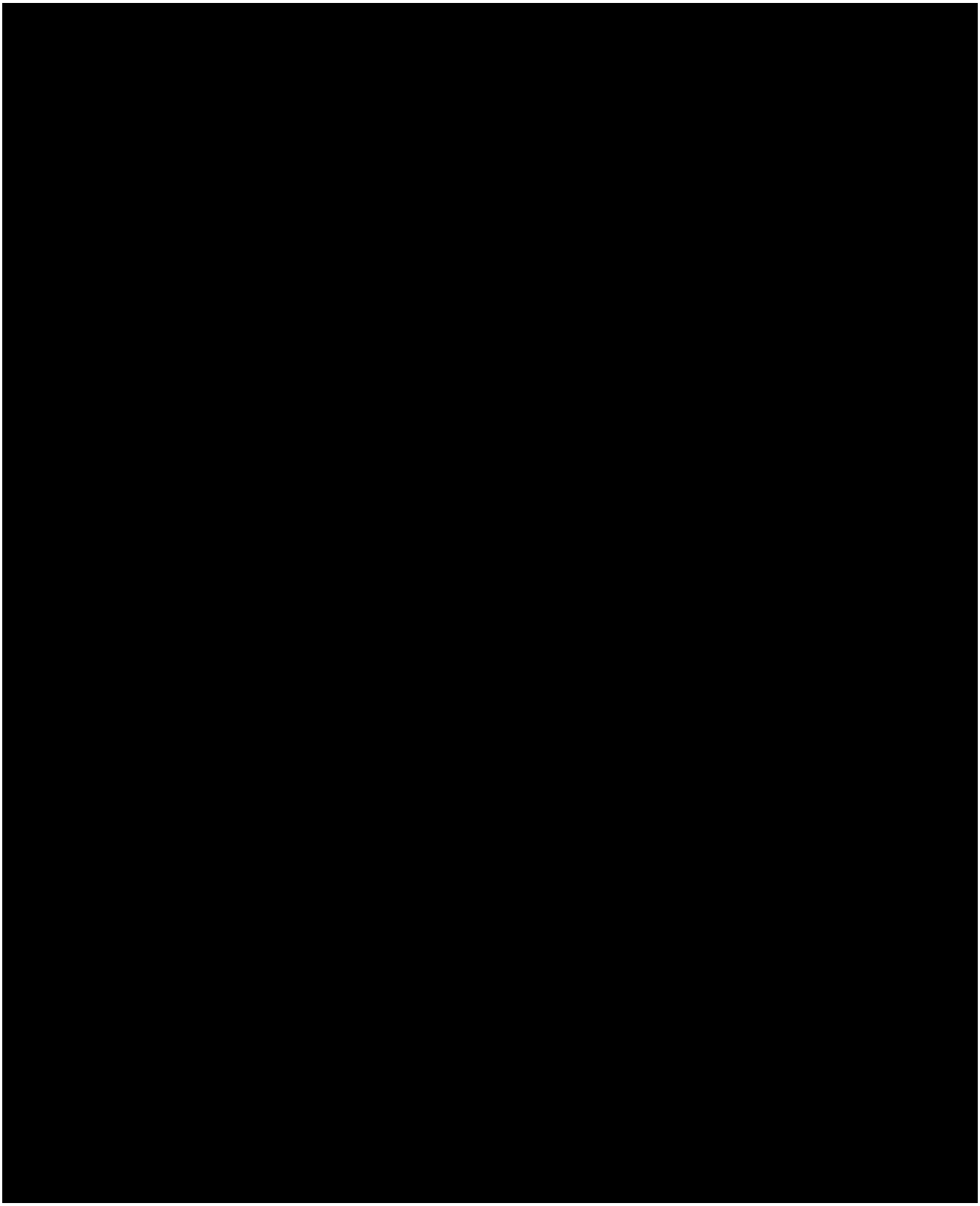
7.0 PROCEDURE

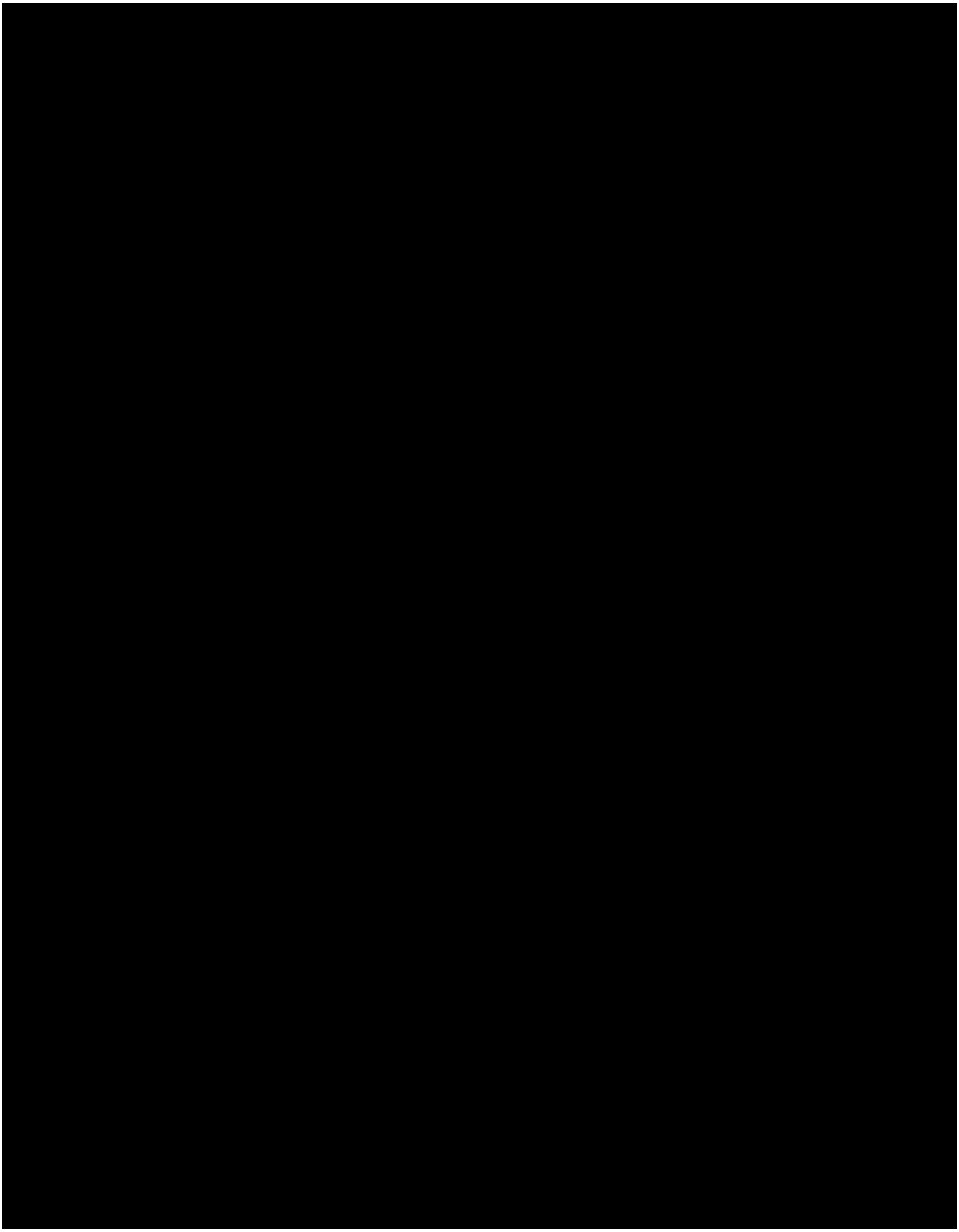
Overview

[redacted]

Recall Activities

[redacted]





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LSL-Led Recall Activities

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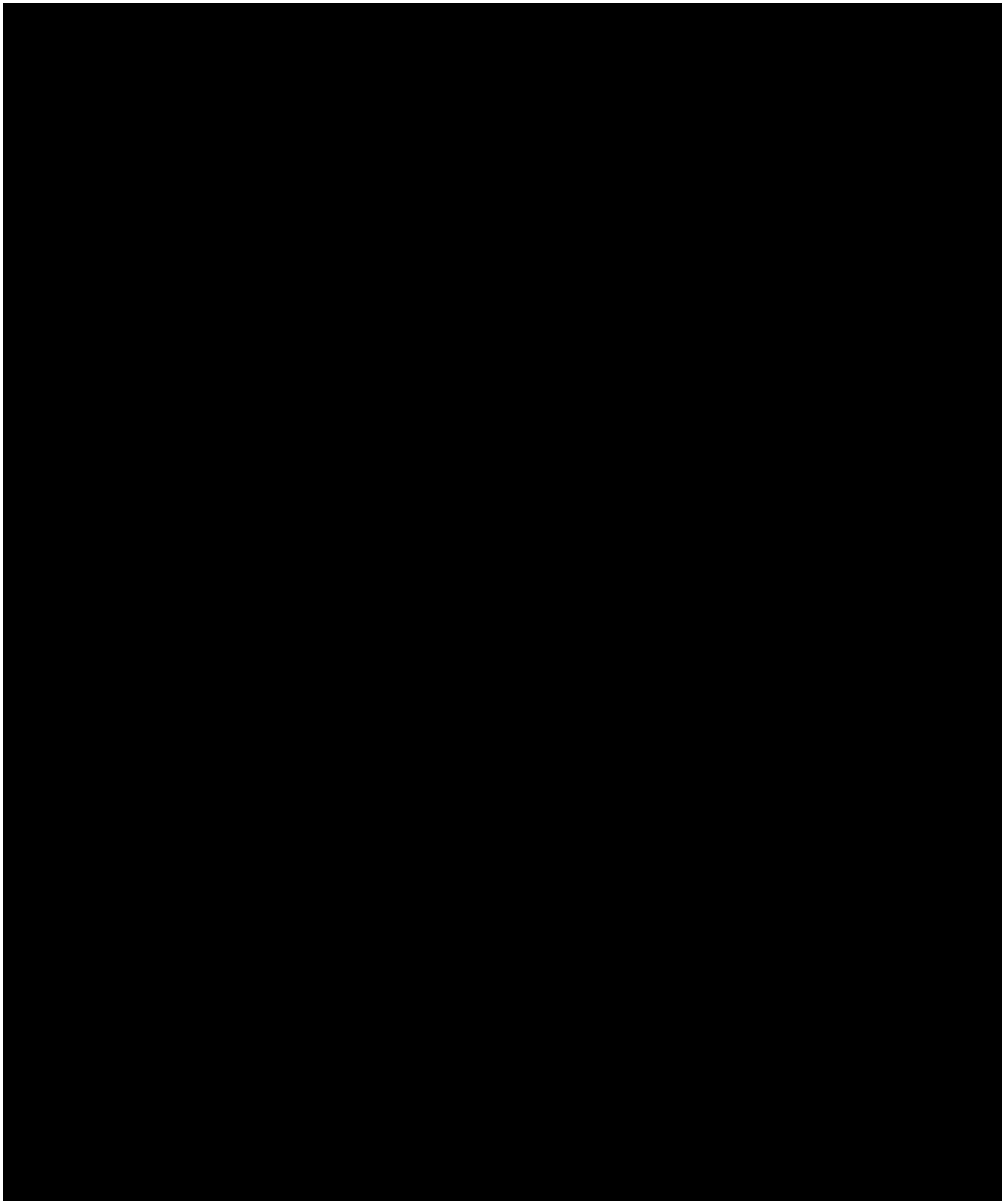


[redacted]

Removals, Corrections or Voluntary Withdrawals

[redacted]

Safety Alerts

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

8.2 All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from CEO/Principal and/or Director of Quality and Regulatory Affairs prior to reproduction or transmission in any form.

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Level 2	☐ Trainer Led – Level 3 with optional Module _____	☐ Trainer Led – Level 4 with Module _____

Trainee: Initial 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 the procedure listed to the employees listed above.

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

LifeScience Logistics			
Title:	Commercial Returned Merchandise		
Number:	SOP 2003	**Rev. Date:**	07-Oct-2022
Rev. Level:	007		

1.0 PURPOSE

The purpose of this procedure is to describe the process to receive, isolate, store and inspect any merchandise returned from a Commercial Customer or Client. This procedure applies to all LSL facilities that warehouse Commercial Clients' 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 400.07 Commercial 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 1350	Deviation/CAPA – Commercial
SOP 1350.01	Deviation Report – Commercial
SOP 2003.02	Returned Merchandise Authorization Log
SOP 2003.03	Free Astray Log
SOP 4001	Handling of Product Complaints
SOP 4003	Destruction of Products
SOP 4004	Client/Customer Feedback – Commercial
WI 200.03	DEA Inventory
WI 200.06	DEA Theft or Loss
WI 400.02	Commercial Inventory Management
WI 400.07	Commercial Returns
WI 400.07.02	DEA Commercial Returns Form
WI 400.09	Commercial Hold and Release
WI 400.09.03	Damaged Product Form – Commercial
WI 400.15	Handling of Client/Customer Feedback – Commercial

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.
Client	LSL's contractual business partner who supplies product to LSL.
Counterfeit	A fraudulent imitation of legitimate merchandise.
Customer	"ship to" location, aka Client's Customer.

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
AM	Account Manager
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	LifeScience 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 MQ1 to align with tasks listed in each document's revision. Approve documents to meet the purpose of the procedure and meet current revision guidelines.

LifeScience Logistics			
Title:	Commercial Returned Merchandise		
Number:	SOP 2003	**Rev. Date:**	07-Oct-2022
Rev. Level:	007		

Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly report any problems or deviations from procedure to Supervisor or designee.

7.0 PROCEDURE

[redacted]

Customer Services Authorization of Returns

[redacted]

LifeScience Logistics			
Title:	Commercial Returned Merchandise		
Number:	SOP 2003	**Rev. Date:**	07-Oct-2022
Rev. Level:	007		

[redacted]

Receiving and Inspecting the Return

[redacted]

Inspection of In-house Returned Merchandise

[redacted]

Client Final Disposition

[redacted]

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

All Life Science Logistics documents are confidential and proprietary. Consent must be obtained from LSL CEO or Quality Leadership Management prior to reproduction or transmission in any form.

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Read and Understand	☐ Trainer Led – Read and Exhibit Competency with optional Module _____	☐ Trainer Led – Read and Exhibit Competency with Module and Optional Assessment _____

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 the procedure listed above and confirm all listed employees completed training as defined.

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

1.0 PURPOSE

The purpose of this procedure is to describe the process to destroy Prescription Drug Program product. This procedure is used once CQCU has determined the product has become a waste.

2.0 SCOPE

Products may require destruction as based on CQCU's disposition.

Product destruction for any reason is performed only at CQCU's direction.

Commercial facilities are out of scope.

Government facilities are out of scope.

Stockpile facilities are out of scope.

3.0 REFERENCES

40 CFR Part 260-262	EPA Resource Conservation and Recovery Act (RCRA)
US DOT 49 CFR parts 390-396	Motor Carrier Safety Standards
SOP 1003	Recalls, Removals, and Corrections
SOP 1031	Vendor Qualification
SOP 1101	Control of Records
SOP 7003	Prescription Drug Returned Merchandise
WI 600.06	Prescription Drug Hold and Release
WI 600.10	Prescription Drug Pick/Pack/Ship

4.0 DEFINITIONS

Certificate of Destruction	Proof of Destruction record provided by the entity contracted by LSL to destroy product, which ensures the product (as defined below) cannot be used in counterfeiting activities
Customer	Agency "ship to" location
Customer Return	Product which was shipped from LSL facilities and sent back to LSL
Hazardous Waste	Waste or combination of wastes of a solid, liquid, contained gaseous, or semisolid form which may cause, or contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness, taking into account the toxicity of such waste, its persistence and degradability in nature, its potential for accumulation or concentration in tissue, and other factors that may otherwise cause or contribute to adverse or chronic effects on the health of persons or other organisms. §243.101 (EPA Definition)
Product	Any LSL owned pharmaceutical, labeling, in-process material, etc.

Transportation Storage Disposal Facility – TSDF	Contracted Vendor to pick up and destroy hazardous or other waste
Waste Profile	Description and characterization of LSL's product, once deemed waste for disposal or destruction

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
DOT	Department of Transportation
EPA	Environmental Protection Agency
LSL	LifeScience Logistics
LQG	Large Quantity Generator
PM	Project Manager
QA	Quality Assurance
QS	Quarantine Shipping
RCRA	Resource Conservation and Recovery Act
SOP	Standard Operating Procedure
SQG	Small Quantity Generator
TSDF	Transportation Storage Disposal Facility (EPA term)
VAWD	Verified Accredited Wholesale Distributors
VSQG	Very Small Quantity Generator

6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
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.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly report any problems or deviations from the procedure to your Supervisor or designee.

7.0 PROCEDURE

Overview

[redacted]

[redacted]

Product Disposition

[redacted]

[redacted]

Product Destruction

[redacted]

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

8.2 All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from CEO/Principal and/or Director of Quality & Regulatory Affairs prior to reproduction or transmission in any form

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Level 2	☐ Trainer Led – Level 3 with optional Module _____	☐ Trainer Led – Level 4 with Module _____

Trainee: Initial 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 the procedure listed to the employees listed above.

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

1.0 PURPOSE

The purpose of this procedure is to describe the process to receive, isolate, store and inspect any 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
AM	Account Manager
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	LifeScience 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.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly report any problems or deviations from procedure to Supervisor or designee.

7.0 PROCEDURE

Background

[redacted]

Customer Services Authorization of Returns

[redacted]

Receiving and Inspecting the Return

[redacted]

LSL "Turns the Truck Around"

[redacted]

Inspection of In-house Returned Merchandise

[redacted]

Final Disposition

[redacted]

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

8.2 All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from CEO/Principal and/or Director of Quality and Regulatory Affairs prior to reproduction or transmission in any form.

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Level 2	☐ Trainer Led – Level 3 with optional Module _____	☐ Trainer Led – Level 4 with Module _____

Trainee: Initial 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 the procedure listed to the employees listed above.

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

Issued by: Quality Assurance
Note: Controlled Copies are identified in SOP footer.

Prepared by: Manager, QA	Name: Kristy Moffatt	Signature/Date: Refer to QT-9 QMS
Reviewed by: Director, Operations	Name: John Zanin	Signature/Date: Refer to QT-9 QMS
Approved by: Director, QA	Name: Nina Kazarians	Signature/Date Refer to QT-9 QMS

1.0 Purpose

To describe a procedure for escalation and management of FDA's Section 804 Importation Program (SIP) Regulatory Agency communications and information requests received by Methapharm Inc. (Methapharm).

2.0 Scope

This procedure applies to Methapharm employees who receive information requests from Regulatory Agencies (federal or state), US Importer representatives or distributor representatives related to prescription drug products supplied by Methapharm under FDA's Section 804 Importation Program (SIP).

3.0 Responsibility

It is the responsibility of Department Management to ensure that the employees performing activities with respect to FDA's Section 804 Importation Program (SIP) are trained on this procedure and follow this SOP as applicable.

4.0 References and Related SOPs

-Section 804(b) through (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(b) through (h))
-US FDA - Importation of Prescription Drugs Final Rule Questions and Answers Guidance for Industry (Small Entity Compliance Guide), May 2022

5.0 Forms/Attachments

None.

6.0 Definitions

6.1 Reguatory Agency: An independent governmental body (state or federal) established by legislative act in order to set standards in a specific field of activity, or operations, in the private sector of the economy and then to enforce those standards (i.e. US FDA, Health Canada).

6.2 SSI: A unique alphanumeric number of up to 20 characters that is affixed by Methapharm to each shipper case of product that is sold to a US Importer.

7.0 Procedure

[redacted]

8.0 Records

[redacted]

9.0 Revision History

[redacted]

LifeScience Logistics			
Title:	Prescription Drug DSCSA Track/Trace		
Number:	WI 600.03	**Rev. Date:**	11-APR-2023
Rev. Level:	001		

1.0 PURPOSE

The purpose of this document is to outline the Prescription Drug Tracking and Tracing processes at LifeScience Logistics to fulfill the regulatory requirements of the Drug Supply Chain Security Act 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 re-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
Decommission	Formal process to remove or deactivate. For example, remove original data or deactivate current systems.
Product Data	Serialized information pertaining to the product
Product Identifier	Standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.
Reconciliation	Process to verify and compare product data to the packaged product.

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.
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	LifeScience 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 LifeScience Logistics procedures.
Vendor/Re-labeler	Responsible for the decommission of original product data and the reserialization and relabeling of the product according to DSCSA and LifeScience Logistics requirements.

7.0 SERIALIZATION OF DRUG PRODUCT

Overview

[redacted]

LifeScience Logistics			
Title:	Prescription Drug DSCSA Track/Trace		
Number:	WI 600.03	**Rev. Date:**	11-APR-2023
Rev. Level:	001		

[redacted]

Receiving Drug Product from Drug Product Wholesaler

[redacted]

Vendor Re-labelling

[redacted]

LifeScience Logistics			
Title:	Prescription Drug DSCSA Track/Trace		
Number:	WI 600.03	**Rev. Date:**	11-APR-2023
Rev. Level:	001		

[redacted]

Re-labelled and Reserialized Product

[redacted]

DSCSA Verification Requirements

[redacted]

8.0 ADDITIONAL INFORMATION

8.1 Control of Records

[redacted]

8.2 Confidentiality Statement

All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from the CEO/Principal and/or Director of Quality and Regulatory Affairs prior to reproduction or transmission in any form.

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Level 2	☐ Trainer Led – Level 3 with optional Module _____	☐ Trainer Led – Level 4 with Module _____

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 the procedure listed to the employees listed above.

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

1.0 PURPOSE

The purpose of this procedure is to define the processes of receiving, storing and following CQCU disposition of saleable and non-saleable returned Prescription Drug merchandise.

2.0 SCOPE

This procedure applies to all saleable and non-saleable returned merchandise within LSL Prescription Drug Program facilities inclusive of domestic or imported RX prescription drugs.

3.0 REFERENCES

21 CFR Part 211.204	Current Good Manufacturing Practices for Finished Pharmaceuticals, Subpart K Returned and Salvaged Drug Products
21 CFR Part 820	Quality System Regulations
SOP 1101	Control of Records
SOP 7000	Prescription Drug Destruction of Products
SOP 7003	Prescription Drug Returned Merchandise
SOP 7003.01	Returned Merchandise Authorization Log – RX
SOP 7003.02	Free Astray Log – RX
WI 600.06	Prescription Drug Hold and Release
WI 600.06.01	Quarantine Placard – RX

4.0 DEFINITIONS

Call Tag	The unique tracking number assigned for carrier pick up for the package to be returned with LSL's carrier account number, name, and address
Free Astray	Return without an RMA number referenced on the return
Organization	Within WMS, the Client Code used for a specific Client
Receipt field	WMS text field for entering RMA number

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
BOL	Bill of Lading
CAS	Customer Account Specialist
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
CRT	Controlled Room Temperature
CS	Client Services
ERP	Enterprise Resource Planning
FA LOG	Free Astray Log
ISM	Inventory Status Modification
LSL	Life Science Logistics
QA	QA

QUAR	Quarantine
RMA	Return Merchandise Authorization
RMA LOG	Return Merchandise Authorization Log
SOP	Standard Operating Procedure
UOM	Unit of Measure
WI	Work Instruction
WMS	Warehouse Management System

6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
Functional Owner	Ensure training requirements by position are listed 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.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly reports any problems or deviations from the procedure to your Supervisor or designee.

7.0 PROCEDURE

Overview

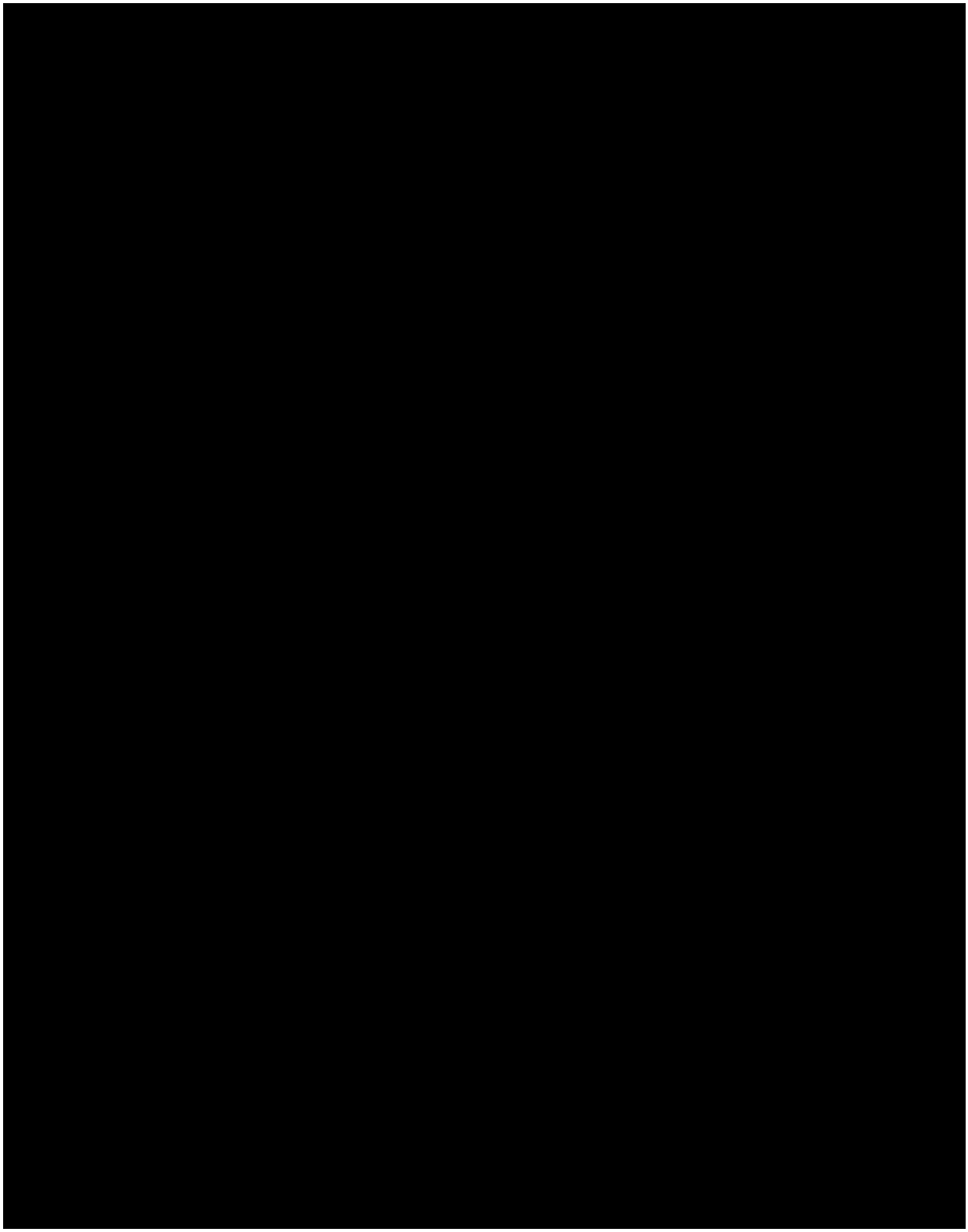
[redacted]

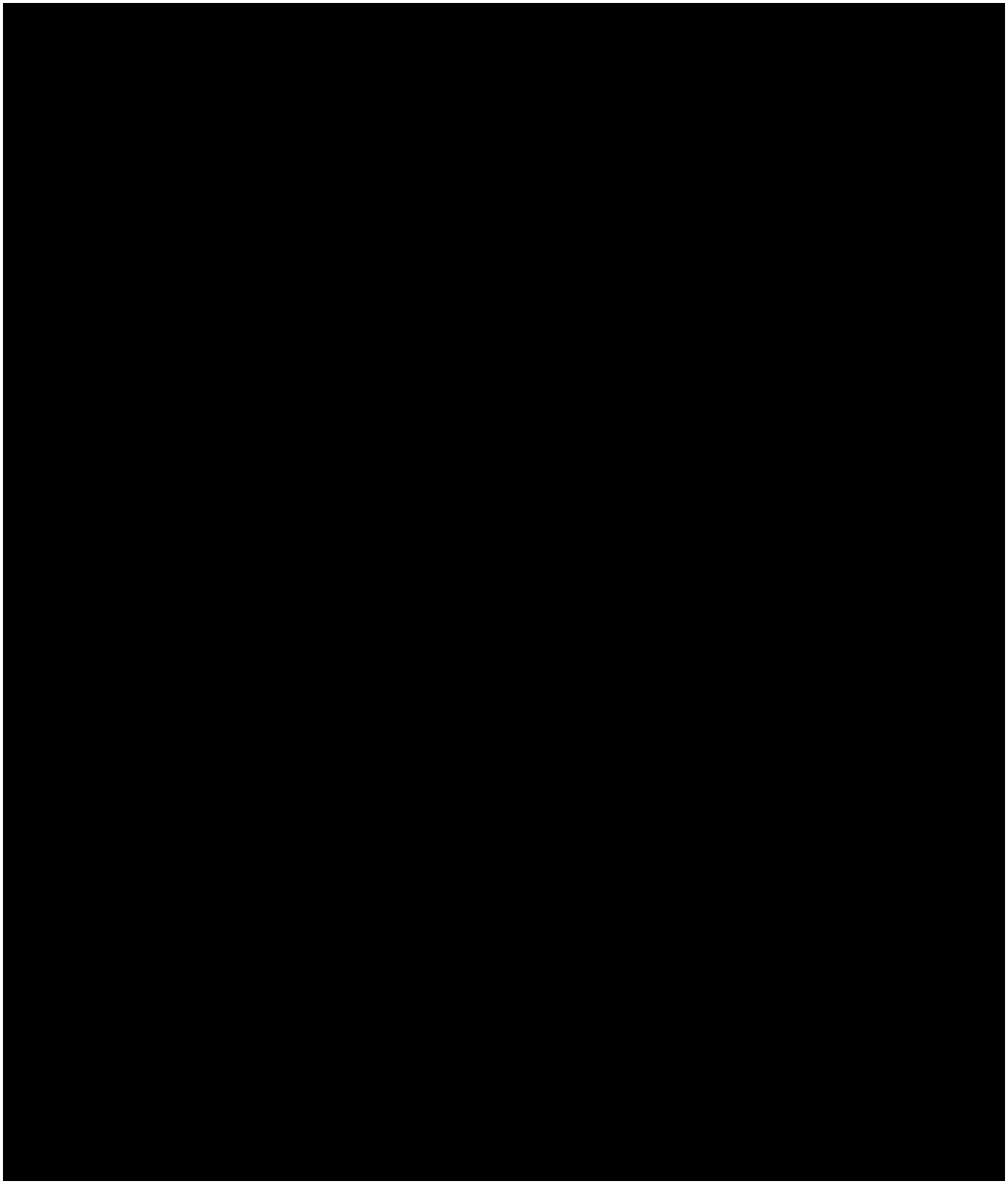
[redacted]

Staging and Inspection

[redacted]

[redacted]





[redacted]

Other Returned Merchandise

[redacted]

CQCU Disposition

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Level 2	☐ Trainer Led – Level 3 with optional Module _____	☐ Trainer Led – Level 4 with Module _____

Trainee: Initial 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 the procedure listed to the employees listed above.

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

1.0 PURPOSE

The purpose of this procedure is to define the process for returning product to vendors and/or shipping quarantined product.

2.0 SCOPE

This procedure applies to all LSL Prescription Drug Program facilities.

Quarantine shipping and returns to vendors are in scope.

Shipping released (not quarantined) product using the Vendor Returns module is within scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
SOP 1101	Control of Records
SOP 7000	Prescription Drug Destruction of Products
SOP 7002	Import/Export – RX
WI 600.06	Prescription Drug Hold and Release
WI 600.27.01	International Shipping for Small Parcel using UPS WorldShip
WI 600.27.02	International Shipping for LTL using UPS WorldShip

4.0 DEFINITIONS

TECSYS Elite	System for inventory, orders, cash applications
Quarantined Product	Product that is physically and/or electronically segregated for quality reasons or at Client request
Vendor	Any Entity as a “ship to” location that is not a customer of LSL’s Client. IE destruction vendor, manufacturer, repackager, Client etc.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
CC	Client Code
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
DMS	Distribution Management System
LSL	LifeScience Logistics
QA	Quality Assurance
QS	Quarantine Shipping
VR	Vendor Return
WI	Work Instruction

6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
Functional Owner	Ensure training requirements by position are updated in MQ1 to align with tasks listed in each document's revision. Approve documents to meet the purpose of the procedure and meet current revision guidelines.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly reports any problems or deviations from the procedure to your Supervisor or designee.

7.0 PROCEDURE

Overview

[redacted]

Quarantine Shipping: DMS

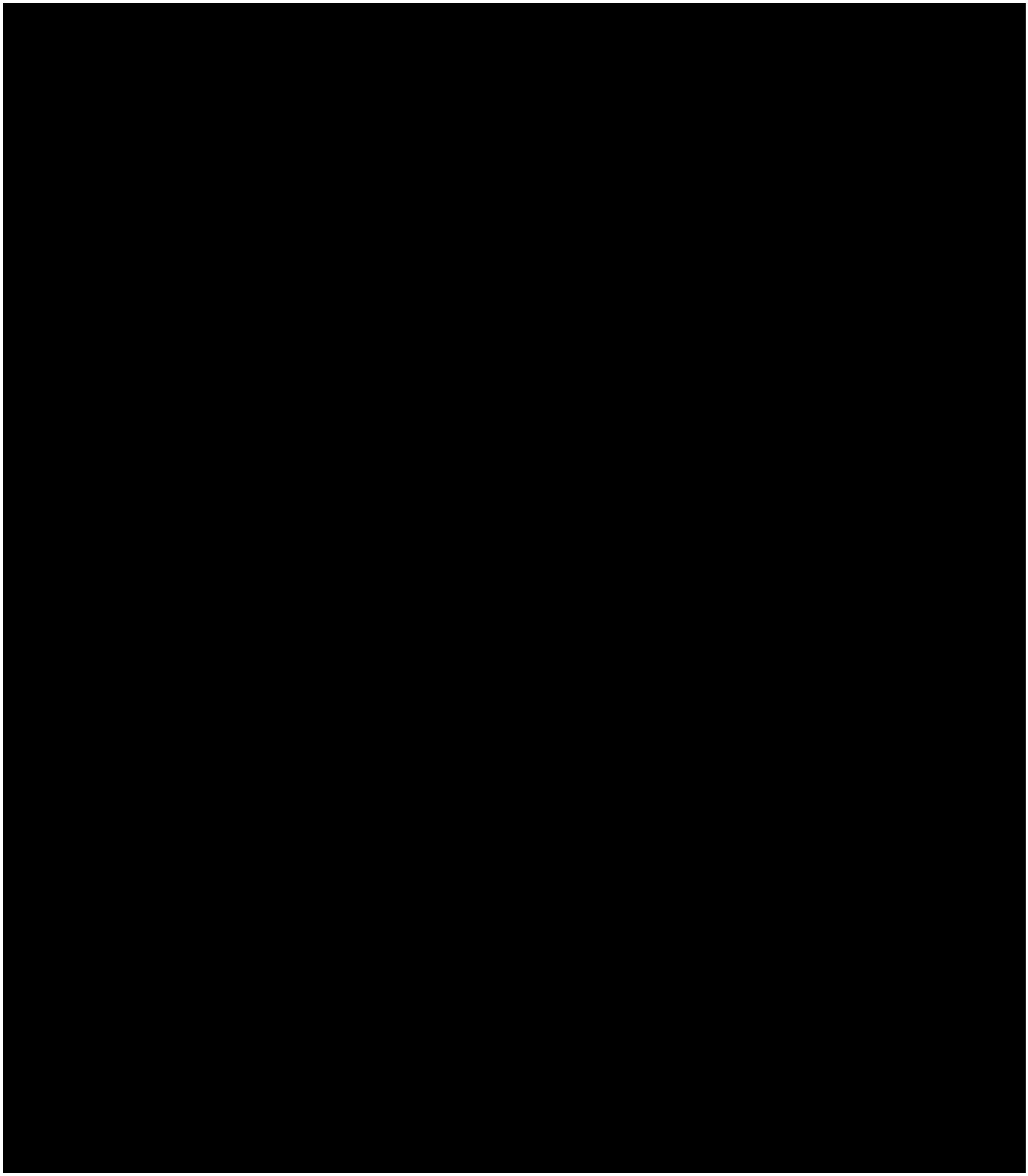
[redacted]

[redacted]

Vendor Return Entry: DMS

[redacted]

[redacted]



8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

Confidentiality Statement

8.2 All LifeScience Logistics documents are confidential and proprietary. Consent must be obtained from the CEO/Principal and/or VP of Quality and Compliance prior to reproduction or transmission in any form.

9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

Training Date	Type of Training		
	☐ Self-Training – Level 2	☐ Trainer Led – Level 3 with optional Module _____	☐ Trainer Led – Level 4 with Module _____

Trainee: Initial 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 the procedure listed to the employees listed above.

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