1.0 PURPOSE

The purpose of this procedure is to define the processes to implement a new Bill-To or Ship-To (wholesaler or end user) for the Prescription Drug Program as well as pricing for all items in this program

2.0 SCOPE

This procedure applies to all Prescription Drug Program items being warehoused and distributed at LSL and all Customers receiving orders from a Prescription Drug Program LSL facility.

Verification of complimentary samples for medical practitioners is out of scope. See SOP 1702, Samples Distribution.

+ LifeScience Logistics receives drugs (prescription finished goods) only from the actual manufacturer of the drugs.

3.0 REFERENCES

21 CFR 205	State Licensing for Wholesale Prescription Drug Distributors
21 CFR 207	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
21 CFR 251	Section 804 Importation Program
DSCSA Section 205	National Standards for Third-Party Logistics Providers Uniform National Policy
SOP 1002	Change Control
SOP 1101	Control of Records
SOP 1102	Create and Edit Controlled Documents
SOP 1702	Samples Distribution
SOP 1900	Hazard Communication Program
SOP 7002	Import/Export – RX
SOP 7000	Prescription Drug Destruction of Products
WI 600.04.01	Customer/Pricing Setup Template – RX
WI 600.06	Prescription Drug Hold and Release
WI 600.17	Prescription Drug License Verification

4.0 DEFINITIONS

Bill-To	Address product is Billed-To; one Bill-To address may link one-to-one with Ship-To addresses or may link to multiple Ship-To addresses.
Client	Entities contracted with LSL which provide pharmaceuticals, medical devices, biologics and healthcare products to an LSL location for the purpose of storage and/or distribution.
Client Implementation Manager	Role applied to an employee who is organizing a new client's implementation information.
Contract Manufacturer	A manufacturer that contracts with a firm for products. It is a form of outsourcing.

Customer	Entities to whom LSL ships products to on behalf of the Client including wholesalers or end users.
DMS	Distribution (Order) Management System
Establishment	Place of business under one management at one general physical location. (21 CFR 207.3 Definitions)
Implementation	All tasks through first distribution
Item	Client's pharmaceutical, medical device, labeling, kits, in-process material, etc. including OTC products.
Item Number	NDC or UPC or other unique product identifier in WMS/DMS.
Kick-Off Meeting	Meeting that occurs to transfer a new Client from the Business Development phase to the implementation phase.
Multiple Quantity	Increments in which Customers can order.
Quality Agreement	Business document between LSL QA and Client QA outlining agreed upon quality issues and reporting timelines.
Rx	Prescription
Ship-To	Address product is shipped to per the order.
Statement of Work	Business document between LSL and Client to state the agreed scope to be covered in working together. Once signed off, any changes to be made to the SOW must be documented with a BD Change Management form. If changes to the SOW impact quality, SOP 1002, Change Control may be required.
Tecsys	LSL's Warehouse Management System.
Virtual Manufacturer	Virtual manufacturer is a company that contracts with a contract manufacturer to produce items for them.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
BD	Business Development
CC	Client Code
CEO	Chief Executive Officer
CQCU	Corporate Quality Control Unit
DMS	Distribution (Order) Management System
DSCSA	Drug Supply Chain Security Act
FDA	Food and Drug Administration
HDMA	Healthcare Distribution Management Association
IC	Inventory Control
ISM	Inventory Status Modification
IT	Information Technology
LSL	LifeScience Logistics
MSA	Master Service Agreement
NDA	Non-Disclosure Agreement
NDC	National Drug Code

OTC	Over the Counter
PC	Partial Case (hold code)
PM	Project Manager
QA	Quality Assurance
QARA	Quality Assurance Regulatory Affairs
RX	Prescription
SBP	State Board of Pharmacy
SD	Short Dated (non-quality hold code)
SDS	Safety Data Sheets
SOP	Standard Operating Procedure
SOW	Statement of Work
UPC	Universal Product Code
VM	Virtual Manufacturer
WAC	Wholesale Acquisition Cost
WI	Work Instructions
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 updated in Quality Management System, QMS 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

Bill-To/Ship-To Setup

[redacted]

[redacted]

Bill-To Licensing

[redacted]

Ship-To Licensing:

[redacted]

Changes to Existing Ship-To Locations

Pricing

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

8.1 All records generated from executing this procedure are retained per SOP 1101, Control of Records.

Confidentiality Statement

[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 of unloading, staging, receiving and put away of Prescription Drug Program items.

2.0 SCOPE

This procedure applies to Prescription Drug Program product receiving. Receipt of supplies are included only if they are inventoried.

Government receiving is out of scope.

Commercial receiving is out of scope.

Stockpile receiving is out of scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
21 CFR 251	Section 804 Importation Program
ISO 13485	Medical Devices – Quality Management Systems
SOP 1003	Recalls, Removals and Corrections
SOP 1101	Control of Records
SOP 1351	Deviation/CAPA – RX
WI 600.02	Prescription Drug Item/Component Setup
WI 600.05.01	Trailer Inspection Sheet – RX
WI 600.05.02	Data Logger Information Form
WI 600.05.03	Prescription Drug Receiving Competency Assessment
WI 600.05.04	Non-Product Small Parcel Receipt Log
WI 600.06.02	Damaged Product Form – RX
WI 600.07	Prescription Drug Initial Sampling and Laboratory Testing
WI 600.08	Prescription Drug Relabeling Requirements and Process
WI 600.11	Prescription Drug Returns
WI 600.14	Prescription Drug Inventory Adjustment

4.0 DEFINITIONS

Adulterated	Product containing any filthy, putrid or decomposed substance; or prepared under unsanitary conditions; or not made according to GMPs.
Bill of Lading (BOL)	A document showing the total number of pallets, cases, or units included in the shipment. It is the contract between the carrier and the Sender and indicates the carrier's driver is responsible for any damage incurred during transit.
Counterfeiting	Deliberately or fraudulently producing or mislabeling a drug's identity to make it appear authentic.
Cubiscan®	Devices used to automate the process of measuring the dimensions and computing the volume of freight in transportation and distribution applications.
Misbranding	Any product label which is incomplete, false, or misleading.
Packing List	Also known as the Packing Slip, it is a list provided by the Sender which lists the details of the item, lot and quantity regarding all pallets included in the shipment.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
ASN	Advanced Shipping Notice
BD	Business Development
BOL	Bill of Lading
CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
CQCU	Corporate Quality Control Unit
CS	Client Services
DMS	Distribution Management System
DR	Damaged Receipt
FDA	Food and Drug Administration
GMPs	Good Manufacturing Practices
IC	Inventory Control
ID	Identification
LSL	LifeScience Logistics
LTL	Less than Truck Load
MHE	Material Handling Equipment

NDC	National Drug Code
PO	Purchase Order
QA	Quality Assurance
PR	Pre-Release (hold code)
REG	Regulatory (hold code)
RF	Radio Frequency Handheld Device
RX	Prescription
SOP	Standard Operating Procedure
TL	Truck Load
TR	Truck Number (Bill of Lading Number)
UOM	Unit of Measure
VAWD	Verified-Accredited Wholesale Distributor
WI	Work Instruction(s)
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 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

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[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)

1.0 PURPOSE

The purpose of this procedure is to define the process of placing product on hold both physically and electronically, and subsequently releasing product from physical and electronic hold based on CQCU direction.

2.0 SCOPE

This procedure applies to all LSL Wholesaler facilities.

Holding returned merchandise is out of scope. See SOP 7003, Prescription Drug Returned Merchandise.

Release of returned merchandise based on CQCU disposition is within scope.

Vendor Returns/Quarantine shipping is out of scope. See WI 600.27, Prescription Drug Vendor Returns and Quarantine Shipping.

WMS Inventory Attribute fields 1, 2 and 3 are reserved for additional product specific information and are out of scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 251	Section 804 Importation Program
21 CFR 820	Quality Systems Regulations
ISO 13485	Medical Devices – Quality Management Systems
SOP 1101	Control of Records
SOP 1351	Deviation/CAPA – RX
SOP 7000	Prescription Drug Destruction of Products
WI 600.02	Prescription Drug Item Setup
WI 600.05	Prescription Drug Receiving
WI 600.06.01	Quarantine Placard – RX
WI 600.06.02	Damaged Product Form – RX
WI 600.06.03	Damaged Product Log – RX
WI 600.06.04	ISM Log – RX
WI 600.07	Prescription Drug Initial Sampling and Laboratory Testing
WI 600.08	Prescription Drug Relabeling Requirements and Process
WI 600.11	Prescription Drug Returns

4.0 DEFINITIONS

Active, Available	WMS locations to store product that is released for filling orders; also known as "Pickable, Reserve"
Client	An entity using the services of LSL based on a contractual agreement.
Electronic Hold	System restraint within the WMS placed on products to prevent inadvertent movement, picking, or shipping. System hold codes prevent Associates from comingling non-conforming or potentially non-conforming product with released product. In WMS, when there is no WMS hold code on a tag, the field is blank.
Item number	WMS unique number for Client product.
Non-Active, Quarantine	WMS locations that are not pickable, regardless of product status
Physical Hold	Physical segregation and/or visual identifier used to indicate a particular product (Tag) is on hold.
Pickable	WMS location term for released, case pick locations as opposed to pallet quantity released locations.
Release	The process of removing product from electronic hold and/or physical hold. Release must be performed by CQCU.
Reserve	WMS location term for released, pallet picks or partial pallet picks vs. Pickable
Suspect Product	Product whose integrity may be compromised or when there is any question of the safety, identity, strength, purity, or quality of the product. If, based on information provided, or the lack of available information, the integrity of the product could be called into question, the product is considered suspect until proven otherwise.
Tag	WMS bar coded and human-readable sticker with a unique number linked to the item/lot/quantity for a given location.
User Codes	WMS free text fields which are not hold or release criteria

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
ASN	Advanced Shipping Notice
CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
CYCC	Cycle Count
DEA	Drug Enforcement Administration
FEFO	First Expiry First Out
IC	Inventory Control
ISM	Inventory Status Modification

LSL	LifeScience Logistics
NDC	National Drug Code
PC	Partial Case
PR	Pre-Release
QA	Quality Assurance
QU	Quarantine Hold Code
RES	Reserve
RMA	Return Merchandise Authorization
SD	Short Date
SOP	Standard Operating Procedure
UOM	Unit of Measure
WI	Work Instruction
WMS	Warehouse Management System
WO	Work Order

6.0 RESPONSIBILITY

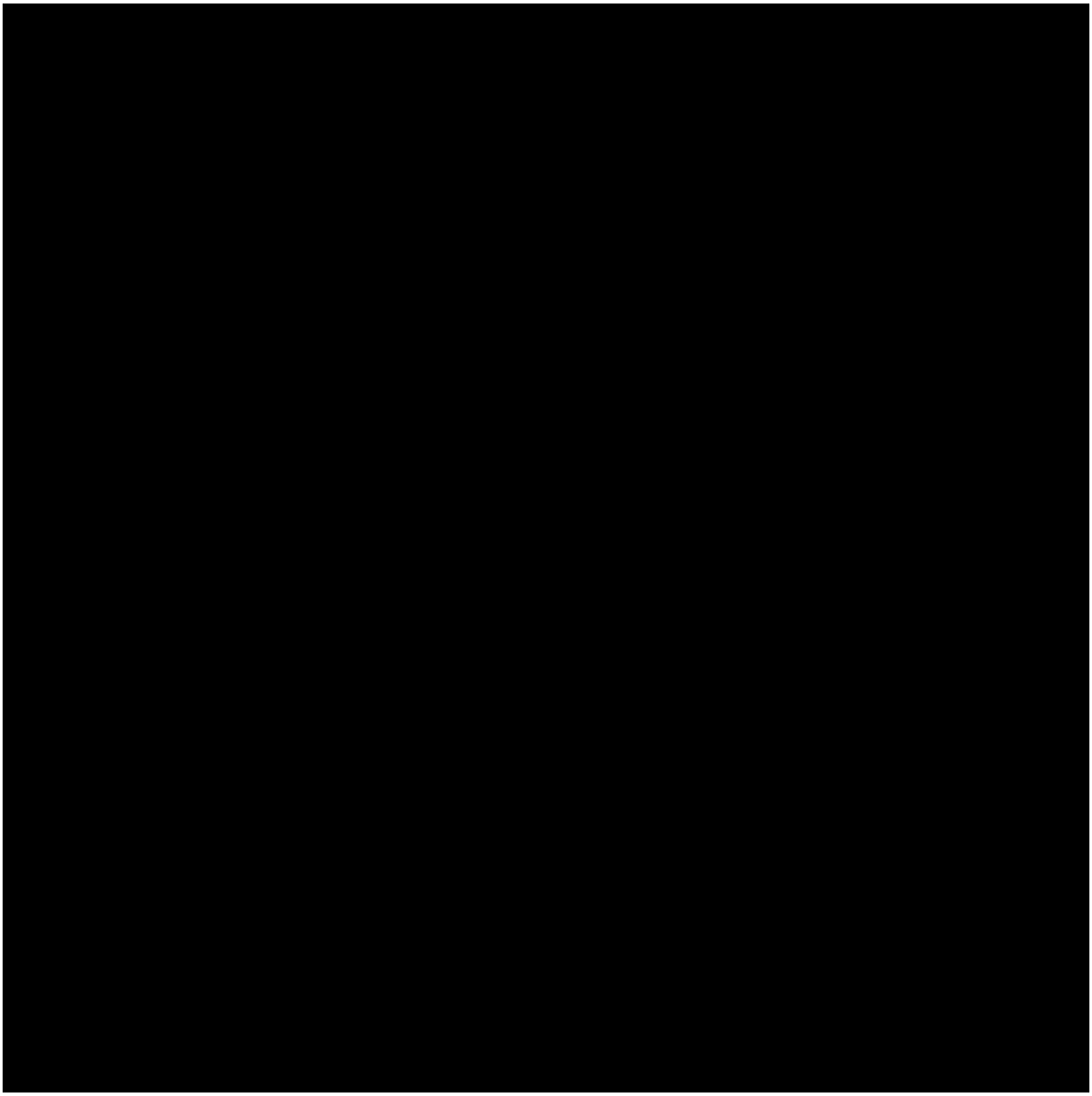
CQCU	Maintain this procedure in accordance with the LSL document and data control system.
Functional Owner	Ensure training requirements by position are updated in MQ1 to align with tasks listed in each document's revision. Approve documents to meet the purpose of the procedure and meet current revision 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.

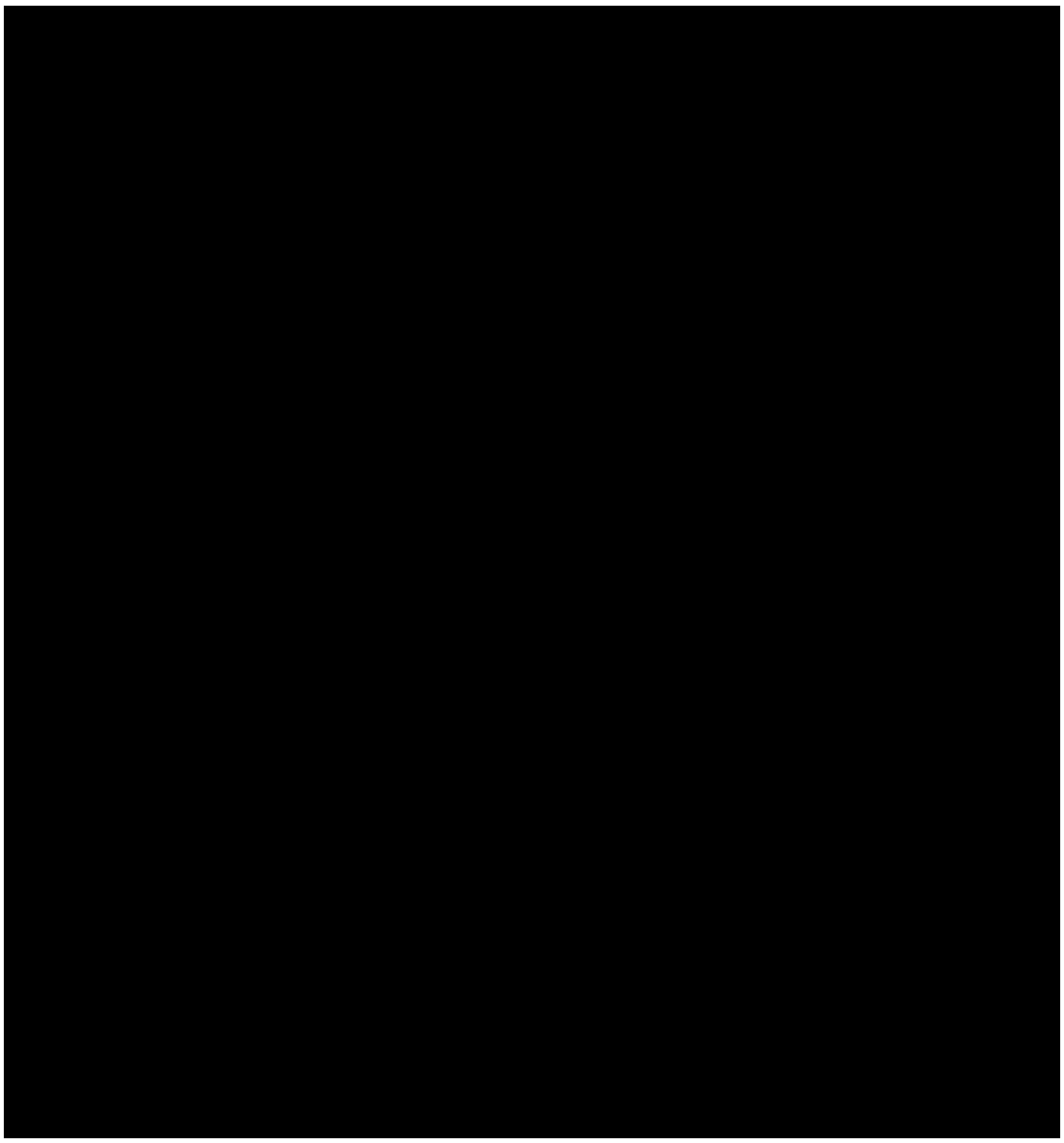
7.0 + PROCEDURE

[redacted]

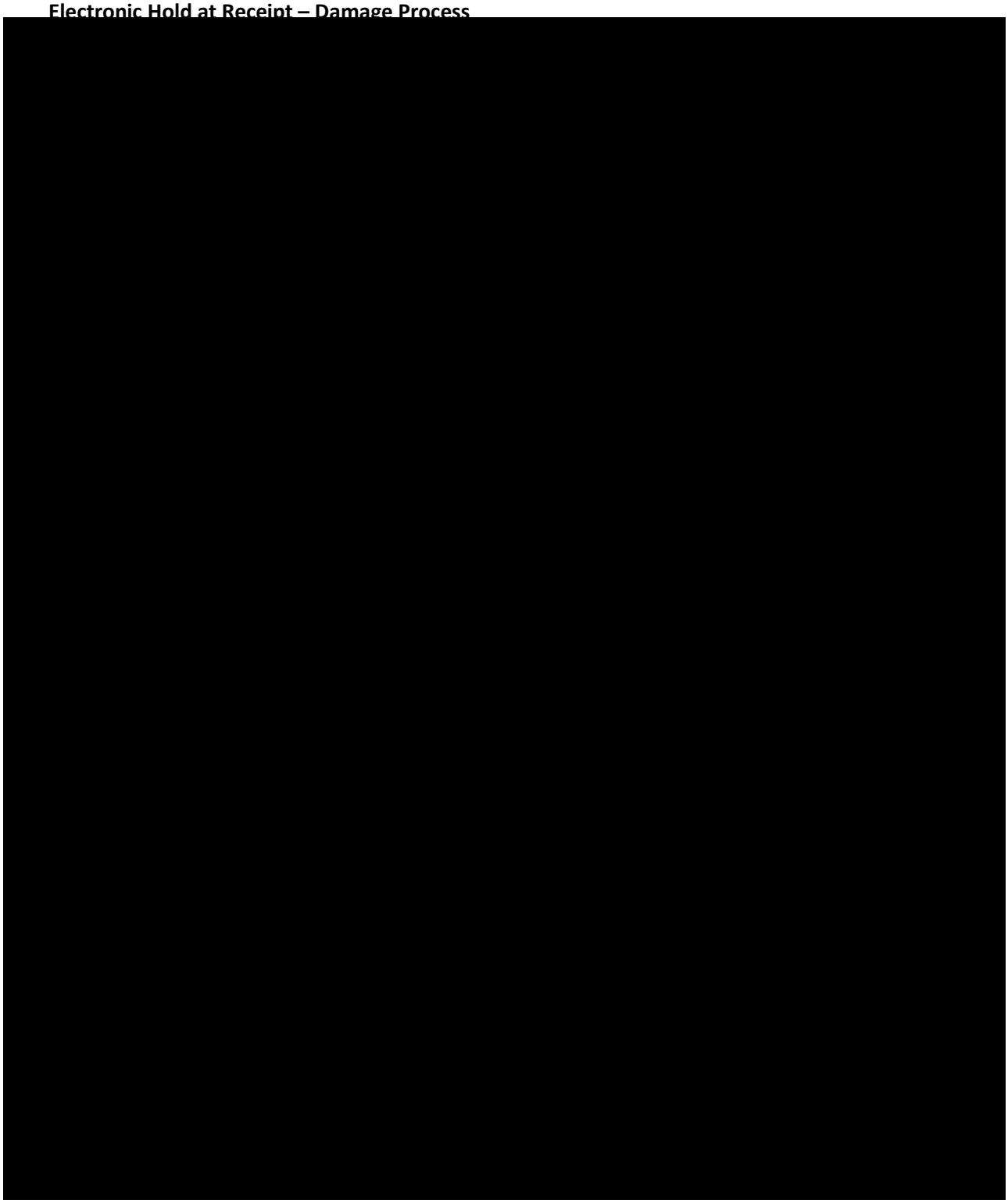
Overview

[redacted]





Electronic Hold at Receipt – Damage Process



[redacted]

QA Hold

[redacted]

[redacted]

ISM Tracking Numbers for Quality Holds/Releases

[redacted]

ISM Record ID and Audit Trail for Quality Holds/Releases

[redacted]

Physical Hold

[redacted]

Electronic Release

[redacted]

Physical Release

[redacted]

Retain Samples

[redacted]

+ Expired Product

[redacted]

Pricing Hold

[redacted]

[redacted]

Short Date Parameters

[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)

1.0 PURPOSE

The purpose of this document is to define the process for relabeling Canadian-approved drug product that has been imported into the U.S. under Section 801 of the Food, Drug and Cosmetic Act, also known as the Canadian Prescription Drug Product Importation Program.

2.0 SCOPE

This procedure is applicable to any facility where the relabeling of drug product is either coordinated or conducted.

Activities not consistent or pertinent to the relabeling of drug product are out of scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1100	Document Control
SOP 1351	Deviation/CAPA – RX
WI 600.05	Prescription Drug Receiving
WI 600.06	Prescription Drug Hold and Release
WI 600.08.01	NDC Product Sampling and Approval Form Template
WI 600.10	Prescription Drug Pick/Pack/Ship
WI 600.27	Prescription Drug Vendor Returns and Quarantine Shipping

4.0 DEFINITIONS

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.
Rev. Level	Initial documents start at revision number 000. As changes are made to the document, the revision number is raised sequentially by whole numbers.

5.0 ABBREVIATIONS/ACRONYMS

CEO	Chief Executive Officer
CFR	Code of Federal Regulations
COA	Certificate of Analysis
COC	Certificate of Compliance
CPDIP	Canadian Prescription Drug Importation Program
CQCU	Corporate Quality Control Unit
DIN	Drug Identification Number
LSL	LifeScience Logistics
NDC	National Drug Code
QA	Quality Assurance
SDS	Safety Data Sheet
SOP	Standard Operating Procedure
WI	Work Instruction

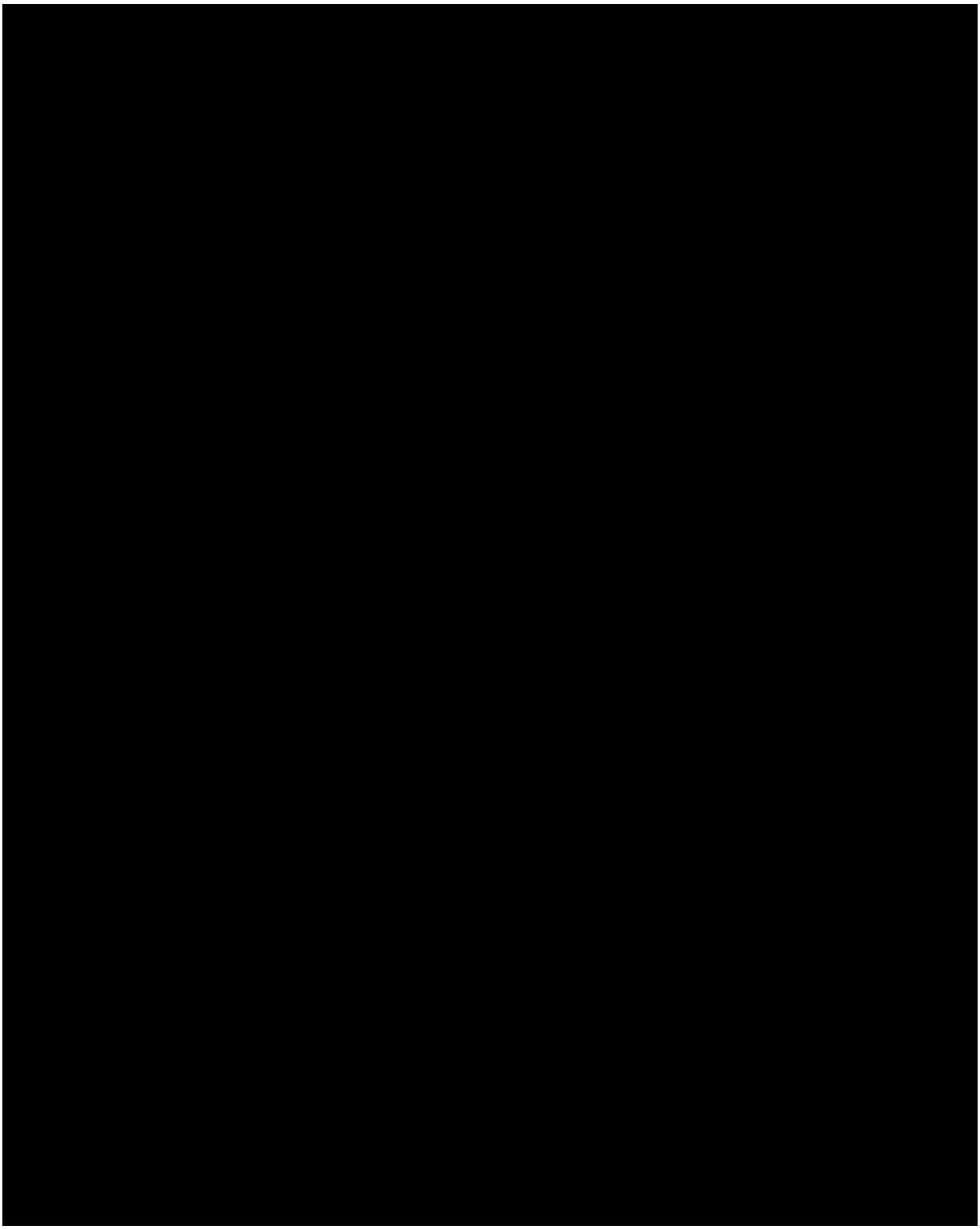
6.0 RESPONSIBILITY

CQCU	Maintain this procedure in accordance with the LSL document and data control system.
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]



[redacted]

PART II: TESTING

[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

[redacted]

[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 picking, packing and shipping orders via WMS within a LifeScience Logistics Prescription Drug Program facility.

2.0 SCOPE

All Prescription Drug Program orders and Prescription Drug Program facilities are in scope.

All government orders and facilities are out of scope.

All commercial orders and facilities are out of scope.

All stockpile orders and facilities are out of scope.

3.0 REFERENCES

21 CFR 211.150	Distribution procedures
21 CFR 820.160	Distribution
21 CFR 251	Section 804 Importation Program
49 CFR 172	Hazardous Materials Provisions
ISO 13485	Medical Devices – Quality Management Systems
SOP 1101	Control of Records
SOP 1351	Deviation/CAPA – RX
WI 600.05.01	Trailer Inspection Sheet – RX
WI 600.06	Prescription Drug Hold and Release
WI 600.06.03	Damaged Product Form
WI 600.10.01	Picking Competency Assessment
WI 600.10.02	Packing Competency Assessment
WI 600.14	Prescription Drug Inventory Management

4.0 DEFINITIONS

Broken Wave	An order that cannot be completed due to a stop in the WMS
Overage	Too many items picked vs. order quantity; either too many of listed item or other items not listed on the order
Shortage	Too few items picked vs. order quantity
Uncontainerized Pick	A pick that has been routed to a location other than a Forward Pick; a pick coming from a reserve location that does not generate a pick label.
UPS WorldShip®	Software to assist with shipping documentation and labeling.
Wave	An organized grouping of orders that have been released for picking

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
BOL	Bill of Lading
CEO	Chief Executive Officer
CFR	Code of Federal Regulations

COB	Close of Business
CQCU	Corporate Quality Control Unit
GDP	Good Documentation Practices
IATA DGR	International Air Transport Association Dangerous Goods Regulations
IPPC/HT	Pallets that comply with the International Plant Protection Convention standards.
IC	Inventory Control
IT	Information Technology
LSL	LifeScience Logistics
LTL	Less than Truck Load
MPL	Master Packing List
NDC	National Drug Code
PC	Personal Computer
PPE	Personal Protective Equipment
QA	Quality Assurance
RF	RF gun used for mobile systemic processing
SOP	Standard Operating Procedure
TL	Truck Load
TMS	Transportation Management System
UOM	Unit of Measure
WI	Work Instruction
WMS	Warehouse Management System (TECSYS)

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 report any problems or deviations from the procedure to your Supervisor or designee.

7.0 PROCEDURE

[redacted]

[redacted]

Order Picking

[redacted]

Cluster Picking

[redacted]

[redacted]

Area Picking

[redacted]

[redacted]

Conventional Picking

[redacted]

Small Parcel Pack Out/ Shipping

[redacted]

[redacted]

Container Verification

[redacted]

[redacted]

TL and LTL Pack Out/Container Verification/Shipping

[redacted]

[redacted]

Discrepancies Found During Verification

[redacted]

Ship Complete

[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 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)

1.0 PURPOSE

The purpose of this procedure is to list the actions to be taken when the physical inventory does not match the system's inventory for quantity or tag information.

2.0 SCOPE

This procedure applies to all LSL Prescription Drug Program products.

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 1351	Deviation/CAPA – RX
WI 600.14.01	Prescription Drug Inventory Adjustment Form

4.0 DEFINITIONS

CAPA	Corrective and Preventive Action
Tag	Bar-coded and human readable product identification label generated by WMS.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
CEO	Chief Executive Officer
CQCU	Corporate Quality Control Unit
IC	Inventory Control
LSL	LifeScience Logistics
QA	Quality Assurance
SOP	Standard Operating Procedure
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 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 reports any problems or deviations from the procedure to your Supervisor or designee.

7.0 + PROCEDURE

Reasons

[redacted]

Completing the Form and Log

[redacted]

[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)

1.0 PURPOSE

The purpose of this procedure is to define the process of inventory management.

2.0 SCOPE

This procedure applies to all inventory of the Prescription Drug Program warehoused/distributed by LifeScience Logistics.

3.0 REFERENCES

21 CFR 211.142	cGMPs for Finished Pharmaceuticals – Warehousing Procedures
21 CFR 820	Quality System Regulations
SOP 1101	Control of Records
WI 600.14	Prescription Drug Inventory Adjustment
WI 600.14.01	Prescription Drug Inventory Adjustment Form
WI 600.06.02	Damaged Product Form

4.0 DEFINITIONS

Physical Inventory	Physical count of inventory as required by CQCU.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
CEO	Chief Executive Officer
CQCU	Corporate Quality Control Unit
IC	Inventory Control
INC	LSL's Commercial facility
LSL	LifeScience Logistics
PI	Physical Inventory
QA	Quality Assurance
RF	Radio Frequency (guns)
SOP	Standard Operating Procedure
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 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

Moves

[redacted]

Replenishments

[redacted]

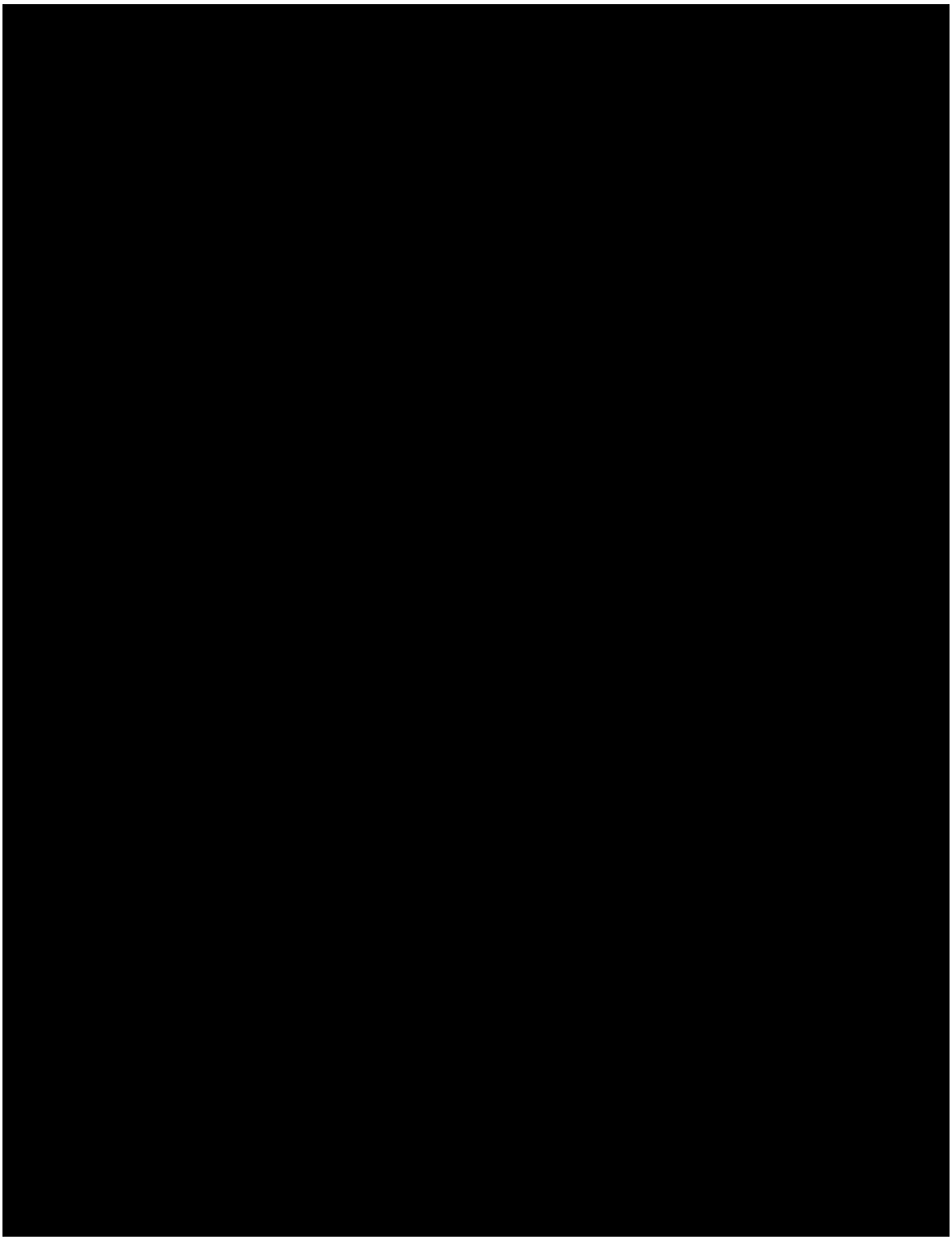
[redacted]

Cycle Count

[redacted]

7.5 Basic Cycle Count

[redacted]



Damages Found – Inventory

WMS Location Management

Put Away Verifications - Adjustments

[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)

1.0 PURPOSE

The purpose of this document is to define the processes and procedures for creating inspection criteria and conducting inspections and approvals for components associated with Section 801 of the Food, Drug, and Cosmetic Act, also known as the Canadian Prescription Drug Importation Program.

2.0 SCOPE

The scope of this document is applicable to associated components used in CPDIP.

Activities associated with products not affiliated with CPDIP are out of scope.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1103	Good Documentation Practices
WI 600.05	Prescription Drug Receiving
WI 600.26.01	Component Inspection Form Template

4.0 DEFINITIONS

N/A	N/A

5.0 ABBREVIATIONS/ACRONYMS

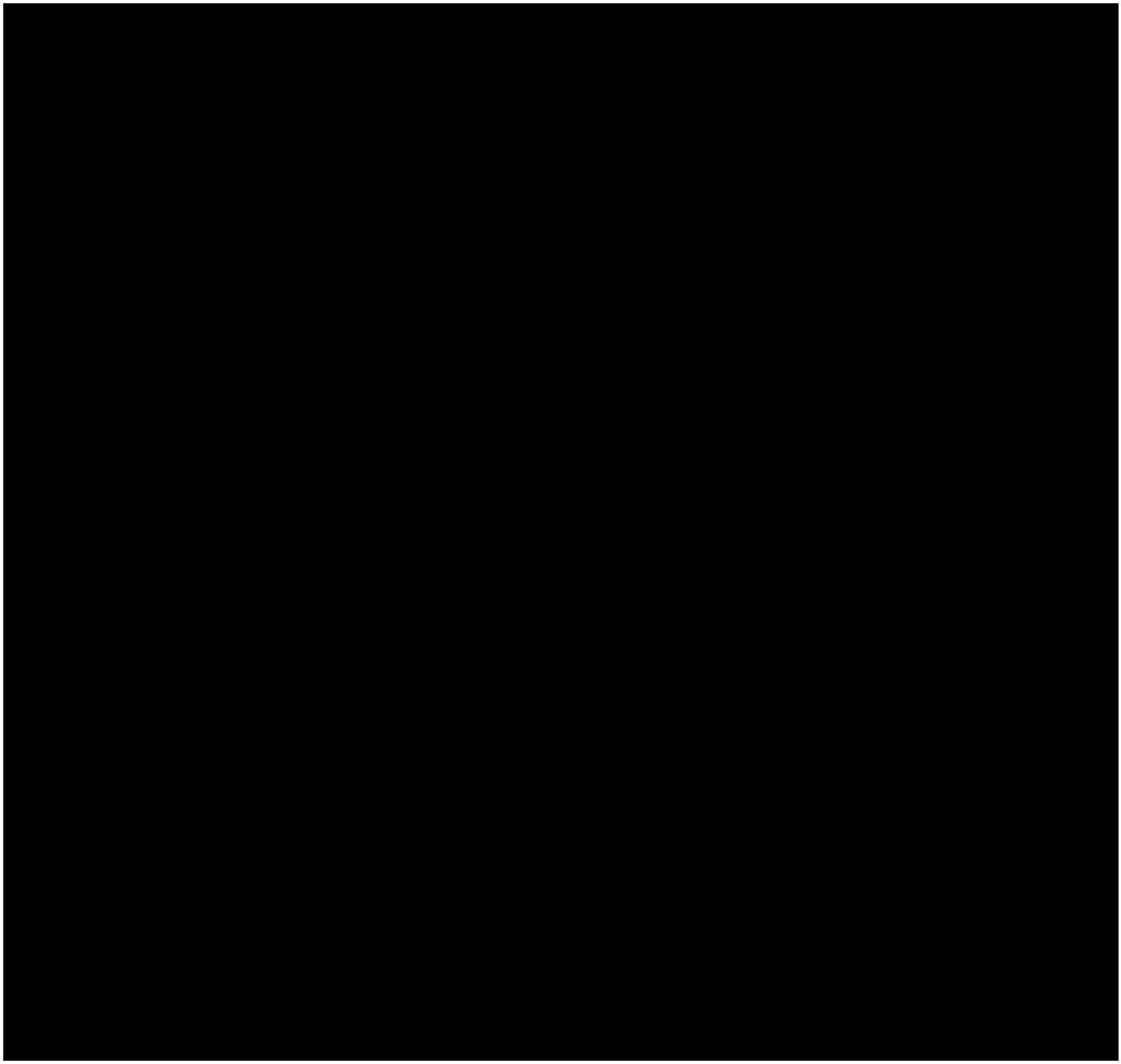
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CoC	Certificate of Conformance
CPDIP	Canadian Prescription Drug Importation Program
CQCU	Corporate Quality Control Unit
LSL	LifeScience Logistics
QA	Quality Assurance
SOP	Standard Operating Procedure
WI	Work Instruction

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



[redacted]

8.0 ADDITIONAL INFORMATION

Control of Records

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9.0 REVISION HISTORY

[redacted]

10.0 TRAINING RECORD

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