

# Current



## LifeScience Logistics

<b>Title:</b>	Control of Records	
<b>Number:</b>	SOP 1101	<b>Rev. Date:</b> 08-Sep-2023
<b>Rev. Level:</b>	029	



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 <b>LifeScience Logistics</b>		
<b>Title:</b>	Control of Records	
<b>Number:</b>	SOP 1101	<b>Rev. Date:</b> 08-Sep-2023
<b>Rev. Level:</b>	029	

**10.0 TRAINING RECORD**

Training Date	Type of Training		
	<input type="checkbox"/> Read and Understand – Self Training	<input type="checkbox"/> Read and Exhibit Competency – Trainer Led with Module/Assessment when applicable	<input type="checkbox"/> 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)



## LifeScience Logistics

<b>Title:</b>	Deviation/CAPA - RX		
<b>Number:</b>	SOP 1351	<b>Rev. Date:</b>	29 APR 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	1 of 13

### 1.0 PURPOSE

The purpose of this procedure is to define minimum requirements for reporting internal and external deviations, including client/customer complaints, and conducting an investigation to reach the root cause and determine the required corrective and preventive actions with due dates.

### 2.0 SCOPE

Government deviations and CAPAs are out of scope. See SOP 1300, Deviation/CAPA – GSA.

Stockpile deviations and CAPAs are out of scope. See SOP 1352, Deviation/CAPA – Stockpile.

Commercial deviations and CAPAs are out of scope. See SOP 1350, Deviation/CAPA – Commercial.

All deviations are considered unforeseen and unintentional. When human error is part of the root cause, the process is investigated for correction and improvement.

Sabotage, falsification of records and intentional harm to LSL resources is out of scope and is handled by the Disciplinary Policy and/or law enforcement as appropriate.

### 3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality Systems Regulations
ISO 13485	Medical Devices — Quality Management Systems
SOP 1031	Vendor Qualification
SOP 1101	Control of Records
SOP 1103	Good Documentation Practices
SOP 1300	Deviation/CAPA – GSA
SOP 1350	Deviation/CAPA – Commercial
SOP 1352	Deviation/CAPA – Stockpile
SOP 1500	External Audits and Inspections
WI 600.06	Prescription Drug Hold and Release
WI 600.07	Prescription Drug Initial Sampling and Laboratory Testing
WI 600.19.01	Deviation Report – RX
WI 600.19.02	Deviation Report e-Log – RX
WI 600.19.03	CAPA Report e-Log – RX
WI 600.19.04	CAPA Report – RX
WI 600.19.05	Deviation/CAPA Extension Request – RX



## LifeScience Logistics

<b>Title:</b>	Deviation/CAPA - RX		
<b>Number:</b>	SOP 1351	<b>Rev. Date:</b>	29 APR 2021
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### 4.0 DEFINITIONS

CAPA	Corrective and Preventive Action – A systematic approach that includes actions needed to correct [correction], avoid recurrence [corrective action], and eliminate the cause of potential nonconforming product and other quality problems [preventive actions].
Client Code	Unique number assigned to clients for anonymity.
Commitment	A single corrective action with a due date.
Correction	Action to eliminate a detected nonconformity. Corrections are typically a one-time fixes. A correction is an immediate solution, also known as containment action.
Corrective Action	Action to eliminate the causes of a detected nonconformity or other undesirable situation. The action should eliminate the recurrence of the issue.
Deviation	Datum or results outside of an expected range; an unfulfilled requirement. Also known as nonconformity.
Effectiveness Check	Documented process to verify that a Corrective Action and Preventive Action was effective and accomplished the objective that was intended.
Fishbone diagram	Root cause analysis tool shaped like a fish skeleton; also known as Cause-and-Effect or Ishikawa diagram
Investigation	Thorough, timely, unbiased, well-documented, and scientifically sound process used to discover the root causes of the problem.
Isolated Event	The type of reported event has never happened before, not person or facility-specific.
Metrics	Quantitative measurements that are collected, recorded, and analyzed to determine whether quality system goals and objectives have been met or exceeded or failed to meet requirements.
Monitor	Observe and check over a period of time; to maintain regular close observation over a process.
Objective Evidence	Data that show or prove that something exists or is true. Objective evidence can be collected by means of observations, measurements, tests or other suitable methods.
Preventive Action	Action to eliminate the cause of a potential nonconformity or other undesirable potential situation in order to prevent occurrence.
Problem Statement	Description of what happened vs. what should have happened, the date the event occurred and was discovered as well as reported, where it happened, How it was discovered, who discovered it, and time of day discovered, as applicable.
Quality	The degree to which a set of inherent characteristics fulfills requirements. A measure of a product's or service's ability to satisfy the client or customer's stated or implied needs.



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Quality System	Formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill service requirements, customer satisfaction and continuous improvement.
Root Cause	A gap in a process input or supporting business system that is, at least partly, responsible for the incident. It is the basic reason why causal factors occur and/or persist.
Root Cause Analysis	Analysis necessary to determine the original or true root cause of a system, product, or process nonconformity. This effort extends beyond the effects of a problem to discover its most fundamental cause.
SharePoint	A web-based collaborative platform LSL uses for electronically filing and storing records. <a href="https://lslog.sharepoint.com/SitePages/Home.aspx">https://lslog.sharepoint.com/SitePages/Home.aspx</a>

### 5.0 ABBREVIATIONS/ACRONYMS

CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
DEA	Drug Enforcement Administration
DEV	Deviation
EC	Effectiveness Check
ISM	Inventory Status Modification
LSL	LifeScience Logistics
QA	Quality Assurance
SISPQ	Safety, Identity, Strength, Purity, and Quality
SOP	Standard Operating Procedure
WI	Work Instruction



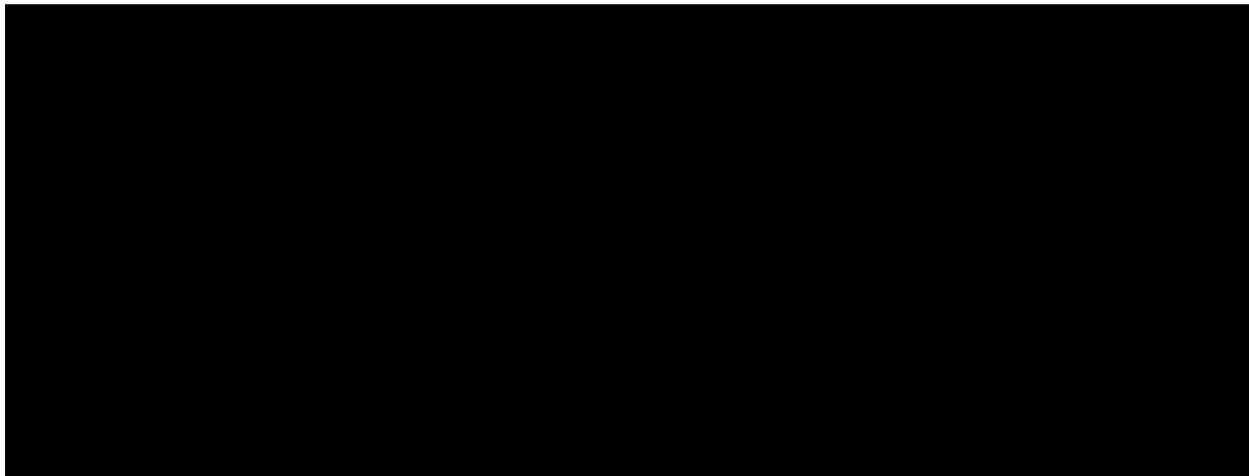
## LifeScience Logistics

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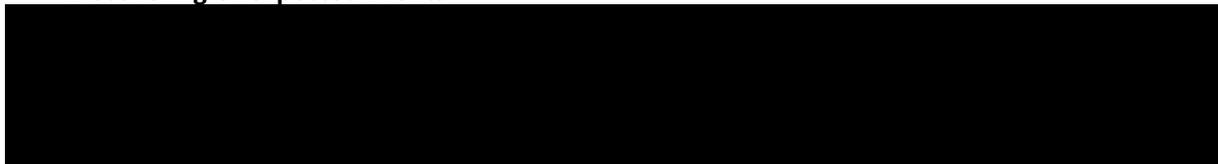
### 6.0 RESPONSIBILITY

CQCU/Functional Owner	Maintain this procedure in accordance with the LSL document and data control system. 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. Determine Risk Level, impact assessment and response due dates. Upon successful completion, approve all Deviation and CAPA Reports. Track aging of Deviation and CAPA Reports. Follow up with assignee to ensure progress of Deviation and CAPA Reports.
Department Management	Review and approve all departmental Deviation and CAPA Reports. Disseminate Deviation and CAPA data to direct reports.
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



#### Discovering Unexpected Events

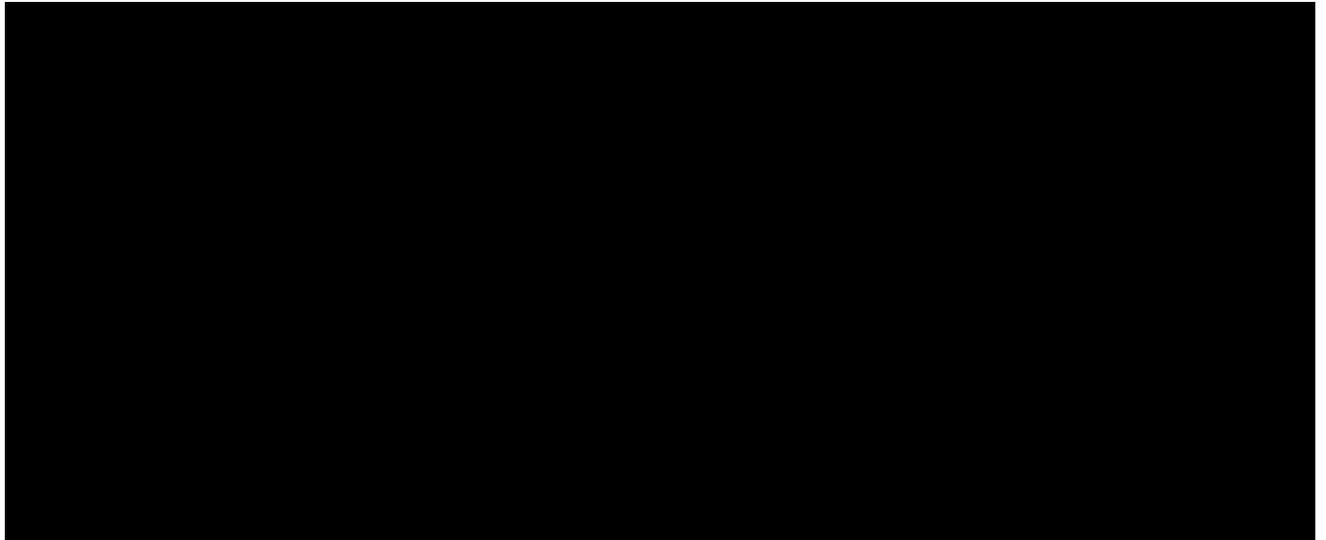


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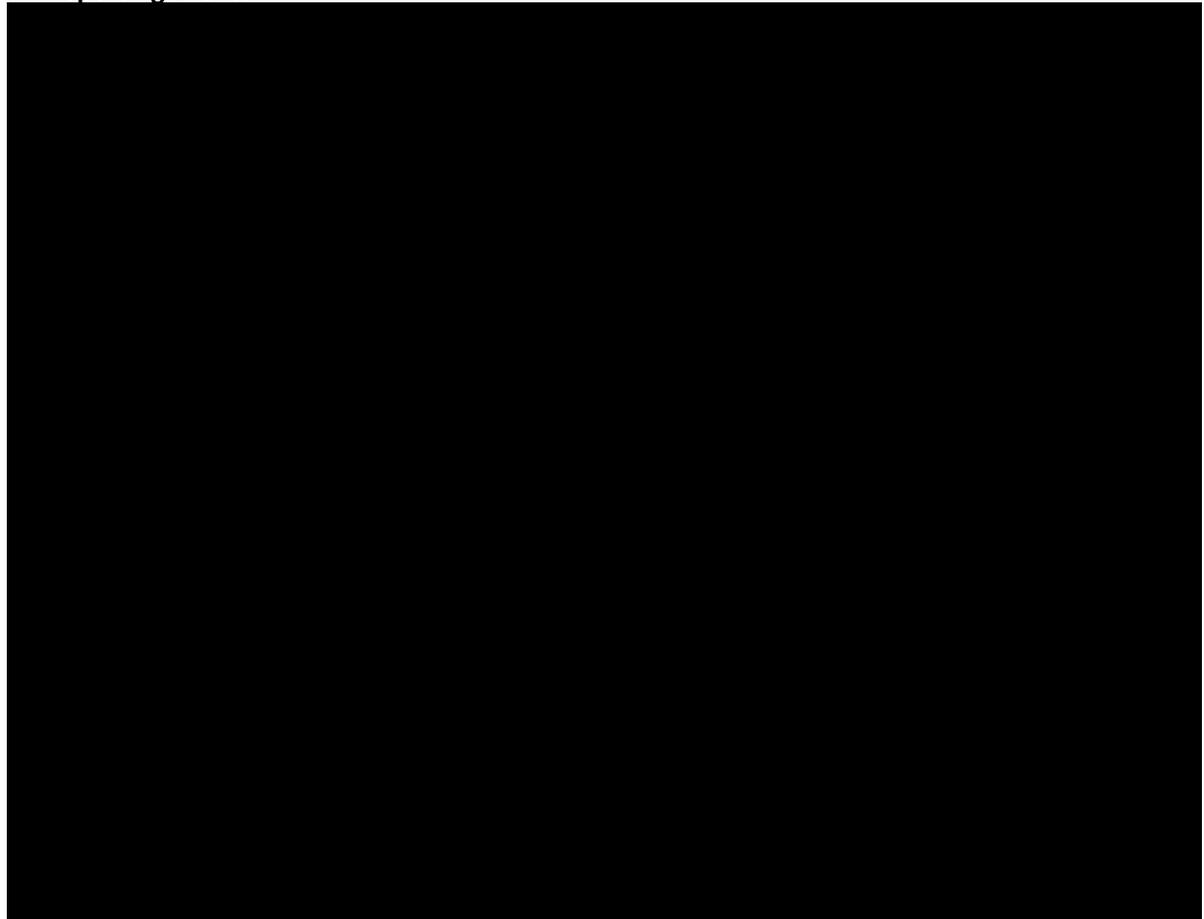


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### Reporting Events

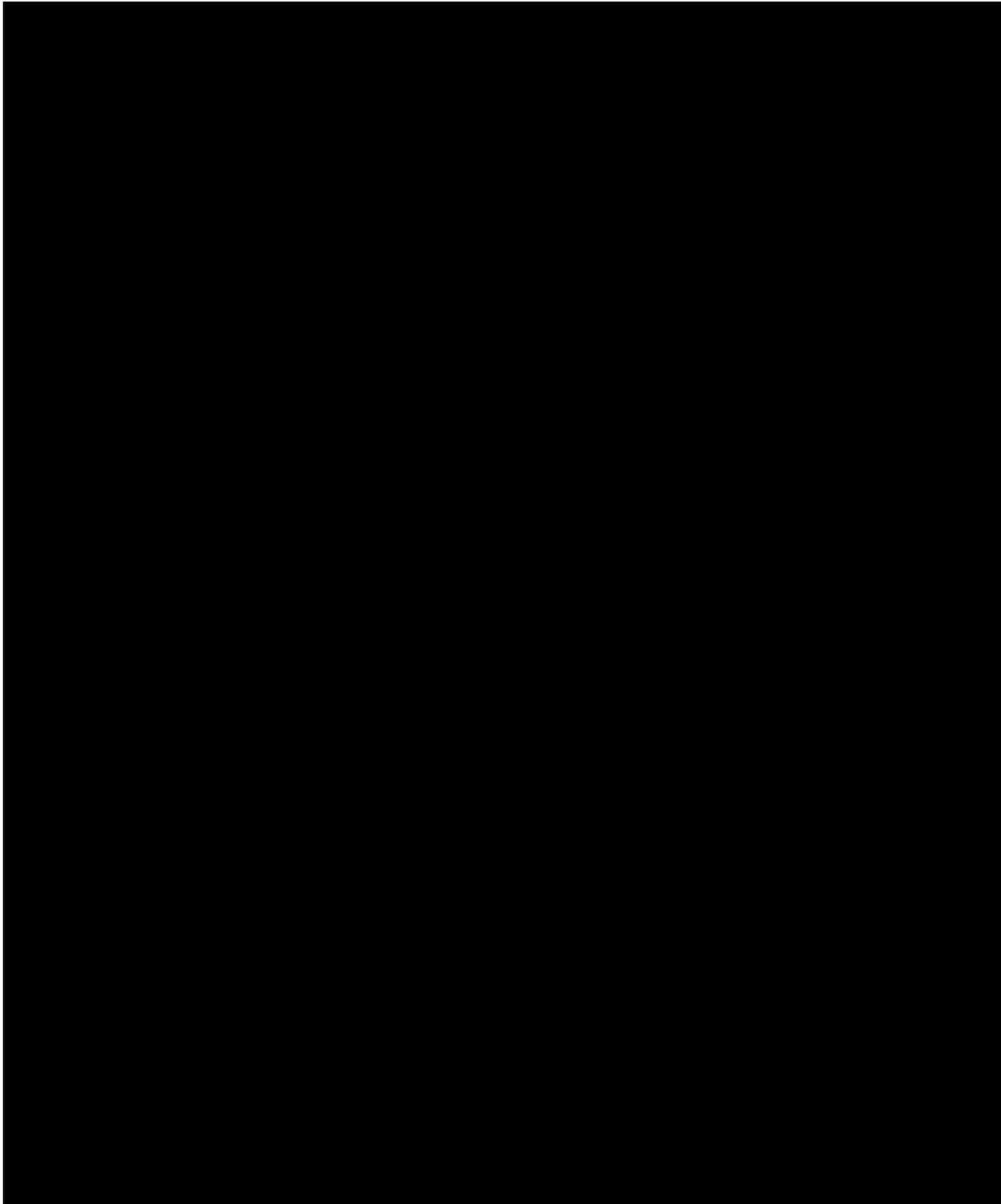


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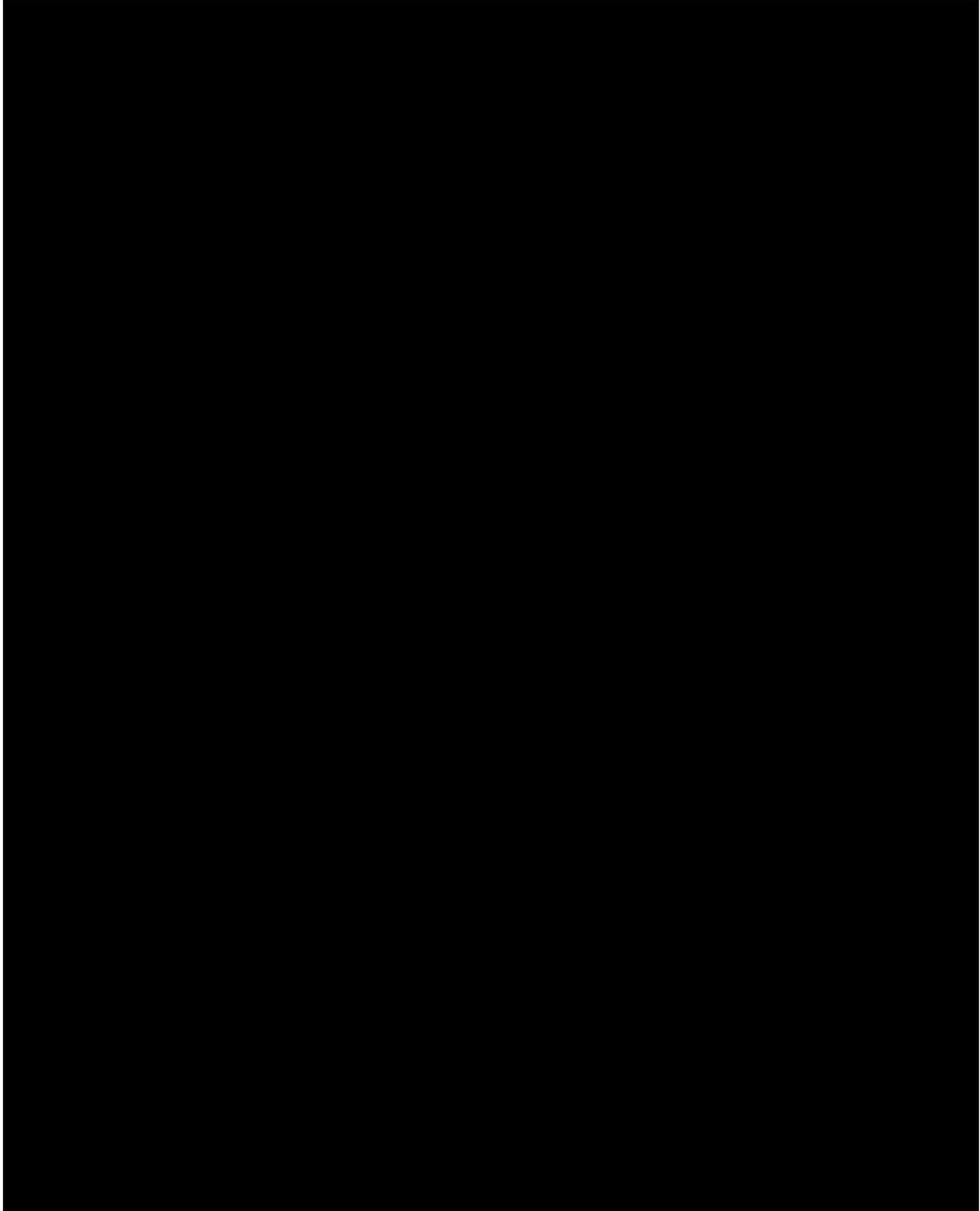


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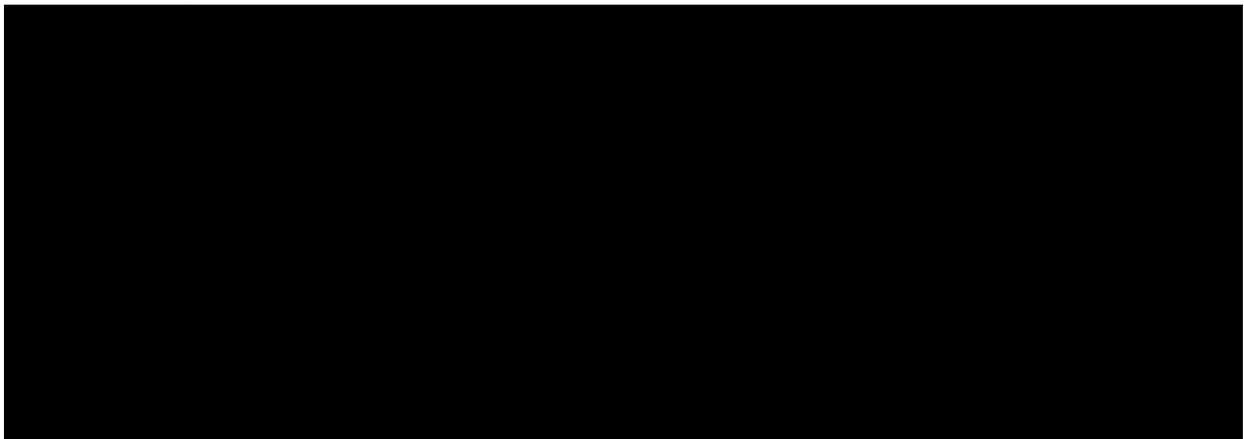


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**Review by CQCU**

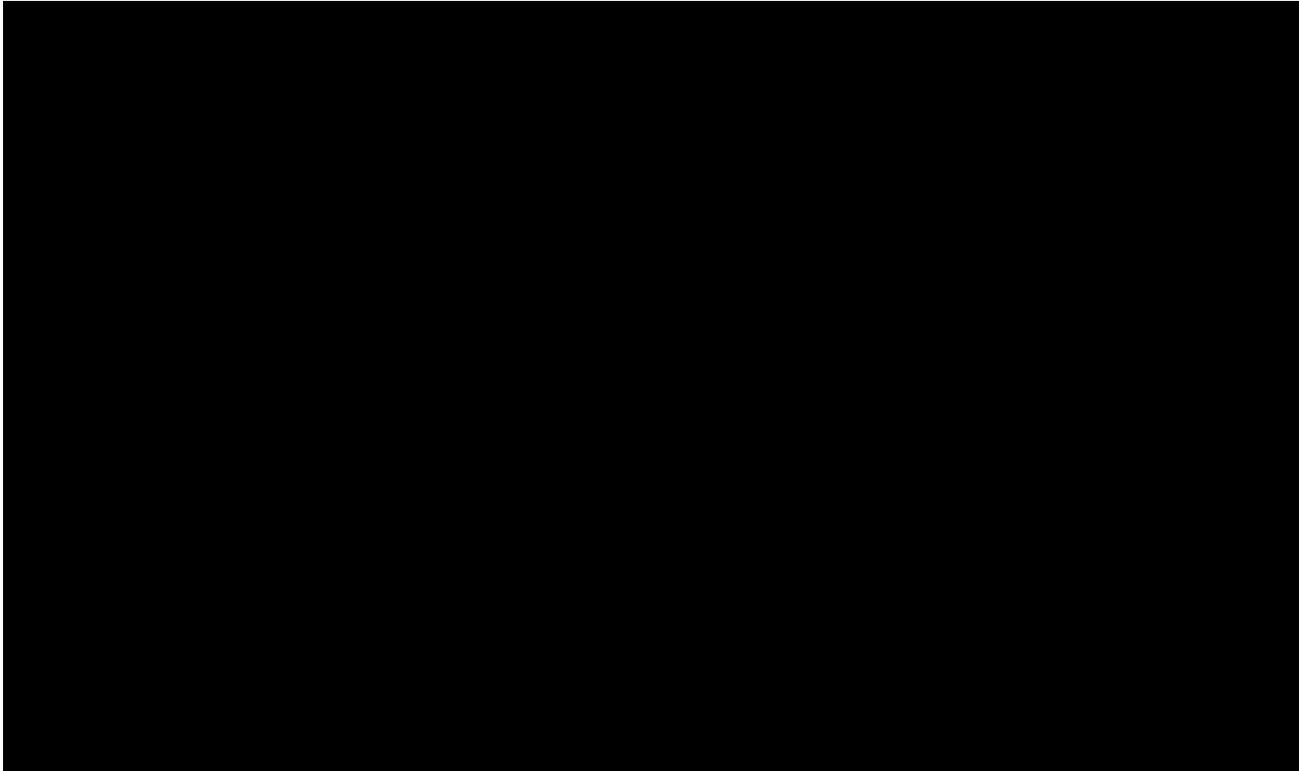


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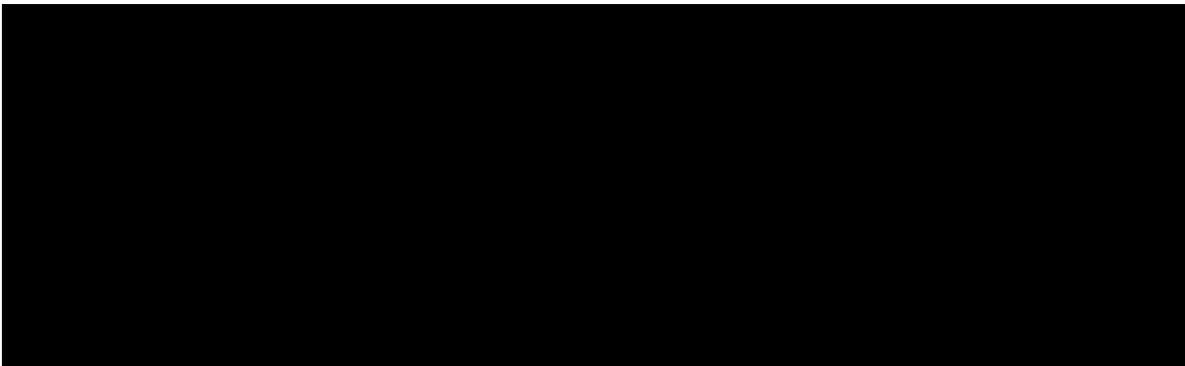


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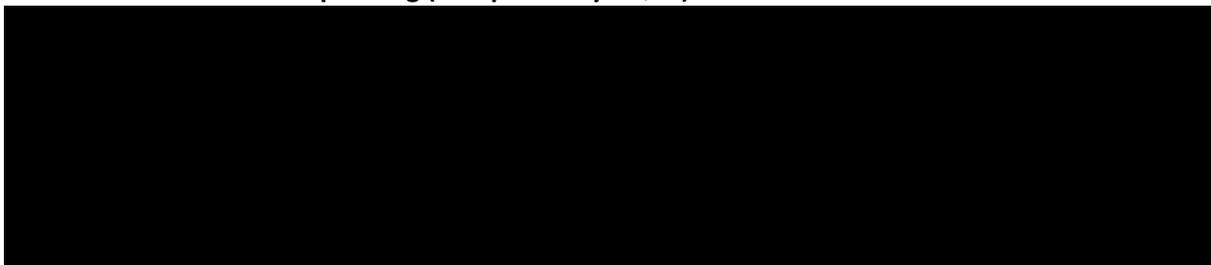
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### Extension requests



### Deviation or CAPA Report Log (Completed by CQCU)

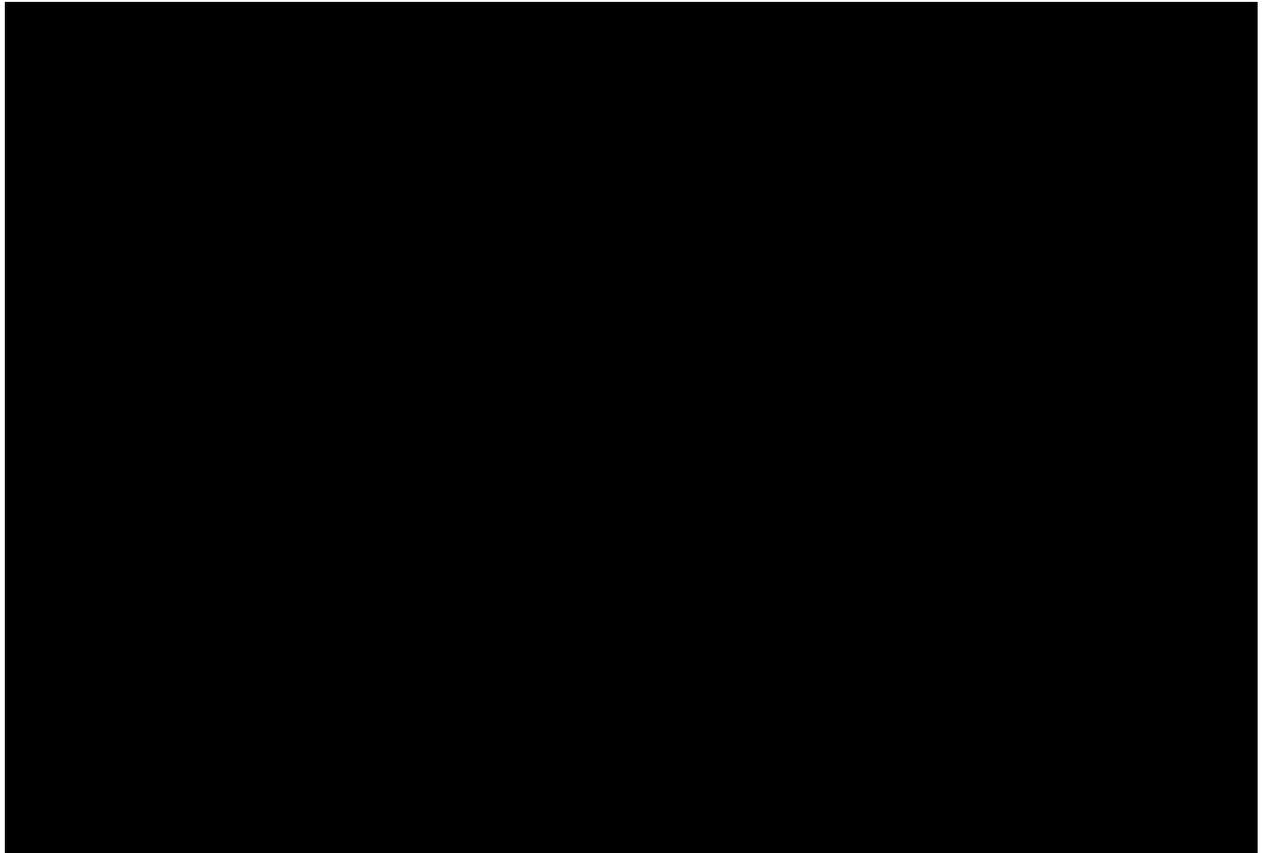


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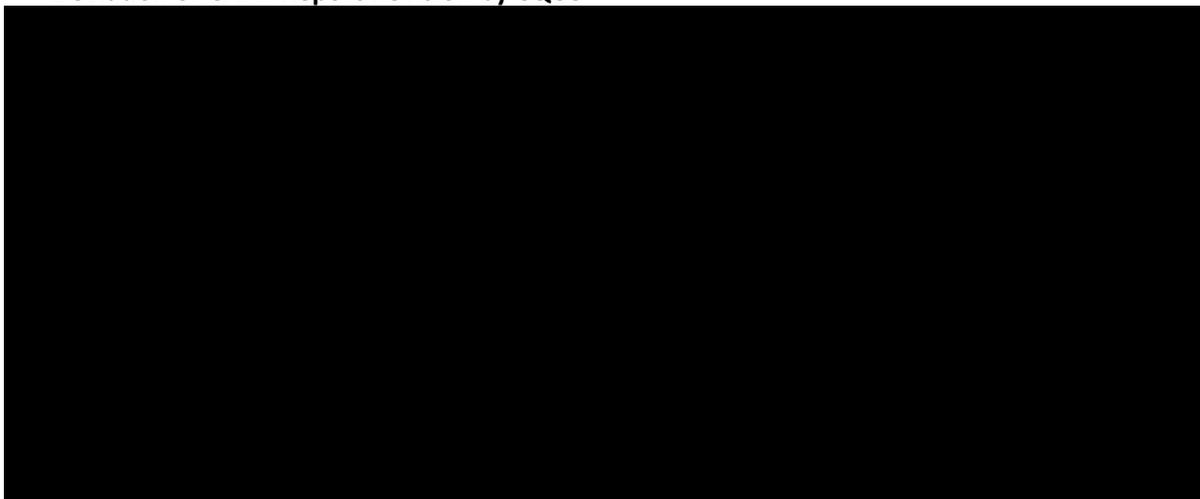


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### Deviation or CAPA Report Revision by CQCU



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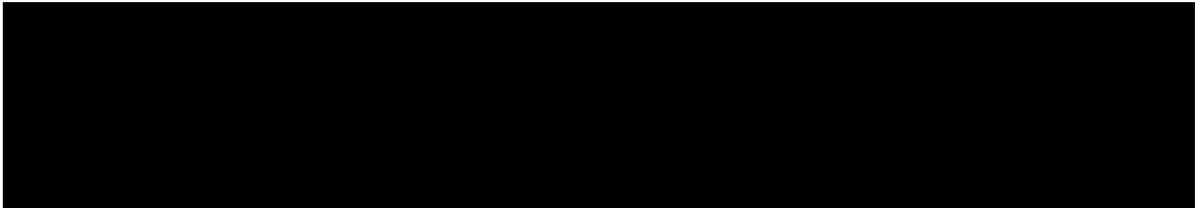
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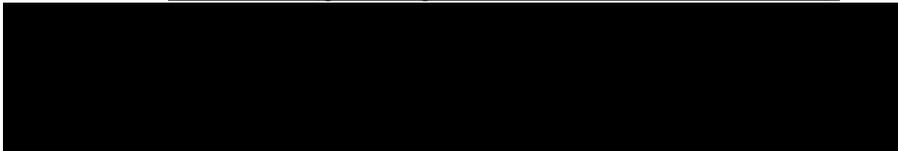
## 8.0 ADDITIONAL INFORMATION Risk Calculation



### 8.2 Severity:



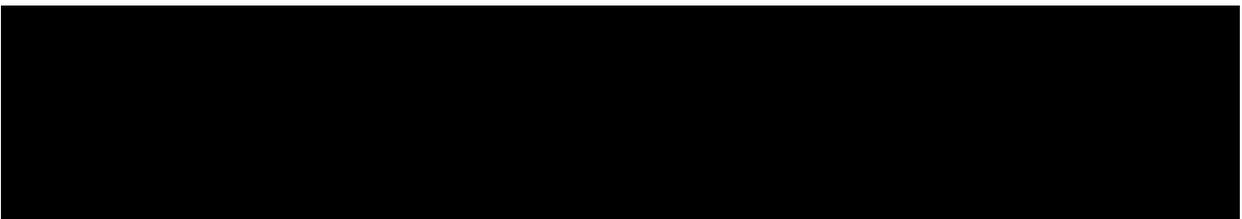
### 8.3 Occurrence (general guidelines over a 6 month review):



### 8.4 Probability of Detection:



### 8.5 Risk Levels:



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### Control of Records

#### Confidentiality Statement

8.7 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

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## LifeScience Logistics

<b>Title:</b>	Response to Cargo Thefts		
<b>Number:</b>	SOP 1601	<b>Rev. Date:</b>	08 JUL 2020
<b>Rev. Level:</b>	005	<b>Page:</b>	1 of 4

### 1.0 PURPOSE

The purpose of this procedure is to define the process of LifeScience Logistics' response when a cargo theft involving an FDA-regulated product has occurred.

### 2.0 SCOPE

This procedure applies to all products shipped by LSL from any of their warehouse facilities.

Warehouse thefts of FDA regulated products are out of scope of this procedure.

For warehouse thefts see SOP 2002, Handling, Storage, Packaging and Distribution.

### 3.0 REFERENCES

SOP 1003	Recalls, Removals, and Corrections
SOP 1101	Control of Records
SOP 2002	Handling, Storage, Packaging and Distribution
WI 200.06	DEA Theft or Loss

### 4.0 DEFINITIONS

Cargo Theft	FDA considers cargo thefts to include tractor-trailer and warehouse thefts of FDA-regulated products, such as prescription drugs, OTC drug products, infant formula, or medical devices which may pose a threat to the public health or a risk to the legitimate supply chain.
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### 5.0 ABBREVIATIONS

CEO	Chief Executive Officer
CQCU	Corporate Quality Control Unit
FDA	Food & Drug Administration
LSL	LifeScience Logistics
OCI	FDA Office of Criminal Investigation
OTC	Over The Counter
QA	Quality Assurance
SOP	Standard Operating Procedure
WI	Work Instruction



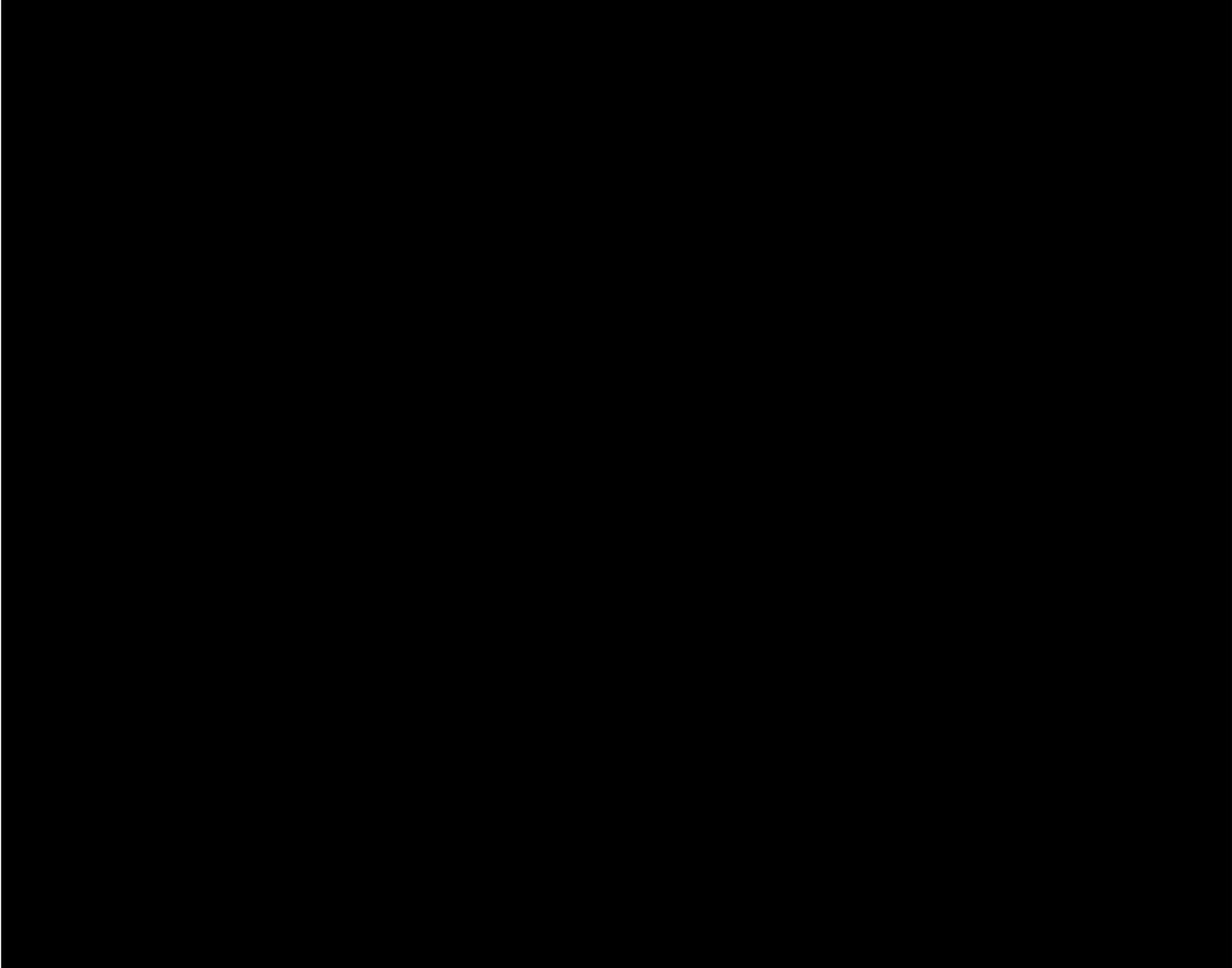
## LifeScience Logistics

<b>Title:</b>	Response to Cargo Thefts		
<b>Number:</b>	SOP 1601	<b>Rev. Date:</b>	08 JUL 2020
<b>Rev. Level:</b>	005	<b>Page:</b>	2 of 4

### 6.0 RESPONSIBILITY

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

### 7.0 PROCEDURE



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## LifeScience Logistics

<b>Title:</b>	Response to Cargo Thefts		
<b>Number:</b>	SOP 1601	<b>Rev. Date:</b>	08 JUL 2020
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### 8.0 ADDITIONAL INFORMATION Control of Records

#### Confidentiality Statement

8.2 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

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## LifeScience Logistics

<b>Title:</b>	Handling, Storage, Packaging & Distribution		
<b>Number:</b>	SOP 2002	<b>Rev. Date:</b>	02 JUN 2021
<b>Rev. Level:</b>	010	<b>Page:</b>	1 of 7

### 1.0 PURPOSE

The purpose of this procedure is to define the steps Life Science Logistics uses to control the handling, storage, packaging and distribution for Client product. This includes awareness and ability to identify suspicious or criminal activity.

### 2.0 SCOPE

Tracing specific lots, batches, or serial numbers for product is out of scope. See SOP 2301, Identification and Traceability.

Response to Cargo Theft is out of scope. See SOP 1601, Response to Cargo Thefts.

Client-specific requirements supersede this SOP.

### 3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practices for Finished Pharmaceuticals
21 CFR 820	Quality System Regulations
DSCSA Section 205	National Standards for Third-Party Logistics Providers Uniform National Policy
ISO 13485	Medical Devices – Quality Management Systems
SOP 1101	Control of Records
SOP 1300	Deviation/CAPA – GSA
SOP 1350	Deviation/CAPA – Commercial
SOP 1351	Deviation/CAPA – RX
SOP 1352	Deviation/CAPA - Stockpile
SOP 1601	Response to Cargo Thefts
SOP 2002.01	First 30 Days: Handling, Storage, Packaging and Distribution Module – INC
SOP 2301	Identification and Traceability
SOP 4004	Client/Customer Feedback – Commercial
WI 100.25	Physical Inventory
WI 200.06	DEA Theft or Loss
WI 300.22	SNS Order Pick
WI 300.23	SNS Order Shipping
WI 400.04	Commercial Pick Pack and Ship
WI 500.04	Stockpile Order Pick
WI 500.05	Stockpile Order Shipping
WI 600.10	Prescription Drug Pick/Pack/Ship

### 4.0 DEFINITIONS

Directed Put-Away	WMS directs where newly received product should be stored.
Illegitimate Product	Credible evidence shows that the product is potentially counterfeit, diverted, or stolen, intentionally adulterated such that the product would result in serious health consequences to humans, subject of a



## LifeScience Logistics

<b>Title:</b>	Handling, Storage, Packaging & Distribution		
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	fraudulent transaction, or appears otherwise unfit for distribution.
Item Number	LSL reference number for a given product, which is used on Tags. This could be an NDC, UPC or other unique reference for identification. Also, one item number stored in different units of measure may have unique item numbers.
Mixed Pallet	A pallet that contains two or more different products or one product with multiple lot numbers.
Pack-out spec	Client specific written specification for shipment of Client product. This may or may not include cold packs, frozen gel packs, etc.
Packaging materials	Per 21 CFR 211.130 Packaging and Labeling – these are controlled by LSL’s Client. This includes Tamper-evident packaging per 21 CFR 211.132
Packing materials	Packing materials are not the product’s primary (bottle) or secondary packaging materials (shelf-unit with lot and expiry date) but are bubble-wrap, Packing list, dunnage and/or corrugated shipping boxes.
Partial Case	A case that contains less product than a full case.
Product	Prescription and non-prescription drugs, devices, kits or other merchandise and its containers, labels and packaging
Returns	Returned Goods
RF Gun	Hand-held bar code readers that work via radio frequency
Suspect Product	Reason to believe that the product is potentially counterfeit, diverted, or stolen, intentionally adulterated such that the product would result in serious health consequences to humans, subject of a fraudulent transaction, or appears otherwise unfit for distribution.
Tag	Physical sticker and WMS unique identifier with both barcodes and human readable numbers.

### 5.0 ABBREVIATIONS/ACRONYMS

CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CQCU	Corporate Quality Control Unit
DEA	Drug Enforcement Administration
DSCSA	Drug Supply Chain Security Act
FDA	Food and Drug Administration
FEFO	First Expired – First Out
LSL	LifeScience Logistics
NDC	National Drug Code
OPS	LSL Operations
QA	Quality Assurance
RF	Radio Frequency
SNS	Strategic National Stockpile
SOP	Standard Operating Procedure



## LifeScience Logistics

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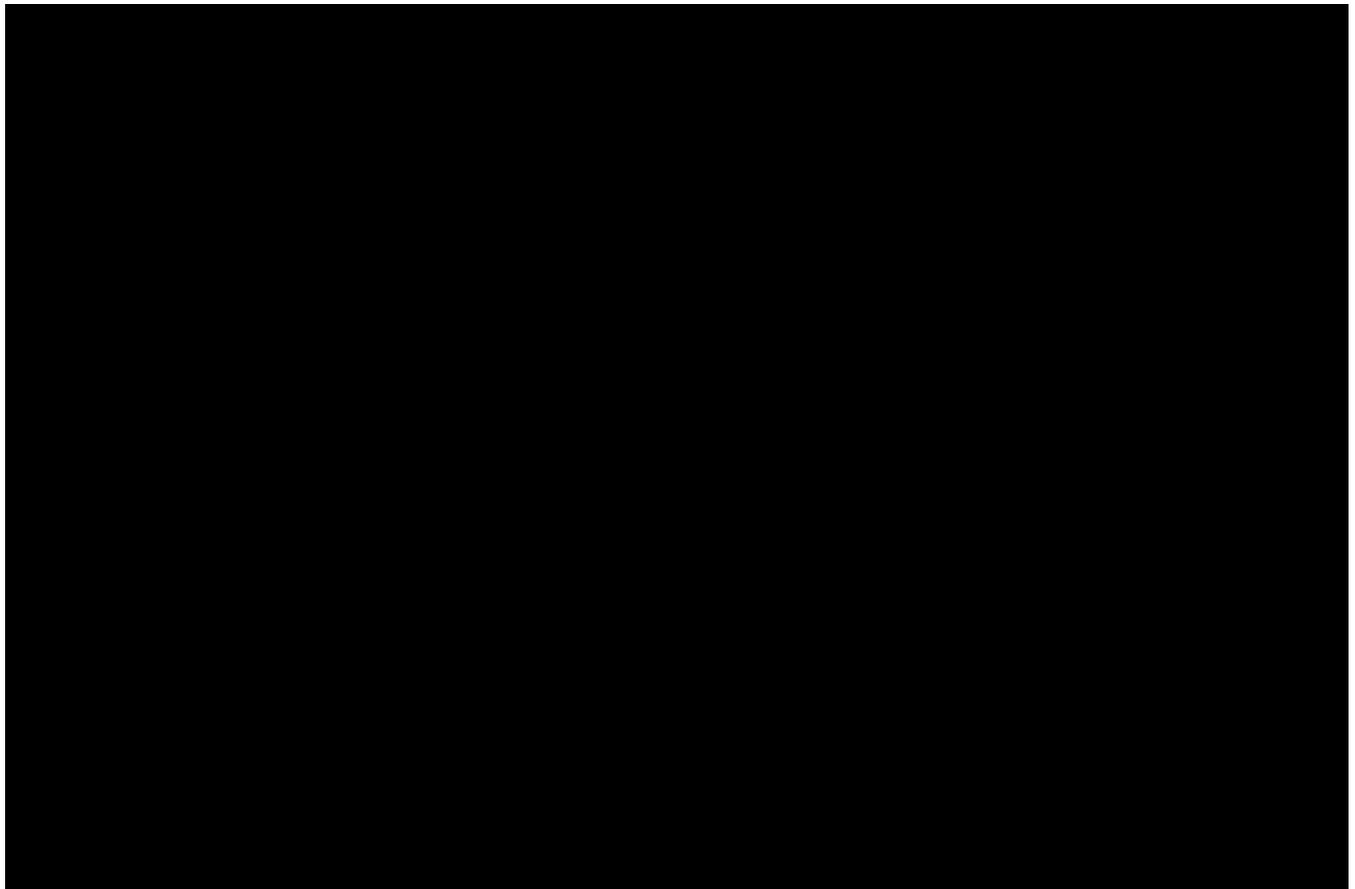
UPC	Universal Product Code
WI	Work Instruction
WMS	Warehouse Management System

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

### 7.0 PROCEDURE

#### + Handling Suspicion of Criminal Activity, Product Losses or Thefts

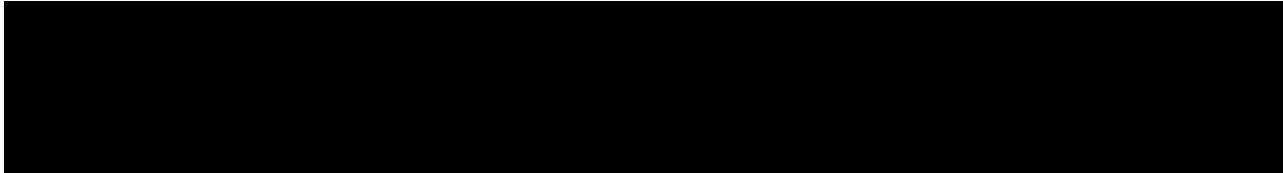


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## LifeScience Logistics

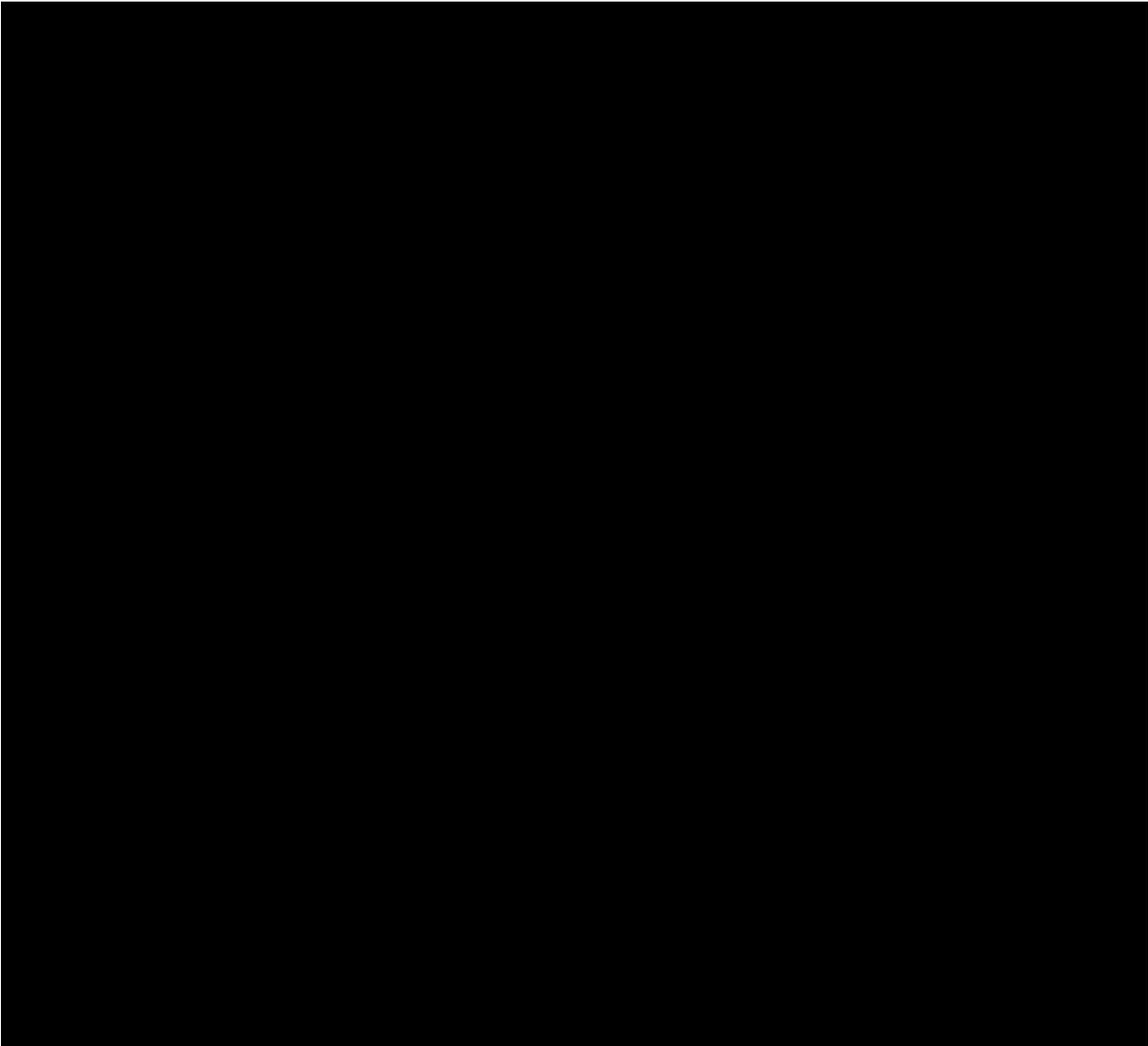
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### + Product Handling and Preservation



### + Client Product Storage



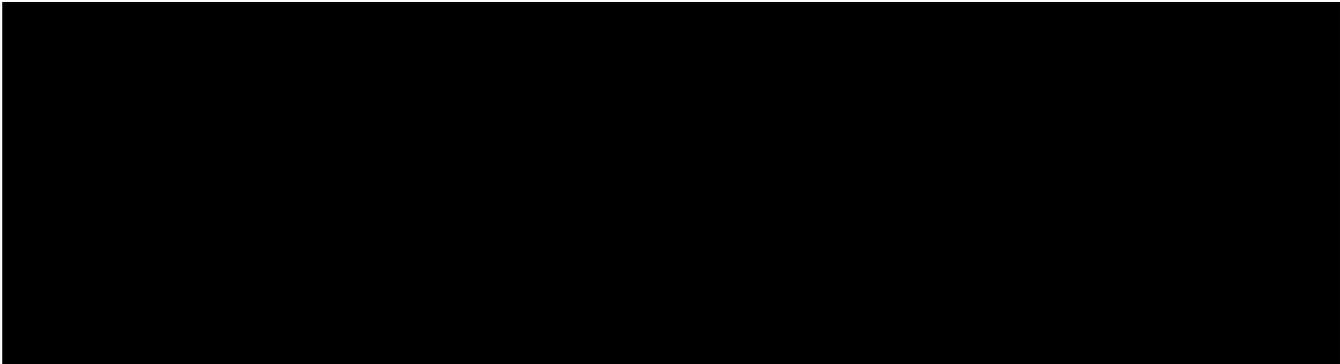
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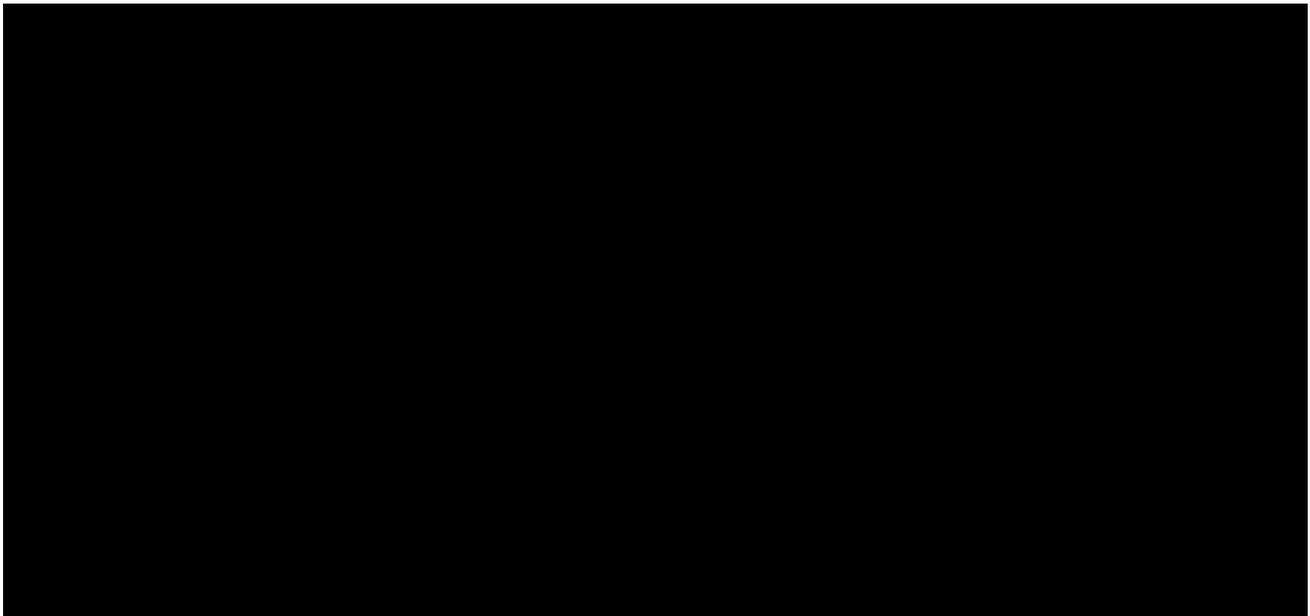


## LifeScience Logistics

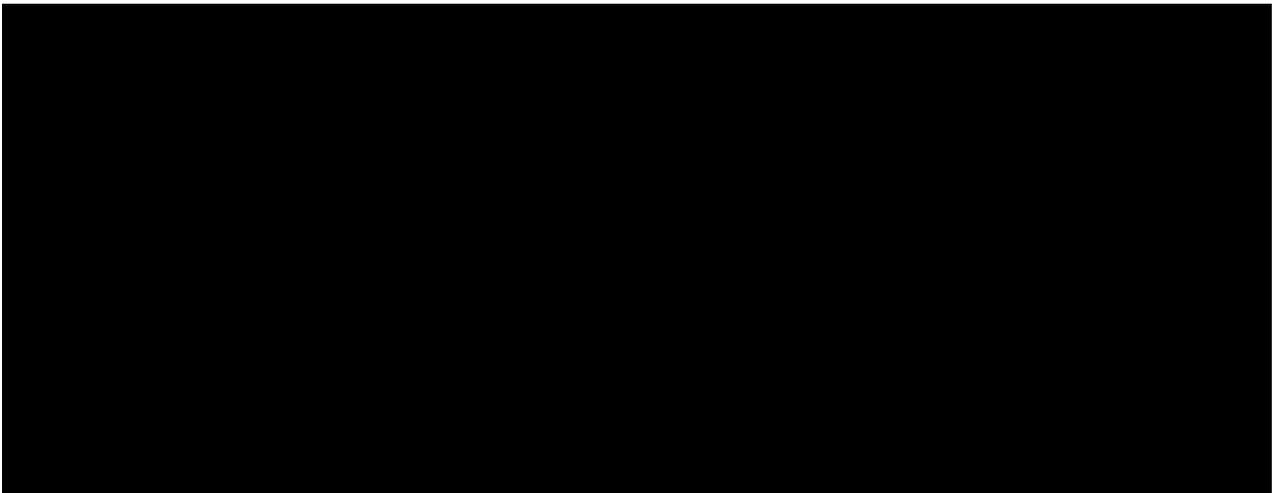
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### Distribution



### Packaging



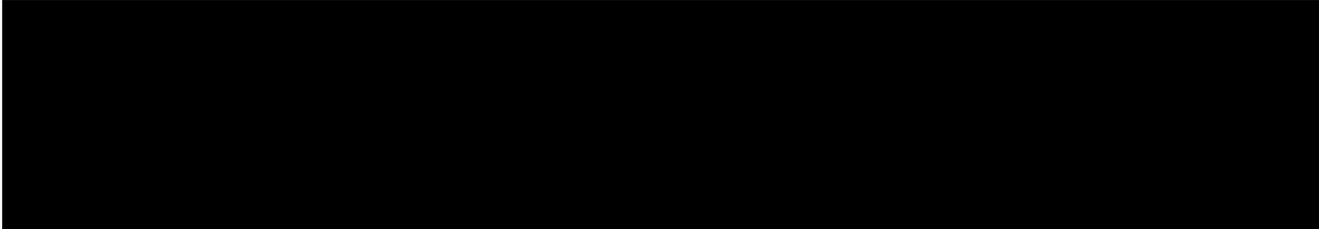
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# LifeScience Logistics

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## + Handling of Quarantine Product



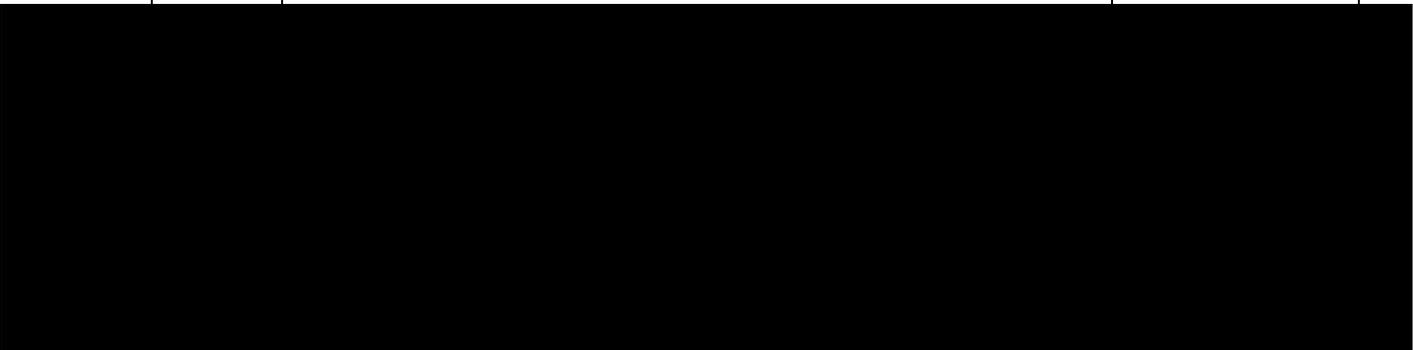
### 8.0 ADDITIONAL INFORMATION Control of Records



#### Confidentiality Statement

8.2 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







## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	1 of 10

### 1.0 PURPOSE

The purpose of this procedure is to define the reporting processes used for the Pharmacovigilance – Post Marketing Reporting at LSL Prescription Drug Program facilities.

### 2.0 SCOPE

This procedure applies to LSL's reporting of Post Marketing Product Events received and managed by the vendor.

This procedure does not apply to customer financial complaints, shipping complaints or customers' inquiries.

This procedure does not apply to product complaints regarding product warehoused at Commercial facilities.

### 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
21CFR 310	New Drugs
ICH E2B	Data Elements for Transmission on Individual Case Safety Reports
SOP 1800	Training and Qualification
SOP 1101	Control of Records
SOP 1100	Document Control
SOP 1351	Deviation/CAPA – RX
WI 600.24.01	Prescription Drug Product Complaint Log
WI 600.24.02	Prescription Drug Product Complaint Report

### 4.0 DEFINITIONS

Adverse Event	An undesirable experience associated with the use of a medical product in a patient.
Individual Case Safety Report	Document used for the reporting of suspected adverse reactions to a medicinal product that occur in a specific patient at a specific point of time.
ICH E2B	Electronic transmission of individual case safety reports.
MedWatch Form 3500A	Form used for reporting Adverse Events to FDA
Periodic Adverse Drug Experience Reports	Safety reports submitted to the USFDA to update and evaluate a medicine's global data and provide information about the drug's safety.
PV-Works	SafetyCall's Pharmacovigilance system.



## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	2 of 10

### 5.0 ABBREVIATIONS/ACRONYMS

ADR	Adverse Drug Reaction
ANDA	Abbreviated New Drug Application
CCDS	Company Core Data Sheet
CEO	Chief Executive Officer
CFR	Code of Federal Regulations
CIOMS I	Council for International Organizations of Medical Sciences common adverse experience reporting form
CMP	Complaint
CQCU	Corporate Quality Control Unit
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
ESG	Electronic Submissions Gateway
FDA	Food and Drug Administration
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
ICSR	Individual Case Study Report
LSL	LifeScience Logistics
MedDRA	Medical Dictionaries for Regulatory Activities
NDA	New Drug Application
PADER	Periodic Adverse Drug Experience Report
PharmD	Doctor of Pharmacy
QA	Quality Assurance
RN	Registered Nurse
SOP	Standard Operating Procedure
WI	Work Instruction

### 6.0 RESPONSIBILITY

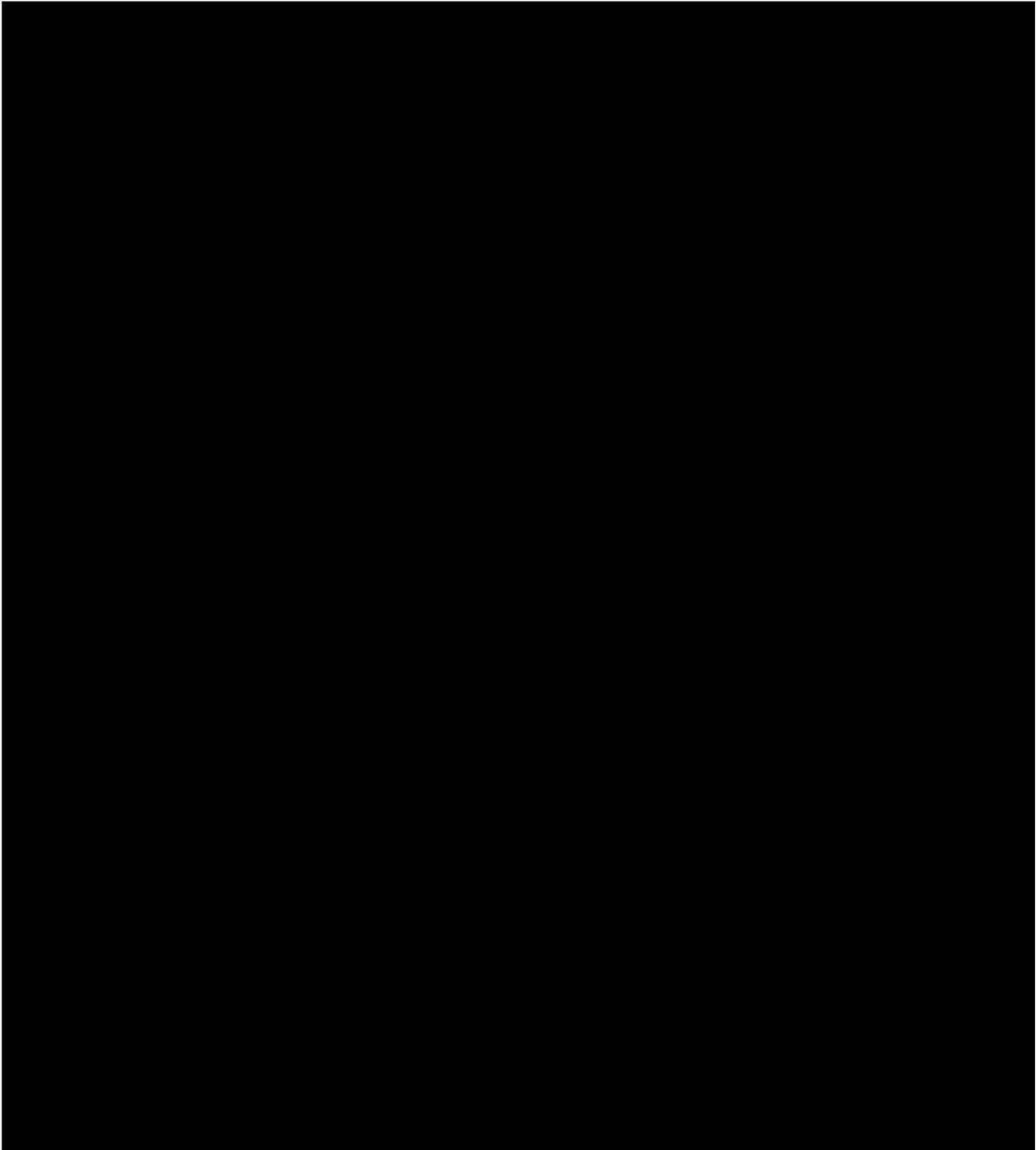
CQCU	Maintain this procedure in accordance with the LSL document and data control system. Overseeing the client responsible for managing LSL product complaints. Managing the reports received from the client.
SafetyCall International	Service Provider/Vendor responsible for the notification of any serious or significant events to LSL.



## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	3 of 10

### 7.0 PROCEDURE

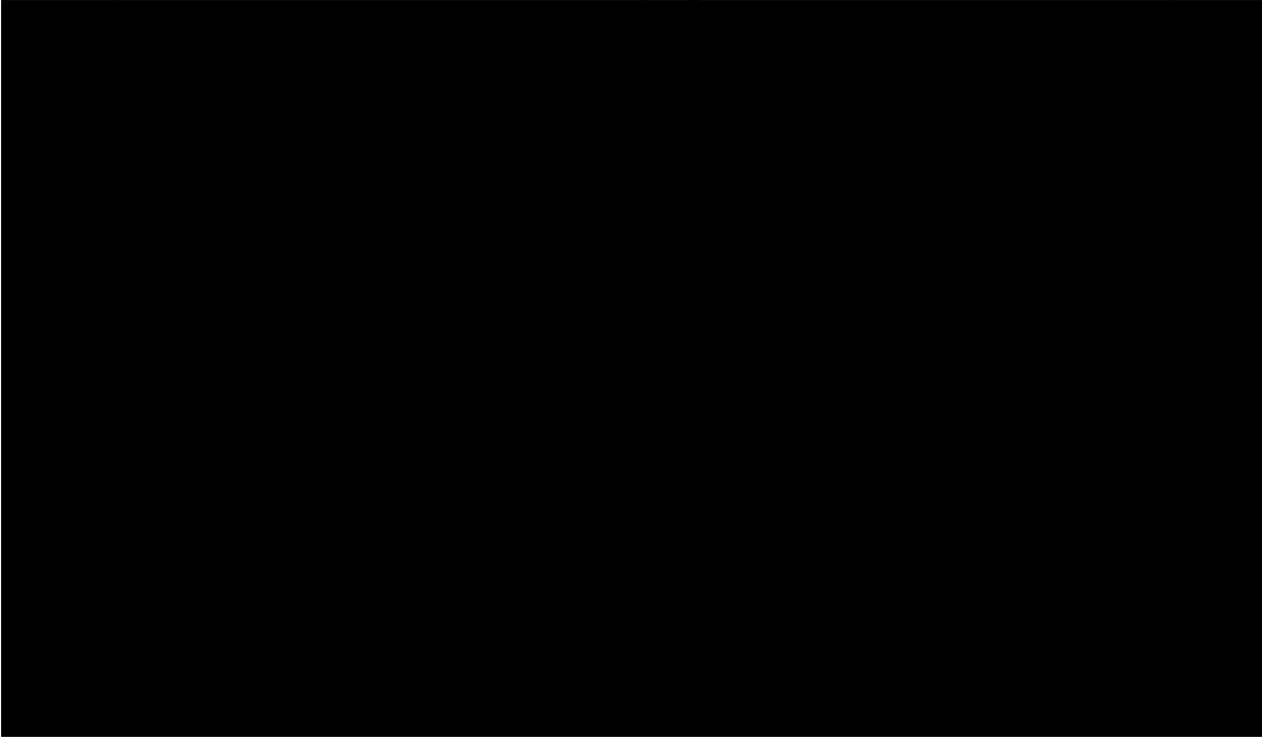


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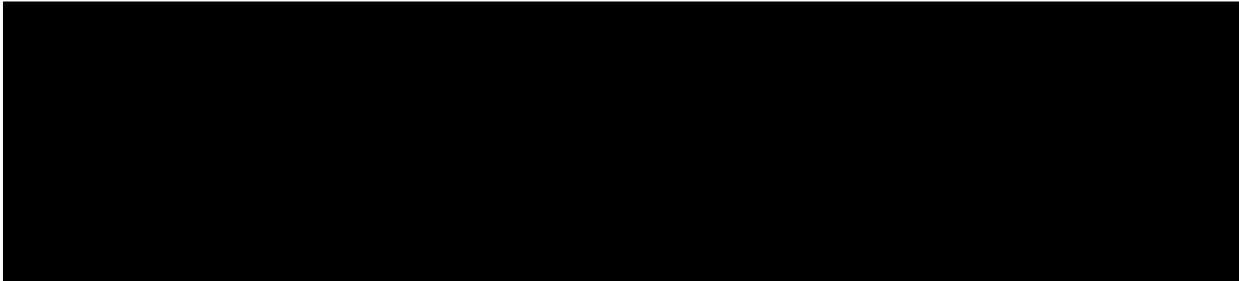


## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	4 of 10



### Complaint Notification and Investigation

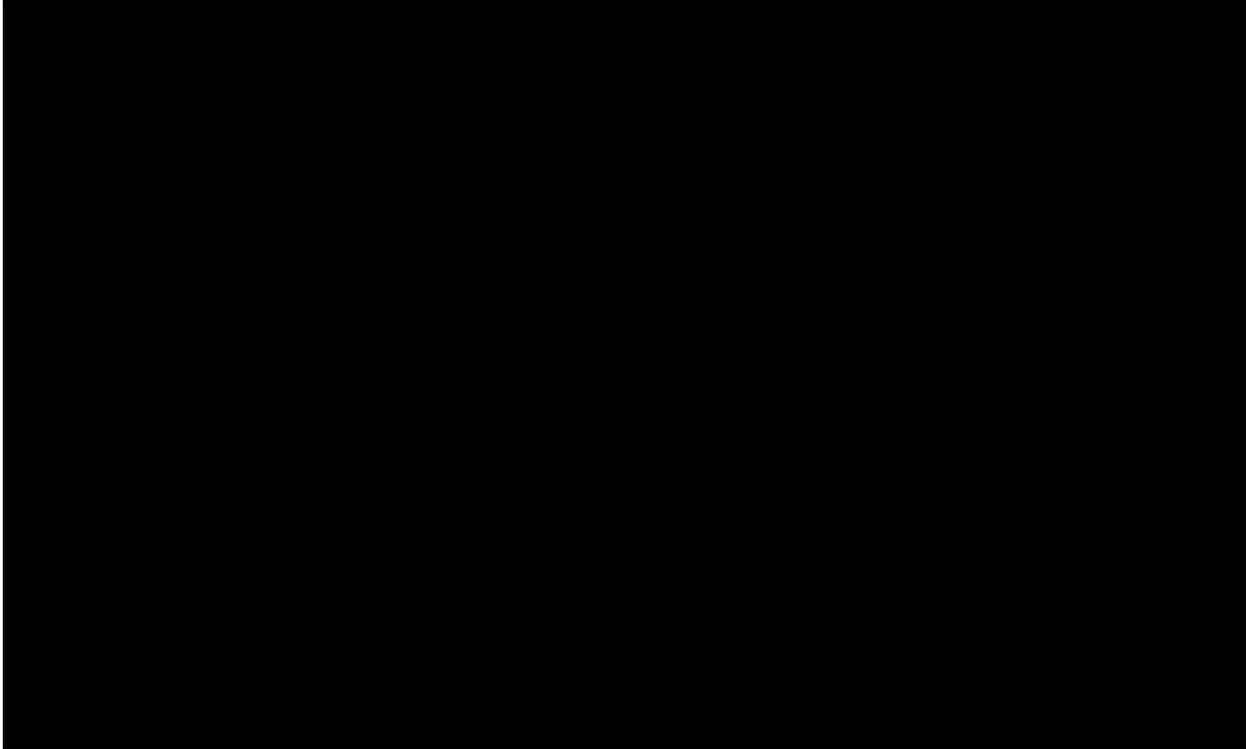


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
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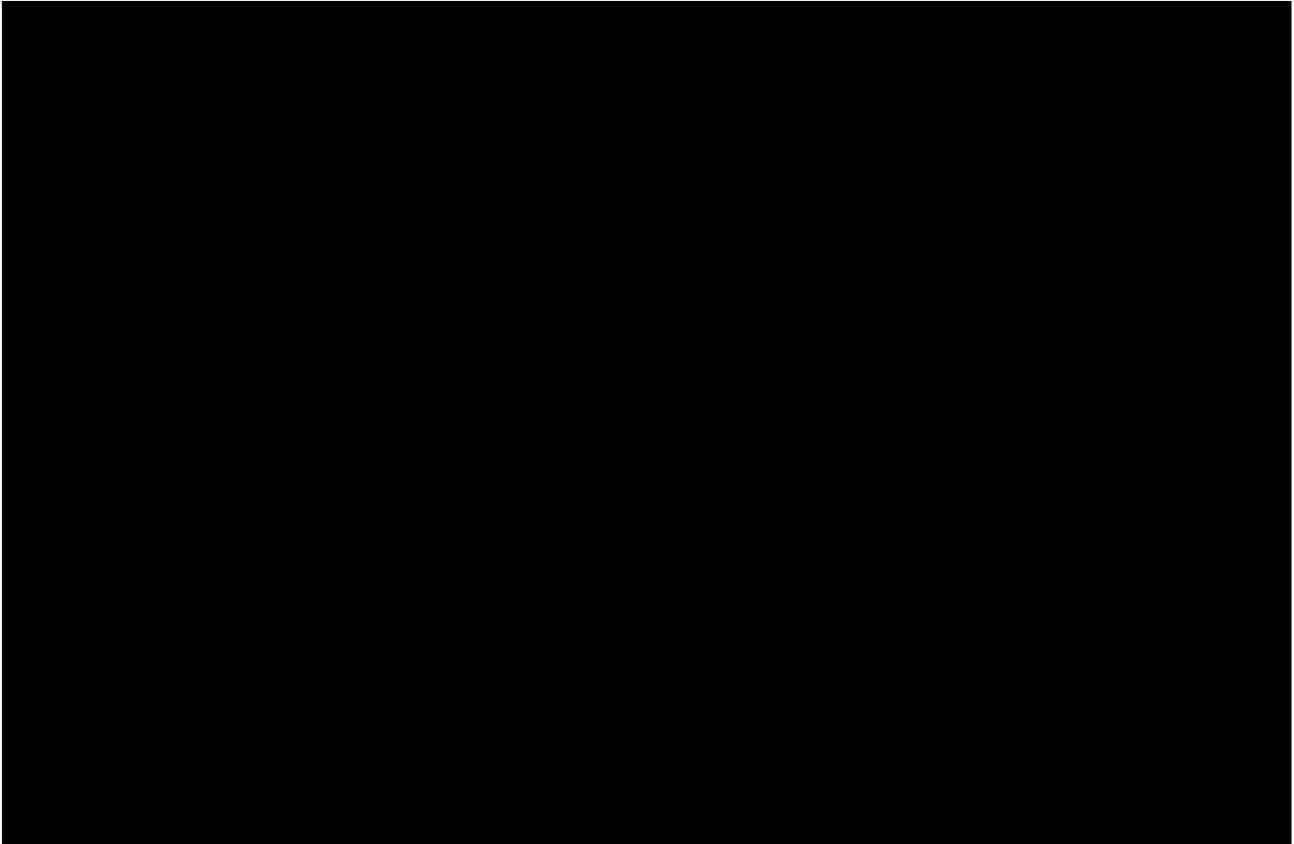


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
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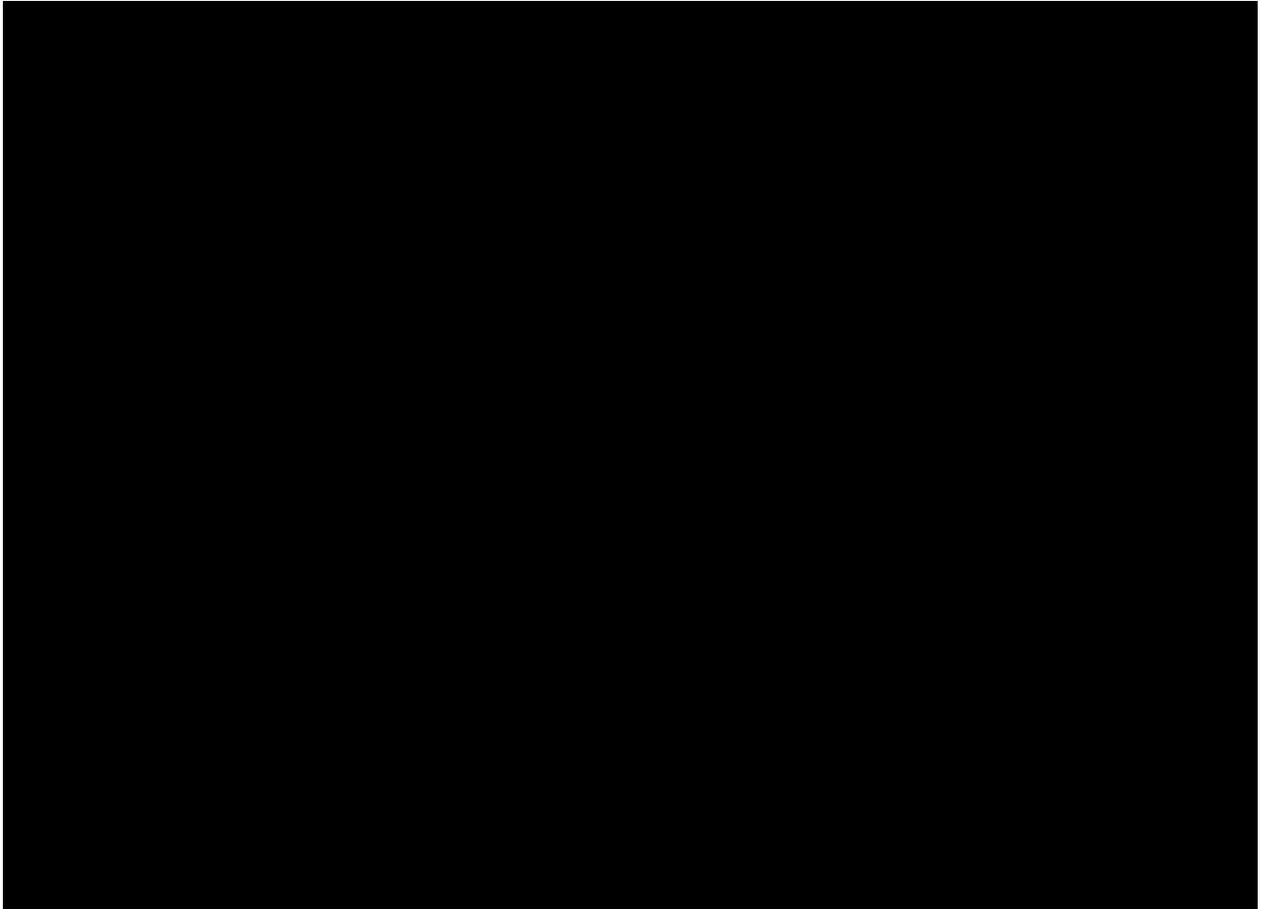


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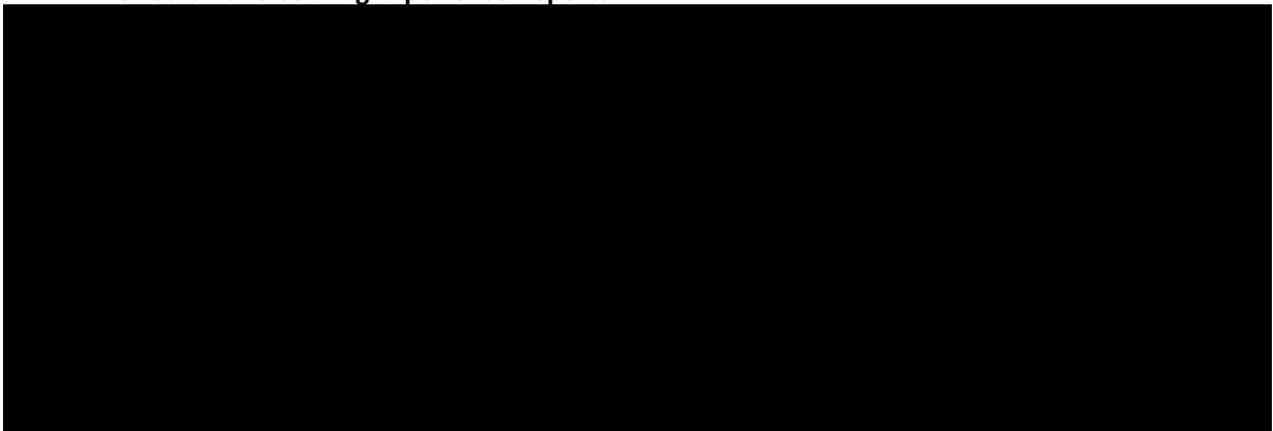


## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	7 of 10



### Periodic Adverse Drug Experience Reports



### Product Complaints Reported Directly to LSL

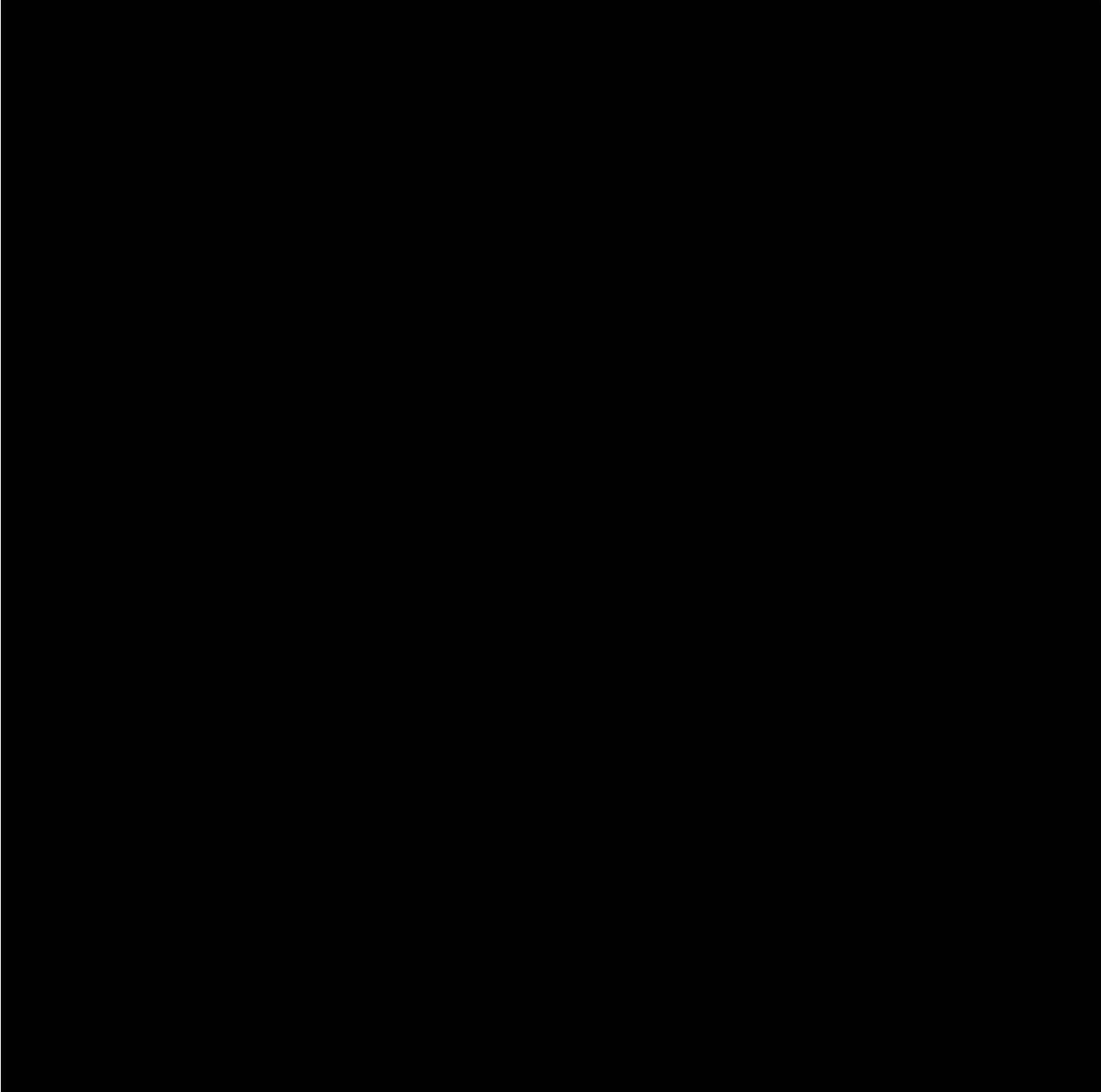


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
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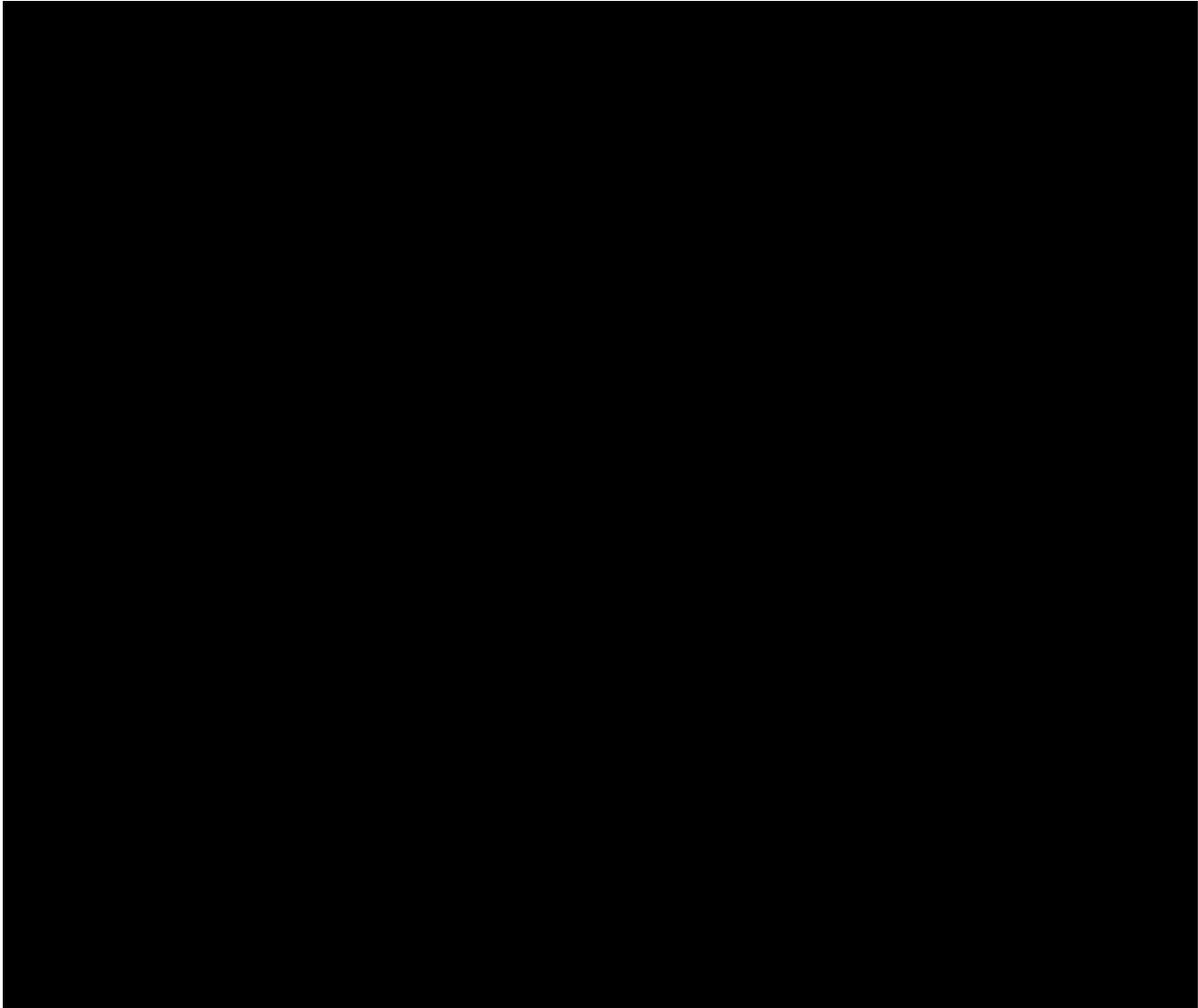


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Pharmacovigilance		
<b>Number:</b>	SOP 7004	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	9 of 10



### 8.0 ADDITIONAL INFORMATION Control of Records



#### **Confidentiality Statement**

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### 9.0 REVISION HISTORY



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 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003
		Page <b>1</b> of <b>11</b>

<b>Issued by: Quality Assurance</b>
Note: Controlled Copies are identified in SOP footer.

Prepared by:	Name:	Signature/Date: Refer to QT-9 QMS
Reviewed by:	Name:	Signature/Date: Refer to QT-9 QMS
Approved by:	Name:	Signature/Date Refer to QT-9 QMS

### 1.0 Purpose

To describe a procedure for the management of receipt of prescription drug products and communications related to the FDA’s Section 804 Importation Program (SIP) that are received at/by Methapharm Inc. (Methapharm).

### 2.0 Scope

- 2.1 This procedure applies to the receipt of incoming prescription drug products (hereinafter referred to as ‘Goods’ received at Methapharm for subsequent export under the FDA’s Section 804 Importation Program (SIP).
- 2.2 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

- QS-015 – Deviations and Non-conformances
- 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

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations SOP Number: AD-206.003
	Effective Date: TBD	Page <b>2</b> of <b>11</b>

## 5.0 Forms/Attachments

AD-206-1 – Stock Receipt – SIP Product

## 6.0 Definitions

- 6.1 Regulatory 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.

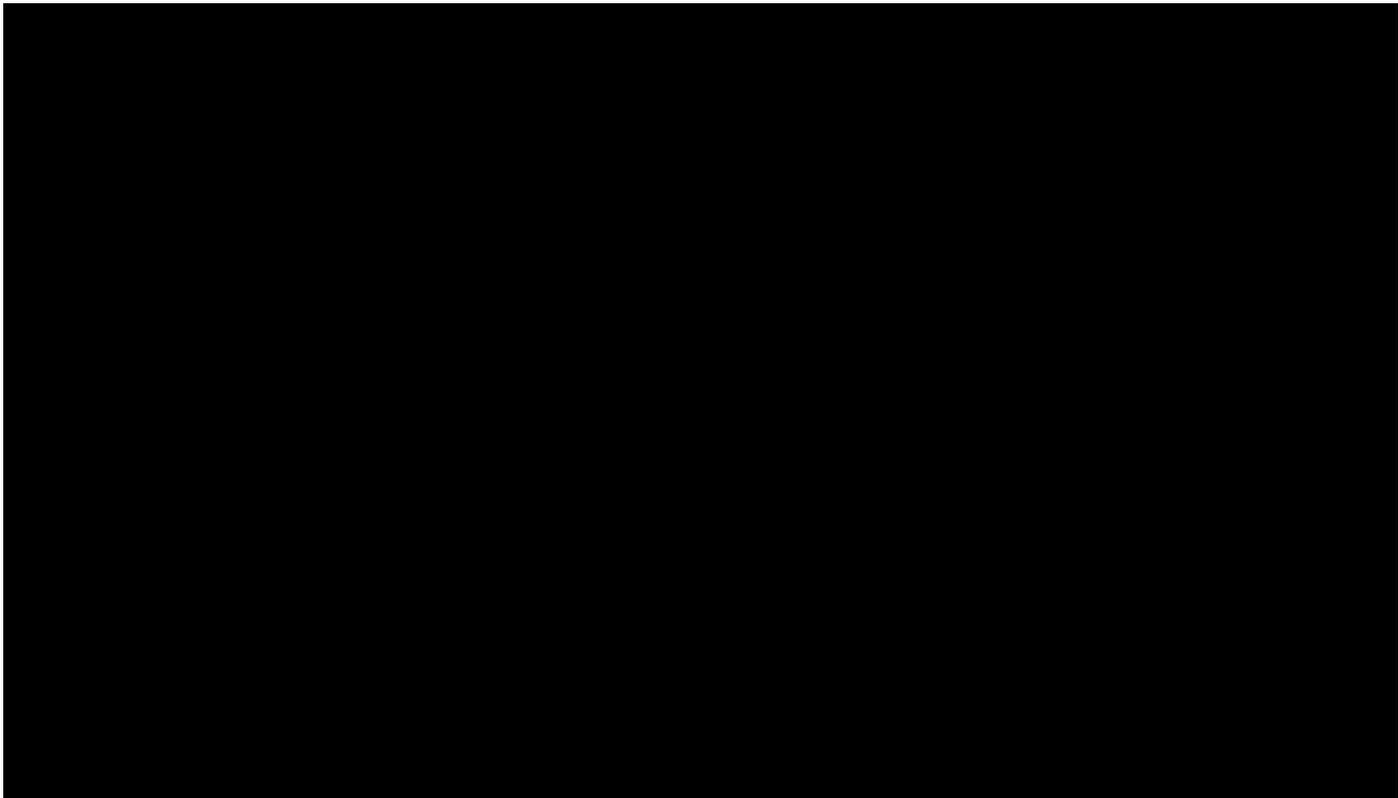
## 7.0 Procedure

### 7.1 Receiving Goods at Methapharm

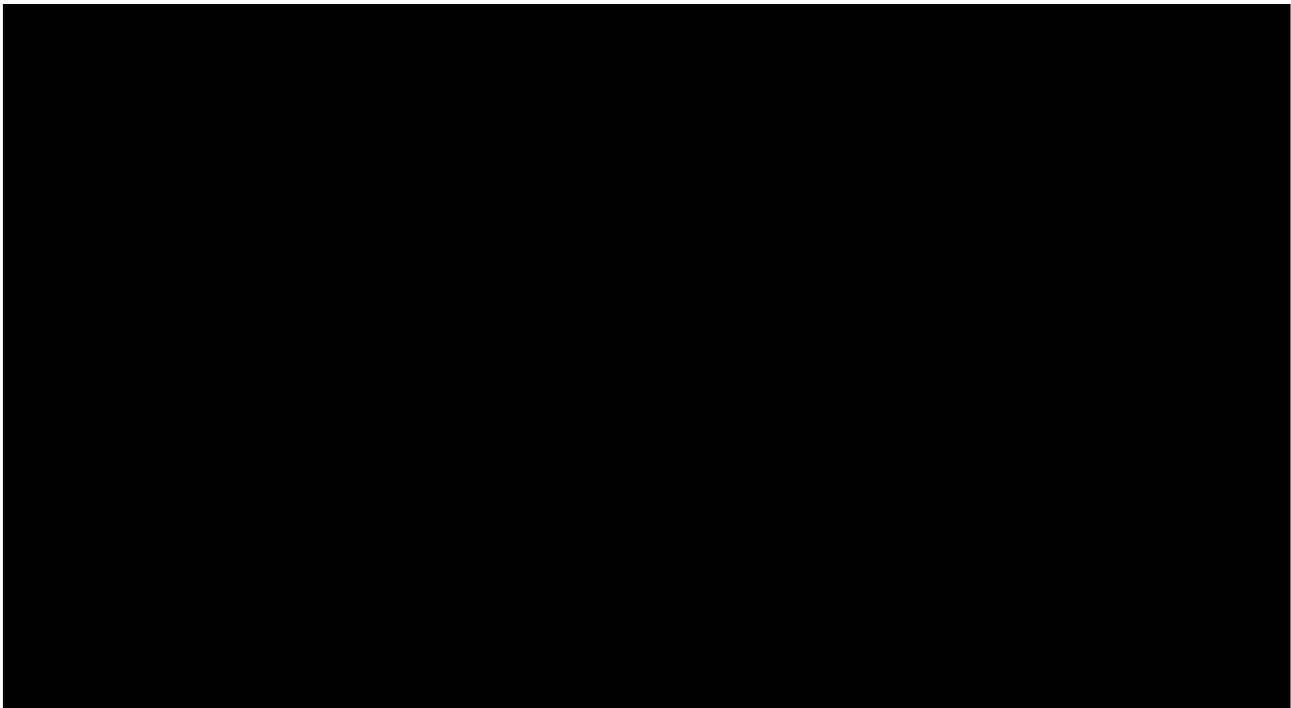


Confidential Trade Secrets

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>3</b> of <b>11</b>

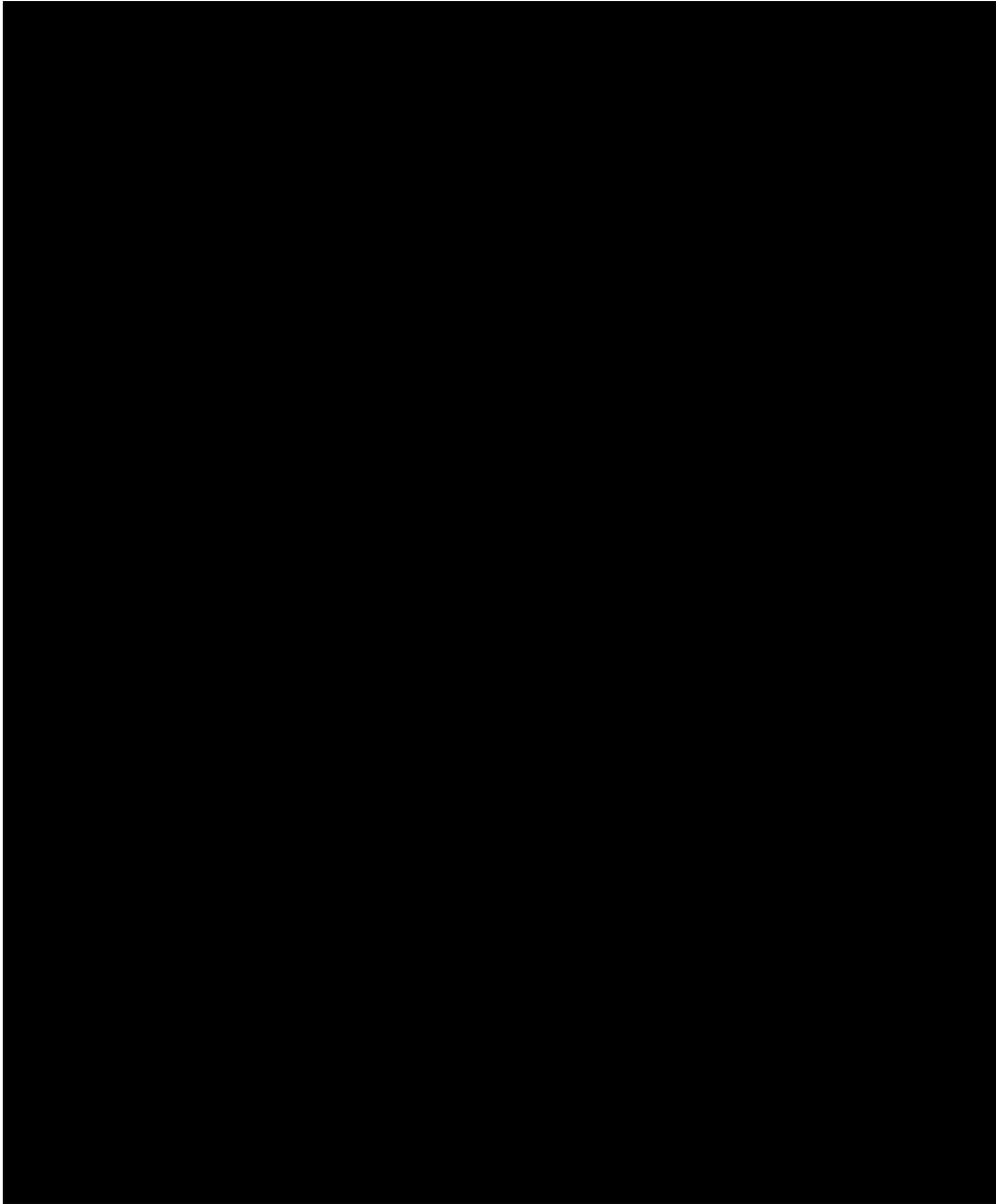


**7.1.2 Inspection (Operations Personnel)**



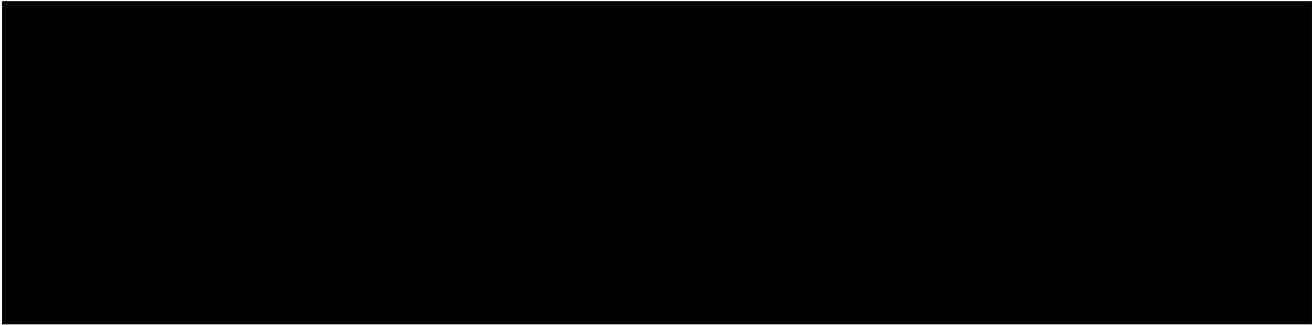
**Confidential Trade Secrets**

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>4</b> of <b>11</b>

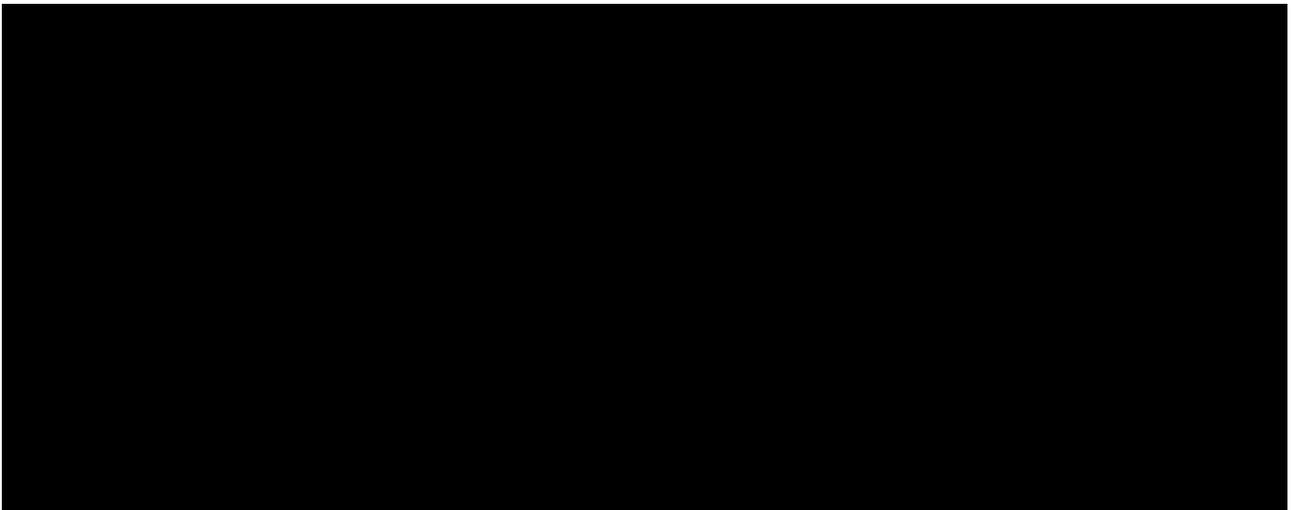
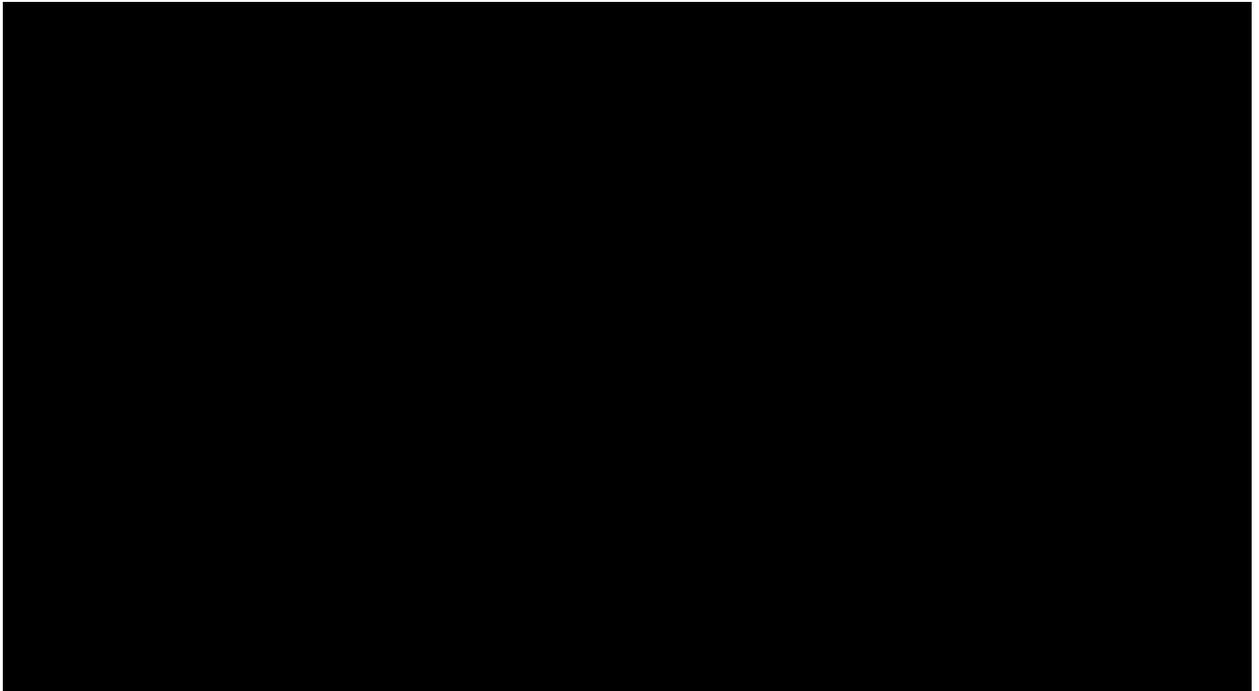


**Confidential Trade Secrets**

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>5</b> of <b>11</b>



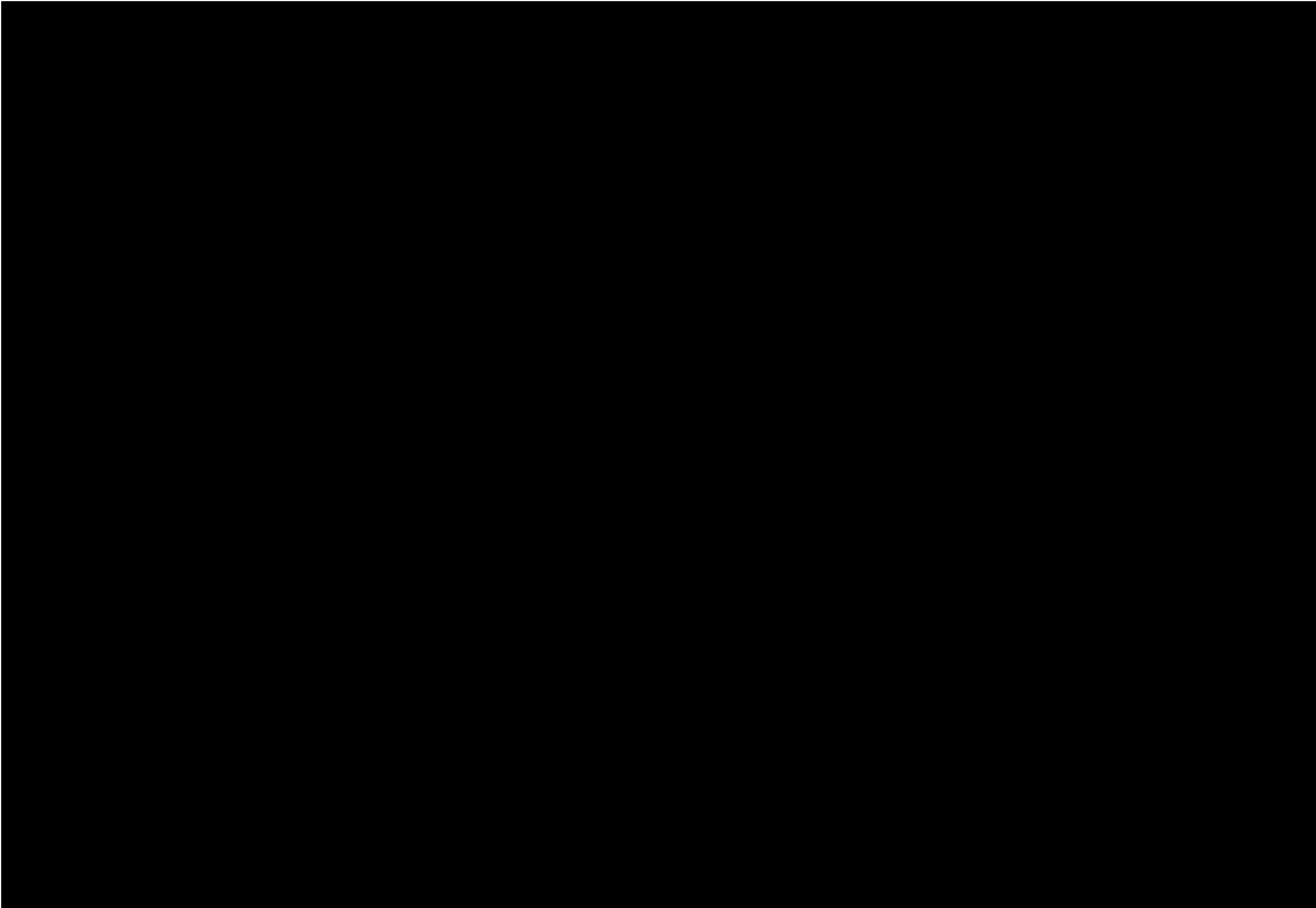
### 7.1.3 QA Verification (Methapharm QA)



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Exempt from disclosure pursuant to Section 119.0715, F.S.

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>6</b> of <b>11</b>

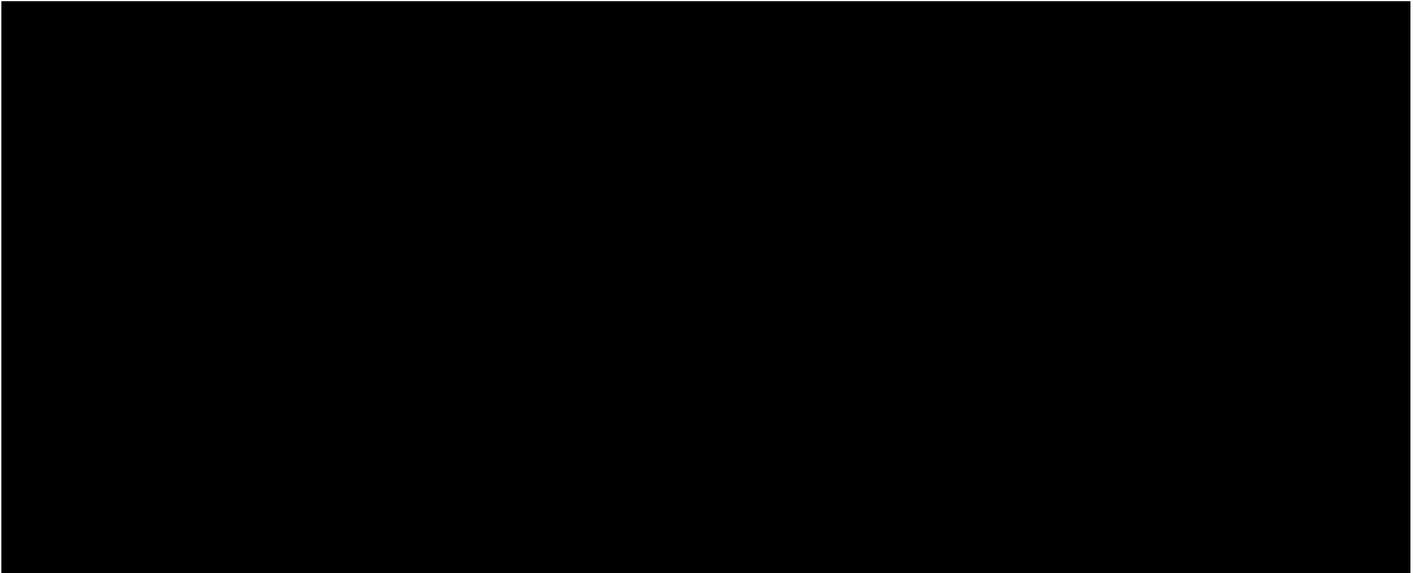


**7.1.5 Movement of Goods (Operations Department)**



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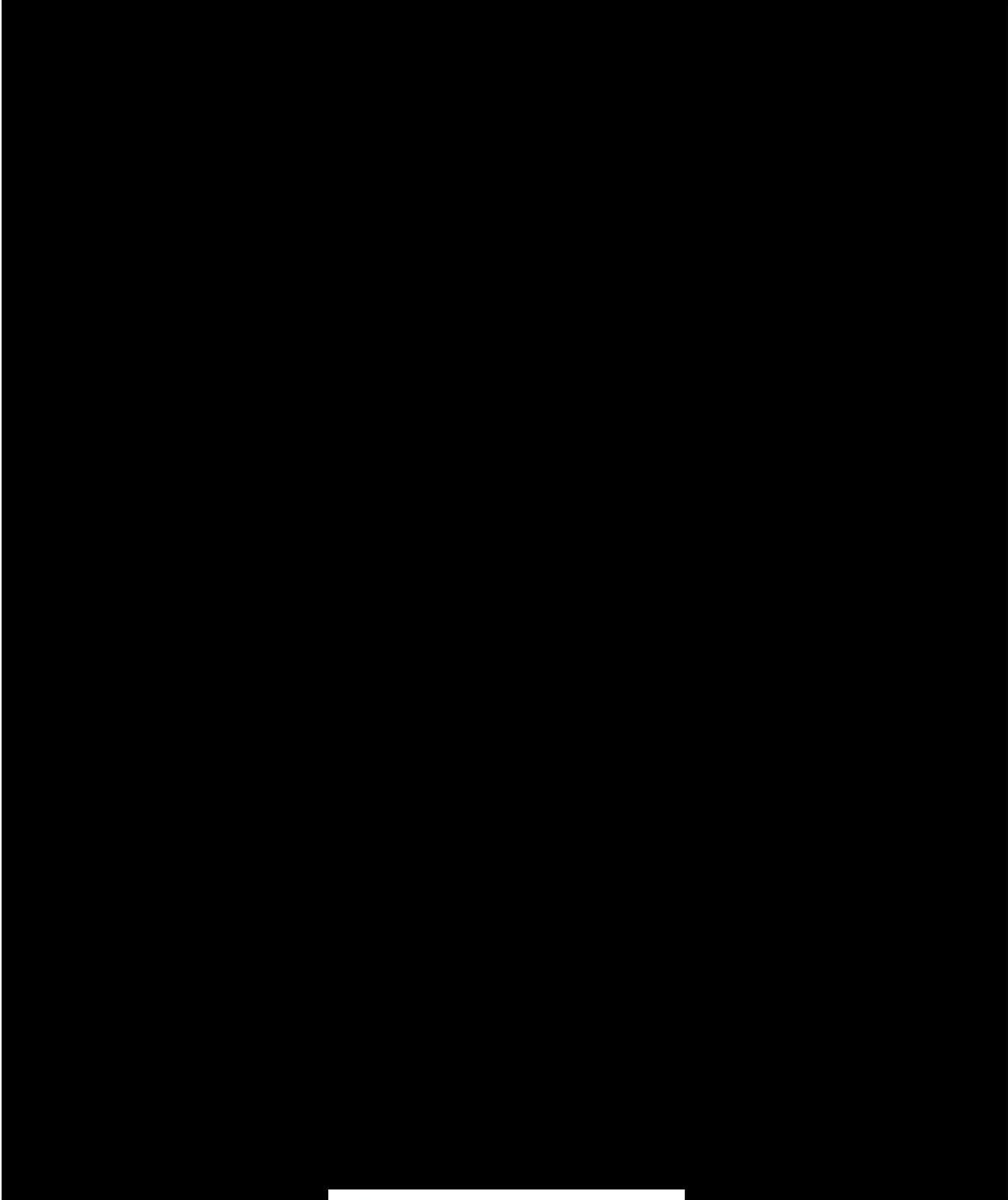
 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>7</b> of <b>11</b>



**Confidential Trade Secrets**

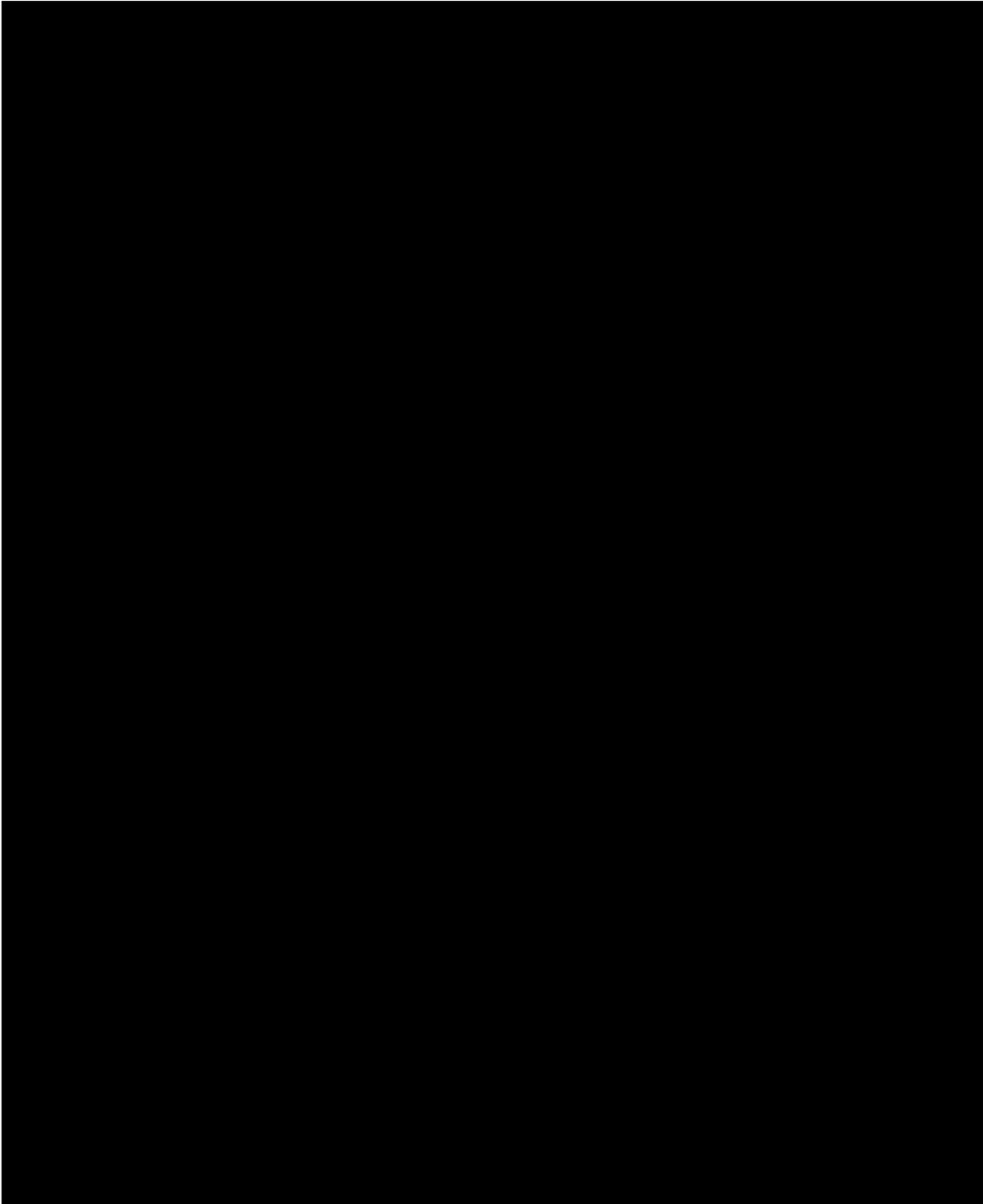
 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>8</b> of <b>11</b>

## 7.2 Investigating and Handling Suspect and Illegitimate Product



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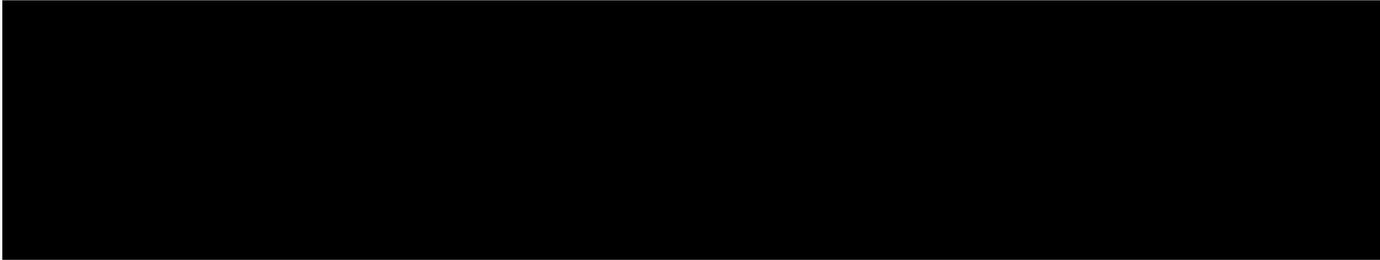
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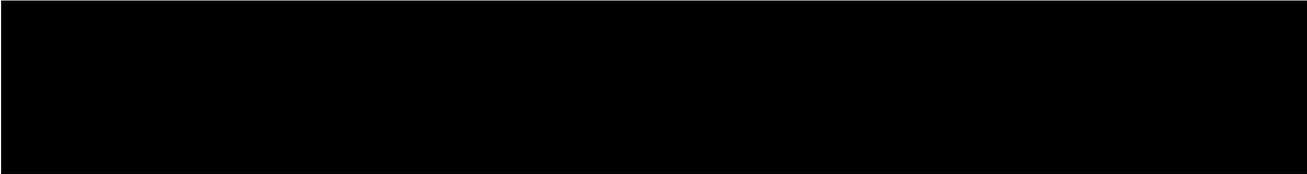
**Confidential Trade Secrets**

Exempt from disclosure pursuant to Section 119.0715, F.S.

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>10</b> of <b>11</b>



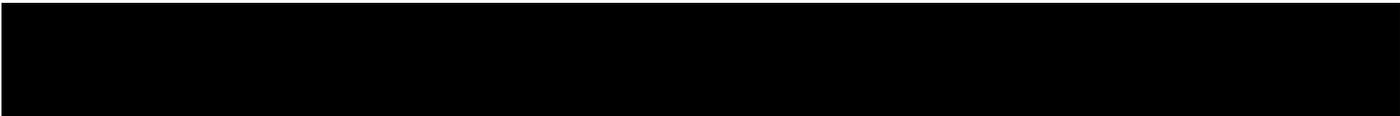
**7.3 Recall**



**7.4 Information Requests**



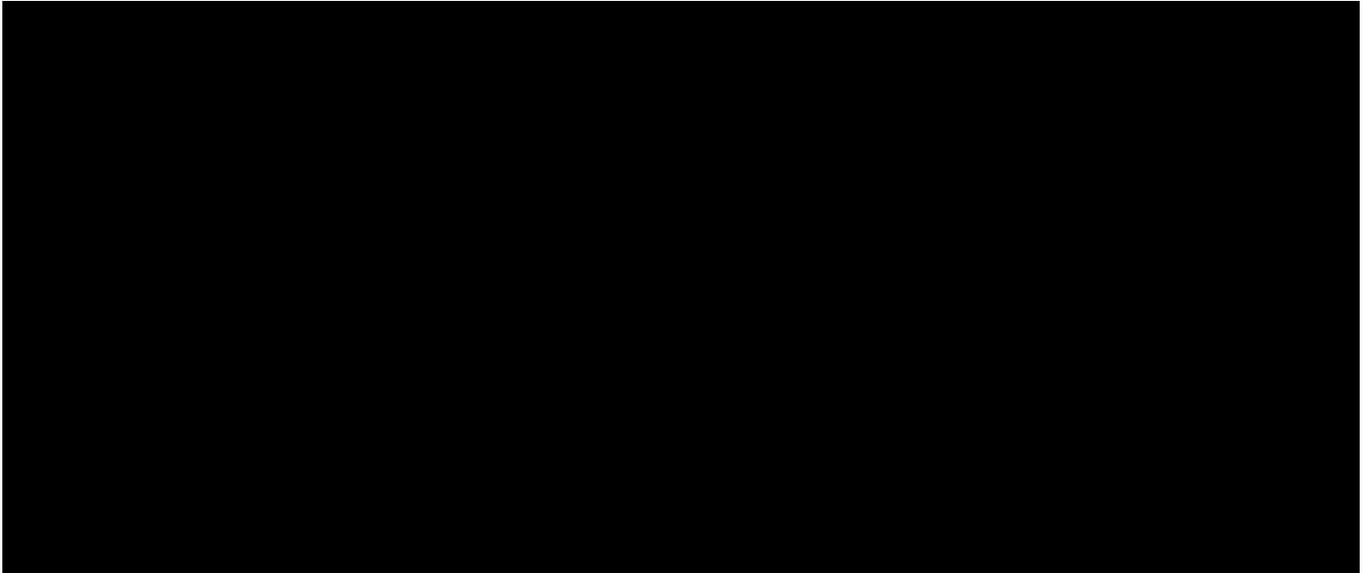
**8.0 Records**



**Confidential Trade Secrets**

 Administrative	Title: <b>Management of SIP Products</b>	Section: Operations
	Effective Date: TBD	SOP Number: AD-206.003 Page <b>11</b> of <b>11</b>

## 9.0 Revision History



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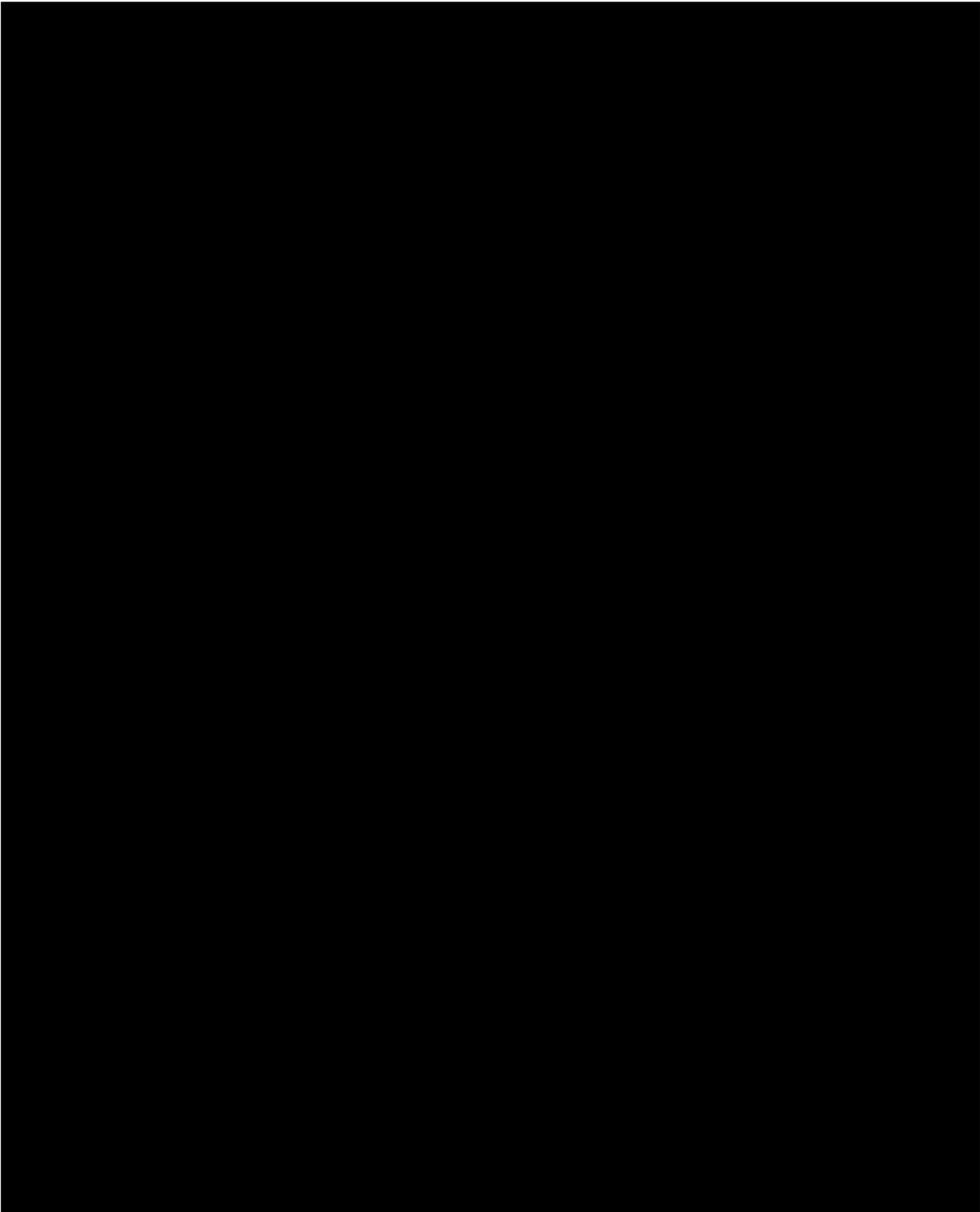


Title: **Stock Receipt – SIP  
Product**

Form AD-206-1.003

Effective Date: **TBD**

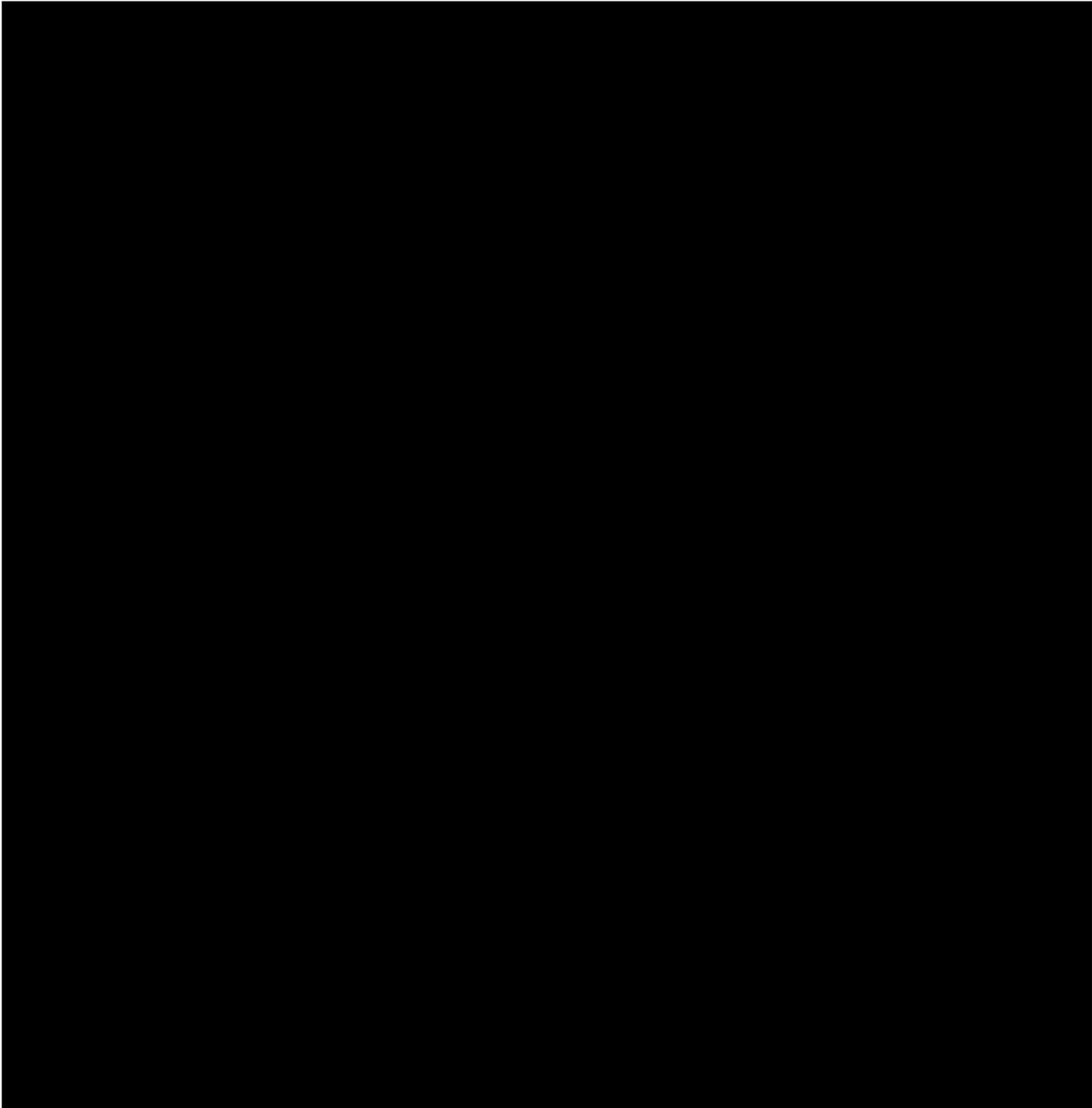
Page **1** of **2**



**Confidential Trade Secrets**

Exempt from disclosure pursuant to Section 119.0715, F.S.

	Title: <b>Stock Receipt – SIP</b> Product	Form AD-206-1.003
	Effective Date: <b>TBD</b>	Page <b>2</b> of <b>2</b>



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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	1 of 11

### 1.0 PURPOSE

This procedure details the process for procuring new SIP products for sale by LifeScience Logistics.

### 2.0 SCOPE

This procedure applies to all LSL Wholesaler locations participating in the Section 804 Importation Program purchasing the imported prescription drugs from the foreign seller.

### 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
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
SOP 1031	Vendor Qualification
SOP 1101	Control of Records
SOP 1502	Vendor Quality Auditing
SOP 7002	Import/Export – RX
WI 600.05	Prescription Drug Receiving

### 4.0 DEFINITIONS

Prescription Drug	A drug that is prescribe by a doctor, bought at a pharmacy, and regulated by the FDA through the New Drug Application (NDA) or Abbreviated New Drug Application process.
-------------------	--

### 5.0 ABBREVIATIONS/ACRONYMS

ANDA	Abbreviated New Drug Application
API	Active Pharmaceutical Ingredient
CEO	Chief Executive Officer
CFR	Code of Federal Regulation
CQCU	Corporate Quality Control Unit
DIN	Drug Identification Number
FDA	Food and Drug Administration
HPFB	Health Products and Food Branch (Health Canada)
LSL	LifeScience Logistics
NDA	New Drug Application
NDC	National Drug Code
QA	Quality Assurance
SIP	Section 804 Importation Program



## LifeScience Logistics

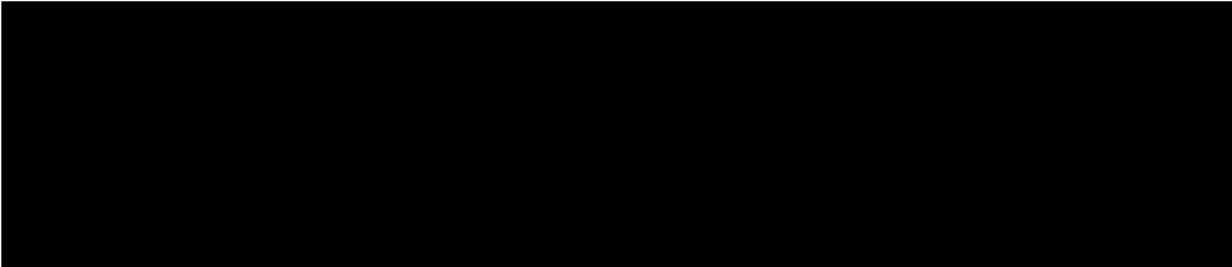
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<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	2 of 11

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



SIP Proposal



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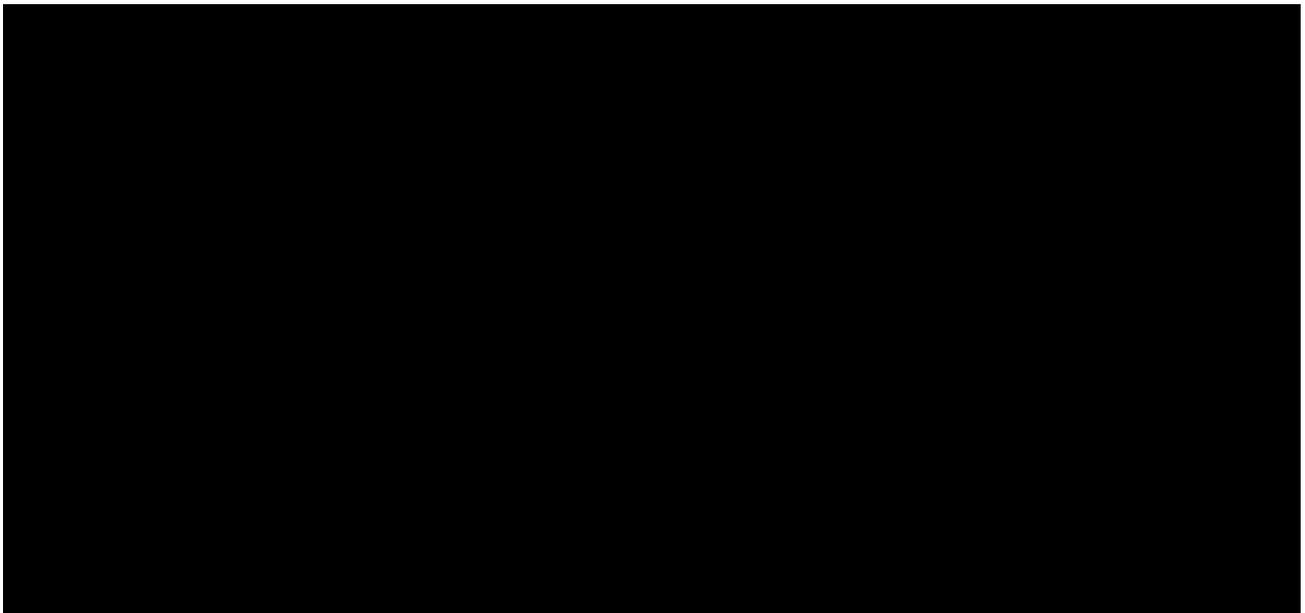


## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	3 of 11



### Importation Plan

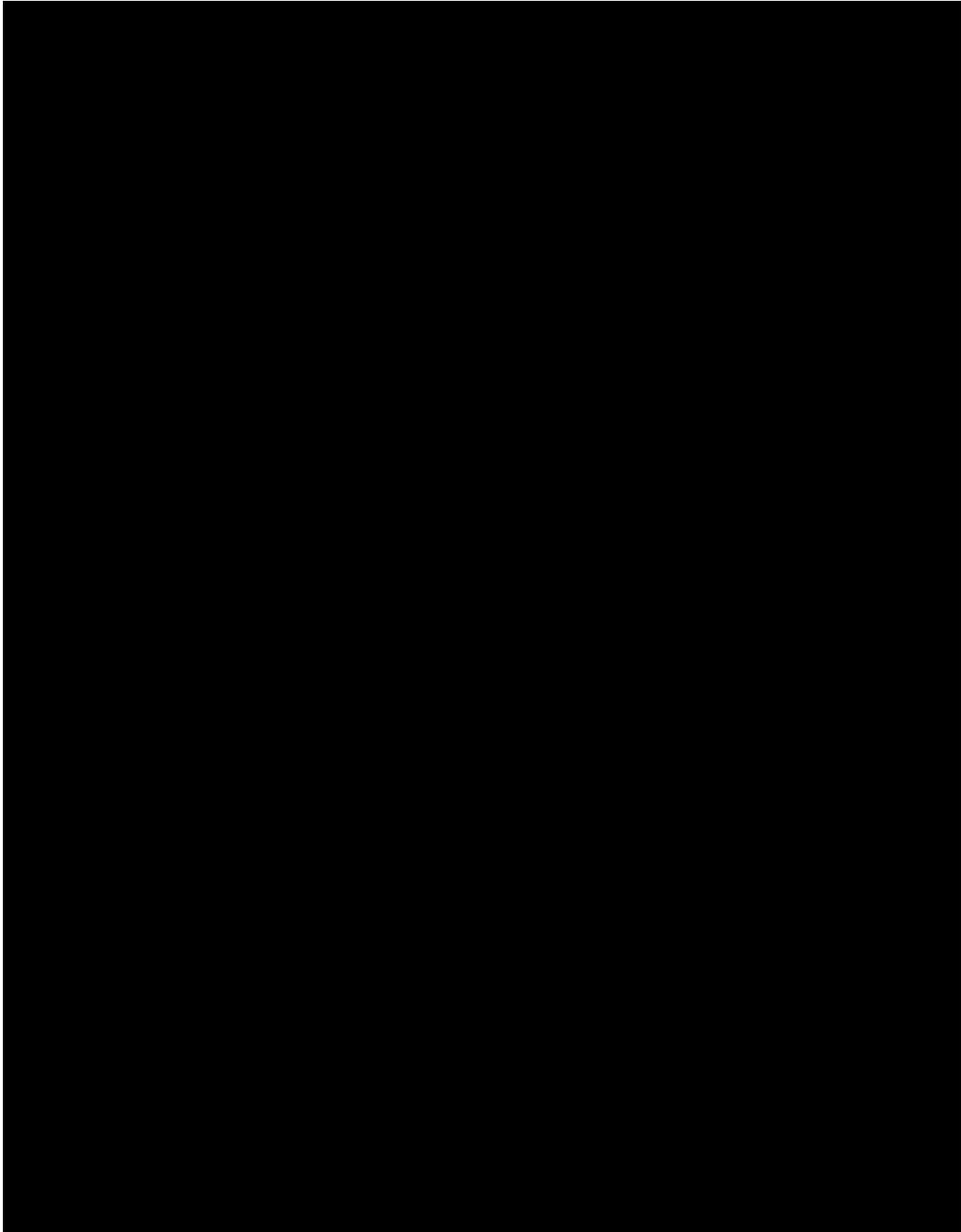


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
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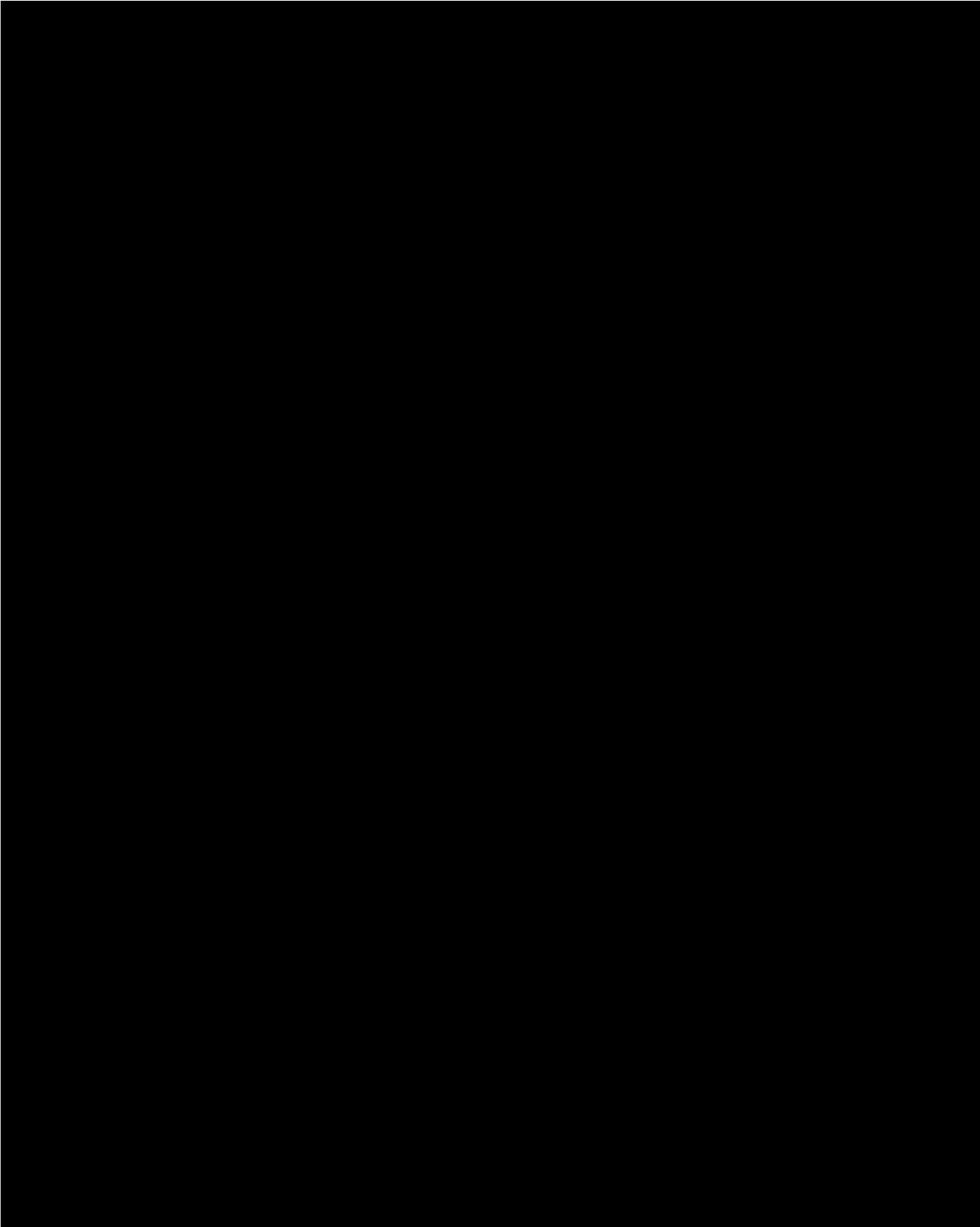


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	5 of 11

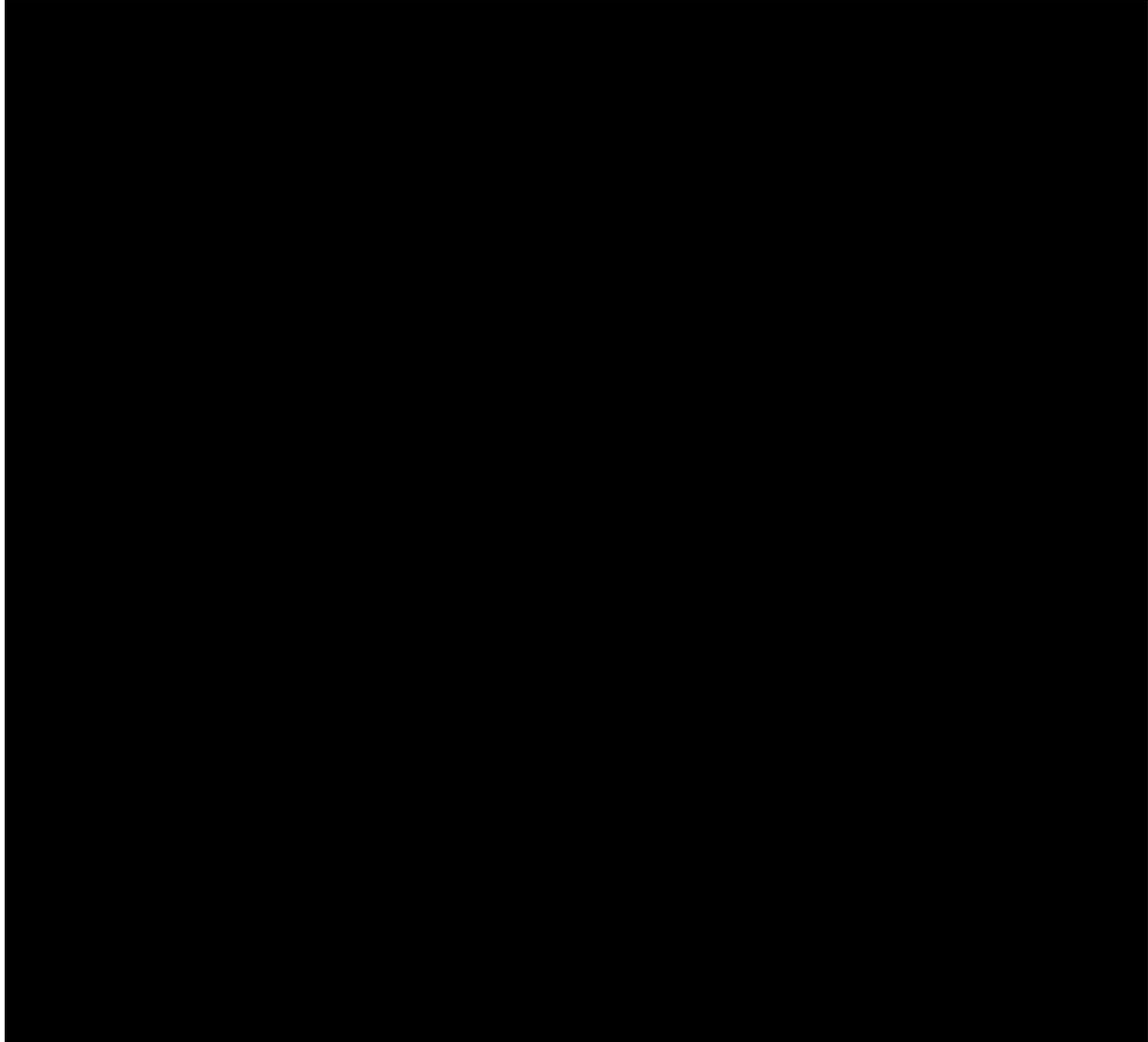


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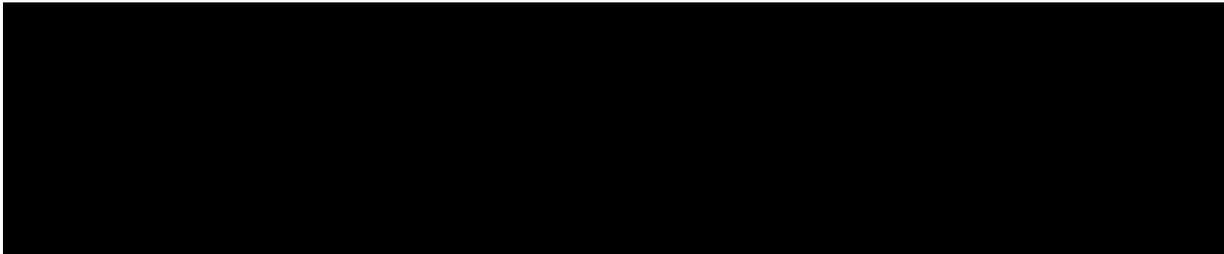


## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	6 of 11



**Pre-Import Request**

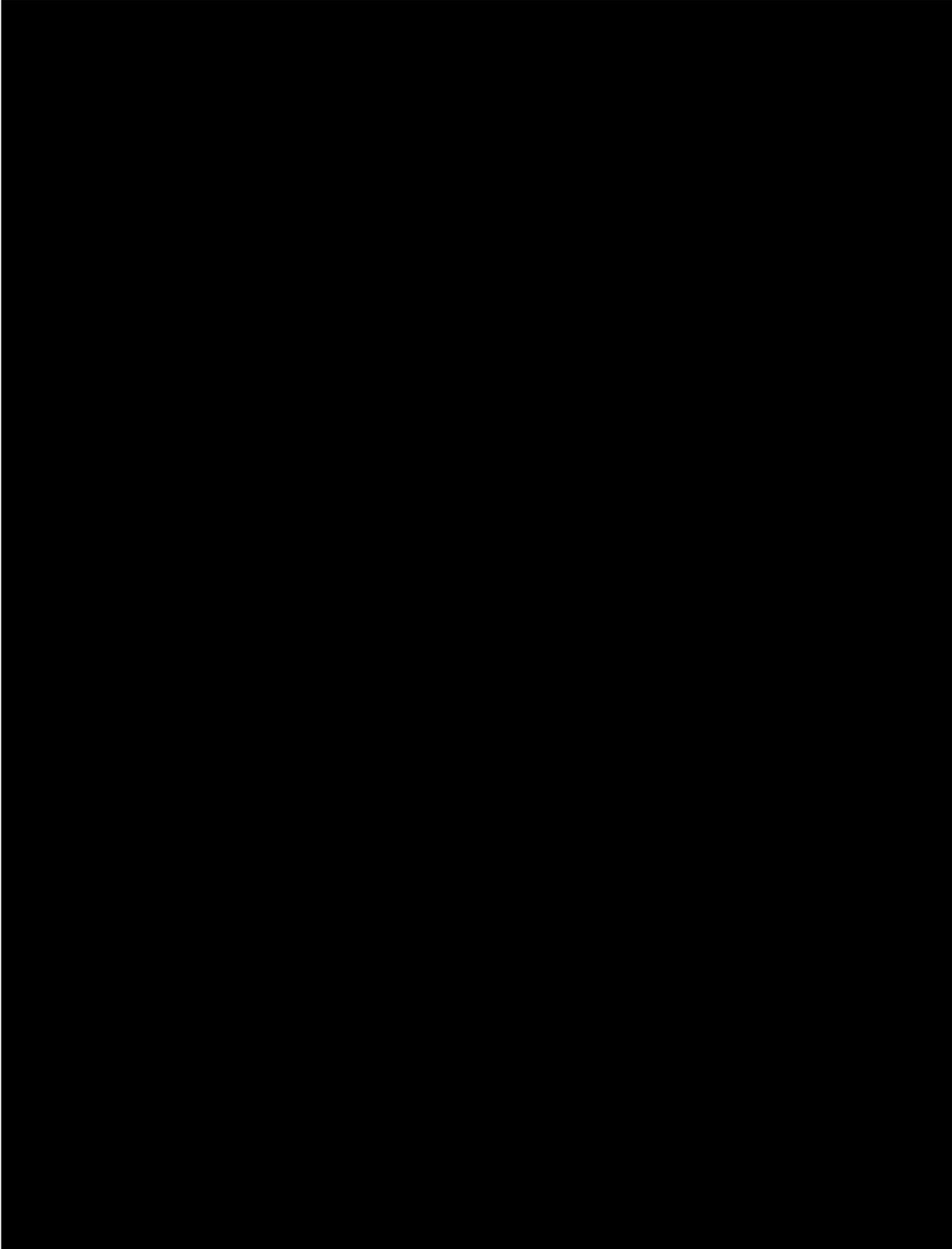


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
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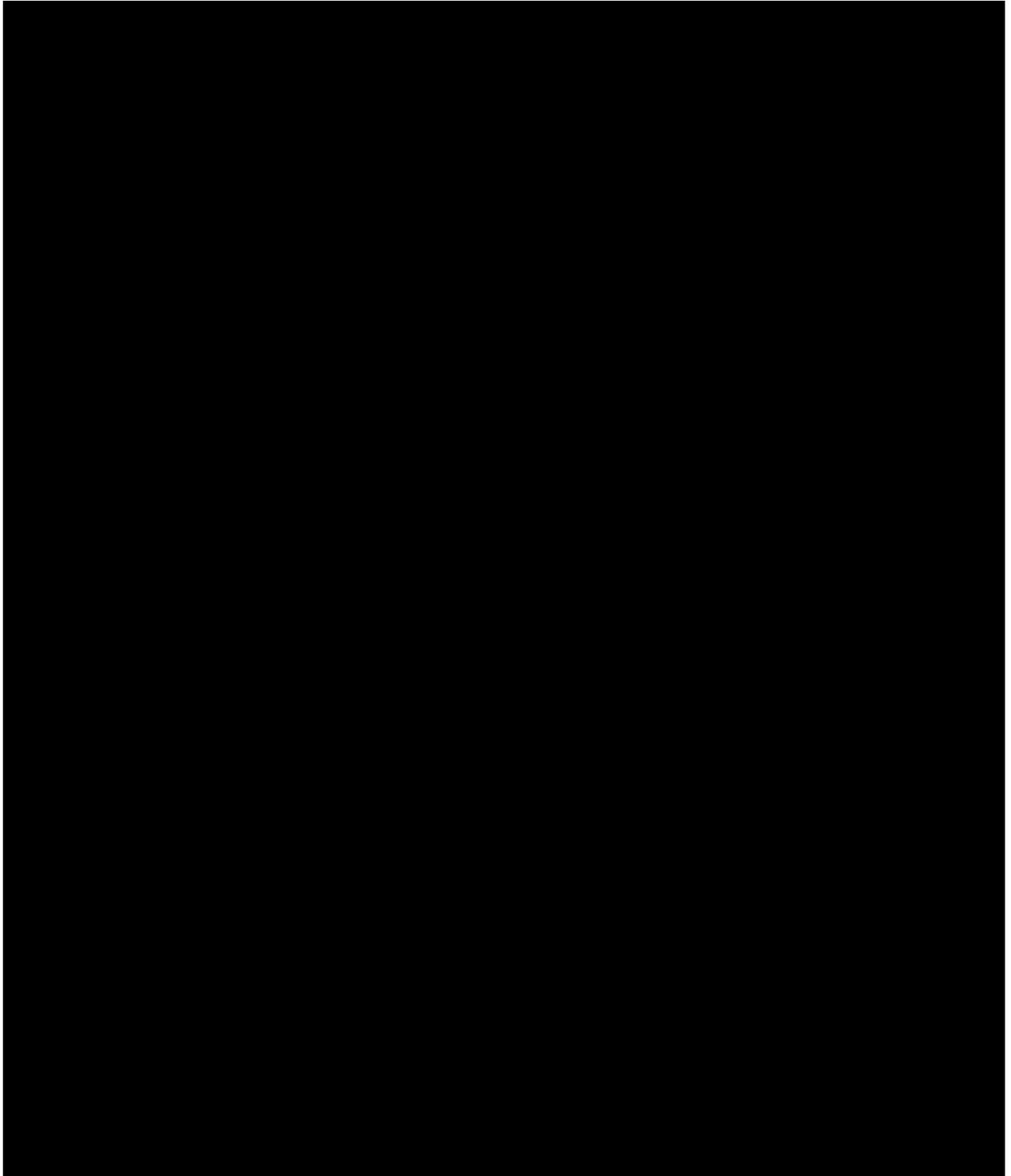


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
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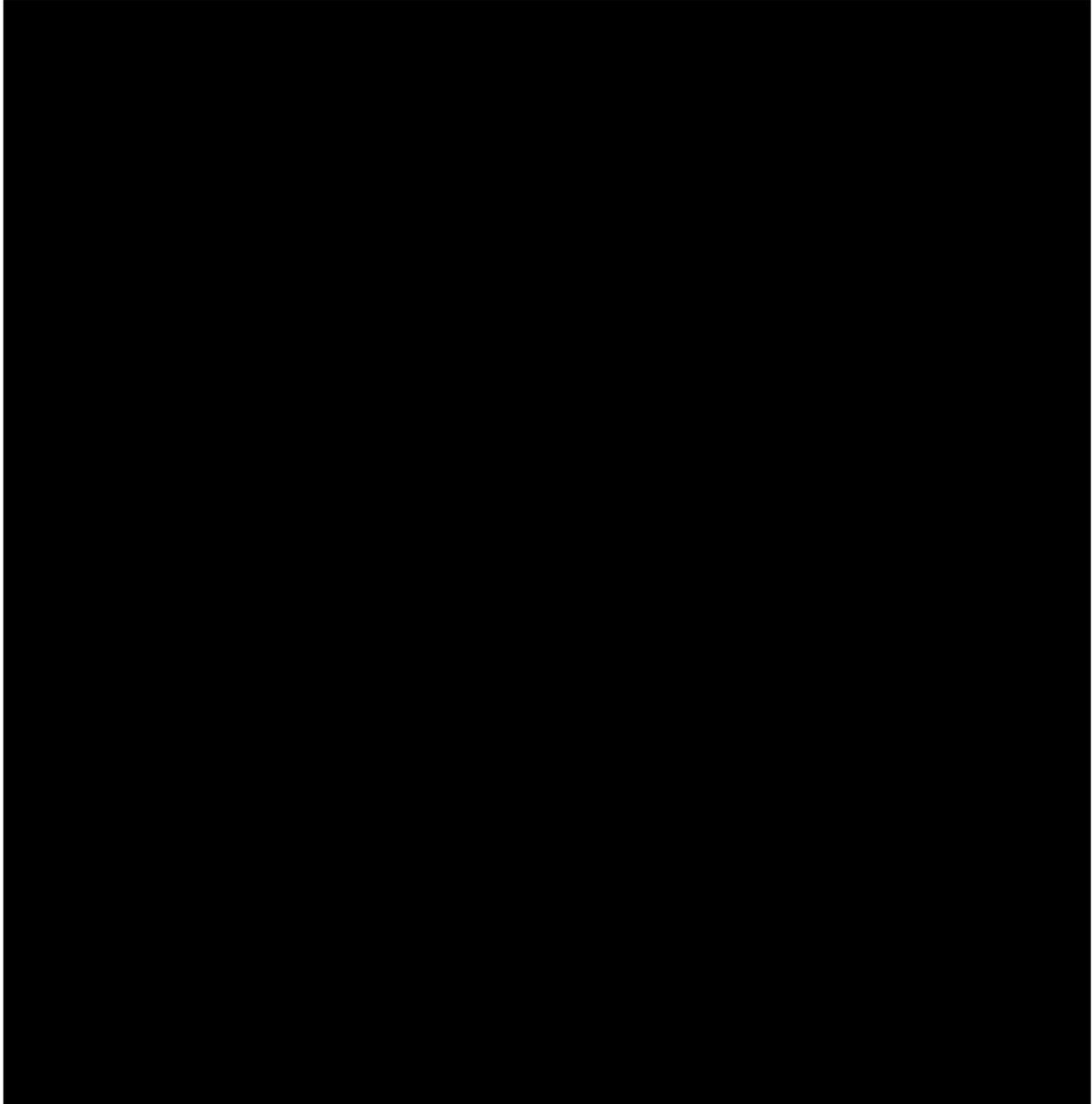


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## LifeScience Logistics

<b>Title:</b>	Prescription Drug Procurement		
<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
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## LifeScience Logistics

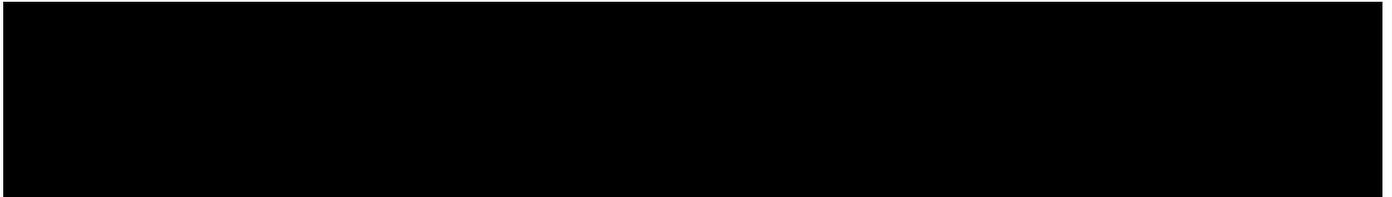
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<b>Number:</b>	WI 600.01	<b>Rev. Date:</b>	13 MAY 2021
<b>Rev. Level:</b>	000	<b>Page:</b>	10 of 11

### 8.0 ADDITIONAL INFORMATION Control of Records



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## LifeScience Logistics

<b>Title:</b>	Prescription Drug DSCSA Track/Trace	
<b>Number:</b>	WI 600.03	<b>Rev. Date:</b> 20-Oct-23
<b>Rev. Level:</b>	002	

### 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 Data (2D Barcode)	A set of information that includes a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier, the standardized numerical identifier, lot number, and expiration date of the product.



## LifeScience Logistics

**Title:** Prescription Drug DSCSA Track/Trace

**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002

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.
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.
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## LifeScience Logistics

**Title:** Prescription Drug DSCSA Track/Trace

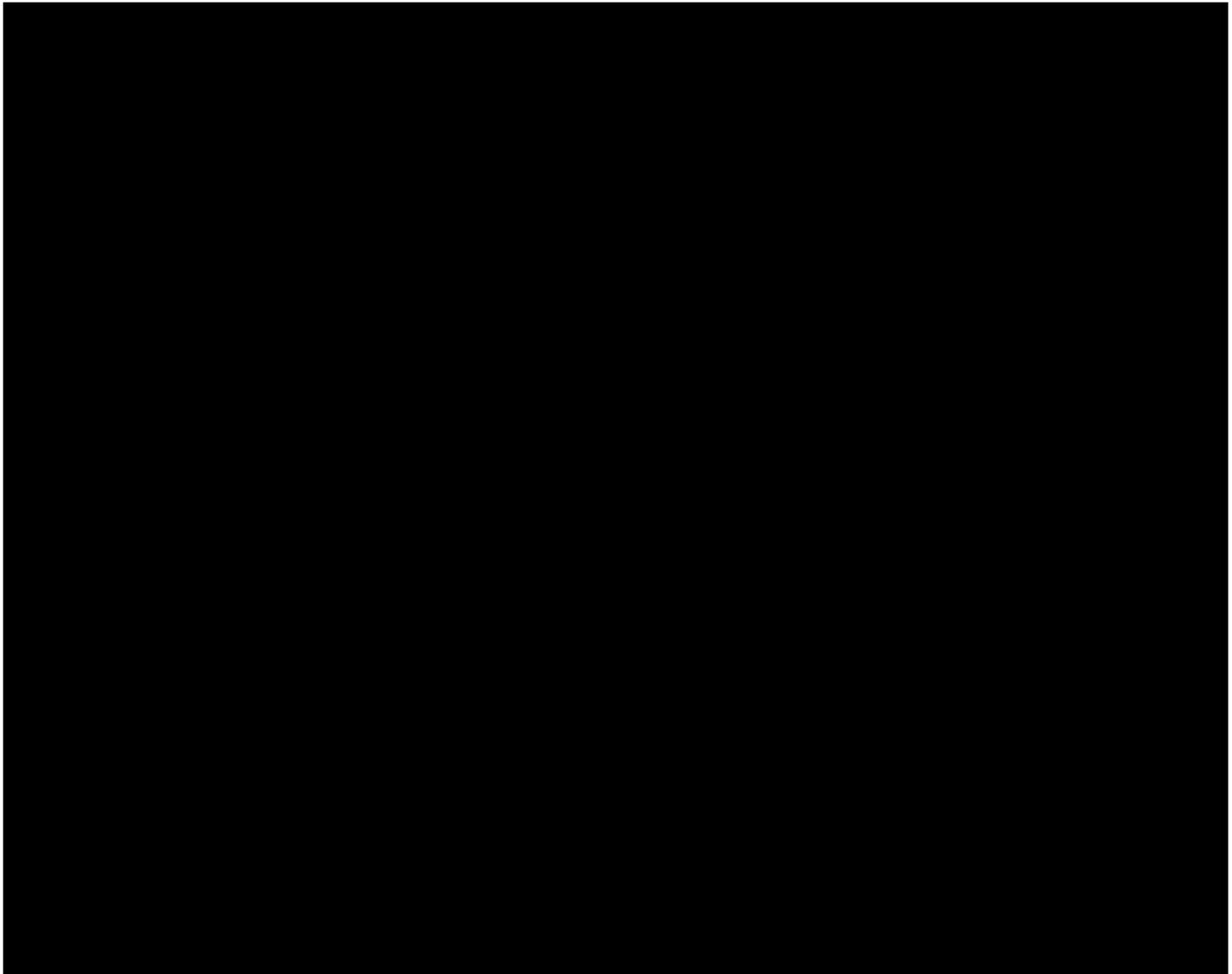
**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002

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





## LifeScience Logistics

**Title:** Prescription Drug DSCSA Track/Trace

**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002

### Receiving Drug Product from the Foreign Seller



## LifeScience Logistics

**Title:** Prescription Drug DSCSA Track/Trace

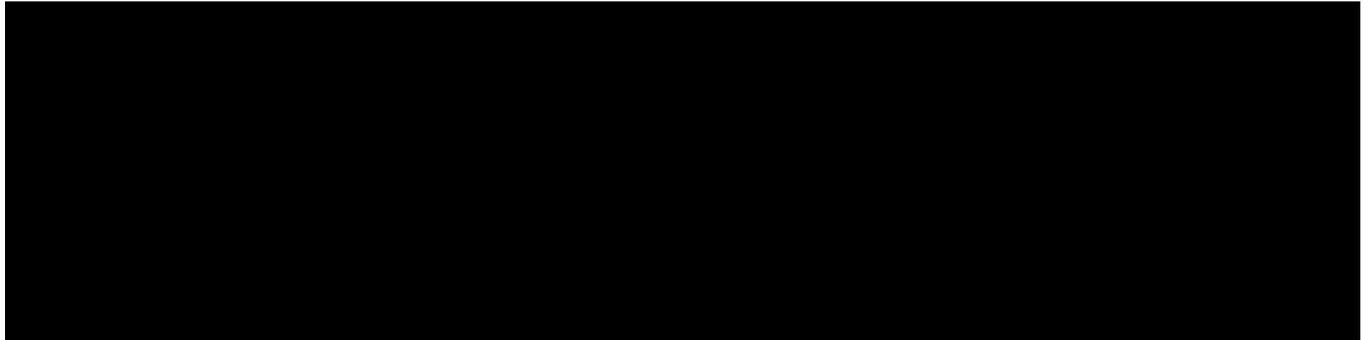
**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002



**Vendor Re-labelling**





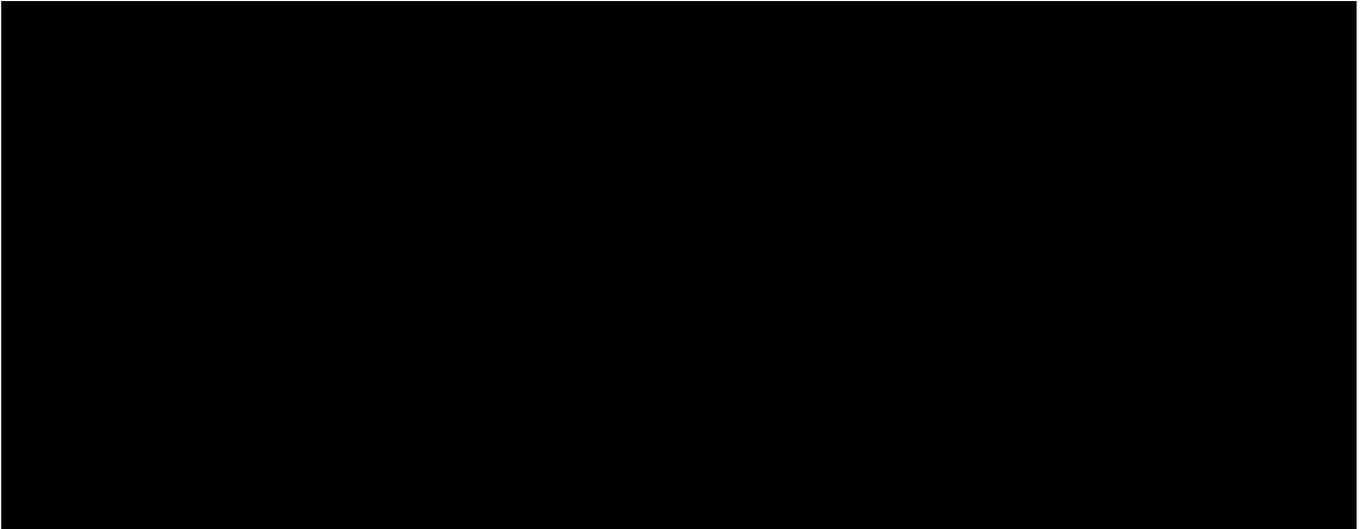
## LifeScience Logistics

<b>Title:</b>	Prescription Drug DSCSA Track/Trace		
<b>Number:</b>	WI 600.03	<b>Rev. Date:</b>	20-Oct-23
<b>Rev. Level:</b>	002		

### Re-labelled and Reserialized Product



### DSCSA Verification Requirements





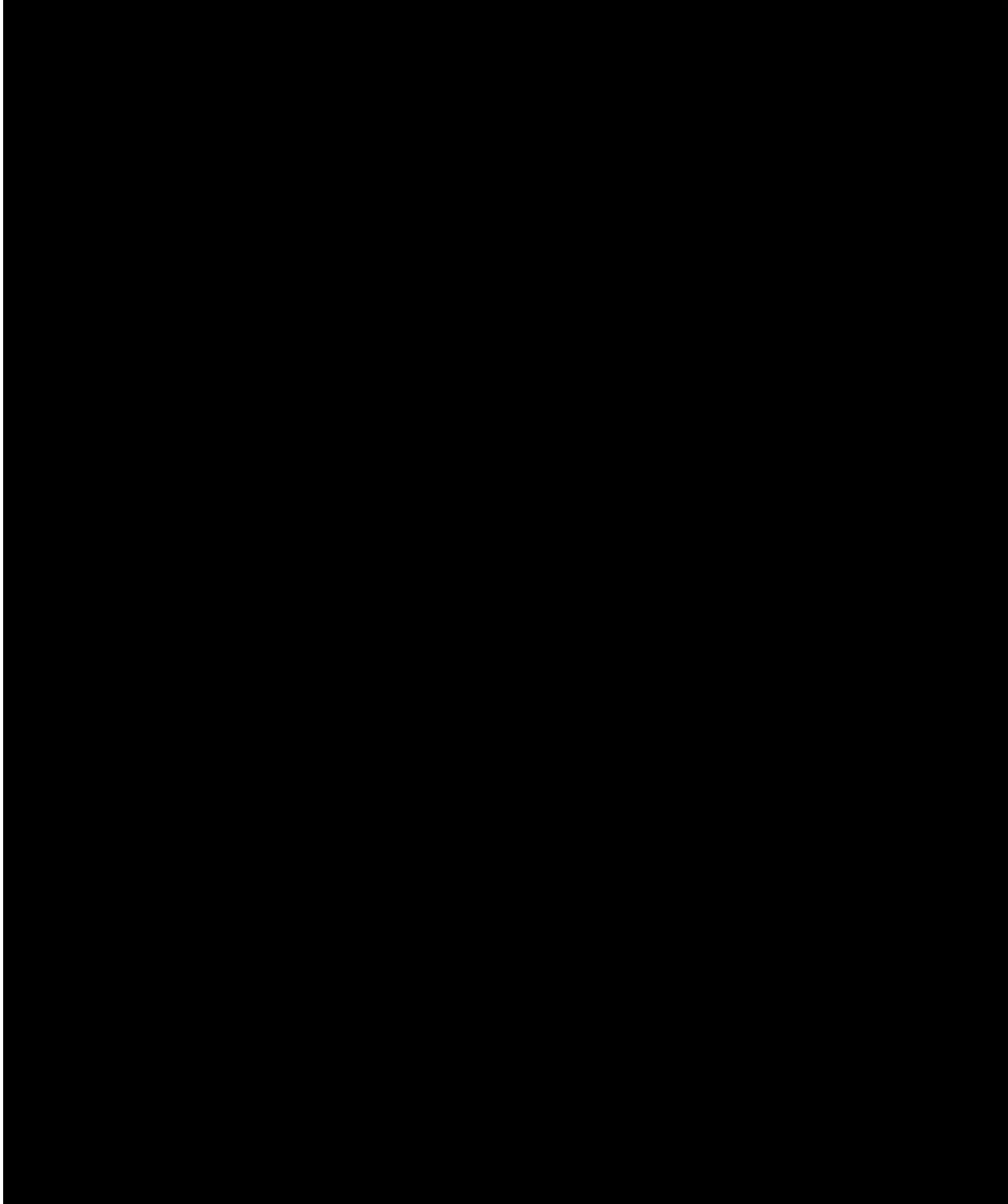
## LifeScience Logistics

**Title:** Prescription Drug DSCSA Track/Trace

**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002





## LifeScience Logistics

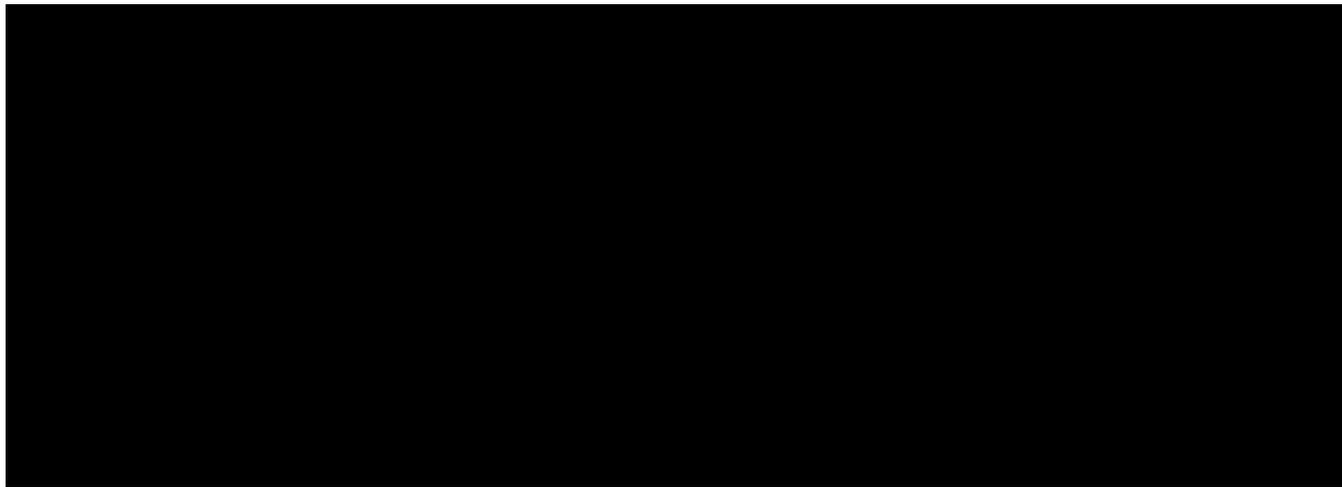
**Title:** Prescription Drug DSCSA Track/Trace

**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002

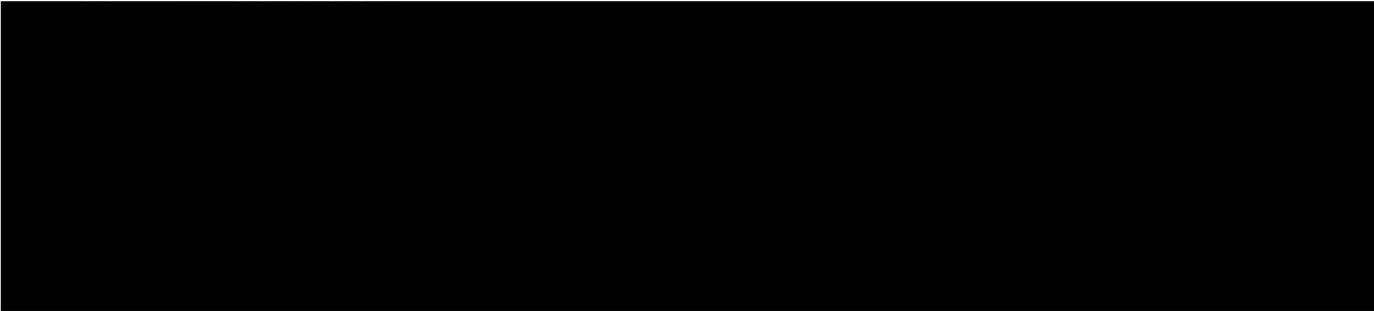
### 8.0 ADDITIONAL INFORMATION Control of Records



#### 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



### 10.0 TRAINING RECORD

Training Date	Type of Training
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## LifeScience Logistics

**Title:** Prescription Drug DSCSA Track/Trace

**Number:** WI 600.03

**Rev. Date:** 20-Oct-23

**Rev. Level:** 002

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