[redacted]

methapharm	Title: **Deviation Report Form**	Form QS-015-1.005
	Effective Date: AUG 2 7 2021	Page **1** of **5**
Prepared By: Mark K. Owusu	Reviewed By: Knobbadt	Approved By: Knobbadt
Date: 11-Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

[redacted]

[redacted]

methapharm	Title: **Deviation Report Form**	Form QS-015-1.005
	Effective Date: AUG 2 7 2021	Page **3** of **5**
Prepared By: Mark Owusu	Reviewed By: [redacted]	Approved By: [redacted]
Date: 11-Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

[redacted]

methapharm	Title: **Deviation Report Form**	Form QS-015-1.005
	Effective Date: AUG 2 7 2021	Page **4** of **5**
Prepared By: Mark K. Owusu	Reviewed By: Khobbati	Approved By: Khobbati
Date: 11-Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

[redacted]

methapharm	Title: **Deviation Report Form**	Form QS-015-1.005
	Effective Date: AUG 2 7 2021	Page **5** of **5**
Prepared By: Mark K. Cuney	Reviewed By: Hubbard	Approved By: Hubbard
Date: 11- Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

[redacted]

Confidential Trade Secrets

methapharm	Title: **Planned Deviation Report Form**	Form QS-015-2.005
	Effective Date: AUG 2 7 2021	Page **1** of **2**
Prepared By: Mark K. Owusu	Reviewed By: [redacted]	Approved By: [redacted]
Date: 11-Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

[redacted]

methapharm	Title: **Planned Deviation Report Form**	Form QS-015-2.005
	Effective Date: AUG 2 7 2021	Page **2** of **2**
Prepared By: Mark K. Owusu	Reviewed By: [signature]	Approved By: [signature]
Date: 11-Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

[redacted]

Confidential Trade Secrets

methapharm	Title: **Evaluation Questionnaire**	Form QS-015-3.005
	Effective Date: AUG 2 7 2021	Page **1** of **1**
Prepared By: Mark K Owusu	Reviewed By: [signature]	Approved By: [signature]
Date: 11-Aug-2021	Date: aug 11. 2021	Date: aug 11. 2021

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Internal Quality Control Plan (IQC)

Overview/Purpose

This internal quality control plan highlights how LifeScience Logistics (LSL) will use its expertise and procedures to customizes processes compliant with the Florida Section 804 Importation Program (FL-SIP). IQC outlines the processes and procedures established to be compliant with 21 CFR 251. All processes are documented in Standard Operating Procedures and Work Instructions, customized for the FL-SIP that encompass regulatory and contractual requirements.

The LSL Quality Assurance department (QA) will maintain oversight over processes involving product introduction into the LSL warehouses located in Indiana and Florida, inclusive of sampling, re-labeling, and final distribution to Florida agencies. QA will also oversee regular review of the quality system through annual internal audits as discussed in LSL's Internal Auditing procedures.

Description of Customizations to LSL Processes

Table 1 in this document outlines the processes and procedures in place for compliance with LSL's quality management system in support of the FL-SIP. Table 2 lists all relevant procedures currently in place as part of LSL's business and quality system. Table 3 lists procedures written and customized for specific use by the FL-SIP. Drafts of all documents are available for review.

Note: Table 1 outlines changes to processes requiring quality oversight. Tables 2 and 3 will list all documents outlined in this plan as well as documents created that do not cover processes directly overseen by QA. Table 4 will list the associated SOP & WI documents to address DSCSA, Adverse Events, Drug Recalls and included in this submission.

Table 1: Current LSL Processes		
Process	**Process Descriptions**	**Association**
Vendor Qualification	The current vendor qualification process covers classification, evaluation, approval, and annual review of vendors. This procedure includes verification requirements specifically for Wholesale Distributors (Foreign Sellers), labelers, and laboratories to ensure that all regulatory and contractual requirements are being met. Requirements for vendors supplying additionally identified and necessary materials will also be reviewed to ensure all vendors being utilized as part of the FL-SIP adhere to all requirements. The document includes a QA checkpoint for qualifying distributors before approval is achieved. Based upon the type of vendor/supplier and the findings of the initial QA assessment, it may be determined that an audit is necessary to further assess the quality system of the vendor.	SOP 1031
Drug Procurement	The process for ordering drugs is being documented and will include a reference to the vendor qualification procedure as well as any additional requirements regarding providing specifications of materials and services required to the vendor. Documentation requirements for bringing product on site at LSL through Import/Export policies will be listed as they pertain to shipments from Canada into the United States. These requirements are reviewed and documented as part of this process. A QA checkpoint will be introduced during verification of additional products being procured.	WI 600.01
Initial Sampling and Laboratory Testing	The process for QA pulling initial samples from drug product arriving from Canadian Wholesale Distributors will be documented, including the creation of a checklist requiring QA signoff prior to samples being submitted for laboratory testing. This process includes specifications for the number of samples pulled based on the batch quantity and testing requirements. This process will also include QA review of the results from the laboratory and handling of test results. Audits and trend analyses will be conducted, as appropriate. LSL standards for receiving product physically and systematically will be documented in the operational procedure.	SOP 2005 WI 600.07
Shipment for Relabeling and Return Receipt	The process for sending product released for shipment to the verified re-labeler, or back-up if needed, is documented. This procedure will outline QA oversight of required paperwork upon shipment of product to the re-labeler, receipt of re-labeled product into inventory, pulling of retain samples of re-labeled product for potential future testing, and placing of approved	SOP 2002 WI 600.27

	product into active inventory once review is complete. Audits and trend analyses will be conducted, as appropriate.	
Inventory Management and Hold Codes	Inventory management processes reflect the requirements of the FL-SIP. The procedure for applying hold codes to product to enhance quality oversight will include additional hold code categories that will allow QA to monitor the product through all stages of the process, from initial receipt of product from the Canadian Wholesale Distributor to the release of re-labeled product into active inventory for distribution. Hold codes that can be used to monitor returned, damaged, and recalled product as well as product under other circumstances, will be documented. Processes for cycle counting, inventory moves, and adjustments due to identified overages or shortages will be documented in these inventory procedures.	WI 600.02 WI 600.04 WI 600.06 WI 600.14 WI 600.15
Returns	The current process for returning product shipped from the LSL Florida facility due to damage, incorrect shipment, product recall, or other issue will be documented as it pertains to the FL-SIP. This includes steps for product being returned to LSL for receipt and storage, completion of inspection, and final disposition. QA will maintain oversight of the returns process and will take additional action when necessary based on the reasoning and frequency of returns.	WI 600.11 SOP 7003
Product Complaints	The current process for documenting and addressing product complaints is updated to meet specifications required by FL-SIP. This process documents QA oversight of monitoring of complaints, as well as how and when corrective and preventive action is introduced to manage current and future complaints. QA will maintain oversight of the product complaint process and will take additional action when necessary based on the type of complaint and/or frequency.	SOP 4001 SOP 7004
Immediate Suspension and Recalled Products	The current LSL procedure, SOP 1003, Recalls, Removals, and Corrections, covers the process for the initiation of a recall, segregation of product currently in the facility, communicating the recall to locations having received product, and segregation of any returned product prior to investigation and disposition of product. This procedure also includes the process for removals, corrections, or voluntary withdrawals and includes the monitoring of recalled product in Canada as well as the United States and communication with all required parties. QA will review and approve all procedures and records related to this process.	SOP 1003

Safe Transportation of Prescription Drugs	The current process of ensuring safe transportation of prescription drug product is being documented in a new procedure including verification of vendors during import and export, use of tracking numbers for outgoing shipments, DSCSA compliance, and maintenance of information regarding this process.	WI 600.04 thru WI 600.10
Theft/Loss	The current LSL procedure, SOP 1601, Response to Cargo Thefts, includes LSL's initial notification of necessary parties that in-transit cargo has been hijacked or stolen, as well as steps for determining potential action based on the circumstances surrounding the incident. QA will review and approve all procedures and records related to this process.	SOP 1601
Audits	The current LSL procedure, SOP 1500, External Audits, and Inspections includes information regarding the handling of audits by external sources such as the FDA and other regulatory bodies. The current LSL procedure, SOP 1501, Internal Audits, encompasses the process for LSL's review of internal processes and procedures to identify needed updates or deviations from current processes.	SOP 1500 SOP 1501
Deviation/CAPA	The current processes for Deviation and CAPA reporting, and documentation include the identification and notification of deviations from current processes, documentation and investigation, establishment of corrective and preventive actions, and escalation to CAPA, if needed. A document specific to FL-SIP was created. Timelines for due dates of separate sections in the process will be updated to match requirements listed in the current Scope of Work. QA will review and approve all procedures and records related to this process.	SOP 1351
Training	The current LSL procedure, SOP 1800, Training and Qualification includes the process for creating and monitoring training for all LSL employees. This procedure documents core requirements for all employees including but not limited to, cGMP, Facility Access, LSL's Emergency Response Plan, and LSL's Quality Manual. This procedure also outlines the process for establishing and reviewing position specific requirements for each LSL employee including CPDIP staff and Foreign Sellers. This procedure will be updated to add training and compliance testing for CPDIP external resources. The needed updates and training plans for all positions that will be created as a result of FL-SIP and will be expanded and consistently evaluated by QA annually.	SOP 1800

Reporting	The LSL process for overseeing and completing any daily, weekly, monthly, quarterly, and annually required reports was created to meet the requirements by the state of Florida, FDA, Canada, or other regulatory bodies with reporting requirements. This includes but is not limited to Adverse Events, Individual Case Safety Reports, Recalls, Market Removals, and Field Alerts. QA will review and approve all procedures and records related to this process.	SOP 1725 WI 600.13
Document Control/Control of Records	Current procedures for Document and Record Control are in place to maintain procedures and any outputs of those procedures. SOP 1100, Document Control, documents LSL's maintenance of quality oversight on all documents added or made obsolete in the quality maintenance system. SOP 1101, Control of Records, provides information for where any records generated by current processes are kept for easy access. QA will review and approve all procedures and records related to this process.	SOP 1100
Pharmacovigilance	LSL is committed to monitoring all processes involved in maintaining pharmacovigilance and establishing checkpoints in all pertinent processes. Quality checkpoints are being established in processes being put in place for the FL-SIP. In areas where formalized processes are already in place, current quality checkpoints are being identified and procedures revised.	SOP 7004

Table 2: Referenced LSL SOP & WI Procedures Relevant to Prescription Drug Importation
SOP 1001.08, Annual cGMP Presentation
SOP 1003, Recalls, Removals, and Corrections
SOP 1005, Statistical Techniques
SOP 1031, Vendor Qualification
SOP 1100, Document Control
SOP 1101, Control of Records
SOP 1102, Create and Edit Controlled Documents
SOP 1103, Good Documentation Practices
SOP 1301, Risk Management
SOP 1400, Validation of Processes
SOP 1402, Master Validation Plan
SOP 1500, External Audits and Inspections
SOP 1501, Internal Audits
SOP 1601, Response to Cargo Thefts
SOP 1800, Training and Qualification
SOP 1900, Hazard Communication
SOP 2004, Business Continuity
WI 100.05, Probe Calibration and certification
WI 100.06, Alarm Testing
WI 100.08, Validation Protocols and Reports
WI 100.11, Sensor Alarm Response
WI 100.28, Archiving and Destruction of Records

Table 3: FL-SIP Processes	
DOC.ID	**Procedures Specific to Florida Prescription Drug Importation**
SOP 1003	Recalls, Removals, And Corrections
SOP 1351	Deviation_ CAPA- Rx
SOP 1601	Response to Cargo Thefts
SOP 2002	Handling, Storage, Packaging & Distribution
SOP 2004	Business Continuity Plan
SOP 7000	Prescription Drug Destruction of Products
SOP 7001	Prescription Drug Process Overview
SOP 7002	Import_ Export - Rx
SOP 7003	Prescription Drug Returned Merchandise
SOP 7004	Prescription Drug Pharmacovigilance
WI 600.01	Prescription Drug Procurement
WI 600.02	Prescription Drug Item Setup/Issuing NDCs and Component Part Numbers
WI 600.03	Prescription Drug DSCSA Track/Trace
WI 600.04	Prescription Drug Customer Setup
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 600.09	Florida Prescription Drug Ordering
WI 600.10	Prescription Drug Pick/Pack/Ship
WI 600.11	Prescription Drug Returns
WI 600.12	Prescription Drug Product Complaints
WI 600.13	Prescription Drug Reporting
WI 600.14	Prescription Drug Inventory Control: Adjustments
WI 600.15	Prescription Drug Inventory Control: Management
WI 600.16	Prescription Drug Contingency Planning
WI 600.17	Auditing Third Parties
WI 600.18	Deviations/CAPA
WI 600.19	Florida Invoicing
WI 600.20	Safe Transportation of Prescription Drugs
WI 600.21	Drug Shortages
WI 600.26	Inspection of Drug Products and Components
WI 600.27	Vendor Returns & Quarantining Shipments

Table 4: FL-SIP Processes	
DOC.ID	**Procedures Specific to Recalls, Removals, Adverse Events, DSCSA, Supply Chain Safety**
SOP 1003	Recalls, Removals, And Corrections
SOP 1601	Response to Cargo Thefts
SOP 7000	Prescription Drug Destruction of Products
SOP 7001	Prescription Drug Process Overview
SOP 7004	Prescription Drug Pharmacovigilance
WI 600.03	Prescription Drug DSCSA Track/Trace
WI 600.11	Prescription Drug Returns
WI 600.12	Prescription Drug Product Complaints
WI 600.13	Prescription Drug Reporting
WI 600.20	Safe Transportation of Prescription Drugs
WI 600.26	Inspection of Drug Products and Components
WI 600.27	Vendor Returns & Quarantining Shipments

Internal Quality Control Plan Approval

Date:

_____

Signature Program Administrator, Agency

_____

Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		

1.0 PURPOSE

The purpose of this procedure is to provide a method to be taken for evaluating potential and current Vendors, Service Providers and Common Carriers used by Life Science Logistics.

2.0 SCOPE

This procedure applies to all Vendors and Service Providers who provide goods and services to Life Science Logistics.

Vendors who provide food and travel services are out of scope.

3.0 REFERENCES

21 CFR 820	Quality Systems Regulations
ISO 13485	Medical Devices – Quality Management Systems
SOP 1002	Change Control
SOP 1031.01	Vendor Information Classification Form
SOP 1031.02	Controlled Vendor Qualification Questionnaire
SOP 1031.03	Vendor Performance Evaluation Form
SOP 1031.04	Controlled Supplier List – ALL
SOP 1031.09	Supplier Corrective Action Report Form
SOP 1031.10	Vendor SCAR Log
SOP 1031.11	Vendor Qualification Approval Form
SOP 1101	Control of Records
SOP 1102	Create and Edit Controlled Documents
SOP 1502	Vendor Quality Auditing
SOP 1502.01	Vendor Quality Auditing Checklist

4.0 DEFINITIONS

Audit	An evaluation of the Vendor/Service Provider to ensure that systems in place meet regulations, LSL, and client requirements. An audit may be onsite or desktop.
Client	An entity owning product and has a contract with LSL to store and distribute their product
Controlled Vendor	Supplier providing goods and/or services to LSL and approved via this procedure. Supplier/ Service provider which interacts with product and/or potentially impact product SISPQ.

Corporate Quality Control Unit (CQCU)	CQCU is the department responsible for the establishment, maintenance, and operation of the Quality Management System. This responsibility includes ownership of the Quality Management System, assessment of the quality of products or services delivered, decisions that directly or indirectly impact the acceptability of products or services delivered, and approve GMP documents and data.
Desk Audit	Audit not performed at the Vendor's location; audit done remotely. Consists of review of documents/qualifications.
Functional Owner	The department, group, or individual responsible for interacting with Vendor. Specifically, the individual within a given department (Facilities, Operations, etc.) that has been assigned a task within Microsoft Planner related to the vendor, its qualification, and performance evaluation, separate and apart from Quality Assurance and Senior Management.
Initiator	Employee who initiates the vendor qualification process
Onsite Audit	An audit conducted at the Vendor's facility.
Senior Management	Associates of Director level or above.
Trusted Vendor	This type of vendor does not require an escort while performing job on-site. Examples are janitor, PM vendor, Pest Control, security, etc.
Uncontrolled Vendor	Vendor that has possible interaction with product but would not affect product SISPQ.
Vendor/Supplier	Any firm who provides goods and/or services to LSL.

5.0 ABBREVIATIONS/ACRONYMS

ATL	LSL facility located near ATL Airport
BWI	LSL facility located near BWI Airport
CEO	Chief Executive Officer
COI	Certificate of Insurance
COR	Corporate Site or Multiple Sites
CQCU	Corporate Quality Control Unit
CR	Change Request
CSL	Controlled Supplier List
CVQQ	Controlled Vendor Quality Questionnaire
DFW	LSL facility located near DFW Airport
ESG	Environmental, Social, Governance

FLL	LSL facility located near Lakeland, FL
ICC	LSL facility located near IND Airport: Clayton
INC	LSL facility located near IND Airport: Suites 100,200, and 300
IND	LSL facility located near IND Airport: Suite 400
INW	LSL facility located near IND Airport: Whitestown
IRS	Internal Revenue Service
IN Area	All LSL sites in the Indiana area (INC, IND, INW, IWC, ICC)
IWC	LSL facility located near IND Airport: Whitestown
ISO	International Organization for Standardization
LSL	Life Science Logistics
NCC	LSL facility located near RDU
NDA	Non-Disclosure Agreement
NYA	LSL facility located near Amsterdam, NY
NYG	LSL facility located near Geneva, NY
NYH	LSL facility located near Hopewell Junction, NY
PM	Preventive Maintenance
QA	Quality Assurance
RA	Regulatory Affairs
SCP	LSL facility located near Prosperity, SC
SEA	LSL facility located near Seattle, WA
SISPQ	Safety, Identity, Strength, Purity and Quality
SCAR	Supplier Corrective Action Report
SDN	Specially Designated Nationals
SOP	Standard Operating Procedure
WI	Work Instruction
VIC	Vendor Information Classification Form
VPE	Vendor Performance Evaluation Form

6.0 RESPONSIBILITY

CQCU as Functional Owner	• Maintain this procedure in accordance with the LSL document and data control system. • 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.

Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		

Quality Management	Ensures Vendor reviews are performed at least once annually. Approves Vendor reviews.
Users (Operations, Facilities, IT, etc. as Functional Owners)	• Understand and perform this procedure as described, including any procedures included by reference. • Ensure Vendors are on the Controlled Supplier List prior to work being performed. Notify CQCU of any potential new vendors for qualification. • Promptly report any problems or deviations from this procedure to your Supervisor or CQCU.

Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
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7.0 PROCEDURE

Overview

[redacted]

Vendor Qualification Process

[redacted]

Vendor Classification Initiation

[redacted]

Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		

[redacted]

Environmental, Social, Governance, and Compliance (ESG)

[redacted]

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EPA SmartWay Transportation Partnership

[redacted]

Customs Trade Partnership Against Terrorism (CTPAT)

[redacted]

Specially Designated Nationals and Blocked Persons List (SDN)

[redacted]

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[redacted]

Environmental Health and Safety Compliance

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[redacted]

Finance Review (Section 2 of the Vendor Information Classification Form)

[redacted]

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LifeScience Logistics			
Title:	Vendor Qualification		
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[redacted]

CQCU Review and Classification Determination (Section 3 of VIC)

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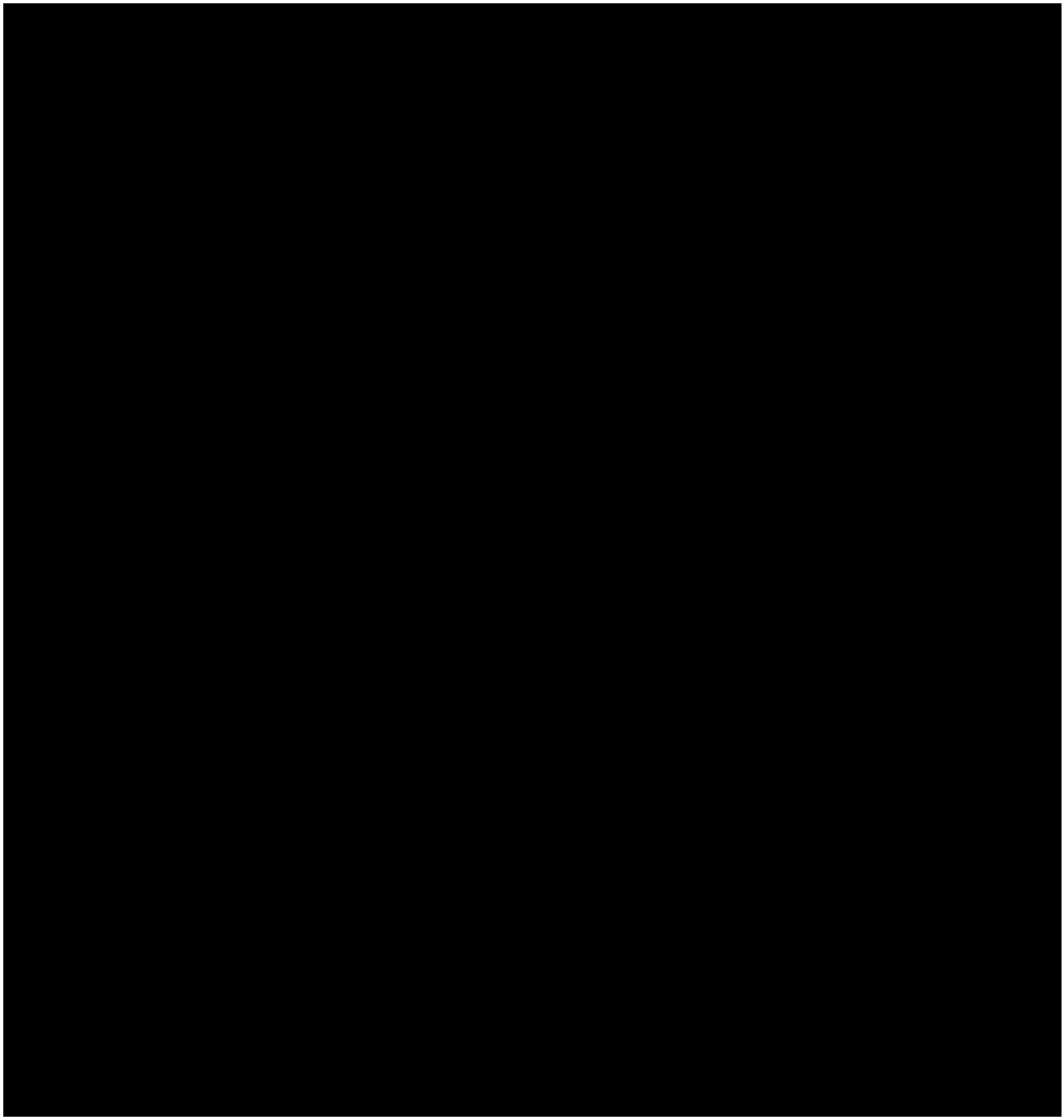

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LifeScience Logistics			
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Rev. Level:	017		

[redacted]

Trusted Vendor Classification and Process

[redacted]

Vendor Evaluation

[redacted]

Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		

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Current

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Vendor Review

[redacted]

Vendor Approval by CQCU

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Current

LifeScience Logistics			
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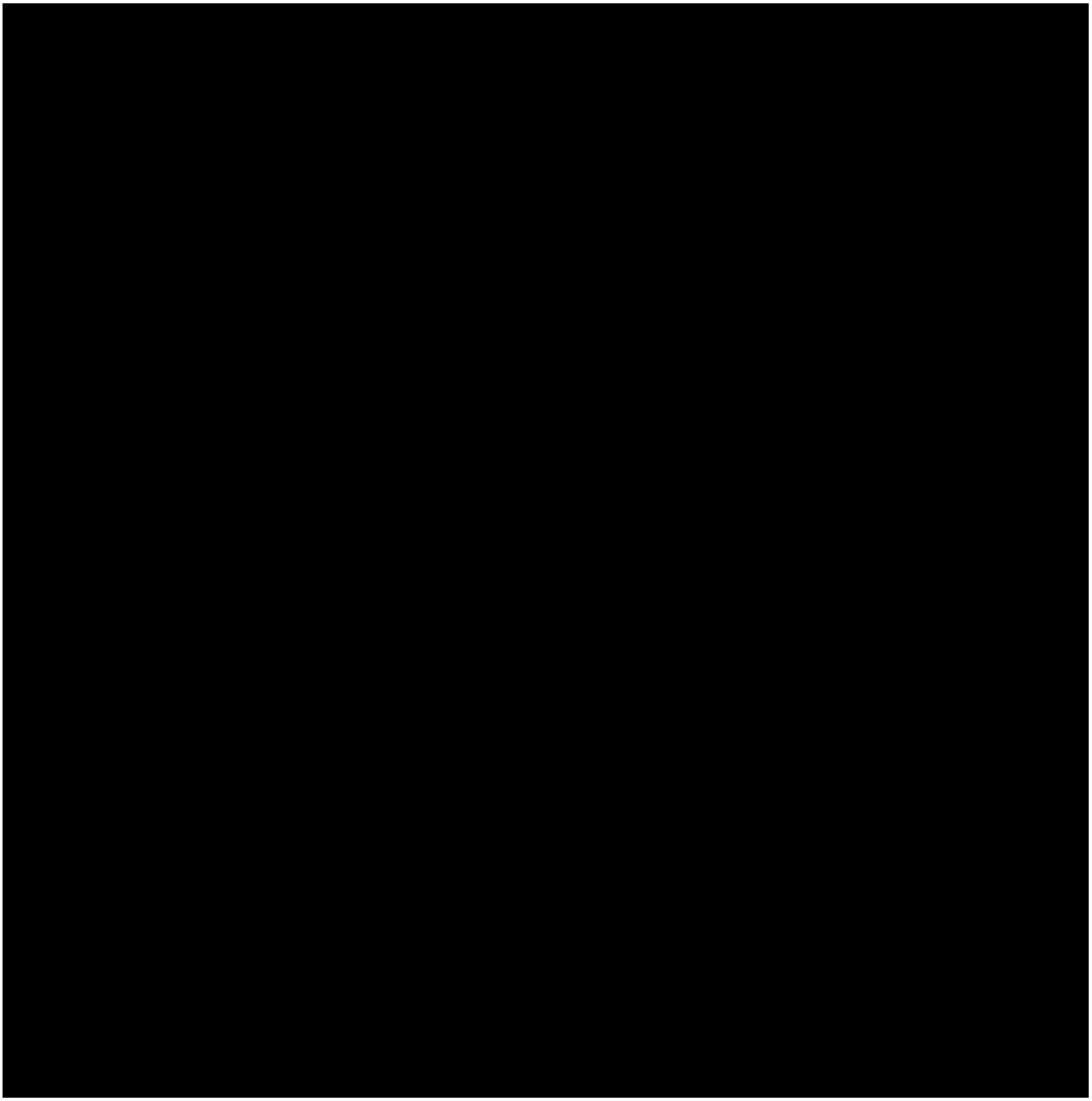
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		



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Current

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Tracking Vendor Documentation and Status

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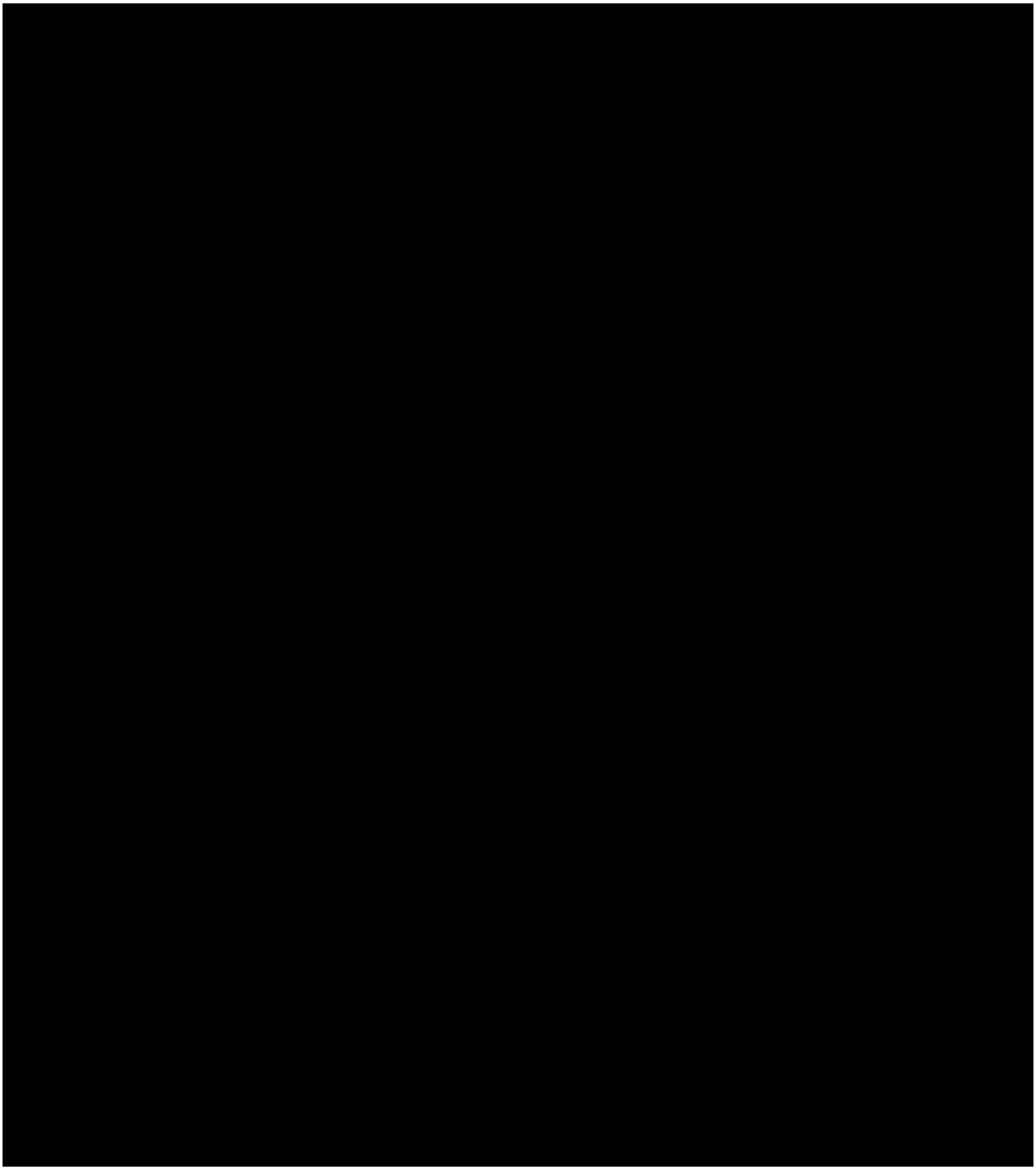
Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		



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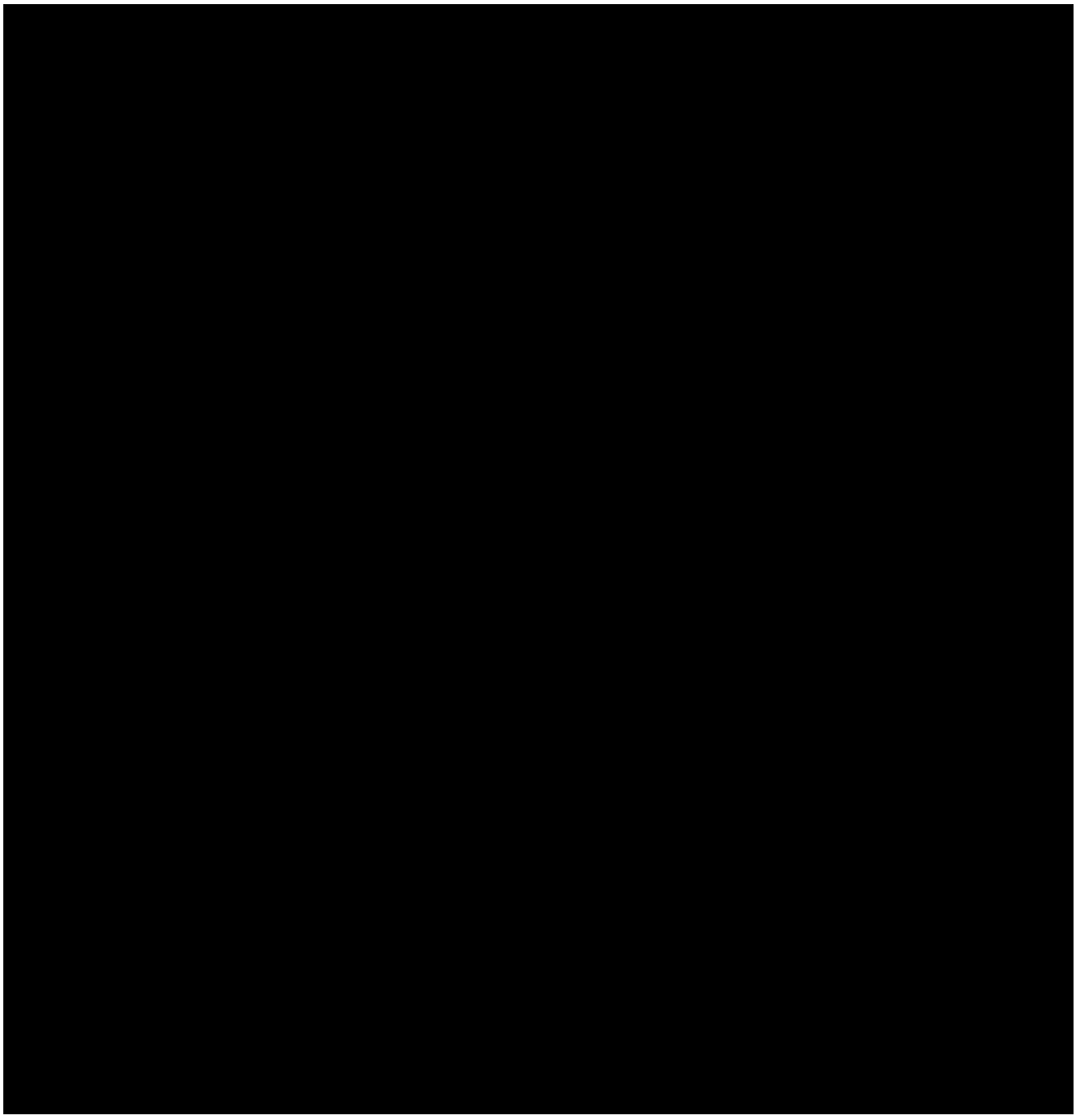
Rev. Level:	017		



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Current

LifeScience Logistics			
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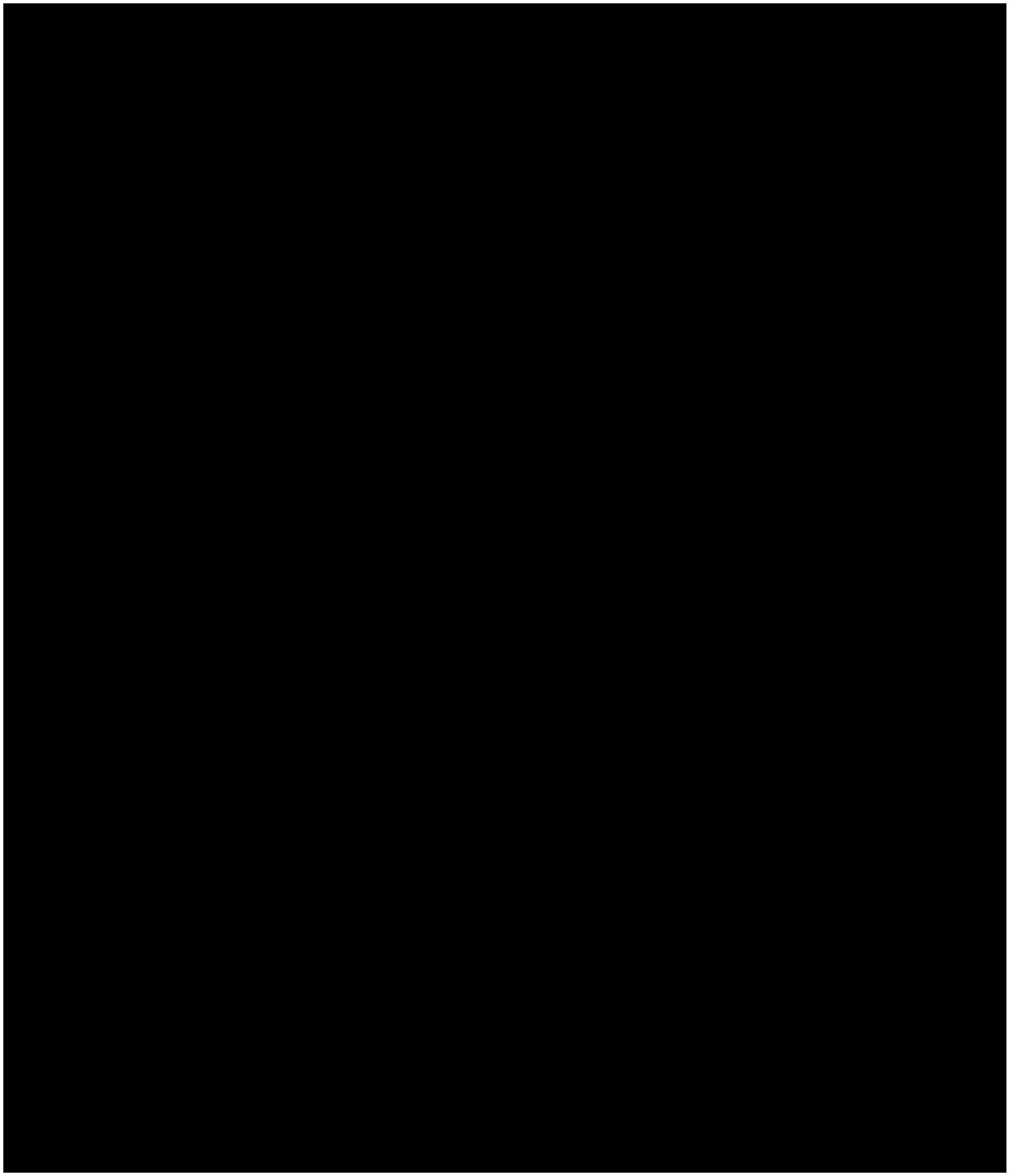
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		



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Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
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Vendor Risk Assessment – for existing vendors of record

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Current

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Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		

[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.

Current

LifeScience Logistics			
Title:	Vendor Qualification		
Number:	SOP 1031	**Rev. Date:**	17-OCT-2023
Rev. Level:	017		

9.0 REVISION HISTORY

10.0 TRAINING RECORD

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

Procedure Name or Description of Training	Procedure Number	Revision Level

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

Trainee Printed Name	Trainee Signature	Department	Date

Trainer: Signature below indicates you have presented training on procedure listed above and confirm all listed employees completed training as defined.

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

LifeScience Logistics			
Title:	Control of Records		
Number:	SOP 1101	**Rev. Date:**	08-Sep-2023
Rev. Level:	029		

1.0 PURPOSE

The purpose of this procedure is to define all records containing documentation, data, records, calculations, approvals and systems that are used in documenting the LSL Quality System and describe the manner in which records are reviewed, compiled, stored, archived and retained including the back-up of electronic records.

2.0 SCOPE

This procedure covers Quality System records which are generated from executing procedures and processes at LSL facilities and includes records that are provided by outside sources. All procedures must also list the records generated from those procedures. If a record does not have a parent document, then a note will be added in SOP 1101.

Other records generated from environmental, health, safety, financial or other LSL processes may follow this procedure.

Retention periods for DEA records are within scope of this procedure.

DEA record handling is out of scope; see WI 200.08, DEA Record Keeping – GSA and WI 200.13, DEA Record Keeping – Commercial.

Table 1 provides the minimum retention period as the current year plus <stated> years.
For Commercial, Client-specific records are not destroyed until confirmation to destroy is obtained from that client. Client-specific requirements may supersede this procedure.

3.0 REFERENCES

21 CFR 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
21 CFR 606	Current Good Manufacturing Practice for Blood and Blood Components
21 CFR 820	Quality Systems Regulations
ISO 13485	Medical Devices – Quality Management Systems
SOP 1002	Change Control
SOP 1003	Recalls, Removals, and Corrections
SOP 1101.02	First 30 Days: Control of Records Module – Commercial
SOP 1103	Good Documentation Practices
WI 100.04	Preventive and Reactive Maintenance
WI 200.08	DEA Record Keeping – GSA
WI 200.13	DEA Record Keeping – Commercial

4.0 DEFINITIONS.

Associated Documents	A child controlled document used with a parent controlled procedure (SOP or WI) linked by document number. Often, associated documents are used to gather data associated with the execution of the parent document. The associated document number is the parent document number followed by ".AA" or ".AAA". Examples of associated documents which are not completed with data or information such as placards, listings, templates, matrices, training slides.
ComplianceQuest	Electronic quality management system LSL uses for maintaining procedures, training records and information.
Controlled Documents	Quality System documents, such as SOPs, WI, forms, charts, product specifications, external standards, product labeling, marketing materials, regulations, standards and other requirements and documents relating to the operation of LSL's Quality Management System. Controlled documents have a title, rev level and rev date.
Forms	Both LSL Associated Documents and from external sources, which are completed with data or required information and become records.
Functional Owners	Director level or designee of the department
+ High Risk Records	Records which are electronically backed up and retrievable, if the original is destroyed.
Low Risk Records	Records which are optionally backed up and have negligible impact if the original is destroyed.
MQ1	LSL's legacy electronic document repository
QMS	Quality Management System
Records	Objective evidence of completion of an activity. Records can be in hard copy (paper) or electronic media, which contain information or data for an LSL process and demonstrate conformance to specified requirements and/or the effective operation of the Quality System. LSL records include any Vendor records required for business or regulatory reasons, such as Certificates of Destruction. Records are maintained in a manner that protects them from the elements. Records are legal documents that may not be altered.
Secured Records	Paper records are stored in locked filing cabinets. Secured records may have additional security via badge access available to limited employees.
SharePoint	A web-based collaborative platform LSL uses for electronically filing and storing records. https://lslog.SharePoint.com/SitePages/Home.aspx

5.0 ABBREVIATIONS/ACRONYMS

ARCOS	Automation of Reports and Consolidated Orders System
ATS	Automatic Transfer Switch
BD	Business Development
BME	Biomedical Equipment
BOL	Bill of Lading
BOP	Board of Pharmacy
CAPA	Corrective and Preventive Action
CEO	Chief Executive Officer
CIM	Client Implementation Manager
CQCU	Corporate Quality Control Unit
CQ	ComplianceQuest
CS	Client Services
DEA	Drug Enforcement Agency
ECS	Environmental Control System
FC	Facility Coordinator
FTP	File Transfer Protocol
GSA	General Services Administration
HR	Human Resources
HVAC	Heating, Ventilation, and Air Conditioning
IC	Inventory Control
JDI	Just Do It
LSL	Life Science Logistics
MHE	Material Handling Equipment
MSA	Master Services Agreement
OSHA	Occupational Safety and Health Administration
PM	Preventive Maintenance
QA	Quality Assurance
QMS	Quality Management System
RMA	Returned Merchandise Authorization
RTU	Roof-Top Unit
SBP	State Board of Pharmacy
SCAR	Supplier Corrective Action Report
SD	Sampling and Dispensing
SDS	Safety Data Sheet
SNS	Strategic National Stockpile
SOP	Standard Operating Procedure
SOW	Statement of Work
VAWD	Verified-Accredited Wholesale Distributor
WI	Work Instruction

6.0 RESPONSIBILITY

CQCU	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, 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. For this procedure, CQCU ensures facility QA Specialists/ Coordinators perform their review of records as listed.
Functional Owner	For this procedure, Functional Owners are responsible for the content, accuracy and timeliness of records generated from their department.
Users	Understand and perform this procedure as described, including any procedures included by reference. Promptly report any problems or deviations from this procedure to Supervisor or designee.

7.0 PROCEDURE

[redacted]

LifeScience Logistics			
Title:	Control of Records		
Number:	SOP 1101	**Rev. Date:**	08-Sep-2023
Rev. Level:	029		

Access Forms

[redacted]

Annual ECS – contains Alarm Testing of WebCTRL, Calibration of Temperature and Humidity Probes and Calibration Certificates

[redacted]

[redacted]

Archiving and Destruction Records

[redacted]

Business Continuity Records

[redacted]

CAPA's/Deviations

[redacted]

Calibration Certificates and Probe Calibration Forms (non-ECS Projects):

[redacted]

Change Requests, including Document Changes

[redacted]

Cleanroom – Batch Records

[redacted]

Cleanroom – Environmental Monitoring and Growth Promotion

[redacted]

Cleanroom – Logbooks

[redacted]

Cleanroom – MetOne Access Forms

[redacted]

Cleanroom – MetOne Monthly Reports and Review Forms

[redacted]

Cleanroom – Zero-Count

[redacted]

LifeScience Logistics			
Title:	Control of Records		
Number:	SOP 1101	**Rev. Date:**	08-Sep-2023
Rev. Level:	029		

Client Specific – Commercial Client's & Customer's License Verifications

[redacted]

Contracts with Clients (i.e. income producing contracts and associated contracts)

[redacted]

Contracts with Vendors

[redacted]

Daily Operator's Checklists

[redacted]

Damaged Product Forms – Commercial and State Stockpile

[redacted]

[redacted]

Data Logger Information Forms

[redacted]

DEA Records (Licenses not included)

[redacted]

Destruction Records – Commercial and Prescription Drug Program

[redacted]

Document Control Admin Checklists

[redacted]

Emergency Services Call List

[redacted]

Employee Signature Cards

[redacted]

LifeScience Logistics			
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Number:	SOP 1101	**Rev. Date:**	08-Sep-2023
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External Audit Records

[redacted]

Hazard Communication (OSHA) Records

[redacted]

Inventory Adjustments – GSA, Stockpile, Commercial, and Prescription Drug Program

[redacted]

Internal Audit Records

[redacted]

Inventory Status Modification Records

[redacted]

JDI Form

[redacted]

Job Function Reports

[redacted]

Licenses, Registrations and Permits – DEA, FDA and State

[redacted]

Maintenance – Preventive & Reactive

[redacted]

[redacted]

Master Cleaning Schedule

[redacted]

Master Service Agreements

[redacted]

Move Reports

[redacted]

New Client Information Form

[redacted]

New and Existing Client: Commercial Customer and Item Checklists

[redacted]

[redacted]

New and Existing Client: Commercial Customer, Item and Pricing Verification Emails

[redacted]

New and Existing: Prescription Drug Program Customer and Pricing Templates

[redacted]

New Item and Component Logs: Prescription Drug Program

[redacted]

New Item and Component Templates: Prescription Drug Program

[redacted]

Obsolete Controlled Documents

[redacted]

On Call Schedule – WebCTRL

[redacted]

Pest Control

[redacted]

Pre-Import Request Submissions

[redacted]

Probe Replacement Documents (Annual) – Vaisala

[redacted]

Process Walk Report Form

[redacted]

Product Complaints

[redacted]

Production Records GSA – i.e. Work Orders, Label Reconciliations, Line Clearances

[redacted]

Quality Agreements

[redacted]

Recalls, Removals, Corrections and Voluntary Withdrawal Records

[redacted]

Receiving for Government and Stockpile – Truck Files – Inbound

[redacted]

[redacted]

Receiving for Commercial – Truck Files – Inbound

[redacted]

Risk Assessment Forms

[redacted]

Safety Reports of Injury or Illness

[redacted]

Sample Requests and Reports – Commercial

[redacted]

Seal Certificate of Conformity – Commercial

[redacted]

Serviceable Product – GSA

[redacted]

Shipping for Government and Stockpile – Outbound Ship Files

[redacted]

[redacted]

Shipping for Commercial and Prescription Drug Program – Truck Files – Outbound (N/A for Small Parcel)

[redacted]

SIP Proposal Submissions

[redacted]

Statement of Work

[redacted]

State Controlled Substance Report

[redacted]

Supplier Corrective Action Reports

[redacted]

[redacted]

DSCSA Data

[redacted]

Temperature Reports (computer generated hard copies) – WebCTRL

[redacted]

Temperature Reports – Vaisala

[redacted]

Training Records – Employee

[redacted]

Vaisala Excursion Log

7.92 CQCU

[redacted]

ULT Freezer Log

[redacted]

Validations

[redacted]

VAWD Renewal Documentation

[redacted]

Vendor Audit Records

[redacted]

[redacted]

Vendor Qualification Forms

[redacted]

Vendor Performance Evaluation

[redacted]

Trusted Vendor List

[redacted]

Ventilator Management Forms – GSA and Stockpile

[redacted]

Visitor Log

[redacted]

Weekly Temperature Review Log – WebCTRL

[redacted]

Work Orders – Commercial

[redacted]

LifeScience Logistics			
Title:	Control of Records		
Number:	SOP 1101	**Rev. Date:**	08-Sep-2023
Rev. Level:	029		

[redacted]

LifeScience Logistics			
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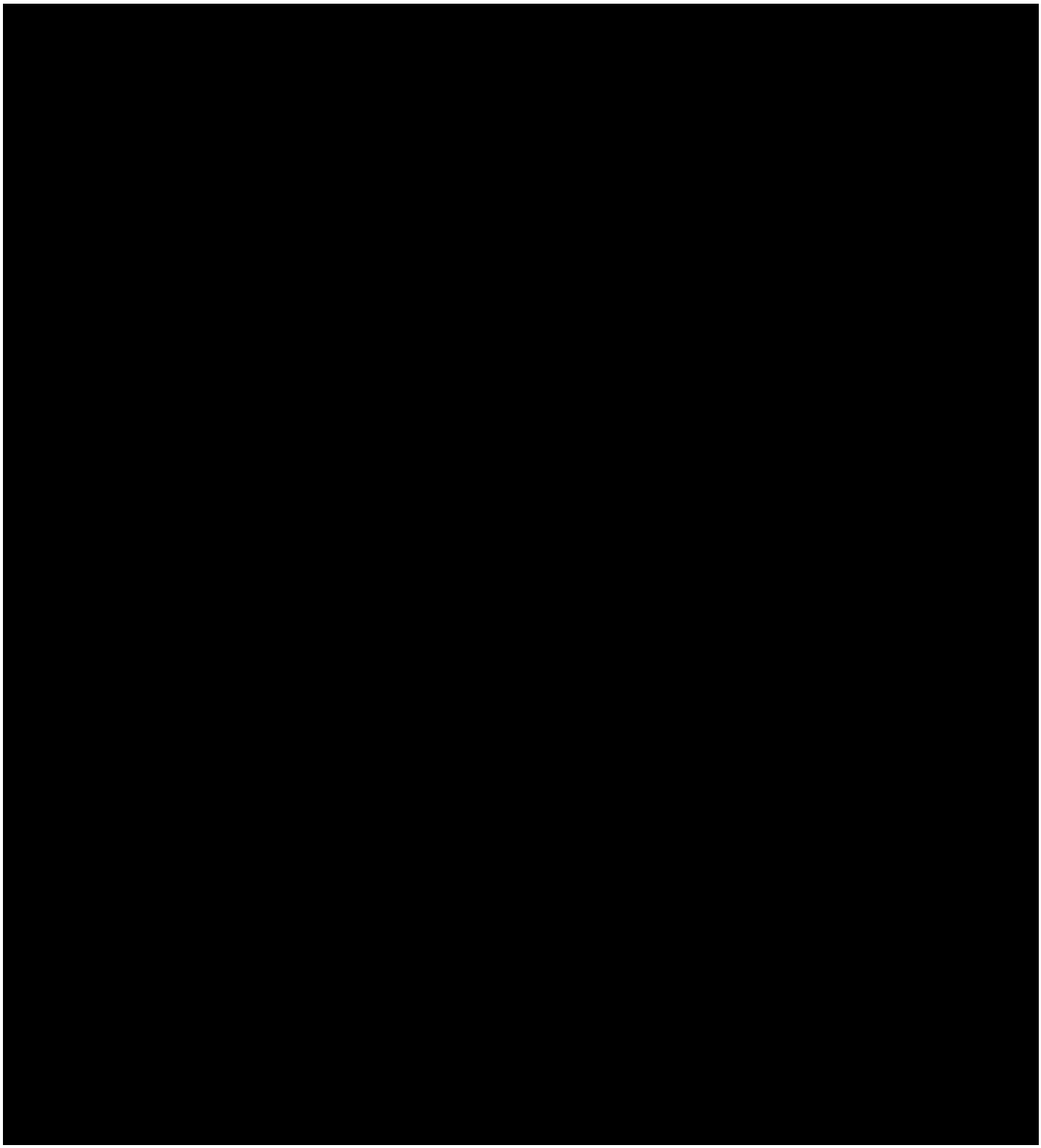
Number:	SOP 1101	**Rev. Date:**	08-Sep-2023
Rev. Level:	029		



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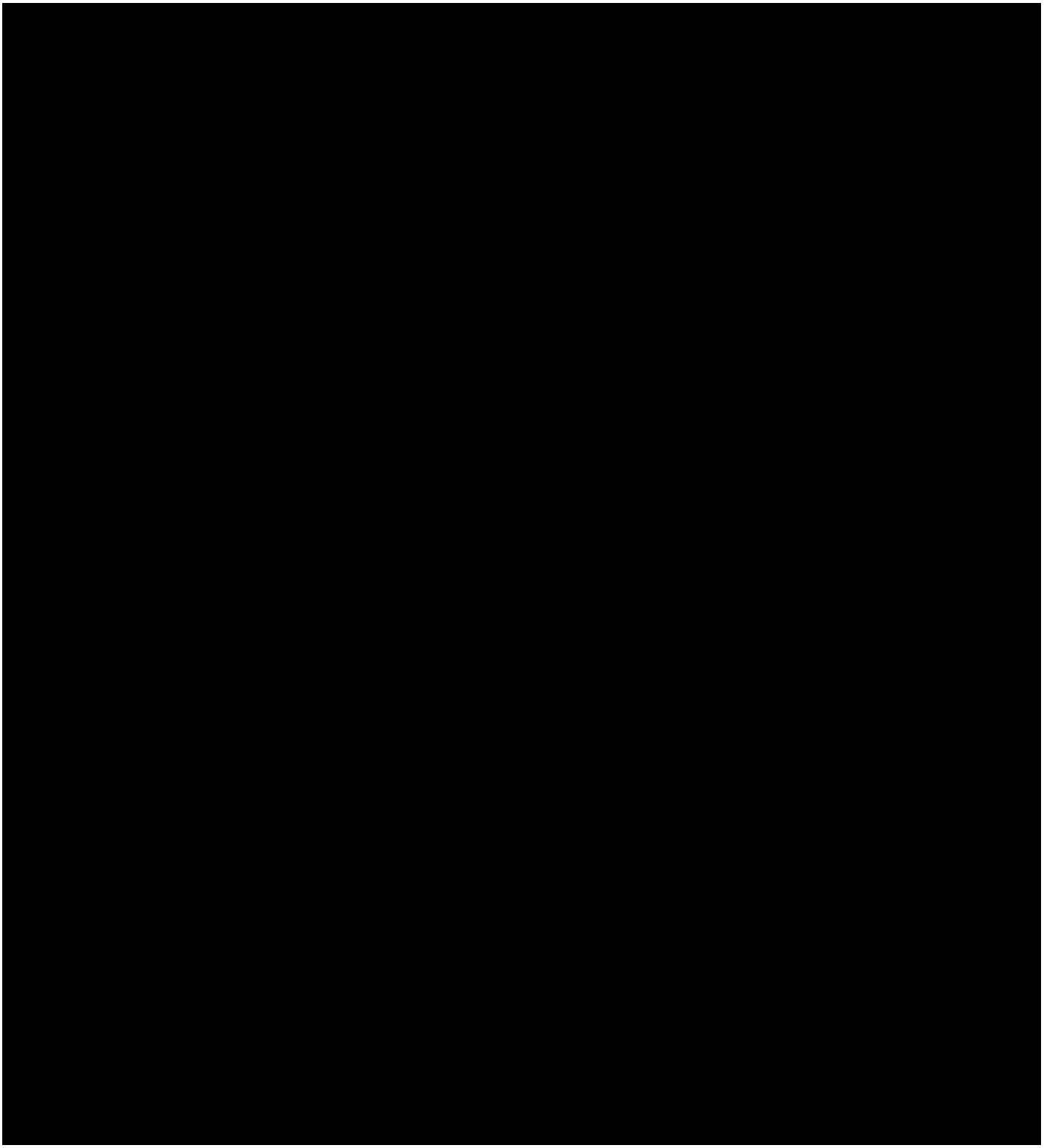

[redacted]

Archiving Records

[redacted]

Destruction of Records

[redacted]

Electronic Record Back-Up

[redacted]

8.0 ADDITIONAL INFORMATION

8.1 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.