LifeScience Logistics			
Title:	Handling, Storage, Packaging & Distribution		
Number:	SOP 2002	**Rev. Date:**	26-Sep-2023
Rev. Level:	011		

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	If activated, 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 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

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10.0 TRAINING RECORD

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

Procedure Name or Description of Training	Procedure Number	Revision Level

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

Trainee Printed Name	Trainee Signature	Department	Date

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

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