~~Current~~ Current

LifeScience Logistics

Title:	Prescription Drug Customer Setup
Number:	WI 600.04
Rev. Level:	001
Rev. Date:	07-NOV-2023

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1.0 PURPOSE

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

2.0 SCOPE

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

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

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

3.0 REFERENCES

21 CFR 205	State Licensing for Wholesale Prescription Drug Distributors
21 CFR 207	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
21 CFR 251	Section 804 Importation Program
DSCSA Section 205	National Standards for Third-Party Logistics Providers Uniform National Policy
SOP 1002	Change Control
SOP 1101	Control of Records
SOP 1102	Create and Edit Controlled Documents
SOP 1702	Samples Distribution
SOP 1900	Hazard Communication Program
SOP 7002	Import/Export – Rx~~X~~
SOP 7000	Prescription Drug Destruction of Products
SOP 7005	Prescription Drug DSCSA Track and Trace Regulatory Requirements
WI 600.04.01	Customer/Pricing Setup Template – Rx~~X~~
WI 600.06	Prescription Drug Hold and Release
WI 600.17	Prescription Drug License Verification

4.0 DEFINITIONS

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

Contract Manufacturer	A manufacturer that contracts with a firm for products. It is a form of outsourcing.
Customer	Entities to whom LSL ships products to on behalf of the Client including wholesalers, ~~,~~ distributors, 3PLs, dispensers, or end users.
Dispenser	A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).
DMS	Distribution (Order) Management System
Establishment	Place of business under one management at one general physical location. (21 CFR 207.3 Definitions)
Implementation	All tasks through first distribution
Item	Client's pharmaceutical, medical device, labeling, kits, in-process Material~~, etc. including OTC products.~~
Item Number	NDC or UPC or ~~other unique~~ product identifier in WMS/DMS.
Kick-Off Meeting	Meeting that occurs to transfer a new Client from the Business Development phase to the implementation phase.
Multiple Quantity	Increments in which Customers can order.
Quality Agreement	Business document between LSL QA and Client QA outlining agreed upon quality issues and reporting timelines.
Rx	Prescription
Ship-To	Address product is shipped to per the order.

Statement of Work	Business document between LSL and Client to state the agreed scope to be covered in working together. Once signed off, any changes to be made to the SOW must be documented with a BD Change Management form. If changes to the SOW impact quality, SOP 1002, Change Control may be required.
Tecsys	LSL's Warehouse Management System.
Trading Partner	A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.
~~Trading Partner~~	~~A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.~~
Virtual Manufacturer	Virtual manufacturer is a company that contracts with a contract manufacturer to produce items for them.

5.0 ABBREVIATIONS/ACRONYMS

AM	Account Manager
BD	Business Development
CC	Client Code
CEO	Chief Executive Officer
CQCU	Corporate Quality Control Unit
CT	Control Tower (Manages Inventory Database)
DMS	Distribution (Order) Management System
DSCSA	Drug Supply Chain Security Act
FDA	Food and Drug Administration
HDMA	Healthcare Distribution Management Association
IC	Inventory Control
ISM	Inventory Status Modification
IT	Information Technology
LSL	LifeScience Logistics

MSA	Master Service Agreement
NDA	Non-Disclosure Agreement
NDC	National Drug Code
OTC	Over the Counter
PC	Partial Case (hold code)
PM	Project Manager
QA	Quality Assurance
QARA	Quality Assurance Regulatory Affairs
Rx	Prescription
SBP	State Board of Pharmacy
SD	Short Dated (non-quality hold code)
SDS	Safety Data Sheets
SOP	Standard Operating Procedure
SOW	Statement of Work
UPC	Universal Product Code
VM	Virtual Manufacturer
WAC	Wholesale Acquisition Cost
WI	Work Instructions
WMS	Warehouse Management System

6.0 RESPONSIBILITY

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

10.0 TRAINING RECORD

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

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

Trainee Printed Name	Trainee Signature	Department	Date

Trainer: Signature below indicates you have presented training on the procedure listed to the employees listed above.

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