Distribution Management Policy

Role	Position/Department	Name	Date
Author			DD YYYY
Reviewer			DD YYYY
Approver			DD YYYY

[Company Name], Inc.

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1. Purpose

The purpose of this Policy is to establish requirements for distribution management operations, ensure proper implementation, and contribute to quality assurance of the products handled by [Company Name], Inc. (hereinafter referred to as "the Company").
This Policy also aims to comply with the requirements of the Quality Management System Regulation (QMSR) and ISO 13485:2016, and to ensure patient safety in the distribution of medical devices.

2. Scope

This Policy applies to management operations related to receiving, storage, packaging, and customer delivery of finished products at the Company.
This Policy applies to all medical devices, including implantable medical devices, life-sustaining devices, and life-supporting devices, and also complies with the requirements of 21 CFR Part 821 (Medical Device Tracking Requirements) and 21 CFR Part 830 (Unique Device Identification Requirements) where applicable.

3. Normative References

21 CFR Part 820 - Quality Management System Regulation (QMSR), effective February 2, 2026
ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2019 - Medical devices - Application of risk management to medical devices

4. Definitions

Term	Definition
Distribution	Activities that include storage, handling, and delivery of a medical device. [QMSR §820.3(m)]
Distribution Records	Records that contain or refer to the location of sufficient information relating to the initial consignee and production identifier to facilitate, if necessary, a recall of the device. [QMSR §820.3(n)]
UDI (Unique Device Identifier)	A unique numeric or alphanumeric code that consists of a Device Identifier (DI) and a Production Identifier (PI), assigned to a medical device for its identification. [21 CFR §801.3]
Initial Consignee	The first person or entity who receives a device for subsequent distribution. [QMSR §820.3(s)]
FIFO	First In, First Out - An inventory management principle where the oldest stock is issued first.
FEFO	First Expired, First Out - An inventory management principle where stock with the earliest expiration date is issued first.
Traceability	The ability to trace the history, application, or location of an entity by means of recorded identifications. [ISO 13485:2016 3.26]

5. Key Requirements for Distribution Management

5.1 Management Responsibility for Distribution

The manager responsible for distribution management shall be the Distribution Department Manager. The Distribution Manager is responsible for compliance with this Policy and related procedures, ensuring personnel competence, and the effectiveness of the distribution process.

5.2 Product Release and Shipment Approval

The Distribution Department shall only distribute finished products that have been approved for release. Release approval shall be documented by the Quality Assurance Manager and recorded in the manufacturing records.

5.3 Order Review and Contract Requirements

The Distribution Department shall review purchase orders and resolve any ambiguities or errors before finished products are distributed. Records of customer order or contract requirements review shall be maintained.

5.4 Shelf Life and Expiration Date Management

When the fitness for use or quality of a finished product deteriorates over time, the procedures shall ensure that expired products or deteriorated products unfit for use are not distributed. Expiration date management procedures shall be established, and periodic inventory checks shall be conducted to prevent distribution of expired products.

5.5 Product Issuing and Dispatch Control

Finished product issuing shall follow FIFO (First In, First Out) or FEFO (First Expired, First Out) principles to ensure product quality and fitness for use.
Distribution personnel shall verify that there are no inconsistencies in the product name, quantity, consignee name, and location. Pre-shipment verification shall confirm and record the following:
• Product identification information (product name, model number, UDI, lot number or serial number)
• Accuracy of quantity
• Official name and delivery address of consignee
• Consistency with customer order
• Accuracy and completeness of product labels
• Completeness of packaging
Label inspection detailed elements (QMSR §820.45 requirements):
• Accuracy of UDI (where applicable)
• Accuracy of lot number or serial number
• Accuracy of expiration date (where applicable)
• Appropriateness of storage condition labeling (temperature, humidity, light, etc., where applicable)
• Completeness of handling instructions (where applicable)
• Completeness of other regulatory required label information
The Quality Assurance Manager shall make the decision regarding whether finished products may be released for shipment. The release decision shall be based on confirmation of manufacturing records, inspection records, and conformity with release criteria, and approval shall be documented and recorded.

5.6 Delivery Service Provider Management and Customer Delivery

The Distribution Department shall entrust the delivery of finished products approved for shipment to contracted delivery service providers. Delivery service providers shall be subject to qualification evaluation, selection, and periodic monitoring in accordance with the purchasing control requirements of ISO 13485:2016 §7.4.
Distribution records shall be created and maintained for shipped products in accordance with the requirements of ISO 13485:2016 §7.5.9. Records shall include or reference the location of the following:
• Name and location of the initial consignee (official name, delivery address, and contact information)
• Name and quantity of shipped finished products (complete product identification: product name,