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Guidance for Temperature-Controlled Medicinal Products — Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment

Guidance for Temperature-Controlled Medicinal Products — Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment Team

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1.0 Introduction

The distribution of life science products is extremely diverse, ranging from raw materials to finished product through the supply chain to the end user. Typically, as the distribution process moves from shipments on pallets to individual packages to delivery to the end patient, the term "Last Mile" is applied. The Last Mile defines the point at which products have reached their final destination (e.g., pharmacy, medical practice, private residence). Product temperature must continue to be maintained within registered storage and/or transport conditions. This may include shipments from a wholesale distributor to a pharmacy where the products are held awaiting customer pick-up or, as the Last Mile process has become an even more complex system, home delivery of products that also include cell and gene therapy.

1.1 Purpose

This technical report provides guidance for establishing a quality management system for distribution of all types of temperature-sensitive medicinal and pharmaceutical products, from preparation of products for transportation at shipping sites to the shipment of products to receiving sites for storage or distribution to patients (end users).

The examples accompanying the points to consider provided herein on how to protect the quality of the product are for demonstrational purposes only.

1.2 Scope

This technical report offers a resource for all stakeholders involved in the pharmaceutical supply chain and provides a model for qualifications from the process design through implementation and operation to verification. The stakeholders include, but are not limited to, the following organization types:

- Pharmaceutical and biotech companies of commercial and clinical medicinal products, including manufacturers, contract manufacture organizations (CMOs), and repackagers
- Health care providers (HCPs)
- Logistic service providers
- Wholesalers
- Distributors (including subcontractors)
- Pharmacies, including mail order, infusion, specialty, and compounding pharmacies
- 503B pharmacies currently in the United States
- Nongovernmental organizations such as the United Nations International Children's Emergency Fund (UNICEF) and Pan American Health Organization (PAHO)

The stakeholders referenced are responsible and accountable for the processes that control the handling, transport, and storage of the product from the point of manufacture to distribution to the patient. The stakeholders need to work closely with the manufacturers who have all the stability data and knowledge necessary to evaluate the excursion.

The content of this document follows the sequence of the model provided in **Figure 1.0-1,** covering process design, process qualification, and ongoing process verification for thermal protection systems in the pharmaceutical supply chain.

Note: Numerous technical reports from PDA and other organizations exist that provide more detail regarding temperature control management. These are listed in the reference **Section 9.0**.