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Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to End Users

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1.0 Introduction

This guidance document complements the information provided in *PDA Technical Report No. 39 (Revised 2021): Guidance for Temperature-Controlled Medicinal Products — Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment* by going beyond manufacturer-focused issues and addressing issues specifically encountered within the "last mile" of the distribution of medicinal products and devices *(1)*. This revision updates the original 2009 technical report to account for expanded regulations, the development and implementation of newer, more advanced technologies and supply chains that have become more extensive and complex *(2)*.

1.1 Purpose and Scope

"Last mile" distribution is an often-used logistical term that refers to the transport of product from the manufacturing facility to the end user. For the purposes of this technical report, last mile is defined as the final transfer of a drug from the manufacturer or wholesaler to the end user which could be either the patient or the entity (e.g., pharmacy, hospital) that provides the drug to the patient. Transfers earlier in the distribution process involve organizations with greater knowledge of the product and the resources to ensure carefully controlled conditions of storage and transport compared to those available to the end user. As such, PDA *Technical Report No. 46 (Revised 2024): Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to End User* provides recommendations and tools based on current best practices to ensure that product quality is maintained until the final handoff.

2.0 Glossary and Abbreviations

The Glossary includes a list of common terms specific to this technical report. Definitions of terms are listed alphabetically and may come from sources such as the U.S. Pharmacopeia, American Society for Testing Materials, International Conference for Harmonisation, International Organization for Standardization, or other PDA technical reports. Definitions quoted from other sources are cited at the end of the definition.

ALCOA+

ALCOA+ is an acronym standing for Attributable, Legible, Contemporaneous, Original, Accurate ("ALCOA") and Complete, Consistent, Enduring and Available ("+"). It is a set of characteristics that all data must meet to ensure data integrity. Adherence to ALCOA+ principles is the basis for Good Documentation Practice.

Corrective Action, Preventive Action (CAPA)

Action to eliminate the cause of a detected nonconformity or other undesirable situation. Corrective action is taken to prevent recurrence, whereas preventive action is taken to prevent occurrence.

Customer

In distribution, the customer is the trading partner or reseller; in direct-to-consumer situations, the customer is the end user who is either the patient taking the product or the person administering the product to the patient such as a physician.

Data Integrity

Data integrity is the degree to which data are complete, consistent, accurate, trustworthy, reliable and that these characteristics of the data are maintained throughout the data life cycle *(3)*.

Downstream

Refers to the demand side of the supply chain that consists of one or more companies or individuals who participate in the flow of pharmaceuticals moving from the manufacturer to the end user.

Good Distribution Practices (GDP)

Defined as the part of quality assurance that ensures the quality of the pharmaceutical