

Technical Report No. 58

Risk Management for

Temperature-Controlled Distribution

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PDA Risk Management for Temperature-Controlled Distribution

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The content and views expressed in this document are the result of a consensus achieved by the authorizing Task Force and are not necessarily views of the organizations they represent.

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1.0 Introduction

This technical report describes risk management for temperature-controlled distribution of pharmaceutical products. It is meant to assist stakeholders in the supply chain to preserve the quality, safety and efficacy of these products during distribution. This guidance document serves to complement the information provided in ICH Q9 guideline (Quality Risk Management) (1) and previously published PDA technical reports no. 39, 46, 52 and 53 (2,3,4,5) by assessing, controlling and reviewing risks with equipment, processes, people and external factors, like weather and natural disasters, during distribution.

1.1 Goal

The goals of risk management in the temperature-controlled distribution of pharmaceuticals, biological medical products and medical devices, hereafter referred to as (pharmaceutical) products, are to:

- Preserve the quality, safety and efficacy of the product
- Understand the distribution process
- Reduce risk
- Understand residual risk
- Improve the effectiveness of the process

The main questions are: What are the risks? How can we manage and mitigate them?

The risks involved in temperature-controlled distribution differ from manufacturing-related risks; rather than contributing to the manufacturing quality of the product, they center on the risk of product degradation. Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) ensure the quality and the efficacy of drug products and guard patient safety by protecting products from detrimental factors, the most prevalent of which in distribution is temperature. Because distribution resides outside the “four-walled compliance” of manufacturing and it is increasingly complex in an expanding global market, distribution risk management is essential. As such, industry-wide guidance on risk management and risk analysis for temperature-controlled distribution benefits pharmaceutical manufacturers, supply chain partners, clinicians and patients.

This document provides specific guidance on the identification, assessment, evaluation, control and review of risks in the distribution process, such as receipt, storage, handling and shipping of bulk, intermediate and finished pharmaceuticals, biological medicinal products and medical devices. It also provides guidance for handling incidents, like temperature excursions, that occur during the distribution process.

This guidance has been developed by the PDA PCCIG Task Force on Risk Management for Temperature-Controlled Distribution, a group that includes representatives from the pharmaceutical industry, suppliers of active and passive shipping systems and temperature monitors, logistic service providers and carriers. This document is written for stakeholders in the pharmaceutical supply chain, including the manufacturer, supplier of active systems, supplier of passive systems, supplier of temperature monitors, logistic service provider, carrier, clinician, handling agent, airline and any other interested reader. It is assumed that the reader is familiar with the ICH Q9 guideline on Quality Risk Management as the same terminology is used in this document. Definitions of terms and acronyms are included in **Sections 2.0** and **2.1**, respectively.

Section 3.0 introduces a conceptual model for temperature-controlled distribution management. The Temperature-Controlled Distribution Management model addresses and characterizes five critical stages of temperature-controlled distribution including Requirements, Design and Qualification, Quality Management System, CAPA Management, and Change Control. The section ends with a