Good Practice Guide

# Cold Chain Management


Connecting a World of Pharmaceutical Knowledge

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**Disclaimer:**
This Guide is intended to provide practical guidance to assist in the specification, design, commissioning and verification of the fixed and passive systems within the pharmaceutical and biopharmaceutical cold chain. The ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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# Preface

Cold chain management is the specialist area of the pharmaceutical and biopharmaceutical distribution system dealing with product that is required to be held and distributed in a temperature controlled environment with the objective of providing safe and effective product to the patient.

The design, development, testing, and monitoring of the systems required to support this endeavor utilize a blend of Good Manufacturing Practice (GMP) and Good Engineering Practice (GEP) together with advanced technology to help provide a safe and reliable distribution system.

This Guide aims to define current good practices in this area, providing information to allow organizations to benchmark their practices and improve on them. The Guide also considers some of the issues relating to sustainability and economics.

The intended audience for this Guide is global with particular focus on US (FDA) and European (EMEA) regulated facilities.

The information provided in this Guide reflects the cumulative knowledge and experiences of the authors, editors, and reviewers with input from members of the ISPE Packaging and HVAC Communities of Practice (COP). There is no single approach to satisfy every situation, but this Guide attempts to provide the background to help readers make an educated choice.

# Acknowledgements

This Guide was developed by a team under the chairmanship of Nicholas Haycocks of Amgen.

## Section Writers and Reviewers

The ISPE Good Practice Guide: Cold Chain Management has been sponsored by engineering executives from owner organizations, consulting firms, and ISPE senior management.

This Guide was produced by a dedicated team of subject matter experts from across the industry. The leaders of this Guide would like to recognize the following participants who took lead roles in the authoring of this document (organization affiliations are as of the final draft of the Guide.)

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# 1 Introduction

## 1.1 Background

Cold chain management is the specialist area of the pharmaceutical and biopharmaceutical distribution system dealing with product that is required to be held and distributed in a temperature controlled environment. Concerns over having adequate control in cold chain is increasing, mainly because of:

- increasing volumes of cold products in the supply chain (demand)
- complexity of cold product (e.g., new types of product, patient specific products)
- complexity of the supply chain (worldwide supply)

Therefore, it is considered critical to have adequate control of all steps and procedures involved, both in manufacturing and quality control and in storage and distribution, to ensure that product quality is maintained.

Understanding the requirements of the cold chain process will help to focus efforts to ensure that activities and development programs add value, are based on robust science, undergo appropriate risk assessment, and meet the expectations of the regulators.

## 1.2 Purpose

This ISPE Good Practice Guide (GPG): Cold Chain Management is intended to provide practical guidance to assist organizations in developing, establishing, documenting, implementing, improving, and maintaining industry good practice for product requiring controlled cold conditions to maintain its safety, efficacy, and quality. These practices include:

- transferring
- packing
- storing
- distributing
- receiving
- unpacking

This Guide is intended to supplement published ISPE Baseline® Guides for facilities (Reference 24, Appendix 5) by providing detailed information and by recommending practices for implementation of cold chain management.

The information provided in this Guide reflects the cumulative knowledge and experience of the authors and reviewers with input primarily from members of the Packaging and HVAC ISPE Communities of Practice (COP).

This Guide defines:

- the application of risk assessment to cold chain management
- a standardized approach to temperature mapping of cold rooms