ISPE Good Practice Guide

Packaging, Labeling, and Warehousing Facilities

Connecting a World of Pharmaceutical Knowledge

ISPE

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Good Practice Guide

Packaging, Labeling, and Warehousing Facilities

Disclaimer:
This Guide describes a risk-based approach to CGMPs and encourages innovative approaches for the design and/or reconfiguration of Packaging, Labeling, and Warehousing (PACLAW) facilities. 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

The goal of the ISPE Good Practice Guide for Packaging, Labeling, and Warehousing (PACLAW) Facilities is to establish consistent guidance that can be incorporated and integrated into the design and/or reconfiguration of PACLAW facilities. The design, construction, commissioning, and qualification of Packaging, Labeling, and Warehousing (PACLAW) Facilities are significant challenges for operations and design professionals, and equipment suppliers. These facilities are required to meet Current Good Manufacturing Practice (CGMP) regulations while complying with all other governing codes, laws, and regulations.

This Guide may be used by industry for the design, construction, commissioning, qualification, and maintenance of new, renovated, and reconfigured PACLAW facilities. The reader is referred to related ISPE guidance for a complete discussion of the “support” issues affecting the design and operation of Packaging, Labeling, and Warehousing Facilities.

Acknowledgments

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Table of Contents

1 Introduction

1.1 Background

The design, construction, commissioning, and qualification of Packaging, Labeling, and Warehousing (PACLAW) facilities are significant challenges for operations and design professionals, and equipment suppliers. These facilities are required to meet Current Good Manufacturing Practice (CGMP) regulations while complying with all other governing codes, laws, and regulations.

The goal of this Guide, the ISPE Good Practice Guide for Packaging, Labeling, and Warehousing Facilities is to establish consistent guidance that can be incorporated and integrated into the design and/or reconfiguration of PACLAW facilities.

To further this goal, this Guide:

- Provides direction on how to comply with the FDA's systems-based approach with a "risk-based inspectional model," as it relates to PACLAW operations.
- Addresses a risk-based approach to CGMPs as related to PACLAW operations.
- Encourages innovative approaches to designing basic CGMP PACLAW facilities.

This Guide was prepared by ISPE with feedback from industry representatives, and the US Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Compliance, Division of Manufacturing and Product Quality.

This Guide recognizes that industry standards evolve over time and reflects the current understanding of these standards at time of publication.

This Guide presents one approach to satisfying CGMPs while providing realistic solutions to business and operational concerns. There may be other approaches that will satisfy regulatory requirements.

1.2 Scope

This Guide may be used by industry for the design, construction, commissioning, qualification, and maintenance of new, renovated, and reconfigured PACLAW facilities. The use of this document for new or existing facilities is at the discretion of the facility owner or operator.

- This Guide uses a risk-based approach as described in ICH Q9 [1] and ASTM E2500 [2].
- This Guide focuses on systems and methods for the prevention of mix-ups, contamination, and cross contamination. Issues addressed include product adulteration, product mix-up, label mix-up, and misbranding.
- The Guide looks at engineering issues that should be considered in order to provide quality, compliant, and cost effective facilities. Quality by design is addressed. Where non-engineering issues are referenced, information is included to show engineers the importance of these topics and the impact they may have on facility design. Non-engineering topics such as Enterprise Resource Planning (ERP) systems, documentation or other operational issues are not covered in detail, and additional advice from Quality Assurance (QA) departments should be sought where additional information is required.