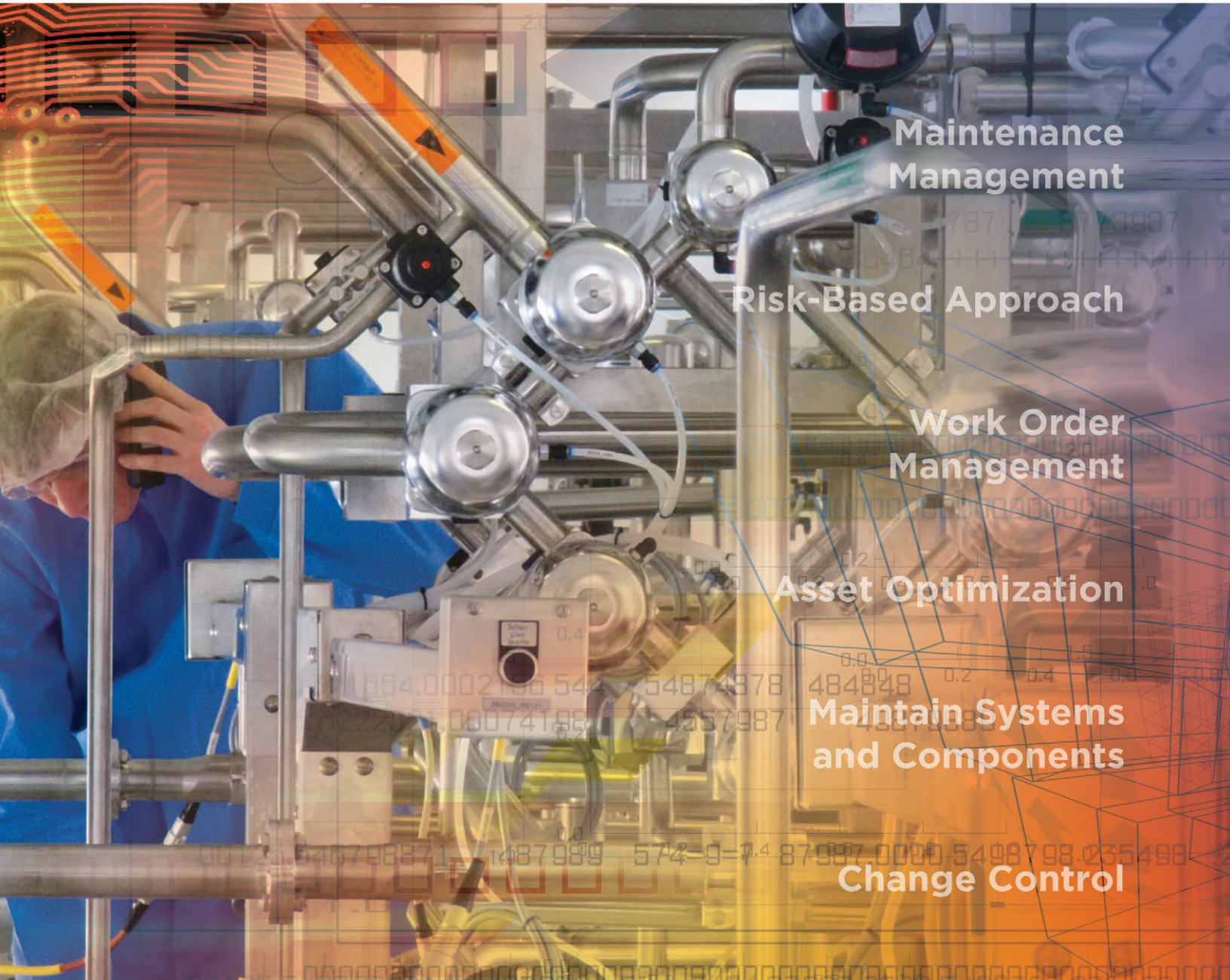




GOOD PRACTICE GUIDE: **Maintenance**

Second Edition



Maintenance
Management

Risk-Based Approach

Work Order
Management

Asset Optimization

Maintain Systems
and Components

Change Control



GOOD PRACTICE GUIDE: **Maintenance**

Second Edition

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Preface

Maintenance can impact both the quality of products and the compliance of pharmaceutical processes. Maintenance Programs have long been recognized as critical to the success of the operations they support.

This Guide focuses on achieving cost-effective compliance with existing regulations and associated guidance. It describes current established good practice and seeks to provide a practical and consistent interpretation of the required elements of a pharmaceutical Maintenance Program, while offering maximum flexibility to enable widespread adaptation and encourage innovation.

This Guide focuses on maintenance in GMP areas and is intended to be used as a tool for the development, implementation, and execution of a Maintenance Program in a pharmaceutical manufacturing environment.

Since the first edition of this Guide, the ICH Q9 risk-based approach has been widely adopted worldwide. This edition reflects alignment with the risk-based approach with respect to maintenance and the industry as a whole. Updates to this edition include consolidating basic and good practices categories, adding clarification on terminology for users, and updating examples.

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1 Introduction

1.1 Background

Maintenance Programs have long been recognized as critical to the success of the operations they support. Maintenance has the potential to affect both the quality of products and the compliance of pharmaceutical processes.

Many pharmaceutical organizations have realized the importance of maintenance, and this has resulted in an increased focus on maintenance processes. This had led to the escalation of requirements being imposed on maintenance operations. In many cases, these increased requirements resulted in added cost and slower execution. In more recent years, the risk-based approach described in ICH Q9 [1] has been applied to Maintenance Programs.

Key themes and practices have become prevalent with respect to Maintenance Programs, e.g.:

- The pharmaceutical industry is using more condition-driven Maintenance Programs based upon operating data derived from Predictive Maintenance (PdM) technologies, rather than performing maintenance on a calendar basis. PdM practices are mature and have been in use in other industries for many years.
- Lean manufacturing concepts and self-directed work teams, borrowed from other industries, affect how maintenance services are delivered.
- Reliability-based techniques, which focus on asset functionality, failure modes, and criticality in the design of Maintenance Plans. Wireless sensors and connected real-time monitoring are becoming more and more prevalent and provide critical information to the user. Smart building techniques are changing the way that facilities are maintained.
- The movement to outsourcing or out-tasking more of maintenance activities adds a level of complexity to Maintenance Programs. A number of organizations are utilizing an Integrated Facilities Management (IFM) model which requires a paradigm shift in the way these services are managed and utilized.

1.2 Purpose

Maintenance practices and trends, coupled with the adoption of the ICH Q9 risk-based approach and the deployment of new technologies, have brought pharmaceutical industry professionals together to update this Guide. This *ISPE Good Practice Guide: Maintenance (Second Edition)* seeks to:

- Help ensure the quality and compliance of maintenance operations and the products impacted by maintenance
- Provide guidance on the latest trends in the maintenance, repair, and improvement of facilities and systems to ensure that organizations are afforded flexibility without impacting the quality of the products
- Recommend a systematic approach aimed at the continual improvement of maintenance operations
- Recommend flexible, standard practices for maintenance professionals that can be applied globally
- Recognize the continuing impact of outsourcing services to third parties and the impact of technology in the production processes
- Control the escalation of non-value generating requirements and cost

This Guide seeks to provide a practical and consistent interpretation of the necessary elements of a pharmaceutical Maintenance Program, while offering maximum flexibility to enable widespread adaptation and encourage innovation.