



Good Practice Guide

Project Management for the Pharmaceutical Industry



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Good Practice Guide

Project Management for the Pharmaceutical Industry

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Preface

The practice of Project Management within the highly regulated world of the pharmaceutical industry provides unique challenges and opportunities. The ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry promotes the integration of GxP with relevant project management activities to ensure that compliance risk is managed both effectively and proactively.

The Guide aims to provide a reference source of good practices for project management for a wide variety of project types within the pharmaceutical industry and benefit to Project Managers and other professionals working on such projects.

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1 Introduction

1.1 Background

The practice of Project Management within the highly regulated world of the pharmaceutical industry provides unique challenges and opportunities. It is considered good project management practice to integrate GxP with relevant project management activities to ensure that compliance risk is managed effectively and proactively. This ISPE Good Practice Guide (GPG): Project Management for the pharmaceutical industry provides good practice approaches which promote the successful integration of these additional requirements.

Throughout the Guide, references to the “pharmaceutical industry” are intended to include all aspects of the industry, including biopharmaceuticals and medical devices.

1.2 Purpose

The purpose of this Guide is to provide a reference source of good practices for project management for a wide variety of project types within the pharmaceutical industry.

The Guide considers how appropriate tools and techniques can support and promote good project management practices and aims to help in sharing of these good practices to facilitate their use within the pharmaceutical industry.

This Guide aims to:

- provide specific guidance on project management in the pharmaceutical industry
- provide a resource for Project Managers and other professionals who are involved in projects in the pharmaceutical industry
- provide a link to project management bodies of knowledge for industries other than the pharmaceutical industry (References 1, 2, and 3, Appendix 3)

The Guide aims to support the:

- development of a common language across the pharmaceutical Project Management community
- access to good project management practice information to enable Project Managers to complete a gap analysis
- development a culture of good project management practice throughout an organization
- development of organizational project management capability, e.g.:
 - a reproducible project delivery system
 - an understanding of the project management requirements for successful project execution
 - enabling project stakeholders to understand the complexities of running a project
 - regular training and skill development for the personnel delivering a project
- development of organizational and individual pharmaceutical project management capabilities through expanding the project management body of knowledge (References 1, 2, and 3, Appendix 3) specific to the pharmaceutical industry