



GOOD PRACTICE GUIDE:
**Good Engineering
Practice**

Second Edition

**Design, Delivery, and
Operation of Engineered Systems**

System Design Practices

System Lifecycle Processes

System Delivery Practices

**Project Engineering
Management**

System Operational Practices





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Good Engineering Practice

Second Edition

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Preface

This ISPE Good Practice Guide aims to provide a definition and explanation of the term Good Engineering Practice (GEP). It describes the fundamental elements of GEP as it should exist in the pharmaceutical industry, encompassing core concepts and engineering practices. The concepts and practices of GEP are fundamental and applicable, to varying degree, to other regulated industries.

It brings together a wealth of information on GEP and provides tools to allow benchmarking of current company practices against what is considered industry good practice.

The Guide includes attachments which provide industry examples, currently in use, of GEP and auditing methods, together with checklists that may be of use to the reader.

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1 Introduction

1.1 Purpose

The purpose of this Guide is to define GEP that supports and enables the design, delivery, and operation of engineered systems in regulated industry. In the context of pharmaceutical engineering and GxP guidance, GEP is frequently referred to as a prerequisite to compliance activities and may be loosely defined in documents. GEP is often used to describe an engineering management system that is expected in a regulated company, but which is not mandated by GxP regulations. For example, effective project progress monitoring and control is not a regulatory issue but is necessary for the efficient operation of a company and is part of GEP.

This Guide considers the entire range of pharmaceutical engineering activity and identifies key attributes of GEP within it, including how GEP relates to and interfaces with GxP. The scope of GEP covers the complete lifecycle of engineering projects and engineered systems from conceptual design to retirement. GEP provides a foundation required across the pharmaceutical industry that other areas, such as GxP, build upon. This Guide also defines and clarifies GEP as an enabling process for Quality Risk Management (QRM)-based integrated Commissioning and Qualification (C&Q) as described in *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification (Second Edition)* [1].

This Guide was developed through the collaboration of representative professionals from various sectors and geographic regions of the pharmaceutical industry with the intention of determining a common understanding of the concept and principles of GEP. This document identifies practices that exemplify how GEP concepts may be applied in the pharmaceutical industry. The aspects of GEP discussed in this Guide are intended to describe the minimum requirements for GEP in engineering activities.

The intended audience for this Guide includes project, process, and other engineers who are involved in the design, delivery, and lifecycle management of engineered systems in the pharmaceutical and other regulated industries. This Guide may be beneficial to other stakeholders involved with such engineered systems, including business, manufacturing/operations, and quality.

1.1.1 Scope

The scope of this Guide incorporates all aspects of engineering related to the design, delivery, and operation of facilities and engineered systems, from conceptual design to retirement, but is focused on engineering practices within the pharmaceutical and other regulated industries. The scope of this Guide includes project engineering management for projects to design and deliver systems within the scope of this Guide. However, business practices such as decision-making processes regarding “what” projects to undertake, including feasibility and other business studies, are outside the scope of this Guide. Additionally, business activities that are upstream from GEP activities (such as Research and Development (R&D), process development, and Manufacturing Science and Technology (MS&T)) that may result in a decision to perform or provide inputs to GEP activities, and that may have many characteristics to which the practices described in this Guide may apply or benefit, are outside the scope of this Guide.

This Guide is by its nature generic, and specific requirements will need to be selected and adapted to suit the individual company. Similarly, the applicability and rigor of engineering practices described in this Guide should be commensurate with the needs of the individual company and with the scale, complexity, and risk of a given engineering process or project. For example, the scope of this Guide can include engineered systems with integrated automation and controls; however, each company must determine the appropriate application of this Guide versus *ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* [2] or other applicable guidance documents for their specific systems.

1.1.2 Benefits

Running a business efficiently requires working practices that will deliver optimum value for a given scope of work. The adoption of GEP can lead to a balance of expenditure and activity in relation to benefits. Benefit is most likely gained when finite resources are focused on identified higher risk aspects or when high risk aspects are more intensely controlled to enable reliable delivery and seamless production. Specific potential benefits include facilitation of speed-to-market of regulated products through efficient delivery of manufacturing facilities and systems and an optimized level of quality oversight, commensurate with the maturity of established GEP.

1.2 Rationale for this Second Edition

The first edition of this Guide was published in 2008. Since that first publication, the pharmaceutical industry and regulators have developed industry standards, best practices, and regulatory guidance around topics that relate to GEP, culminating in particular in *ISPE Baseline Guide: C&Q (Second Edition)* [1] which was published in 2019. The revised C&Q Guide incorporates ASTM E2500 [3], EU GMP Annex 15 [4], ICH Q8, Q9, and Q10 [5, 6, 7], and applicable regulatory guidance. This revision of the *ISPE Good Practice Guide: Good Engineering Practice* incorporates, as applicable, the revision to *C&Q Baseline Guide* [1], and defines and clarifies GEP as an enabling process for QRM-based integrated C&Q.

Additionally, the revised *C&Q Baseline Guide* [1] references an Engineering Quality Process (EQP) that aligns the application of GEP under the overall Pharmaceutical Quality System (PQS) for QRM-based integrated C&Q. This revision of the *GEP Good Practice Guide* describes the EQP, its relationship to the overall PQS, and its application to facilitate GEP as an enabling process for QRM-based integrated C&Q.

1.3 Structure of the Guide

The breadth and coverage of GEP, including how GEP relates to and interfaces with GxP, is covered in Chapter 2.

The structure of the Guide divides GEP activity into the following categories, as shown in Figure 2.1 (Chapter 2) and described in Section 1.4.2:

- Core Concepts
 - Risk Management (Chapter 3)
 - Cost Management (Chapter 4)
 - Organization and Control (Chapter 5)
 - Innovation and Continual Improvement (Chapter 6)
- Practices
 - System Lifecycle Processes (Chapter 7)
 - Project Engineering Management Practices (Chapter 8)
 - System Design Practices (Chapter 9)
 - System Delivery Practices (Chapter 10)
 - Operational Support Practices (Chapter 11)