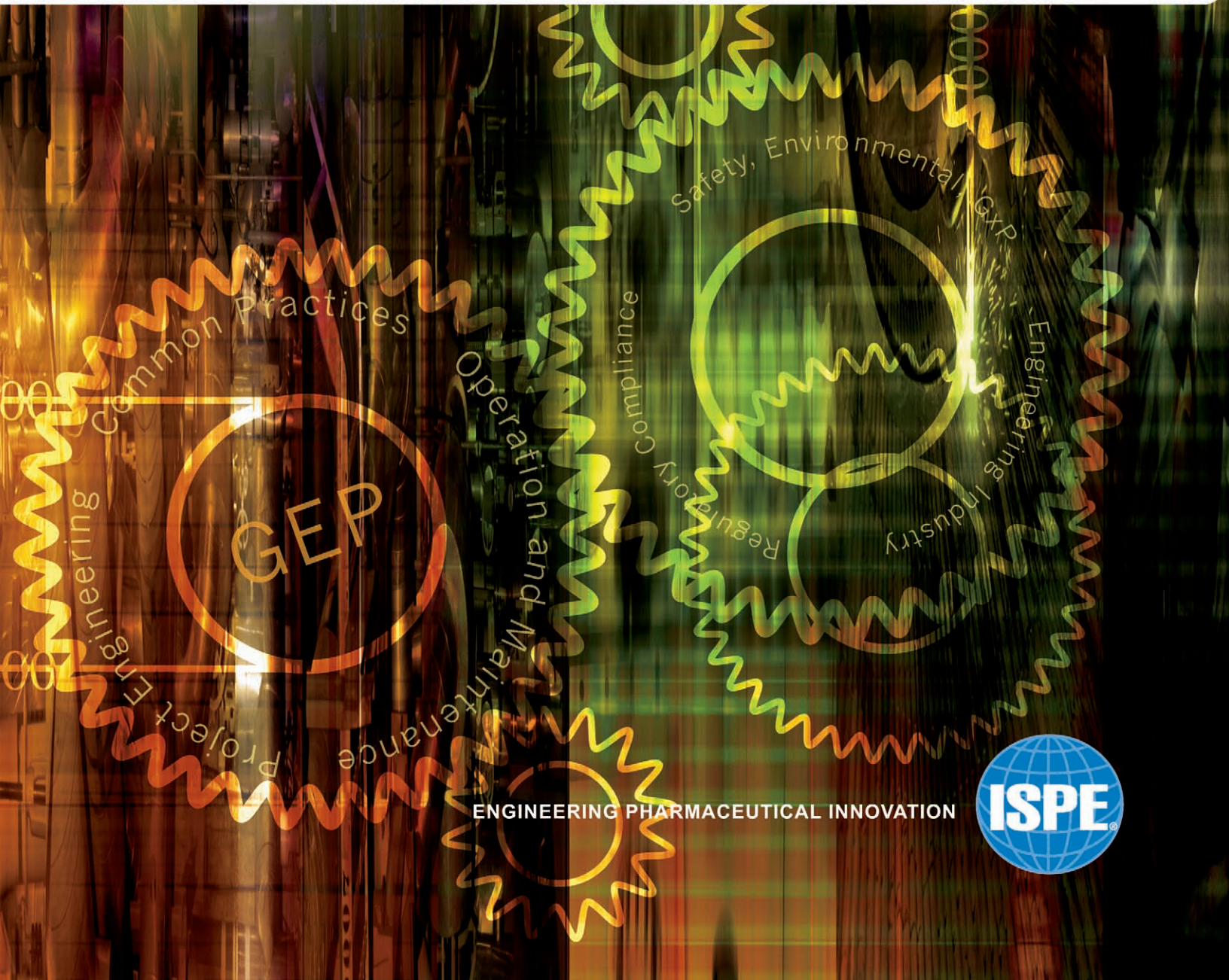




**Good
Practice
Guide**

**Good
Engineering
Practice**



ENGINEERING PHARMACEUTICAL INNOVATION





Good Practice Guide

Good Engineering Practice

Disclaimer:

This Guide is meant to assist pharmaceutical companies in determining a common understanding of the concept and principles of Good Engineering Practice. 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

This ISPE Good Practice Guide: Good Engineering Practice (GEP) aims to provide both a definition and explanation of the term “Good Engineering Practice.” The Guide covers the complete life cycle of engineering, from concept to retirement, and describes the fundamental elements of GEP as they should exist in pharmaceutical and related 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

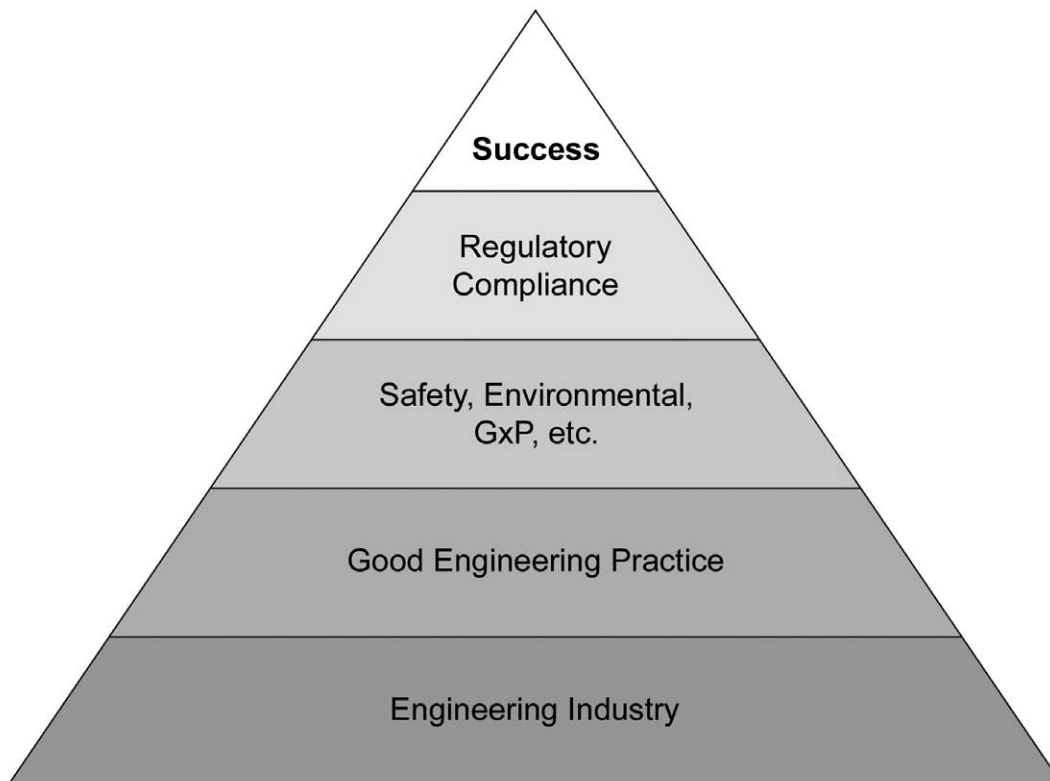
This ISPE Good Practice Guide aims to provide a definition and explanation of the term “Good Engineering Practice” (GEP). It describes the fundamental elements of GEP as they should exist in pharmaceutical and related industries. It should be noted that the concepts are fundamental and applicable in many industries.

1.1 Overview

In the context of pharmaceutical engineering and GxP guidance, GEP is frequently referred to in documents as a prerequisite to compliance activity and may be loosely defined. 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.

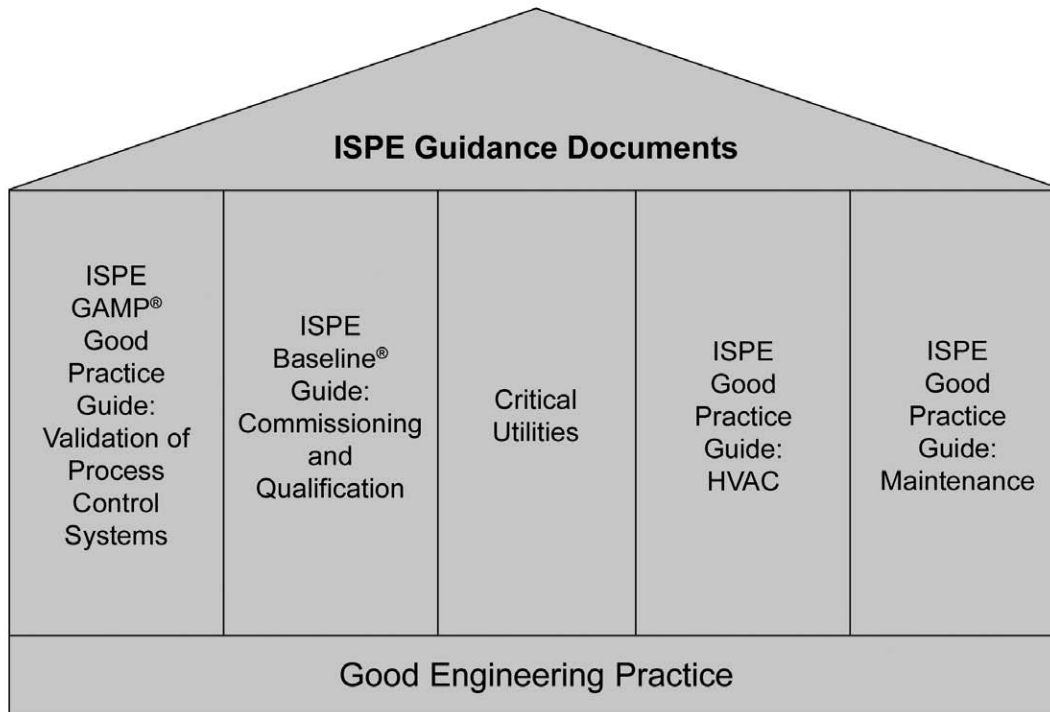
This Guide considers the entire range of pharmaceutical engineering activity and identifies key attributes of GEP within it, including how GEP relates to, and interfaces with GxP. The scope of GEP covers the complete life cycle of engineering from concept to retirement. GEP provides a foundation required across the pharmaceutical industry upon which other areas, such as GxP, build.

Figure 1.1: Positioning of GEP in relation to GxP



The aspects of GEP discussed in this Guide are intended to describe the minimum requirements for GEP in engineering activities.

Figure 1.2: How this GPG relates to other ISPE Technical Documents



The efficient running of a business, demands working practices which will deliver optimum value for a given scope of work. This guide is by its nature generic and specific requirements will need to be selected and adapted.

1.2 Purpose

This document 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 which exemplify how GEP concepts may be applied in the pharmaceutical industry.

1.3 Scope and Benefit Objectives

The scope of this Guide is limited to the healthcare industry but considers all aspects of engineering. The motives for aspiring to practice “good engineering” are wider than the need to comply with GxP regulatory expectations and encompass productivity and business related drivers.

The adoption of GEP should 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.

1.4 Key Concepts

The typical aspects of a GEP program may be categorized into three subsections:

- project engineering