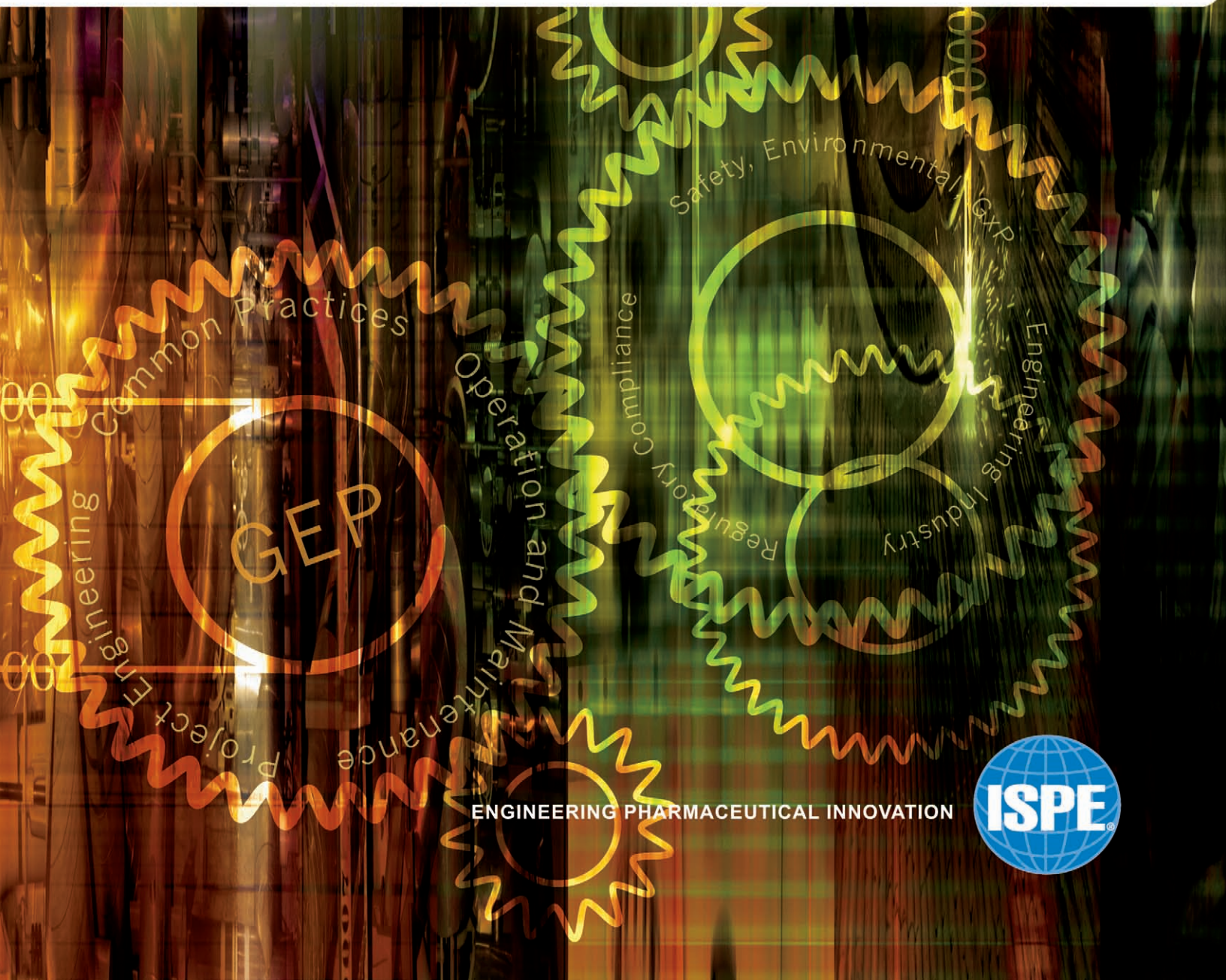
Good Practice Guide

# 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.

*Limitation of Liability*
*In no event shall ISPE or any of its affiliates, or the officers, directors, employees, members, or agents of each of them, be liable for any damages of any kind, including without limitation any special, incidental, indirect, or consequential damages, whether or not advised of the possibility of such damages, and on any theory of liability whatsoever, arising out of or in connection with the use of this information.*



ISBN 1-931879-54-0

# 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.

# Acknowledgements

The ISPE Good Practice Guide (GPG): Good Engineering Practice (GEP) was produced by a Task Team led by Chris Derrett (Schering-Plough Corp., USA) and Mark Foss (Boehringer Ingelheim Ltd., United Kingdom). The members of the task team contributed and reviewed new material.

| | | |
|---|---|---|
| John Andrews | Andrews Consulting Enterprises Ltd. | United Kingdom |
| Joesph Berka | Fluor | USA |
| Nuala Calnan | PM Group | Ireland |
| Tim Cronin | Boehringer Ingelheim | United Kingdom |
| Nick Davies | GlaxoSmithKline | United Kingdom |
| Frank DeMarinis | Purdue Pharma LP | USA |
| Phil DeSantis | Schering-Plough Corp. | USA |
| Roderick Freeman | Teva Parenteral Medicines | USA |
| Nick Haycocks | Amgen | USA |
| Stephen Higham, PE | Genzyme Corp. | USA |
| Les Huffman | Commissioning Agents Inc. | USA |
| Bob Lennon | Commissioning Agents Inc. | USA |
| Thomas Meldgaard Petersen | AlfaNordic | Denmark |
| Neil Winkcup | Pfizer Ltd. | United Kingdom |

The Task Team Leaders would like to express their grateful thanks to the following Team Members for their contribution as technical reviewers of the Guide:

| | | |
|---|---|---|
| Tanveer Ahmed | ABB Ltd. | United Kingdom |
| John Beresford | Haden Freeman Ltd. | United Kingdom |
| Dwayne M. Davis | Shaw Stone & Webster | USA |
| Petter Gallon | AstraZeneca AB | Sweden |
| Angelo Gatto | Sigma Tau SpA | Italy |
| Elizabeth Martinez Flores | Terra Farma SA De CV | Mexico |
| Deepak K. Shukla | Ranbaxy Laboratories Ltd. | India |

**Technical Documents Process and Technology Subcommittee Chairperson**

| | | |
|---|---|---|
| Jan EC Gustafsson | Novo Nordisk A/S | Denmark |

The ISPE GPG: GEP Task Team would like to thank ISPE for technical writing and editing support by Gail Evans (ISPE Technical Documents Writer/Editor) and Sion Wyn (ISPE Technical Consultant).

# Table of Contents

# Table of Attachments

# 1 Introduction

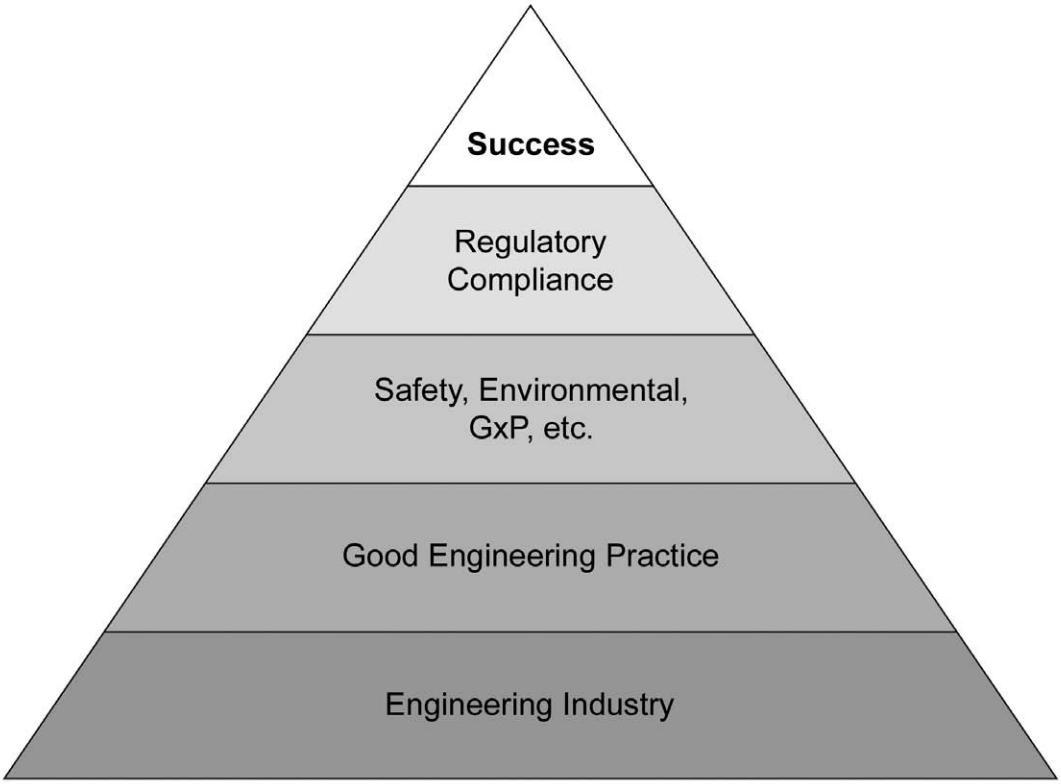
This ISPE Good Practice Guide aims to provide a definition and explanation of the term “Good Engineering Practice” (GEP). It describes the fundamental elements of GEP as they should exist in pharmaceutical and related industries. It should be noted that the concepts are fundamental and applicable in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

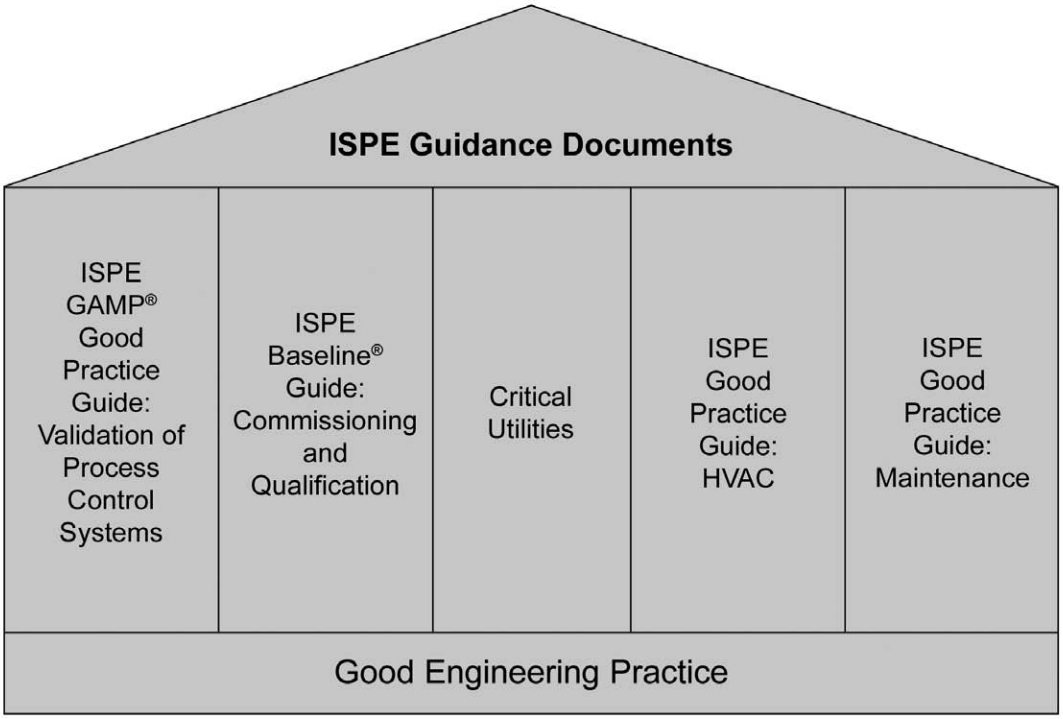
This Guide considers the entire range of pharmaceutical engineering activity and identifies key attributes of GEP within it, including how GEP relates to, and interfaces with GxP. The scope of GEP covers the complete life cycle of engineering from concept to retirement. GEP provides a foundation required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