



GOOD PRACTICE GUIDE:
**Management of
Engineering Standards**



Engineering Standards Program

Standard Work

Knowledge Management

Compliant Designs and Facilities



GOOD PRACTICE GUIDE:

Management of Engineering Standards

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Preface

This ISPE Good Practice Guide on the Management of Engineering Standards has been developed and published by ISPE with the aim to provide to the industry a common understanding and approach to the management of Engineering requirements (Standards) typically set at the corporate level for manufactures, designers, and builders of Pharmaceutical plants and processes. This Guide is a unique opportunity to integrate in a single document the complex body of knowledge required by all professionals involved in the highly regulated pharmaceutical market.

The Guide is intended to promote excellence and knowledge within the pharmaceutical Engineering enterprise and systems. The Guide addresses the knowledge management needs associated with the identification of content, creation, review and approval of Engineering Standards. In addition, the process of keeping content current and compliant through periodic review, as well as successful integration with third party designers/integrators are also addressed.

The Guide is a reference source of good practices covering in a structured way a wide variety of themes, subjects, problems and issues faced across the realm of pharmaceutical design, maintenance, and operation. This Guide is intended to be read in conjunction with other ISPE guidance, International Council for Harmonisation (ICH) guidelines, and industry recognized standards.

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The Guide was produced by a Task Team led by Jeffrey S. Fluharty (Eli Lilly and Co.) and Frank J. Smith (Merck & Co., Inc., Kenilworth, NJ, USA). The collaboration of knowledge is based on the learnings from the former ISPE Engineering Standards Benchmarking Community of Practice (COP).

Core Team

The following individuals took lead roles in the preparation of this Guide:

Jonathan Becker	RPA Engineering	USA
Christopher Derrett	Tintern Tech	United Kingdom
Bryan W. Fluke	RPA Engineering	USA
Jacqueline Glanville	Abbott Laboratories	USA
Francesca A. McBride	Jacobs	USA
Duane A. Mowrey	Eli Lilly and Co.	USA
Joseph P. Wegrzyn	Abbott Laboratories	USA

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Michael Choi	Janssen/Johnson & Johnson	USA
Chris Engel	Jones Lang LaSalle	USA
David Hogenson	Amgen	USA
James Jack	GlaxoSmithKline	United Kingdom
Diana Karnas	Architect	USA
Ted Schnipper	Roche Molecular Systems	USA

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Company affiliations are as of the final draft of the Guide.

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600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA
Tel: +1-813-960-2105, Fax: +1-813-264-2816

www.ISPE.org

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1 Introduction and Business Value

The *ISPE Good Practice Guide: Management of Engineering Standards* is intended to provide guidance on how to establish and maintain an Engineering Standards Program. It covers the entire life cycle of an Engineering Standard, from chartering to retirement. In addition, it includes a description of the governance process for the Engineering Standards Program.

Although it is intended for an Engineering Standards Program, the principles would apply to other document programs.

The application of the recommendations in this Guide are scalable, based upon the size of the organization, number, and type of documents to be managed. For example, a smaller organization may not have Engineering Standards, but could apply the concepts to the maintenance and use of specifications.

Some of the topics in this section will be discussed in more detail in later chapters.

1.1 Business Value

The goals of the Engineering Standards Program should be determined and documented as part of the program charter. Depending upon the size of the program, the resources needed can be several Fulltime Equivalents (FTEs), including the Subject Matter Experts (SMEs), the program management, and governance. The costs to establish and maintain an Engineering Standards Program should be offset by the benefits. Key benefits of having an Engineering Standards Program include:

- Assures the appropriate level of quality, safety, and regulatory compliance is incorporated into engineering designs
- Improves the effectiveness and efficiency of the asset delivery process
- Reduce costs and time to conceptualize, engineer, specify, design, commission, and qualify engineering solutions
- Assures the design solution provides optimal operability and maintainability
- Streamlines engineering information gathering processes by providing a roadmap for engineers to follow to be in compliance with requirements
- Increases productivity by avoiding “reinventing the wheel”. Engineers can focus time on systems that require unique definition
- Reduces cost of new facilities by limiting Architect/Engineer (A/E) firm cost and project time associated with designing every system from scratch
- Reduces variability by documenting proven requirements and driving improvements in facilities and equipment operability and maintainability
- Provides an effective knowledge capture and dissemination process (Knowledge Management System) that is integrated into the engineering process
- Preserves know-how and increases efficiency by retaining reasons of why a specific technical solution has been performed