

Risk Management  
in Space

Pharmaceutical Quality System  
of Strategy

DOI

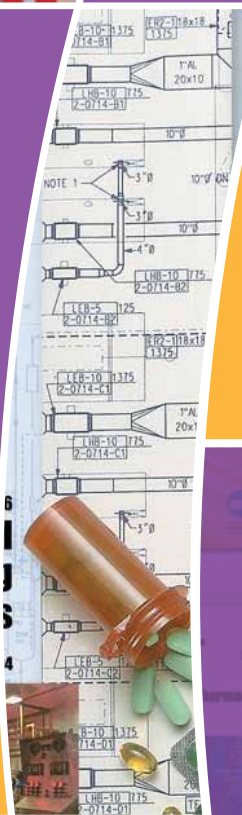
Commissioning and  
Qualification of

The Collective Knowledge of Global  
Industry and Regulatory Experts

# ISPE Publications

## Catalog 2012

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# Give Your Company a Real Foundation for Compliance

Produced by pharmaceutical manufacturing industry professionals, **ISPE** publications provide the practical, “real-world” information you need to help your company build on current best practices to meet and exceed regulatory standards.

**ISPE** Guides result from global collaboration and direct participation by global regulatory agencies, such as the US Food and Drug Administration (FDA), PIC/S, EMA, MHLA, JPMDA, and Health Canada to name a few. ISPE’s Baseline® Guide series was produced in partnership with the US FDA, and ISPE’s world-renowned *GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* engaged a task team of more than 70 subject matter experts and various regulatory authorities around the world, including US FDA, UK MHRA, Afssaps (France), and Regierungspräsidium Darmstadt (Germany).

From promoting better understanding of regulations, to detailing use of computerized systems for quality and compliance, to providing a basic foundation for the design, construction, commissioning, and validation of a manufacturing facility, these one-of-a-kind Guidance Documents are available only through **ISPE**.

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See page 27 for details.

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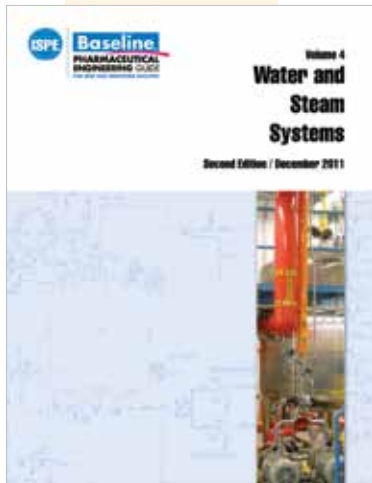
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264 pages, released December 2011

## ISPE Baseline® Guide: Water and Steam Systems (Second Edition)

The *ISPE Baseline® Guide: Water and Steam Systems (Second Edition)* is the only comprehensive guidance of its kind and aims to assist with the design, construction, operation, and maintenance of new water and steam systems that meet current Good Manufacturing Practices (cGMPs) and comply with existing regulations and related guidance.

New chapters covering microbiological considerations, such as biofilm formation, use of sanitizers, sampling, testing, and control levels, as well as the overall impact of microbial considerations on unit operations and finished water have been added.

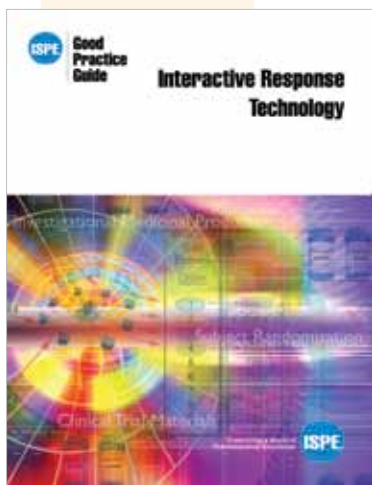
The Guide also has been reviewed by the US Food and Drug Administration (FDA), and their comments have been taken into consideration in the final version of the Guide.

The Guide was written by a global team of critical utilities experts with a combined experience of more than 500 years. Much of the team responsible for the original Water and Steam Systems Baseline Guide has returned to contribute to the revised Guide, providing continuity and longevity of vision to the Guide's contents.

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**Item #:** WAT1211DL

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92 pages, released November 2011

## ISPE Good Practice Guide: Interactive Response Technology

Interactive response technology is a tool that can be used to support multiple business processes, and this Guide describes how the pharmaceutical industry can apply the technology to support various clinical trial activities.

The Guide provides guidance on how to: successfully implement an interactive response technology to manage key clinical trial activities, particularly expiry date management and program pooling; ensure robustness of the technology, contributing to its effectiveness and reliability; and communicate and foster a standardized, industry-wide approach to critical functionality of Interactive Response Technology when used in managing investigational medicinal product

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282 pages, released November 2011

## ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry

The *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry* provides good practice approaches which promote the successful integration of GxP with relevant project management activities to ensure that compliance risk is managed effectively and proactively.

The Guide discusses: the tools and techniques supporting project delivery, the life cycle of a typical project in the pharmaceutical industry, and how compliance to pharmaceutical industry regulations is integrated with the project life cycle.

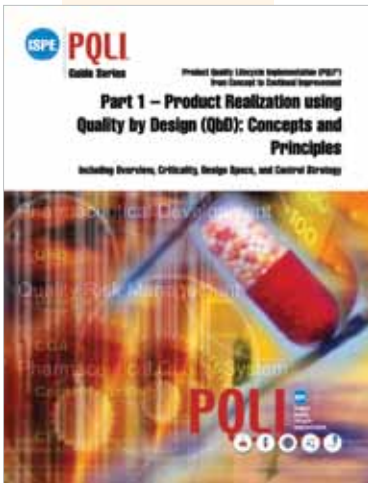
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188 pages, released November 2011

## ISPE Guide Series: Product Quality Lifecycle Implementation (PQLI®) from Concept to Continual Improvement

### Part 1 – Product Realization using QbD, Concepts and Principles

Part 1 includes the topics of Criticality, Design Space, and Control Strategy and addresses product and process development, transfer to, and establishment of, commercial manufacture using science- and risk-based approaches.

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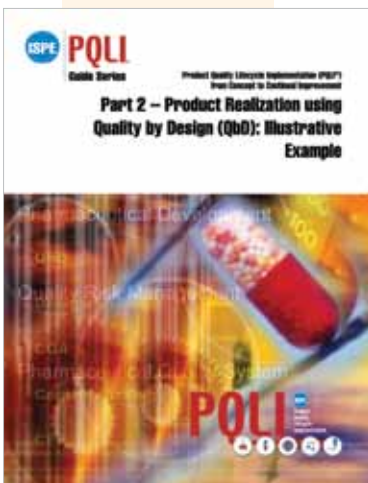
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#### Related Webinar:

- Product Quality Lifecycle Implementation® (PQLI®) 101: Vision, Status and Next Steps



232 pages, released November 2011

## ISPE Guide Series: Product Quality Lifecycle Implementation (PQLI®) from Concept to Continual Improvement

### Part 2 – Product Realization using QbD, Illustrative Example

Part 2 presents the small molecule case study developed by the ISPE PQLI® teams. This case study provides details of the application of the approaches to product and process understanding using quality risk management. Part 2 also refers to the many case studies in the public domain and uses ICH guidelines Q8 (R2), Q9, Q10, together with other relevant ICH guidelines.

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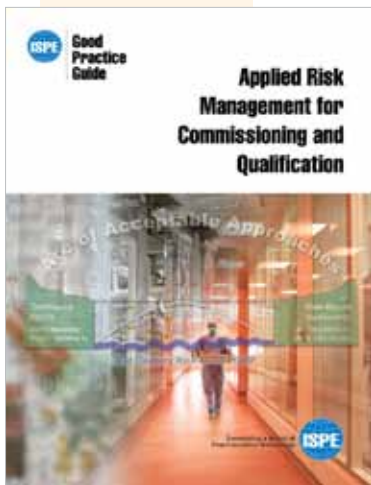
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#### Related Webinars:

- Process Analytical Technology (PAT) Used for PQLI® and QbD: Implementation Update, Examples, and Discussion
- Product Quality Lifecycle Implementation (PQLI®): Focusing on Q10
- Product Quality Lifecycle Implementation (PQLI®): Regional Regulatory Experiences Implementing the ICH Quality Vision



140 pages, released October 2011

## ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification

The *ISPE Good Practice Guide: Applied Risk Management in Commissioning and Qualification* describes how organizations can move from established baseline practice to a more efficient science- and risk-based framework. It illustrates the application of Quality Risk Management to traditional commissioning and qualification practices, linking traditional terminology and approaches to the newer science- and risk-based specification and verification terminology and approaches applied in ICH Q8, Q9, and Q10, ASTM E2500, and *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems and Equipment*.

The approach described in the *ISPE Good Practice Guide: Applied Risk Management in Commissioning and Qualification* allows companies to achieve the benefits of a science- and risk-based model by outlining bridging strategies for organizations with well-established qualification-based Quality Management Systems and providing a roadmap showing the spectrum of potential approaches for this transition.

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204 pages, released September 2011

## ISPE Baseline® Guide: Sterile Product Manufacturing Facilities (Second Edition)

The newly updated *ISPE Baseline® Guide: Sterile Product Manufacturing Facilities* is a complete revision of the original version, and contains recommendations to help facilitate compliance with the latest FDA and EMA guidance. The update is aimed at a truly international audience, as it incorporates a comprehensive tabulation, explanation, and comparison of the cleanliness designations found in FDA, EMA, and ISO guidance documents, allowing for better harmonization in global facility design and a wider breadth of regulatory compliance internationally.

Technical updates contained in the Guide include the use of RABS and isolator technology; facility design; best practices for terminally sterilized and aseptically processed sterile products; and updated guidance on quality attributes of construction and finishes solutions for different grades of facility. The Guide includes informative diagrams and thorough text to explain and compare GMP requirements, providing a platform for developing compliant solutions and allowing firms to follow several different routes to reach a compliant solution.

The new Sterile Product Manufacturing Facilities Baseline Guide consolidates all of ISPE's latest best practice recommendations on sterile manufacturing facility design into one document.

**Bound Item #:** STER0911  
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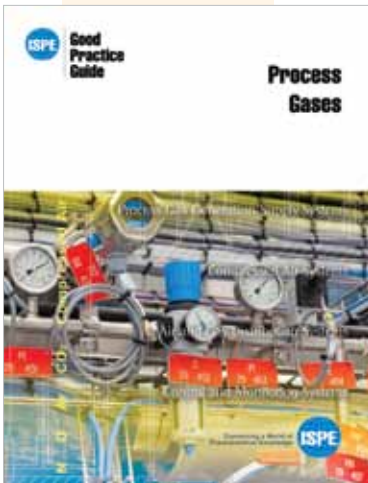
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The bound version is available in Chinese. To purchase, visit [www.ISPE.org/Publications](http://www.ISPE.org/Publications).

### Related Webinar:

- Sterile Guide "Meet the Authors"



108 pages, released July 2011

## ISPE Good Practice Guide: Process Gases

The *ISPE Good Practice Guide: Process Gases* aims to define current good practices within pharmaceutical manufacturing applications, providing information to allow organizations to benchmark their practices, and improve upon them.

This Guide considers gases that come into direct contact with the biopharmaceutical and pharmaceutical manufacturing process streams, including:

- nitrogen
- oxygen
- argon
- carbon dioxide
- compressed air

These process streams include bodily contact surfaces of invasive medical devices and fluid paths of medical devices that are used for intravenous solution, blood, or other critical applications to administer life saving or sustaining fluids.

The Guide focuses on defining cost effective engineering approaches and practices used to deliver a process gas systems for a manufacturing facility in a timely manner that will meet its intended purpose. Information is provided on how to avoid increasing facility installation and operational costs.

Specifically, the Guide addresses the process of designing, constructing, commissioning, and qualifying a process gas system regulated by the FDA or other regulatory authority, such as the EMA. The Guide also addresses international guidelines and regulations.

The Guide aims to clarify gas system issues critical to product quality for the production of biopharmaceutical and pharmaceutical drug substances and drug products.

The Guide promotes science and risk-based to provide an effective basis for the planning, construction, commissioning, and qualification processes for gas systems used to support production.

Five key concepts are applied throughout the Guide:

1. Product and Process Understanding
2. Life Cycle Approach within a Quality Management System
3. Scaleable Life Cycle Activities
4. Science-Based Quality Risk Management
5. Utilizing Supplier Involvement

The Guide is intended to align with:

- ICH Q9 Quality Risk Management
- ASTM E2500-07 Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment

The Guide also considers some of the issues relating to sustainability and economics.

This Guide is written for:

- The Pharmaceutical Manufacturing and Engineering Community – to provide a common language and understanding and a common resource for engineering information related to gas systems.
- Regulatory Professionals – to provide a scientific risk-based approach to demonstrate compliance.
- Quality Professionals – to provide an understanding of which system parameters are important to product quality and patient safety.

**Bound Item #:** IGP GPGAS  
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120 pages, released June 2011

This Guide is intended to cover all pharmaceutical manufacturing (including drug substance, drug product, and biotechnology). It also may be applied to medical device or blood product manufacturing systems and equipment.

#### Key benefits of using this Guide include:

- Improving the ability to meet documented process requirements
- Control risks within the manufacturing process, producing high quality products, and consistently operating to meet product and process requirements

Principles contained in this Guide are applicable to the delivery of new commercial manufacturing capability and may be used during modifications to existing regulated manufacturing facilities.

## ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment

The successful delivery of manufacturing facilities regulated by various authorities, poses significant challenges to manufacturers, engineering professionals, and equipment suppliers.

The new *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment* has been published that provides direction to industry on the implementation of a science- and risk-based approach for demonstrating that pharmaceutical and biopharmaceutical facilities, systems, equipment, and associated automation are fit for intended use and comply with regulatory requirements.

The aim of the Guide is to facilitate the translation of the scientific knowledge about the product and process into documented specification, design, and verification of facilities, systems, and equipment. Specific implementation guidance is given on meeting the expectations of global regulators and is compatible with ICH documents (Q8 (R2), Q9, and Q10) and ASTM E2500-07.

The Guide will be of interest to those following the latest industry and regulatory initiatives, including:

- Product and process understanding
- A science- and risk-based approach
- Application of Quality by Design concepts

The approach described in this Guide focuses on establishing that which is critical for the process, product, and patient, and recommends verification strategies for confirming these critical aspects. The activities described address the verification (or qualification) portion of the validation life cycle upon which process validation is built. The application of key concepts presented in the Guide can provide numerous benefits:

Key Concept	Expected Benefit
Science-based quality risk management	Risk assessment tools based on analyzing risk to the patient will provide better definition of critical aspects, and may save effort in execution (versus system and component impact assessment).
Product and process understanding	Improvements in design to meet science-based process requirements.
Flexible approaches to verification	Improved effectiveness and lower cost of inspections and testing.
Focus on achieving fitness for intended use	Efficient and focused use of resources, ensuring that these resources are directed to quality critical aspects and activities.
Clarification of roles and responsibilities	Better application of resources and better conformance to GxP regulations.
Leveraging supplier activities	Avoiding repeated specification and verification activities.

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#### Related Webinar:

- Baseline® Guide 12 Overview



140 pages, released May 2011

## ISPE Good Practice Guide: Cold Chain Management

Increasing volumes of cold products, the complexity of these products, and the complexity of the associated supply chain are causes for concern. Organizations need adequate control over cold chain of pharmaceutical and biopharmaceutical distribution systems. ISPE recognized the need for guidance in this area. A dedicated team of subject matter experts from across the pharmaceutical and biopharmaceutical industries developed the *ISPE Good Practice Guide: Cold Chain Management*. This Guide provides tools and strategies for Cold Chain Management and to complement work by the Guidance for Temperature Controlled Medicinal Products. It helps to develop, establish, document, implement, maintain and improve industry good practice for product requiring controlled cold conditions. The Guide is intended to provide practical guidance to assist in the specification, design, commissioning and verification of the fixed and passive systems within the cold chain.

The Guide is intended to provide a robust cost effective system to ensure safe, effective product is received by the end users. The Guide covers the process from the point of entry into the manufacturers' controlled temperature storage facility after being packaged through delivery to the distributor or customer premises. Collaboration by team members and the PDA has helped to ensure that guidance is aligned with forthcoming PDA guidance documents. It makes reference to:

- ICH Q8, Product Development
- ICH Q9, Quality Risk Management
- ICH Q10, Pharmaceutical Quality Systems
- US Pharmacopeia
- ASTM E2500 "Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment"
- ASTM E2537 "Standard Guide for Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing"
- Cold chain management is part of the life cycle of a regulated company and understanding the requirements of the cold chain process will help to focus efforts to ensure that: activities add value, solutions are based on robust science, and undergo appropriate risk assessment; therefore, meeting the expectations of the regulators and ultimately provide protection to the patient.

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### Related Webinar:

- Development and Qualification of a Robust Cold Chain Logistics Solution for Bulk Biologics



196 pages; released February 2011

## GAMP® Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems (Second Edition)

This GAMP® *Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems* is a revision of the GAMP® *Good Practice Guide: Validation of Process Control Systems*. It provides guidance and examples on the application of the principles and framework of GAMP® 5: *A Risk-Based Approach to Compliant GxP Computerized Systems* to a wide range of systems, from basic instruments to large, complex, distributed control systems. This Guide aims to achieve process control systems that are fit for intended use and compliant with applicable regulations; providing recommended good practice based on a life cycle approach for the development, maintenance, and management of process control systems.

The Guide applies science-based Quality Risk Management, as described in ICH Q9 and GAMP® 5. It describes the system life cycle from concept to retirement, providing a high level overview of the approach together with guidance on how activities might be scaled based on risk to product quality, system novelty, and complexity as well as other project specific factors.

The Guide also emphasizes that in order to be efficient, appropriate specification and verification activities should be an integral part of the normal system life cycle.

The Guide focuses on those features that are in some way special to process control systems and distinguishes three types of process control systems. These are intended to be used in conjunction with GAMP® categories to highlight system scale and complexity, and to allow a common basis for presenting examples across a range of systems. Examples are introduced in the body of the document, and expanded as appropriate in the Appendices.

### Specific business benefits include:

- Reduction of cost and time taken to achieve and maintain compliance
- Early defect identification and resolution leading to reduced impact on cost and schedule
- Cost-effective operation and maintenance

### Other benefits include:

- A comprehensive overview of current good practice for regulated process control systems
- Harmonized approaches for different types of process control systems
- Definition of the process control system life cycle and discussion of the detailed engineering activities
- Generation of accurate and complete user requirements with an early emphasis on product and process understanding
- Guidance on functionality and structure of process control systems
- Guidance on the supplier services required for regulated environments
- Guidance on effective collaboration between regulated companies and suppliers
- Guidance on leveraging of supplier documentation
- Scalability of approach based on risk, gamp categorization, and other factors

This Guide comprises a Main Body and a set of supporting Appendices, which provide detailed examples for those activities which are in some way special to process control systems. Some technical aspects that are relevant to process control systems are addressed in separate special topic appendices.

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**Individual PDF Download Item #:** GGPGPCS2DL

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### This revision has been significantly updated to align with the concepts and terminology of recent regulatory and industry developments including:

- International Conference on Harmonisation (ICH) Guidance setting out expectations for the application of science- and risk-based approaches to drug development and manufacture supported by pharmaceutical quality systems
- Product Quality Lifecycle Implementation® (PQLI®), ISPE's Global Industry Initiative for a Practical Approach to implementation of International Conference on Harmonisation (ICH) guidances Q8 (R2), Pharmaceutical Development, Q9, Quality Risk Management, and Q10, Pharmaceutical Quality System
- FDA cGMPs for the 21st Century Initiative and associated guidance promoting science-based risk management emerging industry standards such as those produced by the ASTM E55 Committee promoting process understanding, control and capability for drug development and manufacture
- *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment*

\* New Member fee includes one-year membership in ISPE -- a \$239 value. See order form for details.



152 pages; released September 2010

## Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP)

The *ISPE Baseline® Guide: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP)* provides a scientific risk-based approach based on ICH Q9 to manage the risk of cross-contamination to maintain product quality and operator safety. This allows the selection of the appropriate risk control strategies to be implemented on a case-by-case basis to maintain patient safety and assure product quality.

The science of toxicology recognizes the principle of a continuum of hazard associated with all compounds, even within individual classes of compounds. Zero risk is considered scientifically unachievable and not necessary. These compounds, or classes of compounds, have historically included hormones, cytotoxic compounds, genotoxic compounds, live vaccines, and veterinary products. Sensitizers such as Beta-Lactams antibiotics have received particular scrutiny due to severity of risk.

When considering multi-product facilities, to satisfy regulatory requirements risk management processes are necessary to determine and document reasonable and acceptable risk. This Guide provides a process that allows manufacturer's to assess risk and determine where control strategies are necessary to meet acceptable limits for cross-contamination. The control strategies to manage risk can vary from administrative to full dedication or segregation. Typically, some combination of control strategies may be necessary.

### This Guide will:

- Provide an approach to identify highly hazardous drugs
- Provide a risk management/assessment model that gives a clear view on how to address the controls to comply with 21 CFR 211.42(c)
- Discuss how the approach fits into cleaning validation

### Topics covered in the Guide include:

- Concepts and Regulatory Philosophy
- Risk Assessment
- Risk Analysis
- Risk Control
- Risk Acceptance
- Risk Review
- Risk-MaPP Application Examples
- Quality System Requirements
- Risk Identification
- Risk Evaluation
- Risk Reduction
- Risk Management Tools
- Risk Communication

This Risk-MaPP Guide is intended to provide professionals in the pharmaceutical industry with a consistent approach on setting acceptable limits to assess the potential of cross-contamination causing an undue risk to patient safety. This approach is intended to allow manufacturers to contain manufacturing cost while facilitating safe and affordable drug product. This Guide should be used in conjunction with local and/or applicable (multi-national manufacturing platforms) regulatory requirements, and other guidance documents already available to the pharmaceutical manufacturing industry.

The risk management approach should be commensurate with the different levels or degrees of risk to ensure that cross-contamination will be maintained at or below acceptable limits. This Guide addresses methods for determining the acceptable limits, as well as suggestions for documentation of the risk management process.

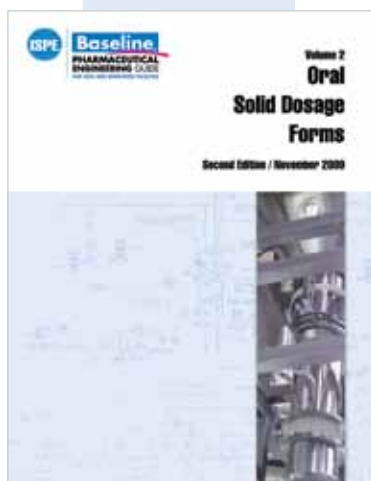
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The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.

### Related Webinars:

- Risk Management Follow-Through
- Risk-MaPP: What is it and Why You Need it!



188 pages; released November 2009

## Oral Solid Dosage Forms (Second Edition)

This revision — the latest ISPE publication reviewed by the US FDA — updates content from the original Oral Solid Dosage Forms Baseline® Guide to current industry standards, practices, and regulatory requirements.

Specifically, it addresses the latest interpretation of GMP requirements, as well as a risk-based approach to regulatory compliance relating to the design, construction, and validation of the OSD manufacturing facility. The product and processing chapter has been expanded with detailed discussion of each critical unit operation and new technological trends, such as continuous processing and implementation of process analytical technology. The Guide provides a comprehensive view of best practices available in the pharmaceutical industry for oral solid manufacturing facility design and construction. A lifecycle approach to project management is emphasized.

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### Related Webinar:

- New Technologies in OSD



188 pages; released June 2007

## Active Pharmaceutical Ingredients, a Revision of Bulk Pharmaceutical Chemicals

This revised Guide builds on the original principles of ISPE's Baseline® Guide Volume 1, Active Pharmaceutical Ingredients (originally entitled Bulk Pharmaceutical Chemicals). It also incorporates and builds on new regulations and guidance, such as: ICH Q7, ICH Q9, GAMP® 4, 21 CFR Part 11, Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (cGMP), FDA Draft Guidance for Industry PAT – Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance, and much more.

**BONUS:** With purchase of API, you will receive the white paper, *A Risk-Based Approach to Defining Levels of Protection within API Facility Design: The Concept of Briefly Exposed (Briefly Open)*, by Stan Newberger and Dr. Trish Melton. This white paper expands and clarifies a new concept introduced in the Guide.

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The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.



196 pages; released July 2004

## Biopharmaceutical Manufacturing Facilities

This Guide is a reference for design, construction, commissioning, and qualification of new facilities for biopharmaceutical Active Pharmaceutical Ingredients (APIs), also known as drug substance. The Guide covers in-line process analytical measurement and control, the use of disposable equipment, enhanced strategies for automation, and alternative methods for protecting the integrity of the product. Produced by Task Teams composed of more than 100 regulatory and industry leaders, the Guide addresses US GMPs, while the GMPs of other countries and regions are covered in the appendices.

**Bound Item #:** BIO0604  
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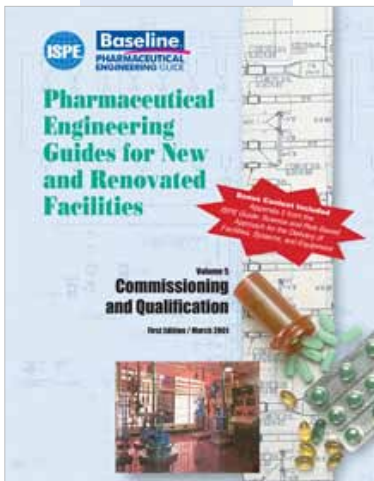
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The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.

### Related Webinar:

- FDA Discusses Biopharm Guide



142 pages; released March 2001

## Commissioning and Qualification

This Guide focuses on engineering approaches and practices for timely, cost-effective delivery of manufacturing facilities, specifically addressing the process of designing, constructing, commissioning, and qualifying the facilities, utilities, and equipment regulated by the FDA or other health authorities. The Guide has incorporated comments from industry representatives, FDA field investigators, and personnel from the FDA's Center for Drug Evaluation and Research (CDER). The Guide is intended primarily for regulatory compliance in the US market, and it may be helpful to manufacturers for meeting European requirements.

**Bound Item #:** CQ0101  
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**Bound/CD Set Item #:** CQELEC

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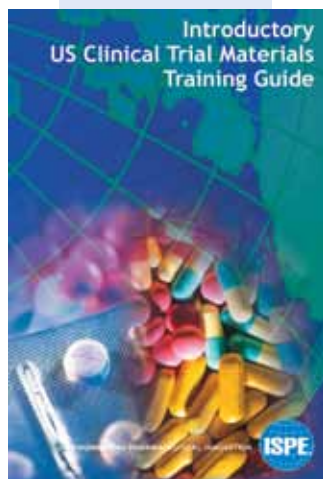
The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.

### New Value Added Content

In an effort to further assist companies in transitioning from traditional impact assessment based qualification approaches to ICH Q9 QRM based approaches found in ASTM E2500 and the ISPE FSE Guide, ISPE will now include Appendix 2 from the *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment* with purchases of the *Baseline® Guide: Volume 5 – Commissioning and Qualification*. The Appendix contains an update for use with the Commissioning and Qualification Impact Assessment Chapter of the *Baseline® Guide*, based on the experiences of project teams and considers the benefits and application of science-based process understanding. By including the Appendix, ISPE hopes to provide an additional value to those purchasing *Baseline® Guide: Volume 5 – Commissioning and Qualification* by showing an updated approach to impact assessments.

### Related Webinar:

- The Key to Successful Commissioning and Qualification



44 pages; released October 2002

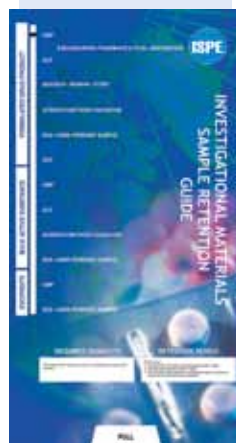
## Introductory US Clinical Trial Materials Training Guide

This Guide is designed to familiarize new clinical trial materials professionals with the terms and related information they need for success. The focus of this Guide is clinical trial material supply units operating under the rules of the US FDA.

Item #: CMGUIDE

**Pricing:**

Member \$15/€12  
Nonmember \$25/€20



Released July 2003

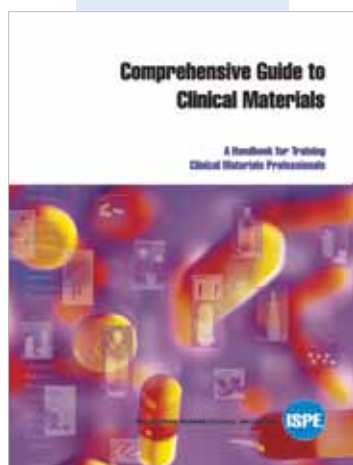
## Investigational Materials Sample Retention Guide

This Guide, a supplement to the Introductory US Clinical Trial Materials Training Guide, assists users in determining quantity and retention time for sample products.

Item #: CMRETGD

**Pricing:**

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Nonmember \$17/€14



120 pages; released July 2006

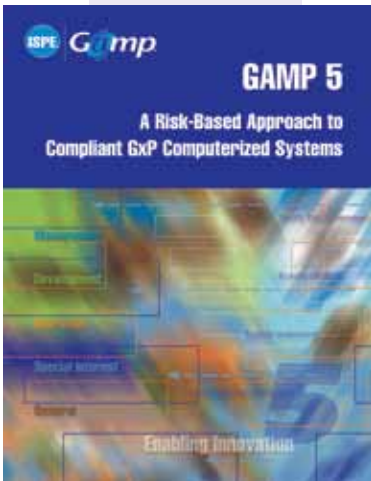
## Comprehensive Guide to Clinical Materials A Handbook for Training Clinical Materials Professionals

The Guide is designed to provide a valuable tool for the development of in-house training sessions for advanced training, building on the topics covered in the Introductory US Clinical Trial Materials Training Guide. It may be used in a classroom setting, and then by attendees to gain more in-depth knowledge and as a reference source for future use.

Item #: CMHB2006

**Pricing:**

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356 pages; released February 2008

## GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems

The new *GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems* provides pragmatic and practical industry guidance that aims to achieve compliant computerized systems that are fit for intended use in an efficient and effective manner, while also enabling innovation and technological advance. The revised Guide describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. A robust quality risk management process based on ICH Q9 principles is central to the approach. GAMP® 5 also contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

### New and Revised Material

Particular emphasis is given in GAMP® 5 on providing a cost effective approach to compliance and demonstrating fitness for intended use. To support this, new and updated guidance is given on the following aspects:

- A complete system lifecycle approach as part of a Quality Management System (QMS), from concept to retirement
- A scalable approach to achieve and maintain GxP compliance driven by novelty, complexity, and risk to patient safety, product quality, and data integrity
- Clarifying the role of the Quality Unit, and introducing the roles of Process Owner, System Owner, and Subject Matter Experts
- In the GMP environment, stressing the importance of clear requirements based on a thorough understanding of the science and of the Critical Quality Attributes (CQAs) of the development and manufacturing process and drug products, to facilitate the adoption of a Quality by Design (QbD) approach
- The leveraging of supplier documentation and knowledge, wherever possible, and subject to satisfactory supplier assessment to avoid unnecessary duplication
- Improving efficiency by promoting practical and effective interpretation of GAMP® guidance
- Maximizing use of documentation from activities such as development and commissioning as verification evidence
- The importance of effective governance to achieve and maintain compliance
- Identifying opportunities for process and system improvements based on periodic review, root-cause analysis, and Corrective and Preventive Action (CAPA)

An exciting new innovation is the CD accompanying the Guide. It provides supporting materials, including differences between GAMP® 4 and GAMP® 5, key diagrams, templates, forms, example documents, and background information. (CD is Windows compatible only.)

**Bound Item #:** 5BOUND

**Individual PDF Download**

**Item #:** 5BOUNDLL

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### Related Webinars:

- A GAMP® Interpretation - Annex 11
- GAMP® 5 Series: Change Management: Computerized Systems including Patch and Upgrade Management
- GAMP® Series: Changing the Industry
- GAMP®5 Series: IT Infrastructure Compliance and Control
- GAMP® 5 Series: Managing Quality in an Outsourced Environment
- GAMP® 5: End-User Applications
- Life After GAMP® 5: What Comes Next?



## GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management (Second Edition)

Calibration is an essential element in ensuring compliance in the pharmaceutical and associated regulated life science industries. To ensure success, calibration should be managed effectively, by appropriately qualified and competent personnel. If neglected, calibration is capable of compromising product and process quality, facility, safety, environmental and patient safety, and dramatically increasing costs.

The *GAMP® Good Practice Guide: A Risk-Based Approach to Calibration Management (Second Edition)* provides guidance in setting up a calibration management system, which will give a structured approach to instrument risk assessment, calibration program management, documentation, and corrective actions, essential to regulatory compliance.

There has been a change in regulatory expectations and in associated industry guidance documents. The FDA has been actively promoting a risk-based approach to GMP as part of the 21st Century Initiative. The change in approach to validation and compliance now puts more focus on the integrity, security, and reliability of process control systems and the instrumentation supporting them. The benefit will be a focused calibration effort that concentrates on risks to product quality and public safety. Such a focus also should be cost-effective.

The Guide has been updated to address the changing environment, while still satisfying international GxP regulatory expectations, current at time of publication. The scope has been widened to include related industries, laboratory, and analytical instrumentation.

**Bound Item #:** GGPGCALMGMT2

**Individual PDF Download**

**Item #:** GGPGCALMGT2DL

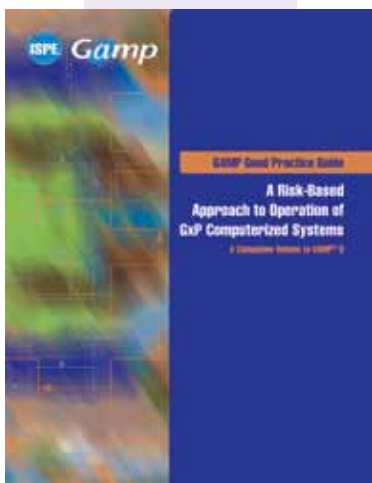
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124 pages; released November 2010



216 pages; released January 2010

## GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems

**A Companion Volume to GAMP® 5**

Regulated computerized systems should be maintained in a demonstrable state of control and in accordance with regulatory requirements. Recovery from a failure to maintain control of a regulated system during the operation phase can be both time-consuming and expensive, and increase the risk to data integrity, product quality, and patient safety. During the operational life of a GxP system, regulators usually focus on the integrity, consistency, and completeness of controls required to maintain compliance.

This Guide highlights the importance of the operation phase of the system lifecycle, when the return on investment for the significant time and resource expended in implementing new computerized systems can be achieved. The Guide will help regulated organizations achieve regulated computerized systems that are fit for intended use and compliant with applicable regulations and provides comprehensive guidance for maintaining control of regulated systems throughout their operational life, including to:

- Provide a better understanding of both the individual operational processes and the inter-relationships between them
- Help organizations assign clear roles and responsibilities to required activities throughout the operation phase
- Embed scaleable risk-based approaches into the definition and management of those internal and external operational processes

When applied as intended, this Guide can provide detailed direction on the required control processes which form a substantial part of an appropriate Quality Management System (QMS).

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**Individual PDF Download  
Item #:** GGPGOGCSDL

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144 pages; released February 2010

## GAMP® Good Practice Guide: Manufacturing Execution Systems - A Strategic and Program Management Approach

The Guide uses a complete lifecycle approach to the development and use of MES for regulated manufacturing as a collection or domain of manufacturing related functions that integrates business and process controls, information flow, and human interaction to facilitate the operation of an organization. It collects and integrates information and knowledge from many disciplines and sources into a single comprehensive guideline and aims to enable organizations to:

- Shorten development and implementation times by leveraging industry experience
- Implement design and testing methods that improve lifecycle activities
- Build compliance into the process
- Provide improved understanding and coordination of the complete manufacturing environment
- Reduce the risk of project failure
- Better balance costs of implementation and operation
- Clarify quality unit resources required for ongoing system operational support

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92 pages; released August 2007

## Electronic Data Archiving

The *GAMP® Good Practice Guide: Electronic Data Archiving* seeks to provide a rational and scalable approach to electronic data archiving through the development of an archiving strategy. The implementation of this strategy should help organizations achieve and maintain regulatory compliance, and to effectively manage electronic records over the long term.

This Guide is intended as a supplement to the main GAMP® Guide and is read in conjunction with the *GAMP® Good Practice Guide: Electronic Records and Signatures*, which provide additional relevant information.

<b>Bound Item #:</b> 4EDA	<b>Bound or PDF Download Pricing:</b>
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96 pages; released November 2005

## Global Information Systems Control and Compliance

This Guide provides an understanding of the issues faced by teams that are tasked with completing a global deployment of an IT system, in particular, to provide some insight into addressing issues of control and regulatory compliance efficiently and effectively. The Guide encompasses a wide range of regulations and guidelines, including US FDA regulations and GPGs, relevant sections of EU GMPs, PIC/S Guidance, Health Canada GMP regulations, and ICH Guidelines.

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128 pages; released September 2005

## IT Infrastructure Control and Compliance

This Guide provides comprehensive guidance on meeting current regulatory expectations for compliant IT Infrastructure platforms, including the need to identify, qualify, and control those aspects impacted by GxP.

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The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.



96 pages; released April 2005

## Validation of Laboratory Computerized Systems

This Guide focuses on laboratory computer systems for regulated healthcare industries subject to Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), or Good Clinical Practice (GCP). Building upon the GAMP® 4 software categories, the Guide provides a rational, scalable approach to the validation of laboratory computerized systems, taking into account systems categorization, and risk assessment processes.

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**Item #:** 4VLCSDL

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The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.



240 pages; released February 2005

## A Risk-Based Approach to Compliant Electronic Records and Signatures

Accuracy and integrity of records and data is essential throughout the product life cycle, from research and development through pre-clinical studies, clinical trials, production and quality control to marketing. This Guide provides further guidance on this topic, and should be read in conjunction with GAMP® 5. This Guide provides comprehensive guidance on meeting current regulatory expectations for compliant electronic records and signatures, emphasizing well-documented, validated systems, and the application of appropriate operational controls. The Guide applies a risk-based approach to implementation.

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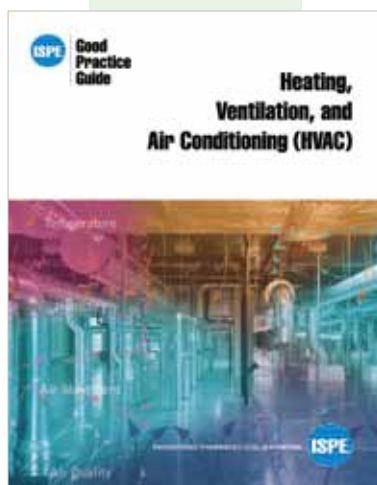
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288 pages; released October 2009

## Heating, Ventilation, and Air Conditioning (HVAC)

HVAC systems can be critical systems that affect the ability of a pharmaceutical facility to meet its objective of providing safe and effective product to the patient. The ISPE Good Practice Guide on HVAC provides designers and the project team with suggestions to help determine the user requirements and the functional design that define the facility's objectives. It also provides options to be considered in creating a design that has low lifecycle cost and that is sustainable.

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### Related Webinars:

- HVAC and Utilities: Special Requirements
- HVAC: Practical Guidance for GMP Facilities



108 pages; released May 2009

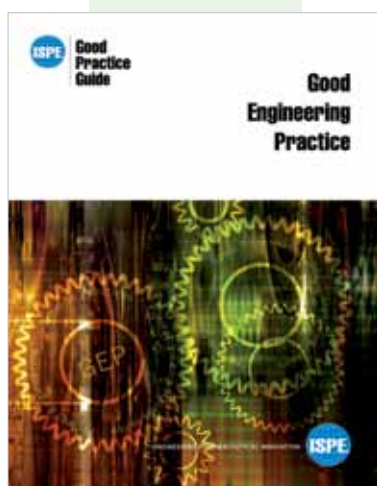
## Maintenance

This Guide provides practical solutions and tools for ensuring quality and compliance of maintenance operations in a regulated industry. Covering current and established practices, this Guide helps achieve technical and regulatory accuracy and cost-effective compliance in a new or existing maintenance program for effective strategy and efficiency. Offering maximum flexibility, this Guide helps to clearly define roles and responsibilities across cross-functional areas and recommends a systematic approach aimed at continuous improvement of maintenance operations.

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- ISPE Good Practice Guide: Maintenance - How to Develop a cGMP Maintenance Program for Regulatory Compliance
- The New Maintenance Good Practice Guide



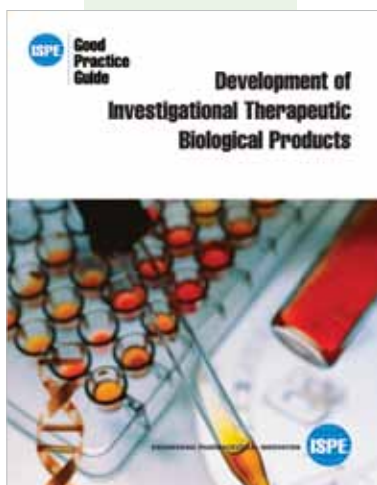
196 pages; released December 2008

## Good Engineering Practice

Good Engineering Practices (GEPs) consist of proven and accepted engineering methods, procedures, and practices that provide appropriate, cost-effective, and well-documented solutions to meet user-requirements and compliance with applicable regulations. GEP underpins activities in the day-to-day operations and forward planning of a pharmaceutical business. The adoption of this methodology leads to a balance of expenditure and activity. In addition, GEP documentation can be leveraged to support verification work. This Guide brings a wealth of information on GEPs and provides benchmarking tools of current company practices against what is considered industry good practice.

The ASTM standard (E2500) builds on the concepts of GEPs and has substantial implications for reductions in cost and time for pharmaceutical capital investment projects.

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## Development of Investigational Therapeutic Biological Products

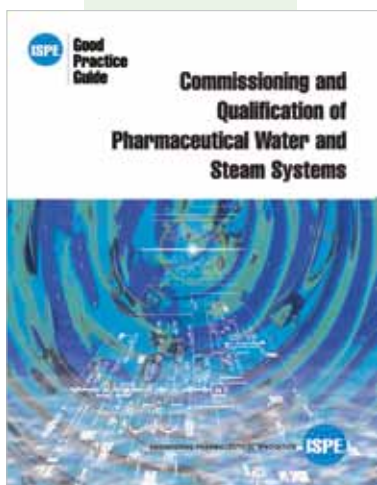
This Guide will consider the major issues that will confront a biopharmaceutical company in moving therapeutic biological products from the laboratory to the clinic and beyond. The Guide is intended to provide readers with an understanding of issues surrounding product and process development, manufacturing, investigational product supply chain management, quality control/quality assurance, and global regulatory requirements for biopharmaceuticals.

It focuses on project planning/management, preclinical/clinical phases, comparability and bridging studies, Active Pharmaceutical Ingredient (API)/Drug Substance (DS)/Drug Product (DP)/placebo process development, manufacturing of DS/DP, process validation, supply chain management of biological investigational products for clinical trials, quality control/quality assurance considerations, and global regulatory strategies.

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92 pages; released August 2007



## Commissioning and Qualification of Pharmaceutical Water and Steam Systems

This Guide provides an alternative approach based on “risk assessment” principles and “process understanding” for the commissioning and qualification of direct impact water and steam systems.

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88 pages; released February 2007



## Assessing the Particulate Containment Performance of Pharmaceutical Equipment

This Guide provides a standard methodology for testing the containment efficiency of solids handling systems under closely defined conditions.

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84 pages; released January 2005

The bound version is available in Japanese. Contact the Japanese Affiliate at [www.ISPE.gr.jp](http://www.ISPE.gr.jp) for details.



128 pages; released March 2003

## Technology Transfer

This Guide provides a standardized methodology for transferring expertise and technology associated with APIs, dosage forms, and analytical methods in a timely and appropriate manner.

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**Related Webinar:**

- Technology Transfer: Introduction

## Other Publication Resources



The original GMP Institute DVDs are no longer available and have been updated to include current content in an online training course format.

Making GMP a lifestyle is now easier to access and implement through the US FDA's Systems-Based Inspection Approach training series of 30 to 60-minute online courses.

Each course provides pre- and post-assessments, downloadable course presentations for note taking, learning reviews highlighting important points, and hot-links to regulatory and industry information to ensure correct application of cGMP regulations for:

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- Packaging and Labeling Systems
- Facilities and Equipment Systems
- Materials Systems
- Production Systems

Also available is a 60-minute Industry Overview: Drug Dosage Forms online course to review the basics. It is from this perspective that we confidently assert: Our Commitment is to Your Success!

Visit [www.ISPE.org/GMPResources](http://www.ISPE.org/GMPResources) for more information.

# Other Publication Resources



## Regulation and Guidance Mini-Handbooks

These handy pocket-size booklets are an ideal way to keep everyone informed of US FDA and ICH regulations and guidelines.

Blood (21 CFR Part 606)  
**Item #:** GMP037  
**Pricing:** \$5/€4

Medical Device (21 CFR Part 820)  
**Item #:** GMP036  
**Pricing:** \$5/€4

ICH Q8R2 - Pharmaceutical Development  
**Item #:** GMP048  
**Pricing:** \$5/€4

Dietary Supplements (21 CFR Part 111)  
**Item #:** GMP049  
**Pricing:** \$5/€4

Pharmaceutical (21 CFR Parts 210, 211)  
**Item #:** GMP035  
**Pricing:** \$5/€4

ICH Q9 - Quality Risk Management  
**Item #:** GMP046  
**Pricing:** \$5/€4

Electronic Records; Electronic Signatures (21 CFR Part 11)  
**Item #:** GMP044  
**Pricing:** \$5/€4

ICH Q7 - APIs  
**Item #:** GMP045  
**Pricing:** \$5/€4

ICH Q10 - Pharmaceutical Quality  
**Item #:** GMP047  
**Pricing:** \$5/€4

Food (21 CFR Part 110)  
**Item #:** GMP038  
**Pricing:** \$5/€4



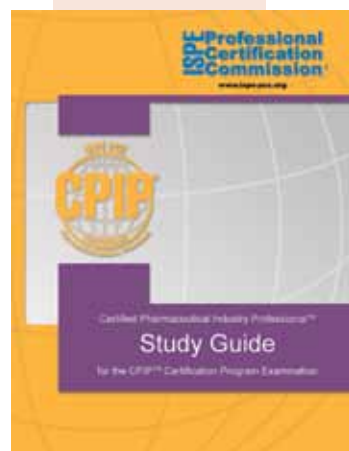
300+ pages; released December 1996

## Medical Device Quality Systems Manual

This manual is US FDA's interpretive guide to the Quality System Regulation. It covers aspects of manufacturing including the design control requirements and contains model procedures and sample forms. This is a must-have for every medical device manufacturing plant!

**Item #:** GMP039

**Pricing:**  
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## Certified Pharmaceutical Industry Professional™ Study Guide

The electronic Study Guide provides a detailed description of knowledge elements to be included in the CPIP™ certification program examination. The Resource Document contains references in the public domain, which can be used to prepare for the examination and/or as an everyday work reference tool.

**Item:** CPIPSTUDY3DL

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Subtract 50% off **PUBLICATIONS SUBTOTAL** only.

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Membership Fee (if elected)

**TOTAL**

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Singapore 339914  
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# ISPE Membership Application

## WHAT IS YOUR PRIMARY COMPANY TYPE? (select only one)

### Manufacturer/Operating

- 1. Traditional Pharmaceuticals
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- 3. Contract
- 4. Generic
- 5. Veterinary Medicine
- 6. Medical Devices/Diagnostics
- 7. Bulk/API
- 8. Cosmetics
- 9. Food/Nutraceuticals

### Service Provider

- 10. Engineering/Architecture
- 11. Consulting
- 12. Validation/Qualification/Commissioning
- 13. CRO – Clinical or Contract Research
- 14. Construction Services Contractor
- 15. Facilities/Equipment Maintenance
- 16. IT/Computer Services

### Supplier

- 17. Equipment/Components
- 18. Packaging Materials
- 19. Clinical/Investigational Products
- 20. Software/Hardware Products
- 21. Chemicals/Intermediates

### Other Organizations

- 22. Academia
- 23. Public Authority/Government
- 99. Other: \_\_\_\_\_

## WHAT IS YOUR PRIMARY AREA OF EXPERTISE? (select only one)

- A. Architect/Engineer/Construction
- B. Clinical/Investigational Products
- C. Health/Safety/Environmental
- D. Information Technology
- E. Logistics/Supply Chain Management
- F. Maintenance
- G. Operations/Manufacturing
- H. Process Control/Automation
- I. Process Development/Technology Transfer
- J. Project Management
- K. Quality Assurance/Control
- L. Regulatory/Compliance
- M. Research and Development
- N. Sales/Marketing/Business Development
- O. Technical Services/Product Support
- P. Training
- Q. Validation/Qualification/Commissioning
- ZZ. Other: \_\_\_\_\_

## YEARS IN INDUSTRY

- 0 - 4       5 - 9       10-14
- 15-19       20+

## AGE RANGE

- 25 and under       46 - 55
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- 36 - 45             66 and above

## WHAT ARE YOUR INTEREST AREAS? (select all that apply)

- A. Active Pharmaceutical Ingredients
- B. Biotechnology
- C. Commissioning and Qualification
- D. Containment
- E. Critical Utilities
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- G. Engineering Standards Benchmarking
- H. Good Automated Manufacturing Practices (GAMP)
- I. Heating, Ventilation, Air Conditioning (HVAC)
- J. Investigational Products
- K. Packaging
- L. Process Analytical Technology
- M. Process/Product Development
- N. Project Management
- O. Sterile Products Processing
- P. Sustainable Facilities
- Q. Certified Pharmaceutical Industry Professional™
- R. Good Control Laboratory Practices
- S. Oral Solid Dosage
- T. Operations Management
- U. GMP's Good Manufacturing Practice
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- Z. Other: \_\_\_\_\_

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  - Brisbane
  - Melbourne
  - New Zealand
  - Sydney
- Belgium
- Brazil
- Central Canada
- China (under development)
- Czech Republic/Slovakia
- France
- Germany/Austria/Switzerland
- India
  - Hyderabad
- Indonesia
- Ireland
- Italy
- Japan
- Korea, Republic of
- The Netherlands
- Nordic (Sweden, Denmark, Norway, Finland, and Iceland)
- Philippines
- Poland

- Singapore
- Spain
- Thailand
- Turkey
- United Kingdom (select one Region)
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  - North East
  - North West
  - Southern
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  - Great Lakes (Ohio, Indiana, Illinois, Michigan, Wisconsin, and Kentucky)
  - Greater Los Angeles Area (Los Angeles, Orange, Ventura, and Riverside Counties)
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  - New England (Connecticut, Western Massachusetts, Rhode Island, Upstate New York, and Vermont)
  - New Jersey (New Jersey, New York, and Northeastern Pennsylvania)
  - Pacific Northwest (Washington and Oregon)
  - Puerto Rico
  - Rocky Mountain (Colorado and Utah)
  - San Diego (San Diego North to South Orange County)
  - San Francisco/Bay Area (Northern California)
  - South Central (Texas, Oklahoma, and Louisiana)

- I do not elect Affiliate/Chapter membership
  - There is not an Affiliate/Chapter in my area



## ISPE Headquarters

600 N. Westshore Blvd., Suite 900  
Tampa, Florida 33609 USA

Tel: +1-813-960-2105

Fax: +1-813-264-2816

Email: [ask@ispe.org](mailto:ask@ispe.org)

## ISPE European Office

Avenue de Tervueren, 300  
B-1150 Brussels, Belgium  
Tel: +32-2-743-4422  
Fax: +32-2-743-1550  
Email: [ispe@associationhq.com](mailto:ispe@associationhq.com)

## ISPE Asia Pacific Office

20 Bendemeer Road  
#04-02/06, Cyberhub  
Singapore 339914  
Tel: +65-6496-5500  
Fax: +65-6496-5599  
Email: [asiapacific@ispe.org](mailto:asiapacific@ispe.org)

## ISPE China Office

Suite 2302, Wise Logic  
International Centre  
66 North Shan Xi Road  
Shanghai  
China 200041  
Tel: +86-2-151-160265  
Fax: +86-2-151-160260  
Email: [china@ispe.org](mailto:china@ispe.org)

