PUBLICATIONS CATALOG

2020

YOU HAVE QUESTIONS. WE HAVE ANSWERS.

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ISPE®

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Look for these titles scheduled for release in 2020.

GPG: Critical Utilities Operational GMP Compliance [working title]

GPG: Cleaning Validation [working title]

GPG: Maintenance (Second Edition)

GPG: Equipment Reliability

GPG: Containment

GAMP RDI Good Practice Guide: Data Integrity – Data Lifecycle

Thank You to Guidance Document Teams

During the 20 years in which ISPE has been publishing Guidance Documents, dedicated volunteers from across the world have contributed their extensive experience and knowledge to produce Guides which benefit the entire global pharmaceutical community.

Volunteer reviewers from both industry and regulatory agencies have also provided real-world commentary on drafts, helping to enhance content. Their contributions continue to be fundamental in maintaining and enhancing the relevance and quality of all ISPE Guidance Documents.

We hope that the entire ISPE membership will join us in recognizing the enormous efforts made by these volunteers so that they can receive the recognition they truly deserve for their indispensable contributions.

The ISPE Guidance Document Development Teams represent participation from numerous pharmaceutical specialties and all regions of the global pharmaceutical community. A list of volunteers, from 2011 to the present, can be found at **ISPE.org/Publications/Guidance-Documents/Teams.**

ISPE Baseline® Guides are the "What"

Each volume in the Baseline® Guide series is a combined effort of industry leaders representing a broad cross-section of manufacturers and industry experts with input from international regulators. The Guides document current industry practice for facilities and systems used for production of pharmaceutical products.

They establish a baseline approach to process and facility design, construction, and specification and verification, based upon a clear understanding of the product and process requirements. The Baseline® Guide principles may also be applied to existing facilities as they are upgraded or modernized.

Volume 1: Active Pharmaceutical Ingredients (Second Edition)

This Guide addresses the engineering aspects of building bulk pharmaceutical chemical manufacturing facilities. Written in cooperation with the FDA, it incorporates the principles of ICH Q7, ICH Q9, 21 CFR Part 11, and PAT.

Available as book or PDF
Published June 2007, 188 pages
Member: **$295/€268** | NonMember: **$595/€541**

Volume 2: Oral Solid Dosage Forms (Third Edition)

The new edition of the Guide considers both current and new technologies, such as Process Analytical Technology (PAT) and continuous manufacturing processes. A new chapter has been added to address containment and cross-contamination in support of the increasing use of highly potent APIs. It also presents an innovative design approach for OSD manufacturing facilities and critical utilities that includes smaller production footprints and space classification considerations and applications.

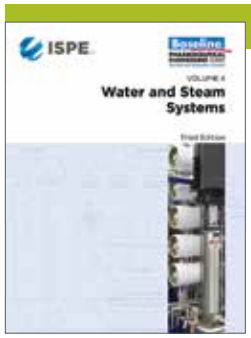
Available as book or PDF
Published November 2016, 240 pages
Member: **$295/€268** | NonMember: **$595/€541**

Volume 3: Sterile Product Manufacturing Facilities (Third Edition)

The revised Guide contains recommendations to help facilitate compliance with the latest FDA and EMA guidance. It includes 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.

Available as PDF
Published April 2018, 244 pages
Member: **$295/€268** | NonMember: **$595/€541**

NEW



Volume 4: Water and Steam Systems (Third Edition)

The latest edition describes new variations in the European Pharmacopoeia for the manufacture of Water for Injection by methods other than distillation. Additional changes include discussions on the global harmonization of water quality attributes, comprehensive pretreatment design, rapid microbial monitoring, ozone for ambient sanitization, and membrane technologies.

Available as book or PDF
Published September 2019, 280 pages
Member: **$395/€359** | NonMember: **$695/€632**

NEW

Volume 5: Commissioning and Qualification (Second Edition)

The intent of this revision is to help the pharmaceutical industry simplify and improve the C&Q process by bringing the "best of the best" together into one document. This Guide also combines concepts from regulatory guidances (e.g., EMA, FDA, ISO). Certain aspects of the C&Q approach described in the previous edition of this Guide are retired and replaced with Quality Risk Management and Good Engineering Practice concepts.

Available as book or PDF
Published June 2019, 212 pages
Member: **$495/€413** | NonMember: **$795/€663**

Volume 6: Biopharmaceutical Manufacturing Facilities (Second Edition)

The second edition of this Guide reinforces the concepts described in the first edition, provides examples of how these concepts can be put into practice, and details the value and benefits of the approach described. The Guide develops concepts to reflect how changes in technology and regulatory conditions affect Biopharmaceutical Facilities without sacrificing product quality, by reducing risk and enhancing the manufacturing control strategy. The Guide applies to new Clinical and Commercial CGMP production facilities for the development and manufacture of biopharmaceutical Active Pharmaceutical Ingredients (or Drug Substances).

Available as book or PDF
Published November 2013, 140 pages
Member: **$295/€268** | NonMember: **$595/€541**

Volume 7: Risk-Based Manufacture of Pharmaceutical Products (Risk-MaPP) (Second Edition)

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. The second edition of the Guide has been updated to include the new EU GMP requirements as well as additional information for cleaning, HVAC, and several scenario-based examples demonstrating the application of the Risk-MaPP tools.

Available as book or PDF
Published June 2017, 182 pages
Member: **$295/€268** | NonMember: **$595/€541**

ISPE Guide

Biopharmaceutical Process Development and Manufacturing

This Guide focuses on the scientific and process engineering principles associated with the design, development, optimization, and implementation of processes that are used in the manufacture of biopharmaceutical drug substance. The concepts presented represent a continuum of process design principles for products that are manufactured for clinical trial use as well as commercial scale production.

Available as book or PDF
Published October 2013, 288 pages
Member: **$295/€268** | NonMember: **$595/€541**

GAMP® Guides and GAMP® Good Practice Guides

GAMP® 5 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 advances.

Reflecting current regulatory expectations and good practices for automated/computerized systems, the GAMP series of Good Practice Guides help to narrow interpretation of regulatory standards for improved compliance and quality, efficiency, and cost reductions. They typically focus on the how.

A Risk-Based Approach to Calibration Management (Second Edition)

This Guide 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. The scope has been widened to include related industries, laboratories, and analytical instrumentation.

Available as book or PDF
Published November 2010, 124 pages
Member: **$195/€177** | Nonmember: **$495/€450**

A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems (Second Edition)

This Guide provides an overview of the lifecycle of laboratory computerized systems, from concept to retirement. It contains steps that scientists, suppliers, and others involved in managing laboratory computerized system acquisition, implementation, and operations can use to verify laboratory systems are fit for their intended use.

Available as PDF
Published October 2012, 160 pages
Member: **$195/€177** | Nonmember: **$495/€450**

A Risk-Based Approach to GxP Process Control Systems (Second Edition)

This Guide applies science-based quality risk management, as described in ICH Q9 and GAMP® 5, for the development, maintenance, and management of process control systems. It describes the system lifecycle from concept to retirement from basic instruments to large, complex, distributed control systems.

Available as book or PDF
Published February 2011, 196 pages
Member: **$195/€177** | Nonmember: **$495/€450**

A Risk-Based Approach to Operation of GxP Computerized Systems (A Companion Volume to GAMP® 5)

The Return On Investment (ROI) for the significant time and resources expended in implementing new computerized systems is achieved during the Operation Phase. This Guide provides detailed information to enable organizations to support their systems more effectively during the Operation Phase of the system lifecycle.

Available as book or PDF
Published January 2010, 216 pages
Member: **$195/€177** | Nonmember: **$495/€450**

ISPE GAMP® 5

Best Seller

A Risk-Based Approach to Compliant GxP Computerized Systems (Fifth Edition)

GAMP® 5 provides pragmatic and practical industry guidance to achieve compliant GxP computerized systems while also enabling innovation and technological advances. This guide is an essential reference for a risk-based validation approach that extends to outsourcing, electronic batch recording, end user applications, and patch management. Also available in German, French, Chinese, Japanese, and Polish.

Available as book or PDF
Published February 2008, 356 pages
Member: **$395/€359** | Nonmember: **$695/€632**

A Risk-Based Approach to Regulated Mobile Applications

Pharmaceutical companies realize that there are structural, control, and regulatory implications when adopting mobile technology. This Guide focuses on the unique and specific issues related to mobile apps and provides comprehensive guidance for maintaining compliance and control throughout the lifecycle by applying GAMP® 5 principles.

Available as PDF
Published October 2014, 96 pages
Member: **$195/€177** | Nonmember: **$495/€450**

A Risk-Based Approach to Testing of GxP Systems
(Second Edition)

This Guide helps the reader to maximize testing efficiency without compromising the quality of GxP systems by focusing testing on areas that have the greatest impact and eliminating duplicate testing. The latest edition contains new information on cloud computing, automated testing, and non-linear development.

Available as book or PDF
Published December 2012, 276 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Electronic Data Archiving

Electronic Data Archiving delves into the processes and issues around the long term preservation of electronic data. It also highlights key considerations in determining an archiving strategy at organizational, technical, and regulatory levels.

Available as book or PDF
Published July 2007, 152 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Global Information Systems Control and Compliance
(Second Edition)

As organizations find themselves operating from multiple sites worldwide, with groups and departments split between multiple geographies, or even using third party distributors, the challenges of information sharing become more complex. This Guide examines the many challenges of deploying a global IT system while complying with the wide range of regulations and guidelines of different countries.

Available as book or PDF
Published February 2017, 164 pages
Member: **$195/€177** | Nonmember: **$495/€450**

IT Infrastructure Control and Compliance
(Second Edition)

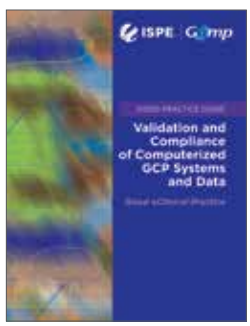
This Guide provides an overview of industry best practices for the design, qualification, and operation of an IT Infrastructure with emphasis on the qualification requirements of the major components. The revision includes guidance on the emergence of cloud and virtualized technologies and includes information to reflect significant changes in the technologies that make up IT infrastructure.

Available as PDF
Published August 2017, 168 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Manufacturing Execution Systems—A Strategic and Program Management Approach

In this Guide, MES is considered to be the complete interactive system of human, electronic, and mechanized functionality to execute manufacturing operations. It uses the framework of GAMP® 5 as a complete lifecycle approach to the development and use of MES for regulated manufacturing.

Available as book or PDF
Published February 2010, 144 pages
Member: **$195/€177** | Nonmember: **$495/€450**



Validation and Compliance of Computerized GCP Systems and Data
(Good eClinical Practice)

This Guide details the unique aspects and considerations for a risk-based approach to validating diverse computerized GCP systems. It places special emphasis on the integrity of clinical data and data flows.

Available as PDF
Published December 2017, 128 pages
Member: **$195/€177** | Nonmember: **$495/€450**

GAMP® Records and Data Integrity Guide

Best Seller

Records and Data Integrity

Records and Data Integrity (RDI) is a comprehensive single point of reference covering the requirements, expectations, and principles of pharmaceutical data integrity. It includes detailed discussions of the regulatory focus areas, the data governance framework, the data lifecycle, culture and human factors, and the application of Quality Risk Management (QRM) to data integrity. RDI is intended as a stand-alone Guide aligned with GAMP® 5 and has also been designed so that it may be used in parallel with guidance provided in GAMP® 5 and other GAMP® Good Practice Guides.

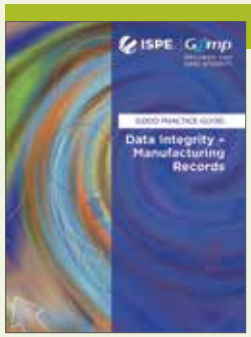
Available as book or PDF
Published March 2017, 152 pages
Member: **$395/€359** | Nonmember: **$695/€632**

Data Integrity—Key Concepts

This Guide integrates tools such as Cultural Excellence and critical thinking skills into data integrity practices to aid companies in meeting regulatory requirements and expectations. Numerous examples of good data integrity practices, along with ways to identify risks and detect issues, are included to assist organizations in developing or raising their data integrity awareness.

Available as book or PDF
Published October 2018, 196 Pages
Member: **$250/€227** | Nonmember: **$550/€500**

NEW



Data Integrity—Manufacturing Records

This Guide provides practical and pragmatic advice on areas such as regulated records, data flows, and risk management approaches, with particular focus on process control systems, manufacturing execution systems, and the interfaces and relationship between them. Additionally, system-specific examples of topics such as segregation of duties and critical validation activities to support data integrity are discussed. Included are "quick wins" – suggestions that can create considerable improvement in the integrity of manufacturing system data with only modest resources.

Available as book or PDF
Published May 2019, 156 Pages
Member: **$250/€227** | Nonmember: **$550/€500**

ISPE Good Practice Guides are the "How"

ISPE Good Practice Guides (GPGs) give practical and technical details on how to apply principles and accepted overall frameworks effectively in specific circumstances. These principles and frameworks may be defined in other ISPE documents (e.g., Baseline® Guides or ISPE Guides). The GPGs would then show how to apply these in practice in different cases. The GPGs may provide information or advice on a particular topic area, type of application, or detailed technology. They may suggest specific solutions in an area where several approaches or outcomes may be valid.

Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems (Second Edition)

This revised Guide discusses the integration of the capital project management process, the commissioning and qualification process, and the on-going operation into the Quality Risk Management (QRM) validation lifecycle. It focuses on items which directly affect quality attributes of water or steam during production, storage, and distribution.

Available as book or PDF
Published July 2014, 120 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Assessing the Particulate Containment Performance of Pharmaceutical Equipment (Second Edition)

This Guide has been updated to address a broader selection of containment technologies and processing equipment. The Guide offers standardized methodologies for evaluating the containment capability of pharmaceutical equipment.

Available as book or PDF
Published May 2012, 104 pages
Member: **$195/€177** | Nonmember: **$495/€450**

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Asset Management

An effective asset management system translates the organization's objectives into asset-related decisions, plans, and activities using a risk-based approach. This Guide provides practical guidance for establishing an asset management system that enables organizations to realize increased value from their assets, both physical and non-physical. It also identifies best practices in strategic asset management as outlined in the ISO 55000 series of standards and provides recommendations, examples, and resources to help organizations in the development or improvement of their asset management system.

Available as PDF
Published November 2019, 116 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Booklet Labels

This Guide was written to create methods for standardizing the format, design, and content of clinical trial booklet labels. Because booklet labels contain vital information for testing sites and subjects, the Guide promotes more consistent use of booklet labels to reduce confusion and non-compliance.

Available as PDF
Published March 2013, 42 pages
Member: **$95/€86** | Nonmember: **$395/€359**

Clinical Supply Systems

This Guide provides a detailed discussion of important areas of clinical supply system functionality, touching on key business requirements to assist interested parties with developing customized clinical supply applications or assessing commercial off the shelf systems for implementation. Examples and requirements for interfacing clinical supply systems involved in the management of IMPs with other internal or external systems are provided. The Guide also contains a list of proposed standard data terminology, along with frequently used equivalent terms, definitions of the data terms, and data formatting standards.

Available as PDF
Published March 2014, 118 pages
Member: **$145/€132** | Nonmember: **$445/€405**

Cold Chain Management

This Guide provides practical guidance to assist in the specification, design, commissioning, and verification of the fixed and passive systems within the cold chain. The Guide covers the process from the point of entry into the manufacturer's controlled temperature storage facility to packaging and through delivery to the distributor or customer premises.

Available as book or PDF
Published May 2011, 140 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Comparator Management

The Comparator Management Guide is a central reference source that establishes strategic and tactical considerations related to comparator sourcing for clinical trials. It identifies good practices for making sourcing decisions and blinding and releasing a comparator for use.

Available as book or PDF
Published February 2012, 84 pages
Member: **$95/€86** | Nonmember: **$395/€359**

Controlled Temperature Chamber Mapping and Monitoring

This Guide details industry good manufacturing practices for the temperature mapping of controlled temperature chambers, development of test acceptance criteria, and a risk-based approach to practices for periodic review of system performance. It considers Commercial Off-the-Shelf (COTS) items, such as freezers and incubators, walk-in cold rooms, and walk-in freezers and custom built units, such as warehouses.

Available as PDF
Published October 2016, 116 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Decommissioning of Pharmaceutical Equipment and Facilities

This Guide provides information on industry good practices to be used for the decommissioning and disposal of assets ranging from a single item of equipment to an entire facility. It contains pharmaceutical industry examples, along with checklists, templates, flowcharts, and example documents, currently in use in decommissioning of pharmaceutical equipment and facilities in the USA and Europe.

Available as book or PDF
Published June 2017, 132 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Development of Investigational Therapeutic Biological Products

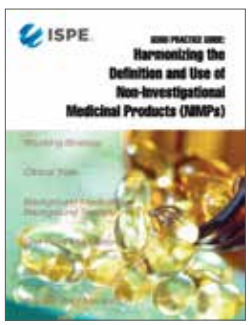
This Guide considers the major issues that confront a biopharmaceutical company advancing therapeutic biological products from the laboratory to the clinic and beyond. It provides readers with an understanding of issues surrounding product and process development, manufacturing, investigational product supply chain management, quality control/quality assurance, and global regulatory requirements for biopharmaceuticals.

Available as book or PDF
Published August 2007, 92 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Good Engineering Practice

Good Engineering Practices (GEPs) consists of proven and accepted engineering methods, procedures, and practices that provide cost-effective and well-documented solutions to meet user-requirements and compliance with applicable regulations. The Guide divides GEP activity into project engineering, common practices, and operation and maintenance. It includes industry examples of GEP and auditing methods, checklists, and benchmarking tools.

Available as book or PDF
Published December 2008, 196 pages
Member: **$195/€177** | Nonmember: **$495/€450**



Harmonizing the Definition and Use of Non-Investigational Medicinal Products (NIMPs)

Pharmaceutical companies can unwittingly overcomplicate their clinical trails because there are currently no complete regulations or practical guidelines for NIMPs. This Guide helps to alleviate the ambiguity surrounding NIMPs by presenting practical approaches to sourcing, packaging and labeling, storage and distribution, drug accountability, traceability, and more.

Available as PDF
Published January 2013, 56 pages
Member: **$95/€86** | Nonmember: **$395/€359**

Heating, Ventilation, and Air Conditioning (HVAC)

The HVAC Guide provides designers and project teams 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 is sustainable.

Available as book or PDF
Published September 2009, 288 pages
Member: **$195/€177** | Nonmember: **$495/€450**

NEW

HVAC and Process Equipment Air Filters

The Guide aims to be a valuable reference on the selection, application, specification, testing, and operation and maintenance of filters in the pharmaceutical industry and is intended to be used as supplement to the HVAC Good Practice Guide, providing detailed information into the subject of air filters in HVAC and process equipment applications. This Guide describes current technologies and their application as it relates to the current guidance.

Available as PDF
Published December 2019
Member: **$195/€177** | Nonmember: **$495/€450**

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. It includes a detailed discussion on managing pooled supplies and the removal of "use-by-dates" from investigational medicinal product labels.

Available as PDF
Published in November 2011, 92 pages
Member: **$145/€132** | Nonmember: **$445/€405**

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, the Guide helps achieve technical and regulatory accuracy and cost-effective compliance in a new or existing maintenance program.

Available as PDF
Published May 2009, 108 pages
Member: **$150/€136** | Nonmember: **$450/€409**

Management of Engineering Standards

This Guide provides a common understanding and approach to the management of Engineering Standards typically set at the corporate level for manufactures, designers, and builders of pharmaceutical plants and processes. It covers the entire lifecycle of an Engineering Standard, from chartering to retirement.

Available as PDF
Published August 2016, 52 pages
Member: **$95/€86** | Nonmember: **$395/€359**

Operations Management

For the purposes of this Guide, operations are defined as the transformative process within a series of activities, along a value chain extending from supplier to customer. *Operations Management* designs, operates, and improves supply chain systems for getting work done. This Guide addresses all operations along the supply chain from the selection of raw materials through the distribution of the final product.

Available as book or PDF
Published April 2016, 166 pages
Member: **$195/€177** |
Nonmember: **$495/€450**

Ozone Sanitization of Pharmaceutical Water Systems

The Guide provides guidance for companies in the evaluation, design, and operation of an ozone system used for sanitizing a high purity GMP pharmaceutical water system. It discusses specific system requirements, as well as associated advantages and disadvantages of using ozone as a water sanitization method.

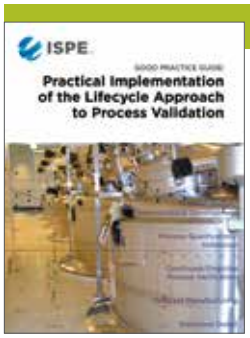
Available as book or PDF
Published July 2012, 144 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Packaging, Labeling, and Warehousing (PACLAW) Facilities

The PACLAW Guide helps companies avoid product adulteration, product mix-up, label mix-up, and misbranding. It covers facility design issues for most primary packaging operations, such as filling of the dosage form in the immediate container/closure system, and other packaging, labeling, and warehousing processes.

Available as book or PDF
Published June 2012, 112 pages
Member: **$195/€177** | Nonmember: **$495/€450**

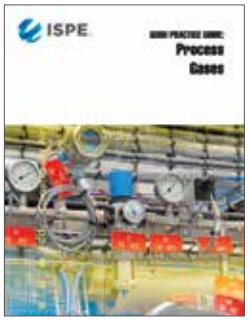
NEW



Practical Implementation of the Lifecycle Approach to Process Validation

The shift in process validation from a one-time event to the product lifecycle approach expected by most global markets has led to significant changes in validation practices. The science and risk-based approach presented in this Guide combines product development knowledge with a structured process performance and product quality monitoring system to provide for validation throughout the product lifecycle. It is intended to assist companies in understanding the application of global regulatory validation requirements by providing step-by-step implementation approaches to PV and leveraging process understanding to promote best practices. The use of statistical rationales within the different stages of the process validation lifecycle is explained. Case studies demonstrating the benefits of some of the Guide's practices in action are also included.

Available as book or PDF
Published March 2019, 208 pages
Member: **$195/€177** | Nonmember: **$495/€450**



Process Gases

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. The Guide addresses the process of designing, constructing, commissioning, and qualifying a process gas system.

Available as book or PDF
Published July 2011, 148 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Project Management for the Pharmaceutical Industry

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

Available as book or PDF
Published November 2011, 282 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Quality Laboratory Facilities

Quality Laboratory Facilities is a comprehensive guide to defining design guidelines for quality laboratories supporting GxP-regulated facilities. It provides a step-by-step process that guides the reader through all phases of establishing a quality lab and all the factors that must be considered at each phase.

Available as book or PDF
Published September 2012, 176 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Sampling for Pharmaceutical Water, Steam, and Process Gases

This Guide establishes good practices for sampling to minimize sample contamination from human contact, error, atmospheric, or environmental conditions. Guidance is provided on aspects of sampling from valve design, the number, location, and placement of sample valves, sampling technique, frequency, and sample storage including delivery to the testing laboratory.

Available as PDF
Published December 2016, 122 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Single-Use Technologies

Single-Use Technology offers increased flexibility while significantly reducing the risk of contamination in manufacturing equipment. This Guide makes it easier for the single-use product supplier and the therapeutics manufacturer to select components, design, and apply single-use technology. It includes a variety of case studies and detailed templates for an implementation that is on schedule with minimal cost.

Available as book or PDF
Published November 2018, 180 pages
Member: **$195/€177** | Nonmember: **$495/€450**

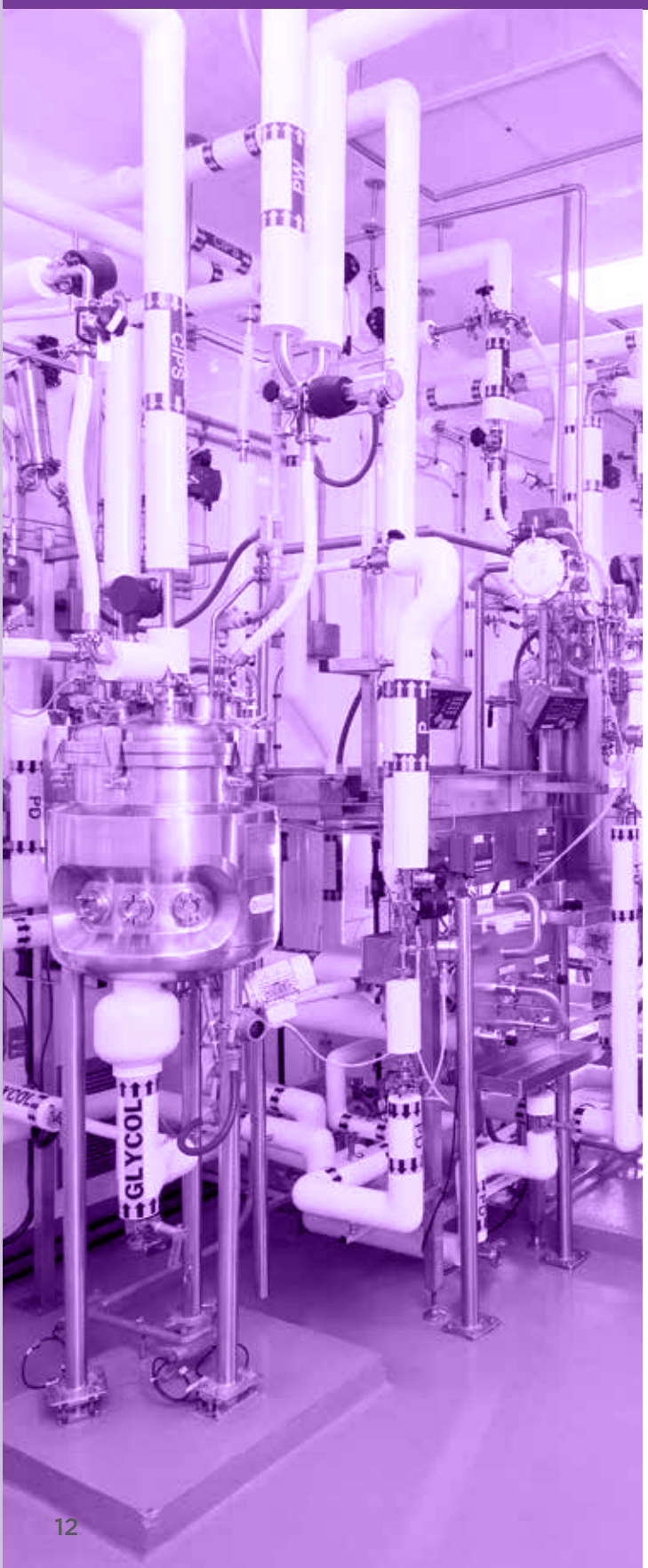
Technology Transfer (Third Edition)

This Guide presents industry good practices for successful and efficient transfer of manufacturing processes and analytical procedures between facilities or laboratories. It covers the principles of technology transfer and also provides some tools for its practical application.

Available as book or PDF
Published December 2018, 152 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Product Quality Lifecycle Implementation (PQLI®) from Concept to Continual Improvement

Product Quality Lifecycle Implementation® (PQLI®) Good Practice Guides provide information on global solutions to implementation challenges of ICH guidance.



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.

Available as book or PDF
Published November 2011, 188 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Part 2—Product Realization using QbD: Illustrative Example

Part 2 of the ISPE PQLI® Guides Series 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.

Available as book or PDF
Published November 2011, 232 pages
Member: **$195/€177** | Nonmember: **$495/€450**

Part 3—Change Management System as a Key Element of a Pharmaceutical Quality System

Part 3 of the ISPE PQLI® Guide Series provides practical, real-world strategies for implementing the change management recommendations of ICH Q10. It also contains information to help translate the holistic approach described in Q10 into an actionable plan that can help companies update and improve their change management practices.

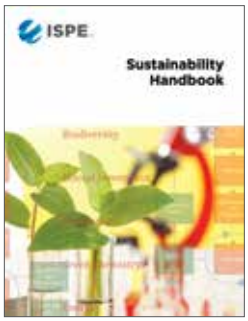
Available as PDF
Published June 2012, 56 pages
Member: **$105/€95** | Nonmember: **$405/€368**

Part 4—Process Performance and Product Quality Monitoring System

Part 4 of the ISPE PQLI® Guide Series provides practical how-to guidance with examples of technical and scientific methodology for adopting a Process Performance and Product Quality Monitoring System (PP&PQMS) in line with the expectations of ICH Q10, Pharmaceutical Quality System.

Available as PDF
Published June 2013, 80 pages
Member: **$105/€95** | Nonmember: **$405/€368**

Handbooks and Affiliate Manuals



Sustainability Handbook

ISPE's first handbook provides information at the front end of projects that will be useful to the project team in understanding sustainability criteria. It includes discussions on legislative and regulatory impacts, sustainability policy making, and ensuring sustainable drug process and manufacture from facility location and design to equipment selection and use.

Available as PDF
Published December 2015, 200 pages
Member: **$95/€86** | Nonmember: **$395/€359**

ISPE D/A/CH Affiliate: Containment Manual (English Translation)

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