2022 CATALOG

PDA Bookstore

Expert Bio/Pharmaceutical Publications and Resources for the Pharmaceutical Manufacturing Industry
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Our technical books, technical reports, and other industry resources are developed by leading experts in the field. Subject to a rigorous peer-review process, our technical documents are sound and reflective of industry best practice. Many of our publications quickly become bestsellers, and our technical reports are recognized by industry professionals around the world as highly valuable resources.

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The PDA Journal

The PDA Journal of Pharmaceutical Science and Technology is considered one of the most relevant and highly cited vehicles for peer-reviewed scientific and technical papers in the pharmaceutical and biotech industries. The Journal is published bimonthly with a circulation of more than 10,000 and is distributed electronically to the PDA membership as a member benefit. PDA members have access to the current volume year and the previous volume year as part of their membership fee.

The Journal is also available by subscription to university and public libraries and government agencies. Institutional subscriptions are also available (see below for more information).

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New Releases

Released in 2021 and 2022, these PDA Technical Books, Technical Reports, and Points to Consider documents are the latest technical resources added to the PDA Bookstore.


This revision of TR 13 aligns with current industry trends and regulatory expectations and provides additional guidance and focus on increased expectations concerning data management and data integrity, qualification and maintenance of controlled environments, and rapid microbiological methods (RMM). It will aid in the establishment of a robust environmental monitoring program that embraces innovation and the principles of quality risk management. Updates regarding microbiological and total airborne particulate control concepts and principles related to facilities involved in the manufacture of sterile pharmaceutical products are also included. April 2022 release. 65 pages.

Digital: Item No. 43558

$180


This technical report presents a holistic approach for performing a microbiological investigation. It provides a framework to assist with focusing on the investigational areas that may contain or contribute to the root cause of data deviations. Distinct areas where microbial data is collected and inspected for deviation investigations are the focus of this document; the roles of other contributors to deviation investigations required for effective root cause analysis are also briefly described. This TR promotes a lifecycle approach, with an emphasis on laboratory and manufacturing investigations of marketed drug products. 2022. 53 pages.

Digital: Item No. 43557

$180
This technical report provides guidance for establishing a quality management system for distribution of all types of temperature-sensitive medicinal and pharmaceutical products. This guidance covers the shipping site, where the product is prepared for transportation, and the shipment of the product, from the product leaving the shipping site until its arrival at the receiving site where it will be stored or distributed to patient (end user). This Technical Report offers a resource for all involved stakeholders in the pharmaceutical supply chain, providing a model for qualifications from the process design through implementation and operation to verification.

2021. 29 pages.

Digital: Item No. 43556

$180 | $325 | $180

This technical report focuses on a technical understanding of glass, its strength, and its limitations, and provides guidance in best handling practices for glass vials throughout the pharmaceutical process. It also reviews typical pharmaceutical glass handling processes; identifies areas of concern; and presents points to consider, guidance, and practical approaches to improve processes.

2021. 48 pages.

Digital: Item No. 43555

$180 | $325 | $180

This technical report is a consensus-based resource surrounding the challenges encountered in using complex package systems and introduces important elements to consider in decision-making. It also offers an examination of the technologies available for package integrity testing not yet established by peer-reviewed research.

2021. 57 pages.

Digital: Item No. 43553

$180 | $325 | $180

This technical report aims to provide clear technical guidance for the development and design of a process validation master plan using a risk-based lifecycle approach, and to provide a comprehensive overview of strategies that may be used to validate a manufacturing process or unit operations.

2021. 52 pages.

Digital: Item No. 43552

$180 | $325 | $180
PDA Technical Report No. 60-3 (TR 60-3)  

This technical report aims to provide clear technical guidance for the development and design of a process validation master plan using a risk-based lifecycle approach, and to provide a comprehensive overview of strategies that may be used to validate a manufacturing process or unit operations. 2021. 53 pages.

Digital: Item No. 43551  
M $180 | NM $325 | G $180

Points to Consider in Remote and Hybrid GMP/GDP Inspections

The new PDA Points to Consider in Remote and Hybrid GMP/GDP Inspections examines advantages and best practices for planning and implementing all types of remote regulatory inspections, including desktop, virtual, and hybrid inspections. It describes best practices that will help all participants engage efficiently and avoid unnecessary or unexpected delays, stressors, or complications in the remote inspection process. The suggestions in this document may be useful to sites that are the target of inspections and to health authorities. 2021. 66 pages.

Digital: Item No. 43554  
M $180 | NM $325 | G $180

PDA Research: 2020 Particulate Matter in Flexible Containers Survey

This survey was conducted to establish a benchmark of current industry practices in the area of visual inspection of injectable products with emphasis on flexible container closure systems. It is intended to obtain more details specific to the role of visual inspection as it pertains to the wide variety of flexible container closure systems. 2021. 45 pages.

Digital Item No. 45017  
M $180 | NM $325 | G $180


This new standard provides guidance on how to establish suitable procedures for the cryopreservation and recovery of biological cells for use in cell and gene therapy products and regenerative medicine manufacturing either as an intermediate step or when cryopreservation is the final step. The guide emphasizes the effect cryopreservation and recovery may have on cell viability and cell function and can provide general guidance during the assessment of regulatory requirements. The best practices and guidance details outlined in the document provide general procedural support for cryopreservation of cell-based products during both early and late phases of product development. 2022. 26 pages.

Digital: Item No. 60003  
M $180 | NM $325 | G $180
Cleanroom Contamination Prevention & Control: A Practical Guide to the Science
EDITORS: Ziva Abraham, Morgan Polen

**BESTSELLER** This text covers risk-based approaches to a cleaning and disinfection program and case studies in contamination control. It provides details on safe building techniques for new cleanrooms and modifications of existing areas by providing a risk-based approach for cleaning and disinfection using good science. It also discusses the dangers of outdated cleanroom and barrier systems designs, and that limited understanding of the real airflows has led to repeat contamination related observations worldwide. Case study examinations discuss the most common causes of contamination and many useful solutions on how to proactively prevent recurring contamination are presented. 2021. 486 pages.

Hardcover: Item No. 17360 | Digital: Item No. 18082

$M$240 | $NM$299 | $G$240

Conducting Compliant Investigations
EDITOR: Jeanne Moldenhauer

In this book, edited by Jeanne Moldenhauer, you will find many different approaches to conducting compliant investigations, where compliant is defined as meeting the requirements of the applicable regulatory documents. The information it provides on conducting investigations that will be acceptable to regulatory investigators will be instrumental in helping you to significantly reduce regulatory risk. 2021. 504 pages.

Hardcover: Item No. 17363 | Digital: Item No. 18087

$M$240 | $NM$299 | $G$240

Digital Transformation and Regulatory Considerations for Biopharmaceutical and Healthcare Manufacturers: Digital Data, Insights, Metrics and Analytics, Volume 2
AUTHOR: Tim Sandle

This second of two volumes details how pharmaceutical and healthcare manufacturers have been embracing digital technologies as part of the transformation of their business models. It covers topics such as new model healthcare, office technology, e-learning, virtual inspections, and more. 2021. 420 pages.

Hardcover: Item No. 17362 | Digital: Item No. 18084

$M$200 | $NM$249 | $G$200

Quality by Design—An Indispensable Approach to Accelerate Biopharmaceutical Product Development
EDITORS: Cristiana Campa and M. Amin Khan

**BESTSELLER** PDA’s newest book, Quality by Design—An Indispensable Approach to Accelerate Biopharmaceutical Product Development, is an important contribution to the ongoing dialogue for accelerating CMC product development bridging strategies for biotherapeutics and vaccines. It illustrates how Quality by Design (QbD) can be a powerful enabler of acceleration, fostering deeper understanding of what is critical, what level of CMC risk is acceptable, and hence what elements of product development can be streamlined. This book also demonstrates how Prior Knowledge is useful to inform QbD-driven risk assessment and focus on non-redundant activities, fostering tailored innovation. 2021. 475 pages.

Hardcover: Item No. 13013 | Digital: Item No. 48005

$M$240 | $NM$299 | $G$240
New Digital Booklets

The Infamous Fungus: Enigmatic, Distinct and Misjudged

AUTHOR: Ziva Abraham

This chapter is taken from the book Fungi: A Handbook for Life Science Manufacturers and Researchers, edited by Jeanne Moldenhauer. This chapter explores all aspects of fungi and mold including their sources, structures, reproduction, as well as their use in every aspect of our lives. 2021. 55 pages.

Digital: Item No. 18086

M $55  |  NM $69  |  G $55

The Study in Risk-Based Manufacturing Environmental Control for Non-Sterile Drug Products (English Translation)

The Kansai Study Group (KSG) of the PDA Japan Chapter (JPDA) published this paper based on a survey of JPDA member companies to offer consensus-based ideas to help pharmaceutical manufacturers establish appropriate, risk-based manufacturing and environmental control systems for quality non-sterile drug products. They determined the five most common themes: HVAC systems, facilities, gowning, cleaning, and cleanliness standards.

For each of these themes, a problem is stated, recommendations are proposed, and a rationale is provided. 2021. 85 pages.

Digital: Item No. 48006

M $180  |  NM $325  |  G $180
PDA Technical Reports

PDA Technical Reports are peer-reviewed global consensus documents written by subject matter experts on a wide variety of industry-related topics. They offer expert guidance and opinions on important scientific and regulatory topics and are used as essential references by industry and regulatory authorities around the world.

Best Sellers

PDA Technical Report No. 22, (TR 22)
Revised 2011 Process Simulation for Aseptically Filled Products

The Task Force charged with updating the document ensured that the new version reflects the continuing changes that have occurred in aseptic processing technology within the global industry over the last decade and a half. 2011. 50 pages.

Digital: Item No. 43226
M $180 | NM $325 | G $180

PDA Technical Report No. 79 (TR 79)
Particulate Matter Control in Difficult to Inspect Parenterals

This Technical Report describes best practices for difficult to inspect (DIP) product lifecycle management, destructive testing, and trending to supplement portions of the guidance given in USP General Chapter <1790>: Visible Particulates in Injection. This Technical Report is intended to provide logical pathways to DIP product inspection and testing to support continual process improvement in the industry. 2018. 36 pages.

Digital: Item No. 43536
M $180 | NM $325 | G $180

PDA Technical Report No. 81 (TR 81)
Cell-Based Therapy Control Strategy

This TR focuses on the development of a risk-based control strategy adapted to cell-based therapy that can mitigate the risk of generating a product of poor quality. 2019. 58 pages.

Digital: Item No. 43538
M $180 | NM $325 | G $180

PDA Technical Report No. 26 (TR 26)
Revised 2008, Sterilizing Filtration of Liquids

PDA’s original Technical Report No. 26, published in 1998, described the use and validation of sterilizing filtration to a generation of pharmaceutical scientists and engineers. This revision was developed in response to enhancements in filtration technologies and recent additional regulatory requirements within the pharmaceutical industry. References to scientific publications and international regulatory documents are provided where more detail and supportive data may be found. 2008. 62 pages.

Digital: Item No. 43230
M $180 | NM $325 | G $180

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Walt Morris, Sr. Director of Publishing and Press Relations
+1 (301) 656-5900, ext. 148 | morris@pda.org
Fundamentals of an Environmental Monitoring Program Annex 1: Environmental Monitoring of Facilities Manufacturing Low Bioburden Products

This technical report is a complementary addendum to PDA Technical Report No. 13 (TR 13, Revised 2014) that provides elements to consider when designing a risk-based environmental monitoring program to support the manufacture of low bioburden products using low bioburden processes. A review of regulatory requirements and the development of risk assessments based on the criticality and complexity of processes is included, along with industry examples of these risk-based approaches. 2020. 29 pages.

Digital: Item No. 43549  
M $180 | NM $325 | G $180

PDA Technical Report No. 84 (TR 84)  
Integrating Data Integrity Requirements into Manufacturing & Packaging Operations

PDA Technical Report No. 84 (TR 84): Integrating Data Integrity Requirements into Manufacturing and Packaging Operations addresses data integrity from the perspective of manufacturing operations. It discusses regulatory trends, risk management concepts, and recommendations for implementing appropriate data integrity controls in manufacturing operations applicable to paper-based, electronic-based, and hybrid systems. The case studies included in this technical report provide examples of how to assess current data integrity risks and implement the concepts presented in the report. 2020. 65 pages.

Digital: Item No. 43547  
M $180 | NM $325 | G $180

Bundle of PDA Technical Reports

PDA Technical Series: Sterilization  
Compilation of Technical Reports and Journal Articles on Pharmaceutical Sterilization

This volume is a convenient and powerful reference for individuals working with sterilization processes for pharmaceutical products. 2014. 424 pages.

Digital: Item No. 43512  
M $500 | NM $940 | G $300

PDA Technical Report Translations

Reporte Técnico No. 1 (Revisado en 2007) Validación de los Procesos de Esterilización por Calor Húmedo: Diseño del Ciclo, Desarrollo, Calificación y Control Continuo


Digital: Item No. 43550  
M $180 | NM $325 | G $180

Reporte Técnico No. 13 (Revisado)  
Fundamentos de un Programa de Monitoreo Ambiental (versión digital de un solo usuario)


Digital: Item No. 43540  
M $180 | NM $325 | G $180
PDA Technical Report No. 56 Revised 2016 (TR 56) Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance) 2016. 36 pages. Digital: Item No. 43530


PDA Technical Report No. 56 (TR 56) Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance) 2016. 36 pages. Digital: Item No. 43530


PDA Technical Report No. 59 (TR 59) Utilization of Statistical Methods for Production Monitoring
2012. 74 pages.  Digital: Item No. 43500

PDA Technical Report No. 58 (TR 58) Risk Management for Temperature-Controlled Distribution
2012. 73 pages.  Digital: Item No. 43499


PDA Technical Report No. 49 (TR 49) Points to Consider for Biotechnology Cleaning Validation 2010. 76 pages.  Digital: Item No. 43488


Older PDA Technical Reports  Price per technical report.  🌟 $50 | 🌌 $100 | 🌙 $50

The price is the same for digital and softcover items.

Digital: Item No. 43315

Digital: Item No. 43232

Digital: Item No. 43311 | Softcover: Item No. 01042

Digital: Item No. 43314 | Softcover: Item No. 01040

Digital: Item No. 43240

Digital: Item No. 43239 | Softcover: Item No. 01034

Digital: Item No. 43235
The Technical Report below is free of charge and available to everyone.


PDA Points to Consider Documents

Points to Consider in Remote and Hybrid GMP/GDP Inspections

The new PDA Points to Consider in Remote and Hybrid GMP/GDP Inspections examines advantages and best practices for planning and implementing all types of remote regulatory inspections, including desktop, virtual, and hybrid inspections. It describes best practices that will help all participants engage efficiently and avoid unnecessary or unexpected delays, stressors, or complications in the remote inspection process. The suggestions in this document may be useful to sites that are the target of inspections and to health authorities. 2021. 66 pages.

Digital: Item No. 43554  M $180 | NM $325 | G $180

Points to Consider for Implementation of Pre-Use Post-Sterilization Integrity Testing (PUPSIT)

This Points to Consider document was developed as part of the PDA/BioPhorum Sterilizing Filtration Quality Risk Management Consortium. It provides the reader with points to consider on how to best implement and execute a pre-use/post-sterilization integrity test (PUPSIT) of the final sterilizing grade liquid filters for products that are not terminally sterilized. 2020. 39 pages.

Digital: Item No. 43546  M $180 | NM $325 | G $180

Points to Consider for Risks Associated with Sterilizing Grade Filters and Sterilizing Filtration

Summarizes the processes and outcomes of the risk Assessment and control mapping exercises performed as part of the PDA/BioPhorum Sterilizing Filtration Quality Risk Management Consortium. It describes the identification of the sterilizing filtration value stream throughout the process. 2020. 27 pages.

Digital: Item No. 43545  M $180 | NM $325 | G $180

Points to Consider for Sensitivity to Oxidation by Peroxide

Addresses aspects to consider in the design, development, processing, instrumentation, materials, and equipment specific to issues with products sensitive to oxidation when exposed to H2O2. This document primarily applies to isolator systems, where vapor phase hydrogen peroxide (VPHP) or vaporized hydrogen peroxide (VHP) is used to decontaminate the system. Current issues and approaches to consider for an oxidation-sensitive product are summarized, and industry experts outline best practices for developing a manufacturing process for drug product. 2020. 24 pages.

Digital: Item No. 43544  M $180 | NM $325 | G $180
Points to Consider for the Aseptic Processing of Sterile Pharmaceutical Products in Isolators

Focusing on important regulatory and technical updates surrounding isolator design, validation, and operations for aseptic processing, this Points to Consider addresses two primary types of isolators – open and closed – and is intended to support identification and use of modern technology. It does not represent a standard or regulatory guidance.

2020. 85 pages.

Digital: Item No. 43543  M $180  NM $325  G $180

Points to Consider for Aging Facilities  2017. 31 pages.

Digital: Item No. 43534  M $180  NM $325  G $180


Digital: Item No. 43527  M $180  NM $325  G $180


Digital: Item No. 43520  M $180  NM $325  G $180


Digital: Item No. 42148

This new standard provides guidance on how to establish suitable procedures for the cryopreservation and recovery of biological cells for use in cell and gene therapy products and regenerative medicine manufacturing either as an intermediate step or when cryopreservation is the final step. The guide emphasizes the effect cryopreservation and recovery may have on cell viability and cell function and can provide general guidance during the assessment of regulatory requirements. The best practices and guidance details outlined in the document provide general procedural support for cryopreservation of cell-based products during both early and late phases of product development. 2022. 26 pages.

Digital: Item No. 60003

M $180 | NM $325 | G $180

ANSI/PDA Standard 04-2021: Phage Retention Nomenclature Rating for Small-and Large-Virus Retentive Filters

This new standard addresses virus-removal filters that retain viruses by a size-exclusion mechanism. It is intended to provide filter suppliers with an approach to standardizing methodology and nomenclature for large- and small-virus retentive filters using bacteriophage as a model and to assist users/manufacturers in selecting the most appropriate filter for their specific application needs. 2021. 25 pages.

Digital: Item No. 60001

M $180 | NM $325 | G $180

ANSI/PDA Standard 05-2021: Consensus Method for Rating Filters for Mycoplasma Reduction

This standard describes a filter challenge test for standardizing test parameters across laboratories using 47 mm discs and using A. laidlawii as the test organism. While this standard is primarily to educate users and filter manufacturers about best practices for mycoplasma reduction filtration, this test is also to be used by the filter manufacturers to validate a mycoplasma-retentive filter within a manufacturing process and to qualify a filter for a mycoplasma retentive claim. 2021. 22 pages.

Digital: Item No. 60002

M $180 | NM $325 | G $180

ANSI/PDA Standard 001-2020: Enhanced Purchasing Controls to Support the Bio-Pharmaceutical, Pharmaceutical, Medical Devices and Combination Products Industries

A standard guidance for the selection and control of suppliers of purchased goods and services that can impact product quality and patient safety. 2020. 19 pages.

Digital: Item No. 60000

M $180 | NM $325 | G $180
PDA Surveys

PDA Research: 2020 Particulate Matter in Flexible Containers Survey
This survey was conducted to establish a benchmark of current industry practices in the area of visual inspection of injectable products with emphasis on flexible container closure systems. It is intended to obtain more details specific to the role of visual inspection as it pertains to the wide variety of flexible container closure systems. 2021. 45 pages.

Digital Item No. 45017

M $180 | NM $325 | G $180

PDA Research: PDA Post-Approval Change Issues and Impacts Survey
Conducted in July 2020, this report includes data on 106 diverse respondents who manufacture all types of drug products (DPs) and the active pharmaceutical ingredients (APIs) for each. It provides experts’ views on the most significant post-approval change issues faced by these manufacturers. By understanding these challenges, regulators and industry together can develop effective solutions and prioritize issues with greatest impact on global operations. 2021. 57 pages.

Digital Item No. 45016

M $180 | NM $325 | G $180

PDA Research: 2019 PDA Traceability of Primary Packaging Survey
Serialization in the pharmaceutical supply chain is a growing effort to improve shortcomings within the current track and trace processes. The survey will help PDA members, industry, and regulators understand the current state of demand and issues surrounding track and trace and attain additional insight to the discussions that may be occurring at the site level to improve controls and traceability of drug product from production to the patient. 2020. 19 pages.

Digital Item No. 45015

M $180 | NM $325 | G $180

PDA Research: 2019 Sterile Lyophilized Drug Product Loading Survey
This survey is designed to align and expand PDA’s insight on current practices for companies that manufacture sterile lyophilized drug products and conduct lyophilizer loading. It also provides insight into how today’s lyophilizer loading area operations can be improved to reduce contamination from personnel. Each of the 91 respondents is involved in lyophilizer activities within their current companies and possess an understanding of their companies’ procedures and needs. 2019. 26 pages.

Digital Item No. 45014

M $180 | NM $325 | G $180
PDA Surveys

PDA Research: 2019 Technology Transfer Industry Survey
The 2019 Technology Transfer Industry Survey is designed to investigate current practices and learn how companies conduct technology transfers, including their technology transfer processes, knowledge and risk management systems, documentation, and business strategies. 2019. 26 pages.
Digital: Item No. 45013

PDA Research: 2017 PDA Glass Quality Survey
This survey is designed to assist in the identification of glass container quality concerns and development of solutions to overcoming them. Survey topics include glass sampling and inspection practices, product complaints and recalls due to glass defects, and quality oversight. 2018. 56 pages.
Digital: Item No. 45012

PDA Survey: 2017 PDA PUPSIT Survey
In March 2017, PDA conducted a benchmarking survey to better understand the current situation regarding sterile filtration and the implementation of Pre-Use Post Sterilization Integrity Test, or PUPSIT, among large pharmaceutical companies. Due to increased enforcement of section 113 of Annex 1 by European regulatory agencies, manufacturers of sterile medical products are finding they must modify their manufacturing processes to incorporate the PUPSIT and/or are not able to justify its exclusion on risk-based principles. The survey was open to PDA members with subject-matter expertise in PUPSIT and who hold the manager level position in biologic process development, manufacturing, validation, and/or quality. Readers are encouraged to draw his/her own conclusions from the presented summarized data and responses. 2018. 24 pages.
Digital: Item No. 45011

PDA Research: 2017 PDA Aseptic Processing Survey
This survey explores aseptic processing practices for global secondary manufacturing (finished product filling/packaging), while taking into consideration the changes and needs of the modern, global, sterile, healthcare product manufacturing industry. 2017. 169 pages.
Digital: Item No. 45010
PDA Survey: 2015 Aging Facilities
This survey clarifies the meaning of an aging facility, process, and analytics and explores the types and effectiveness of preventative measures. The survey also identifies the obstacles encountered when improvements are made and what actions should be taken to overcome potential obstacles. 2016. 32 pages.

Digital: Item No. 45009
M $150 | NM $250 | G $150

PDA Survey: 2015 Particulate Matter in Difficult to Inspect Parenterals
This survey summarizes current practices in the inspection and control of particles in DIP products and packaging materials. Findings include aspects of current processes in manual, semi-automated, and automated inspection, along with sampling plans and acceptable quantity limits used. 2016. 77 pages.

Digital: Item No. 45008
M $150 | NM $250 | G $150

PDA Survey: 2015 Particulate Matter in Oral Dosage Forms
This survey documents current practices used by drug product manufacturers, active pharmaceutical ingredients manufacturers, excipient manufacturers, packaging/primary container manufacturers, and consultants/regulators to control, inspect, sample, and test particulate matter, intrinsic and extrinsic in oral dosage forms. 2016. 93 pages.

Digital: Item No. 45007
M $150 | NM $250 | G $150

PDA Survey: 2014 Visual Inspection
In August of 2014, the fourth in a series of surveys was launched by PDA to better understand and document current industry practices in this important area. Past PDA Visual Inspection surveys in 1996, 2003, and 2008 have provided practical guidance and insight to those working in this field. The purpose of this survey was to document current industry practice for visual inspection of injectable products. 2015. 22 pages.

Digital: Item No. 45006
M $150 | NM $250 | G $150

PDA Survey: 2014 Quality Culture Metrics
This publication presents the results of the PDA Quality Culture Metrics Surveys conducted in September and October 2014. The objectives of these surveys were to understand the maturity of quality culture in industry at the time and to identify appropriate attributes of quality culture that can be measured. 2015. 39 pages.

Digital: Item No. 45005
M $150 | NM $250 | G $150

This benchmarking survey was designed to solicit feedback on and evaluate industry status of the application of the principles established in the FDA Process Validation Guidance for Industry of 2011. 2014. 27 pages.

Digital: Item No. 45004
M $150 | NM $250 | G $150
PDA Technical Books

PDA Technical Books are scientific and regulatory publications specifically developed for the resource needs of pharmaceutical and biopharmaceutical professionals. Edited and authored by industry and regulatory experts and thought leaders, these books are practical guides and references related to specific topics.

Expand your library and increase your knowledge of important industry topics!

Aseptic and Sterile Processing: Control, Compliance and Future Trends
EDITORS: Tim Sandle and Edward C. Tidswell

Digital: Item No. 18038
M $260 | NM $325 | G $240

Assuring Data Integrity for Life Sciences
EDITOR: Siegfried Schmitt
This book provides a truly global perspective on data integrity and the solutions available to address this serious issue. It includes two main sections: the regulatory and historic background of data integrity, and practical advice on how to prevent or rectify data integrity breaches. 2016. 408 pages.

Hardcover: Item No. 17335 | Digital: Item No. 18016
M $265 | NM $329 | G $220

Audit and Control for Healthcare Manufacturers: A Systems-Based Approach
AUTHORS: Tim Sandle and Jennifer Sandle
Audits are an important part of quality assurance and the quality management system. With the help of PDA’s book, Audit and Control for Healthcare Manufacturers: A Systems-Based Approach, you can ensure the quality and effectiveness of your processes, systems, and personnel is maintained throughout your organization! 2019. 862 pages.

Hardcover: Item No. 17351 | Digital: Item No. 18059
M $240 | NM $299 | G $220

Biofilm Control in Drug Manufacturing
EDITORS: Lucia Clontz and Carmen M. Wagner
This book provides guidance for preventing and controlling biofilm contamination in pharmaceutical and biopharmaceutical processing. 2012. 496 pages.

Digital: Item No. 17986
M $240 | NM $299 | G $190 $152

Biological Indicators for Sterilization Processes
EDITORS: Margarita Gomez and Jeanne Moldenhauer
2008. 536 pages. Hardcover: Item No. 17268
M $280 | NM $349 | G $190 | $140

LEGEND: M = Member Pricing | NM = Non-Member Pricing | G = Government Pricing
Biotechnology: From Idea to Market
EDITORS: Fred Mermelstein, Richard Prince, Carl Novina

An invaluable guide and reference for anyone involved in the development of a product, from idea generation through commercialization. The goal of this book is to provide a comprehensive overview for students and professionals alike in how to think about and to navigate the necessary development process for healthcare product candidates, including biologics, new chemical entities, and other related products that address medical need. This instructional text enables anyone at any level or in any sector of the industry to easily achieve a basic knowledge of the critical steps (or the questions to ask) to properly evaluate an idea or technology, develop a viable product candidate, and ultimately advance it to the marketplace. 2019. 1064 pages.

Hardcover: Item No. 17352 | Digital: Item No. 18060

M $295 | NM $369 | G $295

Cleaning and Cleaning Validation, Volumes 1 and 2
EDITOR: Paul L. Pluta

Cleaning and Cleaning Validation is a series of volumes presenting current knowledge and approaches to cleaning and cleaning validation of pharmaceuticals, medical devices, and associated products, consistent with current regulatory documents and expectations. Case studies presented throughout the volumes supplement basic information with useful real-life experiences. 2013.

Digital: Item No. 17987

M $535 | NM $679 | G $465

Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 4
AUTHOR: Destin A. LeBlanc

Volume 4 complements Destin LeBlanc’s earlier three books on the same subject. This book modifies and updates LeBlanc’s monthly Cleaning Memos originally published from January 2013 through December 2016. More than half of the chapters in the book address setting limits in one way or another, so the use of health-based limits will require balanced reading (and thinking) for an overall understanding. 2017. 253 pages.

Digital: Item No. 18027

M $240 | NM $299 | G $210

Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volumes 1, 2, and 3
AUTHOR: Destin A. LeBlanc

The three volumes that make up Cleaning Validation: Practical Solutions for Pharmaceutical Manufacturing contain a complete, modified, and updated collection of the author’s Cleaning Memos. In all volumes, each Cleaning Memo is presented as a chapter, with the chapters re-organized by common topics rather than chronologically as they appear in the original format. The benefit to having three volumes at hand, in addition to gaining full insight into 12 years of subject matter expert advice, is the accessibility of information by common subject. 2013.

Digital: Item No. 17981

M $635 | NM $790 | G $435

Available for Individual Purchase

Volume 1 (Digital: Item No. 18033)
Volume 2 (Hardcover: Item No. 17289 Digital: Item No. 18034)
Volume 3 (Hardcover: Item No. 17310 Digital: Item No. 18035)

M $265 | NM $229 | G $180
Cleanroom Microbiology
AUTHORS: Tim Sandle and R. Vijayakumar

This book is about cleanrooms and controlled environments in relation to the pharmaceutical and healthcare sectors. With its focus on cleanroom microbiology, this book is applicable to both the sterile and non-sterile pharmaceutical sectors.

2014. 600 pages.
Digital: Item No. 17983
M $240 | NM $299 | G $210

Cold Chain Chronicles: A practitioner’s outside-the-box perspectives on the importance of temperature-sensitive drug stewardship
AUTHOR: Kevin O’Donnell

Noted pharmaceutical cold-chain expert Kevin O’Donnell relates a series of engaging stories carefully crafted to elevate awareness, understanding, and criticality of temperature-sensitive drug products throughout the supply chain, not only for the stakeholders involved, but also for the consumer in us all. 2014. 182 pages.
Hardcover: Item No. 17323 | Digital: Item No. 17980
M $210–$168 | NM $259–$207 | G $190–$152

Combination Products: Implementation of cGMP Requirements
EDITOR: Lisa A. Hornback

This book explores the unique aspects and considerations for implementation of cGMP in a combination product environment. It includes comprehensive information from leaders in the industry regarding the unique requirements for several common combination products situations. 2013. 200 pages.
Digital: Item No. 17951
M $210–$168 | NM $259–$207 | G $170–$136

Computerized Systems in the Modern Laboratory: A Practical Guide
AUTHOR: Joseph G. Liscouski

This book provides laboratory staff and managers with a solid understanding of the tools available, how to successfully purchase and implement the technology, and how to develop a plan for application and evaluation in order to meet regulatory requirements.
2015. 432 pages.
Hardcover: Item No. 17329 | Digital: Item No. 18003
M $265 | NM $299 | G $210

Contamination Control in Healthcare Product Manufacturing, Volume 5
EDITORS: Russell E. Madsen and Jeanne Moldenhauer

The fifth volume in PDA’s popular series, Contamination Control in Healthcare Product Manufacturing, explores practical approaches to leverage environmental monitoring data to improve performance, how to design a risk-based environmental monitoring program for non-sterile manufacturing, the clinical relevance of objectional microorganisms, and much more!. 2018. 510 pages.
Hardcover: Item No. 17350 | Digital: Item No. 18055
M $240 | NM $299 | G $210
Contamination Control in Healthcare Product Manufacturing, Volume 4
EDITORS: Russell E. Madsen and Jeanne Moldenhauer

This book is an essential complement to any contamination control library! Volume 4 is a useful reference guide when combined with the previous three volumes. 2016. 402 pages.

Hardcover: Item No. 17336 | Digital: Item No. 18017
| M $240 | NM $299 | G $210

Contamination Control in Healthcare Product Manufacturing, Volumes 1, 2, and 3
EDITORS: Russell E. Madsen and Jeanne Moldenhauer

Fifty global subject matter experts share their broad experiences in all aspects of healthcare product manufacturing contamination control in this three-volume set. The first volume contains chapters that are predominantly centered on microbial issues. Volume 2 addresses some microbial issues, but also focuses on other types of contamination. Volume 3 discusses extensive subjects in aseptic contamination control. 2014. Digital: Item No. 17976
| M $580 | NM $720 | G $510

Available for Individual Purchase
Volume 1 Digital: Item No. 17952
Volume 2 Digital: Item No. 17974
Volume 3 Digital: Item No. 17975
| M $240 | NM $299 | G $210

Contamination Prevention for Nonsterile Pharmaceutical Manufacturing
AUTHOR: Andrew Dick

This handbook on Contamination Prevention for Nonsterile Pharmaceutical Manufacturing offers guidelines for best practices to be deployed within a manufacturing facility. It explains where the most common microbiological risks to nonsterile manufacturing reside and how to prevent contamination in key areas. Designed for easy reading, this practical guide walks readers through decision-making steps, including how to set up a facility, what types of equipment to acquire, how to maintain it, and how to clean and sanitize equipment and facilities. 2018. 119 pages.

Digital: Item No. 48002
| M $210 | NM $259 | G $190

Digital Transformation and Regulatory Considerations for Biopharmaceutical and Healthcare Manufacturers: Digital Technologies for Automation and Process Improvement, Volume 1
AUTHOR: Tim Sandle

This first-of-two volume release takes an in-depth look at the digital technologies that are impacting the pharmaceutical and healthcare landscape now and into the future. It explores what each technology does, the potential use of the technology and the practical aspects for its implementation, along with the changes to culture and structure necessitated by digital transformation. This first volume covers process-centric themes and related regulatory aspects and standards. 2020. 378 pages.

Hardcover: Item No. 17361 | Digital: Item No. 18083
| M $200 | NM $249 | G $200
Effective Implementation of Audit Programs

AUTHOR: Miguel Montalvo

This well-researched text is a must have for personnel involved in the implementation and execution of critical programs, auditors, auditees, and outsourcing providers! 2017. 390 pages.

Hardcover: Item No. 17340 | Digital: Item No. 18026

M $210 | NM $259 | G $190

Encyclopedia of Rapid Microbiological Methods, Volume 4

EDITOR: Michael J. Miller

This volume complements the author’s previous three volumes by offering new techniques, case studies, new equipment, and much more. Details about quality control, choosing appropriate methods, future use and technologies, and mass spectrometry are included. 2013. 608 pages.

Hardcover: Item No. 17308 | Digital: Item No. 17988

M $335 | NM $419 | G $290 | $232

Encyclopedia of Rapid Microbiological Methods, Volumes 1, 2, and 3

EDITOR: Michael J. Miller

Introductory volumes of the Encyclopedia of Rapid Microbiological Methods series describes the rapid methods currently available and focuses on regulatory initiatives currently in place that will help pharmaceutical microbiologists begin the journey of implementing rapid microbiological methods in their facilities. 2005/2006.

Digital: Item No. 17989

M $795 | NM $989 | G $685 | $548

Environmental Monitoring: A Comprehensive Handbook, Volume 8

EDITOR: Jeanne Moldenhauer

Volume 8 of the Environmental Monitoring Handbook series is a mixture of new topics and new takes on previously discussed topics. In this Volume, you will find information about regulatory/compendial updates, testing methods, risk methods and tools, and routine (and non-routine) monitoring. This Volume is a must have for anyone involved with environmental monitoring! 2017. 257 pages.

Hardcover: Item No. 17343 | Digital: Item No. 18039

M $260 | NM $325 | G $240

Environmental Monitoring: A Comprehensive Handbook, Volumes 1, 2, and 3

EDITOR: Jeanne Moldenhauer

Regulatory bodies worldwide have all established standards and guidelines for environmental control. Unfortunately, the requirements are not equivalent across documents and nations. These three volumes describe methods for developing and operating an appropriate, sustainable microbiological program for production and the laboratory.

Digital: Item No. 18007

M $800 | NM $1,000 | G $700 | $560
Environmental Monitoring: A Comprehensive Handbook, Volumes 4, 5, 6, and 7

EDITOR: Jeanne Moldenhauer

The Environmental Monitoring series, edited by Jeanne Moldenhauer, provides guidance through the ins and outs of the multitudinous aspects of compliance. This collection of volumes is a must have for anyone involved with environmental monitoring concerns.

Digital: Item No. 18006

M $1,340 | NM $1,072 | G $930

Fungii: A Handbook for Life Science Manufacturers and Researchers

EDITOR: Jeanne Moldenhauer

NEW This text can help identify and ameliorate fungal and mold problems and contains a wealth of information as a guide and reference. Many topics are discussed relevant to the food and agriculture industries, including the biology of fungi, outbreaks associated with pharmaceutical drug products and medical devices, mycotoxins, fungal biodegradation and remediation, and strategies for a rapid and accurate fungal identification. The text also contains a lengthy fungal glossary. 2019. 813 pages.

Hardcover: Item No. 17355 / Digital: Item No. 18063

M $240 | NM $299 | G $240

Ethylene Oxide Sterilization Validation and Routine Operations Handbook

AUTHOR: Anne F. Booth

2007. 203 pages. Digital: Item No. 17942

M $225 | NM $279 | G $180

Essential Microbiology for QP Candidates

AUTHOR: Nigel Halls


Hardcover: Item No. 17265 | Digital: Item No. 18024

M $250 | NM $309 | G $180
Global Sterile Manufacturing Regulatory Guidance Comparison

The Global Sterile Manufacturing Regulatory Guidance Comparison – With link to Comparison Spreadsheet compares regulatory guidance documents issued by the U.S. FDA, the EU, the Pharmaceutical Inspection Convention/Scheme, and the World Health Organization. 2016. 99 pages.

Digital: Item No. 48000
M $180 | NM $325 | G $180

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fifth Edition, Revised and Expanded

AUTHOR: James L. Vesper and Tim Sandle

BESTSELLER GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fifth Edition, Revised and Expanded examines 34 elements that are typically included in a modern pharmaceutical quality system, including Data Integrity. Each quality system element has an overview section, some risk-related questions, and 3-10 expectations. Each expectation is explored in more detail, and examples are provided from GMP references, including the U.S. FDA, Health Canada, the European Union, the World Health Organization, and the International Conference on Harmonization (ICH). 2018. 690 pages.

Hardcover: Item No. 17349 | Digital: Item No. 18054
M $240 | NM $299 | G $220

Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1

EDITORS: Siegfried Schmitt

BESTSELLER Following an introduction to the subject of Good Distribution Practice (GDP), the first volume of this book covers key topics related to five main points: the applicable GDP regulations worldwide, including serialization; an overview of the requirements of Qualified Persons and Responsible Persons in GDP; GDP as part of the Quality Management System; an industry perspective on GDP; and a practical GDP checklist. 2019. 578 pages.

Hardcover: Item No. 17353 | Digital: Item No. 18061
M $210 | NM $259 | G $210

Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 2

EDITORS: Siegfried Schmitt

BESTSELLER Following an introduction to the subject of Good Distribution Practice (GDP), in the second volume, dive into supply-chain risk mitigation, serialization, and packaging as it relates to risk assessments. This text and its companion Volume 1 will help drive down costs and improve efficiency. 2019. 420 pages.

Hardcover: Item No. 17354 | Digital: Item No. 18062
M $210 | NM $259 | G $210

Hosting a Compliance Inspection

AUTHOR: Janet Gough

2001. 120 pages. Digital: Item No. 17923
M $145 | NM $179 | G $80

Introduction to Environmental Monitoring in Pharmaceutical Areas

AUTHOR: Michael Jahnke

M $72 | NM $93 | G $51
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<td>114</td>
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<td>2017</td>
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<td>Microbial Control and Identification: Strategies Methods Applications</td>
<td>Dona Reber and Mary Griffin</td>
<td>2018</td>
<td>592</td>
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Microbial Identification: The Keys to a Successful Program

EDITORS: Mary Griffin and Dona Reber

The Editors of this book assembled a team of subject matter experts who share their expertise on microbial identifications (IDs) in this thoughtfully edited volume. This invaluable book includes details about viral and mycoplasma ID methods, challenges and case studies on fungal IDs, use of science-based risk assessment for objectionable organisms, microbial IDs for medical devices and cosmetics, and much more. 2012. 447 pages.

Digital: Item No. 17953
M $240 | NM $299 | G $190

Microbial Risk and Investigations

EDITORS: Karen Zink McCullough and Jeanne Moldenhauer

This book provides a wealth of information on microbial investigations and dealing with aberrant data. Many of the chapters include case studies that can provide guidance for common situations that may occur at your facility. 2015. 867 pages.

Hardcover: Item No. 17328 | Digital: Item No. 18005
M $260 | NM $325 | G $240

Microbiological Culture Media: A Complete Guide for Pharmaceutical and Healthcare Manufacturers

AUTHOR: Tim Sandle

Taking into account that 90 percent of quality control microbiology remains reliant upon culture-based methods, this unique text focuses on microbiological culture media as applied to pharmaceutical microbiology. This book takes into consideration that innovations continue to arise with new media recipes that are formulated for the selection of new strains for the application of media in conjunction with rapid microbiological methods. In 23 chapters, the book covers how media is used in the modern pharmaceutical microbiology setting and recaps the past, signals the future, and helps interpret the present. 2017. 582 pages.

Hardcover: Item No. 17345 | Digital: Item No. 18041
M $240 | NM $299 | G $210

Microbiological Monitoring of Pharmaceutical Process Water

AUTHOR: Michael Jahnke

2002. 70 pages. Digital: Item No. 17919
M $120 | NM $149 | G $95

Microbial Risk Assessment in Pharmaceutical Clean Rooms

AUTHORS: Berit Reinmueller and Bengt Ljungqvist

M $95 | NM $119 | G $75
Microbiology in Pharmaceutical Manufacturing, Second Edition, Revised and Expanded, Volumes 1 and 2

EDITOR: Richard Prince

The first edition of Microbiology in Pharmaceutical Manufacturing, published in 2001, is the best-selling PDA/DHI book of all time. The completely revised and extended edition raises the bar by offering practical and current industrial and regulatory perspectives. Twenty new chapters were added and 16 new authors contributed their expertise to provide updated and expanded microbiological information for the benefit of a global audience of stakeholders. 2008.

Digital: Item No. 17991

Available for Individual Purchase

Volume 1 (Digital: Item No. 18051)
Volume 2 (Digital: Item No. 18052)

PDA Technical Series: Endotoxin Analysis and Risk Management

PDA Technical Series: Endotoxin Analysis and Risk Management is a collection of published research on the topic from the PDA Journal of Pharmaceutical Science and Technology. This volume is intended for those in the industry who perform and/or are responsible for the quality testing and manufacture of biopharmaceutical products. For those concerned with the phenomenon of “Low Endotoxin Recovery,” two articles from the PDA Journal are included. 2019. 170 pages.

Digital: Item No. 48004

PDA Technical Series: Pharmaceutical Glass


A decade ago, the focus on the quality of pharmaceutical glass was sharpened with a series of product recalls due to findings of glass particulates in finished products. The PDA Technical Series: Pharmaceutical Glass shows that much work has been done to help understand this issue and other quality issues pertaining to glass.

The publication of this book supports a major initiative launched by PDA in 2017 to connect pharmaceutical manufacturers and glass suppliers to prepare for complex products and manufacturing processes of the future. 2018. 225 pages.

Digital: Item No. 48003

Pharmaceutical Contamination Control: Practical Strategies for Compliance

EDITOR: Nigel Halls


PDA Technical Books

www.pda.org/bookstore 27

EDITOR: Barbara Jentges

The book presents a condensed overview of the regulatory systems and processes for marketing a drug product in the three major global regions: Japan, the United States, and the European Union. 2016. 164 pages.

Hardcover: Item No. 13011 | Digital: Item No. 48001
M $150 | NM $180 | G $120

Pharmaceutical Outsourcing: Quality Management and Project Delivery

EDITORS: Trevor Deeks, Karen Ginsbury, and Susan Schniepp

This book is intended to set forth and explore the best practices for contract organizations from various perspectives: the contract organization, the contracting organization, and the regulators. The editors and authors have experience with outsourcing and have published a comprehensive, practical guide with the goal of offering sound, reasonable advice to the outsourcing community, focusing mainly on contract manufacturing. 2013. 518 pages.

Digital: Item No. 17992
M $240 | NM $299 | G $210

Pharmaceutical Quality Control

Microbiology: A Guidebook to the Basics

AUTHOR: Scott Sutton
2007. 205 pages. Digital: Item No. 18025
M $235-165 | NM $289-200 | G $155-110

Phase Appropriate GMP for Biological Processes: Pre-Clinical to Commercial Production

EDITOR: Trevor Deeks

BESTSELLER This book provides succinct and practical guidance on how to develop a biological drug product and, at the same time, stay within the regulatory expectations at each phase of the development process!

Within this book, you can find chapters on:
• Current manufacturing and process development of Regenerative Medicine Advanced Therapy Products (RMATs), or as they are known in the EU, Advanced Therapy Medicinal Products (ATMPs)
• Quality systems and GMP requirements for Phase 1 to Phase 3 manufacturing
• The impact of the Clinical Trials Directive on European GMP expectations and the role of the QP
• The latest USP guidance on the transfer of analytical methods, validation and verification of compendial procedures
• And, much more

2018. 525 pages.

Digital: Item No. 18042
M $240 | NM $299 | G $220

Pharmaceutical Quality

EDITOR: Richard Prince
2004. 758 pages. Hardcover: Item No. 17207
M $320-225 | NM $399-280 | G $210-150
Practical Aseptic Processing Fill and Finish, Volumes 1 and 2
EDITOR: Jack Lysfjord

Aseptic processing technology has changed with the use of advanced aseptic processing techniques such as blow-fill-seal isolators and restricted access barrier systems. This book explores these changes and how they impact aseptic processing. 2009.

Digital: Item No. 17993
M $425 - $340 | NM $530 - $424 | G $290 - $232

Available for Individual Purchase
Volume 1 Digital: Item No. 18036
Volume 2 Digital: Item No. 18037
M $265 - $212 | NM $329 - $263 | G $180 - $144

Quality by Design: Putting Theory into Practice
EDITOR: Siegfried Schmitt

This book is written with all stakeholders in mind, including regulatory agencies, the healthcare industry, and suppliers. The process of adoption, implementation, and interpretation of quality by design is currently the key driver helping the industry bring products to market faster and, at the same time, providing maximum assurance of product quality. 2011. 360 pages.

Digital: Item No. 17985
M $240 - $168 | NM $259 - $207 | G $155 - $124

Radiation Sterilization: Validation and Routine Operations Handbook
AUTHOR: Anne F. Booth
M $225 - $158 | NM $279 - $200 | G $180 - $130

Rapid Sterility Testing
EDITOR: Jeanne Moldenhauer

In this book, you will find a history of the sterility test methodology and detailed discussions that provide the regulatory requirements and allowances for gaining approval of rapid sterility test methods. 2011. 501 pages.

Hardcover: Item No. 17302 | Digital: Item No. 17994
M $250 - $200 | NM $309 - $247 | G $200 - $160

Recalls of Pharmaceutical Products: Eliminating Contamination and Adulteration Causes
AUTHOR: Tim Sandle

Are you prepared for recalls relating to pharmaceutical and healthcare medications and medical devices? This book contains details about recalls from start to finish, including advice on how to handle a recall and, more importantly, how they can be avoided. Read about regulatory perspectives, trends and primary causes for product recalls, notable recalls and lessons, quality metrics, and supply chain risk management. You can also find relevant information designed to help about labels, packaging, data integrity, methods to ensure GDP, and other industry best-practices. 2020. 728 pages.

Hardcover: Item No. 17357 | Digital: Item No. 18076
M $239 | NM $299 | G $239
Recent Warning Letters: Review for Preparation of an Aseptic Processing Inspection, Volume 1
AUTHOR: Jeanne Moldenhauer
2010. 195 pages. Digital: Item No. 18020

|  M | $200 | $196 |  NM | $349 | $245 |  G | $195 | $140 |

Recent Warning Letters: Review for Preparation of a Non-Sterile Processing Inspection, Volume 2
AUTHOR: Jeanne Moldenhauer
2010. 332 pages. Digital: Item No. 18021

|  M | $280 | $196 |  NM | $349 | $245 |  G | $195 | $140 |

Risk Assessment and Management for Healthcare Manufacturing: Practical Tips and Case Studies
AUTHOR: Tim Sandle

The book is divided into four sections that present a formal approach to risk. Sections focus on risk assessment and hazards; common risk assessment tools and problem-solving approaches; “soft skills” that help in conducting risk assessments; and case studies exploring the problems and events that occur with pharmaceuticals and healthcare, against which the reader can consider real-life problems. The wide range of topics covered includes risk considerations for aging pharmaceutical facilities, application of quality risk management to cleanroom design, and process incident investigation. 2016. 730 pages. Digital: Item No. 18064

|  M | $225 | $180 |  NM | $279 | $223 |  G | $180 | $144 |

Risk Assessment and Risk Management in the Pharmaceutical Industry: Clear and Simple
AUTHOR: James L. Vesper
2006. 292 pages. Digital: Item No. 17995

|  M | $255 | $204 |  NM | $319 | $255 |  G | $160 | $128 |

Risk-Based Compliance Handbook
AUTHOR: Siegfried Schmitt
2008. 188 pages. Digital: Item No. 17973

|  M | $168 |  NM | $210 |  G | $130 |

Risk-Based Software Validation: Ten Easy Steps
AUTHORS: Janet Gough and David Nettleton

This book offers a systematic, 10-step approach, from the decision to validate to the assessment of the validation outcome, for validating configurable, off-the-shelf computer software that generates data or controls information about products and processes subject to binding regulations. 2006. 183 pages. Digital: Item No. 18064

|  M | $225 | $180 |  NM | $279 | $223 |  G | $180 | $144 |

Root Cause Investigations for CAPA: Clear and Simple
AUTHOR: James L. Vesper

This text, based on workshops led by instructor and author James Vesper, provides practical tools for both a thorough understanding of risk-based CAPA investigations and regulatory acceptable applications. 2020. 332 pages.

Hardcover: Item No. 17359 | Digital: Item No. 18081

|  M | $240 |  NM | $299 |  G | $240 |
Software as a Service (SaaS): Risk-Based Validation with Time-Saving Templates

AUTHOR: David Nettleton, Janet Gough

From this book, you will learn a systematic, step-by-step approach for validating configurable off-the-shelf software that generates data or controls information about products and processes subject to regulations. 2020. 182 pages.

Hardcover: Item No. 17358 | Digital: Item No. 18080

M $225 | NM $279 | G $215

SOPs Clear and Simple: For Healthcare Manufacturers

AUTHORS: Susan Schniepp, Brian Matye and Jeanne Moldenhauer

There are four simple sentences that define the concept of compliance and its relationship to Standard Operating Procedures (SOPs) – Say what you do. Do what you say. Prove it. Improve it. Despite this concept seeming simple, the number one topic of 483 observations for biologics, drugs, and devices from 2013 through 2017 included failure to follow SOPs, procedures not in writing, and lack of adequate procedures.

In this comprehensive guide, gain practical insight into the need for SOPs, how to write them, and what should be included in them. Explore the application of SOPs to the pharmaceutical, biotechnology, and medical device industries. This useful text offers a simple, yet, straightforward approach to writing SOPs, highlighting their importance in maintaining compliant operations critical to manufacturing quality products.

Upon finishing this book, you’ll be able to not only write out SOPs but also follow them to fully maintain compliance. 2019. 177 pages.

Hardcover: Item No. 17348 | Digital: Item No. 18053

M $220 | NM $269 | G $200

Square Root of (N) Sampling Plans: Procedures and Tables for Inspection of Quality Attributes

AUTHORS: Joyce Torbeck and Lynn Torbeck

The goal of Joyce and Lynn Torbeck’s book is to illustrate that the square root of (N) plans are statistically correct and can be used in applications that minimize risk to patients. 2013. 127 pages.

Hardcover: Item No. 17314 | Digital: Item No. 17982

M $210 | NM $259 | G $170

Steam Sterilization: A Practitioner’s Guide

EDITOR: Jeanne Moldenhauer


M $118 | NM $150 | G $118

Sterility Testing of Pharmaceutical Products

AUTHOR: Tim Sandle

This book presents the sterility test as a final product release test as seen in the past, the present, and with a view toward the future. It is designed for quality assurance personnel, production staff, microbiologists, students, and those with an interest in medicinal products.

2013. 379 pages.

Digital: Item No. 17996

M $240 | NM $299 | G $210

Systems Based Inspection for Pharmaceutical Manufacturers

EDITOR: Jeanne Moldenhauer


M $224 | NM $280 | G $156
Technology and Knowledge Transfer: Keys to Successful Implementation and Management
EDITORS: Mark Gibson and Siegfried Schmitt
Written by global subject matter experts, this book offers the practical experience needed to obtain a competitive edge. This book will help companies take a proactive approach to streamlining and optimizing their technology transfer processes to ensure successes.
2014. 474 pages.
Digital: Item No. 17984
M $265 | NM $329 | G $210

The Bacterial Endotoxins Test: A Practical Guide
EDITOR: Karen Zink McCullough
BESTSELLER This unique book is a collection of interdependent chapters that are part lab manual, part essay, part historical context, part consultant, and part plain-sage advice that provides a practical and compliant approach to the execution and use of the bacterial endotoxins test.
2011. 434 pages.
Digital: Item No. 17997
M $210 | NM $259 | G $165

The Internal Quality Audit
AUTHORS: Monica Grimaldi and Janet Gough
2001. 100 pages. Digital: Item No. 17921
M $145 | NM $179 | G $85

Thermal Validation in Moist Heat Sterilization
EDITOR: Jeanne Moldenhauer
The various authors cited in this book have a wealth of practical experience in thermal validation of moist heat sterilization processes. This book is an essential reference guide for managers, supervisors, and all others concerned with preparing validation plans acceptable to regulators worldwide.
2011. 301 pages.
Digital: Item No. 17998
M $225 | $180 | NM $279 | $223 | G $180 | $144

Torbeck’s Statistical Cookbook for Scientists and Engineers
AUTHOR: Lynn D. Torbeck
In the Statistical Cookbook for Scientists and Engineers, you will find tried and true, practical statistical “recipes” that provide a book of specific and unique statistical modules useful for evaluation of industrial studies. These modules are designed for the busy industrial worker, who needs to apply statistical techniques with the assurance he or she is using the technique correctly.
2017. 241 pages.
Hardcover: Item No. 17344 | Digital: Item No. 18040
M $210 | NM $259 | G $190
Trend and Out-of-Trend Analysis for Pharmaceutical Quality and Manufacturing Using Minitab®

AUTHOR: Lynn D. Torbeck
This book is for pharmaceutical professionals working in product discovery, development, manufacturing, quality assurance, and quality control. It presents a basic introduction to data, trend, and out-of-trend definitions and proposes terminology to clarify the use of the word “control” in several contexts. Outtakes from FDA warning letters, plant audits, and investigations for trend and out-of-trend are presented to highlight the Agency’s viewpoint. 2015. 195 pages.

Digital: Item No. 18012
M $210 | NM $259 | G $190

Validating Enterprise Systems: A Practical Guide

AUTHOR: David Stokes
This book describes the latest tools, techniques, and regulatory information needed to validate enterprise systems. 2012. 467 pages.
Hardcover: Item No. 17303
Digital: Item No. 18000
M $225 | NM $279 | G $175 $140

Validation by Design: The Statistical Handbook for Pharmaceutical Process Validation

AUTHOR: Lynn Torbeck
2010. 225 pages. Digital: Item No. 17999
M $185 | NM $230 | G $150

Validation Master Plan: The Streetwise Downtown Guide

AUTHOR: Trevor Deeks
2002. 49 pages. Digital: Item No. 17927
M $120 | NM $149 | G $95

Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies

AUTHOR: Stephan Krause
M $280 | NM $349 | G $200

Visual Inspection and Particulate Controls

AUTHORS: D. Scott Aldrich, Roy T. Cherris, and John G. Shabushnig
BESTSELLER This book is a practical guide for the control of visible defects and contamination in pharmaceutical products. It is intended for product inspectors and lab support personnel and for those who use inspection results or are responsible for inspection operations. Meant to educate seasoned inspectors on the principles of microscopy and familiarize seasoned microscopists with the elements of visual inspection, this book describes ways to find visible defects and what to do with them once found. 2016. 373 pages.
Digital: Item No. 18015
M $240 | NM $299 | G $210

www.pda.org/bookstore
Water Activity Applications in the Pharmaceutical Industry


This book examines the fundamentals and relationships of water activity, ranging from the measurement of moisture content, water activity, and water sorption isotherms, to ways in which water activity affects microorganisms, chemical reaction rates, drug product formulation and processing and physical properties, water activity as a hurdle, and applications of water activity management in the pharmaceutical industry. 2009. 310 pages.

Digital: Item No. 18085

M $175 | NM $220 | G $175

Why Life Science Manufacturers Do What They Do in Development, Formulation, Production and Quality: A History

AUTHOR: Lynn D. Torbeck

In a passionate retrospective of a successful career built on thinking statistically and applying that approach to quality in pharmaceutical manufacturing, Lynn Torbeck has created a "must read" for anyone involved in product development, formulation, manufacturing, and quality. Each of the 45 chapters in this book address a specific aspect of applied statistics and provides pragmatic applications to such topics as: Can we save the Technical Conference?; %RSD friend, Foe or Faux?; OOS, OOT, OOC and OOSC; and more. 2015. 435 pages.

Hardcover: Item No. 17333 | Digital: Item No. 18014

M $210 $168 | NM $259 $207 | G $190 $152
PDA Booklets/Guides

PDA Booklets are excerpted from a larger publication, chosen for the relevance of content, expertise of the author, and industry demand.

5 Year Summary of FDA Biologics 483s: 2015-2019
AUTHOR: Jeanne Moldenhauer
This booklet takes the publicly available yearly inspection data from the U.S. FDA and presents it in a more useful, digestible format. It also includes analysis into the observations of biologics products for the past five years, including trend observations and a breakdown of the most common observations. 2020. 34 pages.

Digital: Item No. 18077
M $100 | NM $129 | G $90

5 Year Summary of FDA Medical Device 483s: 2015-2019
AUTHOR: Jeanne Moldenhauer
The form FDA 483, “Inspectional Observations,” is a form used by the FDA to document and communicate concerns discovered during the inspections of medical device manufacturing plants. This booklet takes the publicly available yearly inspection data from the U.S. FDA and presents it in a more useful, digestible format. It also includes analysis into the observations of device products for the past five years including trend observations and a breakdown of the most common observations. 2020. 36 pages.

Digital: Item No. 18079
M $110 | NM $139 | G $100

Biopharmaceutical Validation and Technical Transfer
AUTHOR: Russell E. Madsen
This document discusses why and how to validate and transfer a process. It offers a helpful example, includes protocol details and discusses non-traditional process validation, life cycle management, change management, and much more. 2018.

Digital: Item No. 18058
M $120 | NM $150 | G $120

Cleaning SOPs: Five Proven and Validated SOPs
AUTHOR: Anne Marie Dixon-Heathman
Cleaning and sanitation is a common 483 citing. The cleaning methods in these five SOPs have been proven and validated. They are based upon published information in US standards and ISO standards. Renowned global expert, Anne Marie Dixon-Heathman offers invaluable details that will assist you in reducing the risk of surface contamination to processes and products. In short, they work!

SOPs included are:
• Cleaning and Disinfection of Biosafety Hoods
• Cleaning and Disinfection of Laminar Flow Hoods
• Cleaning and Disinfection of Aseptic Cleanrooms
• Cleaning and Disinfection ISO 7-8
• Cleaning and Sanitization - CNC.

2018. 37 pages.

Digital: Item No. 18057
M $240 | NM $299 | G $240
Key Features of a Biosafety Program for the Biopharmaceutical Industry

AUTHOR: Jessica Avizinis

This reprint from Microbial Control and Identification: Strategies, Method and Applications, edited by Dona Reber and Mary Griffin, demonstrates how microbial identification knowledge is a cornerstone in the concept of microbial and contamination control programs. 2020. 48 pages.

Digital: Item No. 18072

Managing the Pharmaceutical Cold Chain

AUTHOR: Steve Winyard

This chapter is reprinted and available individually from Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1, edited by Siegfried Schmitt, a text that collects in one place invaluable and comprehensive regulatory, manufacturing, and distribution guidance and reference. 2020. 18 pages.

Digital: Item No. 18075

Overview of Conventional and Emerging Microbial Identification Methods

AUTHOR: Frank E. Matos, Jennifer R. Reyes

This reprint from Microbial Control and Identification: Strategies, Method and Applications, edited by Dona Reber and Mary Griffin, demonstrates how microbial identification knowledge is a cornerstone in the concept of microbial and contamination control programs. 2020. 47 pages.

Digital: Item No. 18071

Lessons of Failure Library

EDITOR: Russell E. Madsen and Maik W. Jornitz

Russell Madsen and Maik Jornitz have assembled and edited fascinating stories of incidents from their own experiences and those of other long serving industry practitioners and experts. Reprinted from their text: Lessons of Failure: When Things Go Wrong in Pharmaceutical Manufacturing, these vignettes offer both what can go wrong and key problem-solving points to take away and apply. 2020. 30 pages.

Digital: Item No. 18066

Manufacturing Biopharmaceuticals From Start-Up to Commercialization

AUTHOR: Joseph Waggett and Laura Roselli

The magnitude of knowledge and experience required to have a meaningful impact on biotechnology product approvals and market success is monumental. For the first time, this expertly crafted chapter is reprinted from Biotechnology: From Idea to Market, edited by Fred Mermelstein, Richard Prince, and Carl Novina, and offered electronically. These detailed advisories are written to provide valuable guidance. 2020. 39 pages.

Digital: Item No. 18068

Quality Control Testing Throughout the Product Development Lifecycle

AUTHOR: Daniel Prince, Martell Winters, Richard Prince

The magnitude of knowledge and experience required to have a meaningful impact on biotechnology product approvals and market success is monumental. For the first time, expertly crafted chapter is reprinted from Biotechnology: From Idea to Market, edited by Fred Mermelstein, Richard Prince and Carl Novina and offered electronically. These detailed advisories are written to provide guidance. 2020. 37 pages.

Digital: Item No. 18069
Quality Risk Management in the Context of Viral Contamination

**AUTHOR:** CAACB

This reprint from *Microbial Control and Identification: Strategies, Methods, and Applications*, edited by Dona Reber and Mary Griffin, demonstrates how microbial identification knowledge is a cornerstone in the concept of microbial and contamination control programs. 2020. 51 pages.

**Digital:** Item No. 18070

- **M** $55
- **NM** $69
- **G** $45

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Regulatory Affairs Role in Product Development

**AUTHOR:** David L. Rosen

The magnitude of knowledge and experience required to have a meaningful impact on biotechnology product approvals and market success is monumental. For the first time, this expertly crafted chapter is reprinted from *Biotechnology: From Idea to Market*, edited by Fred Mermelstein, Richard Prince, and Carl Novina and offered electronically. These detailed advisories are written to provide valuable guidance. 2020. 40 pages.

**Digital:** Item No. 18067

- **M** $55
- **NM** $69
- **G** $45

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Serialisation Regulations in the EU and USA

**AUTHOR:** Daniel Kavanagh

This chapter is reprinted and available individually from *Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1*, edited by Siegfried Schmitt, a text that collects in one place invaluable and comprehensive regulatory, manufacturing and distribution guidance and reference. 2020. 16 pages.

**Digital:** Item No. 18073

- **M** $55
- **NM** $69
- **G** $45

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Toward an Integrated Cold Chain

**AUTHOR:** Alan Kennedy

This chapter is reprinted and available individually from *Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1*, edited by Siegfried Schmitt, a text that collects in one place invaluable and comprehensive regulatory, manufacturing, and distribution guidance and reference. 2020. 34 pages.

**Digital:** Item No. 18074

- **M** $55
- **NM** $69
- **G** $45
Pharmaceutical Manufacturing: Understanding Your Process Series
Over the past 15 years, PDA/DHI has published more than 1,000 practical scientific and regulatory chapters, written by global subject matter experts. These informative collections have been designed to help you stay abreast of new technology, streamline your processes, and comply with regulations. Get background information and hands-on applications in an electronic format on three vital topics: cleaning and cleanrooms, sterilization, and environmental monitoring.

Cleaning and Cleanrooms
EDITORS: Jeanne Moldenhauer and Tim Sandle
This collection features a two-part history of cleaning and cleanrooms, classifications, supplies, sanitization, and several other important topics. 2017. 114 pages.
_Digital: Item No. 18028_

$120 | NM $150 | G $120

Environmental Monitoring, Volume 2: Practical Approaches
EDITOR: Jeanne Moldenhauer
Learn about rapid microbiological monitoring, environmental monitoring for sterility test isolators, and how to present environmental monitoring data to internal and external stakeholders. 2017. 92 pages.
_Digital: Item No. 18032_

$120 | NM $150 | G $120

Environmental Monitoring, Volume 1: Establishing the Process
EDITOR: Jeanne Moldenhauer
Discover how to design and implement a control program, monitor microbiology laboratories, and more. 2017. 175 pages.
_Digital: Item No. 18031_

$120 | NM $150 | G $120

Sterilization: Establishing the Process
AUTHOR: Tim Sandle
Navigate compliance aspects of sterility testing, containment system sterility, and sterility test failure investigations. 2017. 193 pages.
_Digital: Item No. 18029_

$120 | NM $150 | G $120

Sterilization: Practical Approaches
AUTHOR: Tim Sandle
Explore practical approaches to sterility testing, gamma irradiation for single-use disposables, ophthalmic preparations, and contamination control. 2017. 106 pages.
_Digital: Item No. 18030_

$120 | NM $150 | G $120
Pharmaceutical and Biopharmaceutical Manufacturing: Understanding Your Process Series

RISK MANAGEMENT LIBRARY

The U.S. FDA now takes a risk-based approach to biomanufacturing. With high regulatory expectations described in 21CFR 600 and other international regulations, these perspectives will enable you to manage risks involved in safely producing healthcare products for patient consumption. Written by subject matter experts, these convenient, electronic texts define risk, discuss hazards and risks, provide tools to help you evaluate risk, and develop effective strategies for dealing with risk.

Each text discusses your risk concerns and contains practical details and applications, includes extensive lists of international regulations for reference, and suggests PDA Technical Reports and other PDA resources for further guidance.

Risk Management Library Volume 1: Lifecycle Risk Management
EDITORS: Edwin Bills and Stan Mastrangelo
Written by experienced authors, this Volume offers insight into the risk management processes, management considerations, and strategies in product development, implementation of risk management for non-product software, and the future of risk management. 2018. 126 pages.

Digital: Item No. 18044
M $100 | NM $125 | G $100

Risk Management Library Volume 2: Practical Approaches to Risk-Based Compliance
AUTHOR: Siegfried Schmitt
This Volume offers guidance in implementing process analytical technology (PAT), discusses the challenges and pitfalls of applying a science and risk-based approach in research and manufacturing, and presents documented evidence for risk-based compliance. 2018. 92 pages.

Digital: Item No. 18045
M $100 | NM $125 | G $100

Risk Management Library Volume 3: Practical Approaches to Risk Assessment and Management
AUTHOR: James L. Vesper
In this Volume, well-respected global experts give an overview of the risk management process and the tools required, including risk-related documents and records and techniques for auditing a risk management program. 2018. 56 pages.

Digital: Item No. 18046
M $100 | NM $125 | G $100

AUTHOR: Tim Sandle
Receive expert guidance on major topics, such as regulatory perspectives on risk and five insightful case studies to help develop the best approaches to problem solving based upon the “What if” and “five whys” method. 2018. 150 pages.

Digital: Item No. 18047
M $100 | NM $125 | G $100

Risk Management Library Volume 5, Risk Problem Solvers: Failure to Follow Established Procedures
EDITORS: Russell E. Madsen and Maik W. Jornitz
Sometimes even well-designed systems are thwarted by human behavior, causing a series of blunders that common sense says could not have happened. In this Volume, you’ll find 10 examples and solutions to problems arising from failure to follow established procedures. 2018. 56 pages.

Digital: Item No. 18048
M $100 | NM $125 | G $100
Risk Management Library Volume 6, Risk Problem Solvers: Lack of Process Understanding

EDITORS: Russell E. Madsen and Maik W. Jornitz
This Volume discusses diagnosis and corrective actions to common problems, such as incorrect batch records, contaminated product complaints, contamination, environmental monitoring, and many other subjects.
2018. 102 pages.
Digital: Item No. 18049
M $100 | NM $125 | G $100

Auditing the CMO

AUTHORS: Thomas Thorpe and Jessica Walker
2013. 28 pages.
Digital: Item No. 17955
M $55 | NM $69 | G $45

Caveats of Bacterial Endotoxin Testing

AUTHOR: Kevin Williams
2007. 35 pages.
Digital: Item No. 17938
M $55 | NM $69 | G $30

Best Practices in Implementing Quality Agreements

AUTHOR: Kenneth Drost
2013. 22 pages.
Digital: Item No. 17956
M $55 | NM $69 | G $45

Cleaning and Disinfection

EDITORS: Russell Madsen and Maik W. Jornitz
This Volume describes 24 problems and offers solutions regarding everything from bioburden contamination in a contained water system to filter integrity, customer complaints, process control failures, and many more real-world problems that were solved with adequate investigations. 2018. 122 pages.
Digital: Item No. 18050
M $100 | NM $125 | G $100
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<td>Sandra Lowery</td>
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<td>John Lindsay</td>
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<td>Gordon Farquharson and Richard Johnson</td>
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<td>Jeanne Moldenhauer</td>
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<td>James Cooper and Cheryl Moses</td>
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You asked, we listened!

PDA members requested more options for membership categories that better align with the benefits they are using, and we delivered!

PDA is introducing a new membership structure, which will go into effect in spring of 2022.

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The cost of membership will be based on the benefits provided in that tier, and all new and renewing members will be eligible for any discounts applicable to your membership category.

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To learn more about our community, please visit www.pda.org.