2022 CATALOG

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Expert Bio/Pharmaceutical Publications and Resources for the Pharmaceutical Manufacturing Industry

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#PDAbookstore

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To help you keep up with a bio/pharmaceutical industry that is progressing at record pace, PDA is committed to providing you with the professional tools and resources you need to stay current with the latest advances.

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.

In this rapidly evolving industry, knowledge is your most important asset! Find all of the information you need in PDA's vast inventory of resources at pda.org/bookstore.

The PDA Journal
journal.pda.org

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.

PDA Technical Report No. 13 Revised 2022 (TR 13) Fundamentals of an Environmental Monitoring Program

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

M $180 | NM $325 | G $180

PDA Technical Report No. 88 (TR 88) Microbial Data Deviation Investigations in the Pharmaceutical Industry

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

M $180 | NM $325 | G $180

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PDA Technical Report No. 39 Revised 2021 (TR 39) Guidance for Temperature-Controlled Medicinal Products - Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment

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

M **$180** | NM **$325** | G **$180**

PDA Technical Report No. 87 (TR 87) Current Best Practices for Pharmaceutical Glass Vial Handling and Processing

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

M **$180** | NM **$325** | G **$180**

PDA Technical Report No. 86 (TR 86) Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing

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

M **$180** | NM **$325** | G **$180**

PDA Technical Report No. 85 (TR 85) Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers

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

M **$180** | NM **$325** | G **$180**

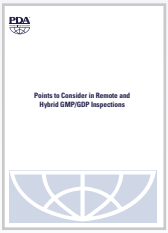
PDA Technical Report No. 60-3 (TR 60-3) Process Validation: A Lifecycle Approach, Annex 2: Biopharmaceutical Drug Substances Manufacturing

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**

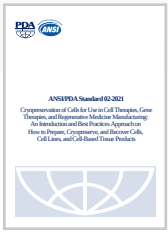
PDA Research: 2020 Particulate Matter in Flexible Containers Survey

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**

ANSI/PDA Standard 02-2021: Cryopreservation of Cells for Use in Cell Therapies, Gene Therapies, and Regenerative Medicine Manufacturing: An Introduction and Best Practices Approach on How to Prepare, Cryopreserve, and Recover Cells, Cell Lines, and Cell-Based Tissue Products.



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**

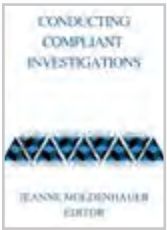
BESTSELLER This text covers risk-based approaches to a cleaning and disinfection program and case studies in contamination control. It provides details on safe building techniques for new cleanrooms and modifications of existing areas by providing a risk-based approach for cleaning and disinfection using 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.*

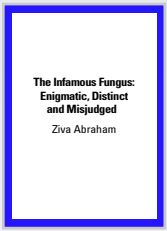
Hardcover: Item No. 13013 | Digital: Item No. 48005

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)

BESTSELLER 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**

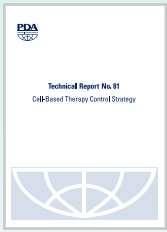
PDA Technical Report No. 79 (TR 79) Particulate Matter Control in Difficult to Inspect Parenterals

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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+1 (301) 656-5900, ext. 148 | morris@pda.org

PDA Technical Report No. 13-2 (TR 13-2) 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

2007. Translated in 2020. 58 pages.

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)

This Technical Report is now available in Spanish in a digital format.

2014. Translated in 2019. 42 pages.

Digital: Item No. 43540

M **$180** | NM **$325** | G **$180**

Price per technical report. ***Digital:*** M **$180** | NM **$325** | G **$180**

The Technical Reports below are listed by published year and TR number (descending order).

PDA Technical Report No. 88 (TR 88) Microbial Data Deviation Investigations in the Pharmaceutical Industry 2022. 53 pages. *Digital: Item No. 43557*

PDA Technical Report No. 39 Revised 2021 (TR 39) Guidance for Temperature-Controlled Medicinal Products - Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment 2021. 29 pages. *Digital: Item No. 43556*

PDA Technical Report No. 87 (TR 87) Current Best Practices for Pharmaceutical Glass Vial Handling and Processing 2021. 48 pages. *Digital: Item No. 43555*

PDA Technical Report No. 86 (TR 86) Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing 2021. 57 pages. *Digital: Item No. 43553*

PDA Technical Report No. 85 (TR 85) Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers 2021. 52 pages. *Digital: Item No. 43552*

PDA Technical Report No. 60-3 (TR 60-3) Process Validation: A Lifecycle Approach, Annex 2: Biopharmaceutical Drug Substances Manufacturing 2021. 53 pages. *Digital: Item No. 43551*

PDA Technical Report No. 13-2 (TR 13-2) Fundamentals of an Environmental Monitoring Program Annex 1: Environmental Monitoring of Facilities Manufacturing Low Bioburden Products 2020. 29 pages. *Digital: Item No. 43549*

PDA Technical Report No. 84 (TR 84) Integrating Data Integrity Requirements into Manufacturing & Packaging Operations 2020. 65 pages. *Digital: Item No. 43547*

PDA Technical Report No. 54-6 (TR 54-6) Formalized Risk Assessment for Excipients 2019. 45 pages. *Digital: Item No. 43542*

PDA Technical Report No. 83 (TR 83) Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response 2019. 40 pages. *Digital: Item No. 43541*

PDA Technical Report No. 82 (TR 82) Low Endotoxin Recovery 2019. 128 pages. *Digital: Item No. 43539*

PDA Technical Report No. 81 (TR 81) Cell-Based Therapy Control Strategy 2019. 58 pages. *Digital: Item No. 43538*

PDA Technical Report No. 80 (TR 80) Data Integrity Management System for Pharmaceutical Laboratories 2018. 63 pages. *Digital: Item No. 43537*

PDA Technical Report No. 79 (TR 79) Particulate Matter Control in Difficult to Inspect Parenterals 2018. 36 pages. *Digital: Item No. 43536*

PDA Technical Report No. 78 (TR 78) Particulate Matter in Oral Dosage Forms 2017. 30 pages. *Digital: Item No. 43535*

PDA Technical Report No. 77 (TR 77) The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology 2017. 40 pages. *Digital: Item No. 43531*

PDA Technical Report No. 60-2 (TR 60-2) Process Validation: A Lifecycle Approach, Annex 1: Oral Solid Dosage/Semisolid Dosage Forms 2017. 40 pages. *Digital: Item No. 43532*

PDA Technical Report No. 54-5 (TR 54-5) Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems 2017. 107 pages. *Digital: Item No. 43533*

PDA Technical Report No. 76 (TR 76) Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging 2016. 59 pages. *Digital: Item No. 43529*

PDA Technical Report No. 75 (TR 75) Consensus Method for Rating 0.1µm Mycoplasma Reduction Filters 2016. 22 pages. *Digital: Item No. 43528*

PDA Technical Report No. 74 (TR 74) Reprocessing of Biopharmaceuticals 2016. 33 pages. *Digital: Item No. 43526*

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. 73 (TR 73) Prefilled Syringe User Requirements for Biotechnology Applications 2015. 117 pages. *Digital: Item No. 43525*

PDA Technical Report No. 72 (TR 72) Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guid ance 2015. 64 pages. *Digital: Item No. 43524*

PDA Technical Report No. 71 (TR 71) Emerging Methods for Virus Detection 2015. 52 pages. *Digital: Item No. 43523*

PDA Technical Report No. 70 (TR 70) Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities 2015. 75 pages. *Digital: Item No. 43522*

PDA Technical Report No. 69 (TR 69) Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations 2015. 73 pages. *Digital: Item No. 43521*

PDA Technical Report No. 57-2, (TR 57-2) Analytical Method Development and Qualification for Biotechnology Products 2015. 59 pages. *Digital: Item No. 43519*

PDA Technical Report No. 54-4, (TR 54-4) Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations: Annex 3: Case Studies in the Manufacturing of Biotechnological Bulk Drug Substances 2015. 82 pages. *Digital: Item No. 43518*

PDA Technical Report No. 67, (TR 67) Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics 2014. 70 pages. *Digital: Item No. 43516*

PDA Technical Report No. 66, (TR 66) Application of Single-Use Systems in Pharmaceutical Manufacturing 2014. 152 pages. *Digital: Item No. 43515*

PDA Technical Report No. 65, (TR 65) Technology Transfer 2014. 67 pages. *Digital: Item No. 43514*

PDA Technical Report No. 13 Revised, (TR 13) Fundamentals of an Environmental Monitoring Program 2014. 39 pages. *Digital: Item No. 43513*

PDA Technical Report No. 64 (TR 64) Active Temperature-Controlled Systems: Qualification Guidance 2013. 58 pages. *Digital: Item No. 43509*

PDA Technical Report No. 63 (TR 63) Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials 2013. 27 pages. *Digital: Item No. 43507*

PDA Technical Report No. 62 (TR 62) Recommended Practices for Manual Aseptic Processes 2013. 30 pages. *Digital: Item No. 43505*

PDA Technical Report No. 61 (TR 61) Steam In Place 2013. 61 pages. *Digital: Item No. 43503*

PDA Technical Report No. 60 (TR 60) Process Validation: A Lifecycle Approach 2013. 102 pages. *Digital: Item No. 43502*

PDA Technical Report No. 54-3 (TR 54-3) Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations: Annex 2: Case Studies in the Manufacturing of Pharmaceutical Drug Products 2013. 53 pages. *Digital: Item No. 43511*

PDA Technical Report No. 54-2 (TR 54-2) Implementation of Quality Risk Management for Pharmaceutical & Biotechnology Manufacturing Operation: Annex 1: Case Study Examples for Quality Risk Management in Packaging & Labeling 2013. 63 pages. *Digital: Item No. 43504*

PDA Technical Report No. 43, Revised 2013 (TR 43) Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing 2013. 190 pages. *Digital: Item No. 43508*

PDA Technical Report No. 33, Revised 2013 (TR 33) Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods 2013. 59 pages. *Digital: Item No. 43510*

PDA Technical Report No. 3, Revised 2013 (TR 3) Validation of Dry Heat Processes Used for Depyrogenation and Sterilization 2013. 40 pages. *Digital: Item No. 43506*

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. 57 (TR 57) Analytical Method Validation and Transfer for Biotechnology Products 2012. 74 pages. *Digital: Item No. 43497*

PDA Technical Report No. 55 (TR 55) Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries
2012. 91 pages. *Digital: Item No. 43494*

PDA Technical Report No. 54 (TR 54) Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations
2012. 61 pages. *Digital: Item No. 43493*

PDA Technical Report No. 30, Revised 2012, (TR 30) Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat
2012. 34 pages. *Digital: Item No. 43234*

PDA Technical Report No. 29, Revised 2012 (TR 29) Points to Consider for Cleaning Validation
2012. 105 pages. *Digital: Item No. 43501*

PDA Technical Report No. 53 (TR 53) Guidance for Industry: Stability Testing to Support Distribution of New Drug Products 2011. 29 pages.
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PDA Technical Report No. 52 (TR 52) Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain 2011. 36 pages.
Digital: Item No. 43491

PDA Technical Report No. 22, (TR 22) Revised 2011 Process Simulation for Aseptically Filled Products
2011. 50 pages. *Digital: Item No. 43226*

PDA Technical Report No. 51 (TR 51) Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use 2010. 42 pages. *Digital: Item No. 43490*

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PDA Technical Report No. 15, Revised 2009 (TR 15) Validation of Tangential Flow Filtration in Biopharmaceutical Applications 2009. 52 pages.
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PDA Technical Report No. 45, (TR 45) Filtration of Liquids Using Cellulose-Based Depth Filters
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PDA Technical Report No. 44, (TR 44) Quality Risk Management for Aseptic Processes 2008. 42 pages.
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PDA Technical Report No. 41, Revised 2008 (TR 41) Virus Filtration 2008. 62 pages.
Digital: Item No. 43313 | Softcover: Item No. 01041

PDA Technical Report No. 26, (TR 26) Revised 2008, Sterilizing Filtration of Liquids 2008. 62 pages.
Digital: Item No. 43230

PDA Technical Report No. 14, (TR 14) Validation of Column-Based Chromatography Processes for the Purification of Proteins 2008. 38 pages.
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PDA Technical Report No. 1, Revised 2007, (TR 1) Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control 2007. 54 pages.
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Older PDA Technical Reports

Price per technical report. M $50 | NM $100 | G $50

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PDA Technical Report No. 38, (TR 38) Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing and Controls Documentation 2006. 30 pages.
Digital: Item No. 43315

PDA Technical Report No. 28 Revised, (TR 28) Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals 2006. 24 pages.
Digital: Item No. 43232

PDA Technical Report No. 42, (TR 42) Process Validation of Protein Manufacturing 2005. 28 pages.
Digital: Item No. 43311 | Softcover: Item No. 01042

PDA Technical Report No. 40, (TR 40) Sterilizing Filtration of Gases 2005. 44 pages.
Digital: Item No. 43314 | Softcover: Item No. 01040

PDA Technical Report No. 35, (TR 35) A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry 2001. 24 pages.
Digital: Item No. 43240

PDA Technical Report No. 34, (TR 34) Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products 2001. 25 pages.
Digital: Item No. 43239 | Softcover: Item No. 01034

PDA Technical Report No. 31, (TR 31) Validation and Qualification of Computerized Laboratory Data Acquisition Systems 1999. 12 pages.
Digital: Item No. 43235

PDA Technical Report No. 27, (TR 27) Pharmaceutical Package Integrity 1998. 48 pages.
Digital: Item No. 43231

PDA Technical Report No. 16, (TR 16) Effect of Gamma Irradiation on Elastomeric Closures 1992. 13 pages. *Digital: Item No. 43222*

PDA Technical Report No. 20, (TR 20) Report on Survey of Current Industry Gowning Practices 1990. 5 pages. *Digital: Item No. 41239*

PDA Technical Report No. 19, (TR 19) Rapid/ Automated ID Methods Survey 1990. 7 pages.
Digital: Item No. 43225

PDA Technical Report No. 12, (TR 12) Siliconization of Parenteral Drug Packaging Components 1988. 14 pages. *Digital: Item No. 43217*

PDA Technical Report No. 11, (TR 11) Sterilization of Parenterals by Gamma Radiation 1988. 9 pages.
Digital: Item No. 43216

PDA Technical Report No. 10, (TR 10) Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers 1988. 26 pages. *Digital: Item No. 43215*

PDA Technical Report No. 5, (TR 5) Sterile Pharmaceutical Packaging: Compatibility and Stability 1984. 137 pages. *Digital: Item No. 43210*

The Technical Report below is free of charge and available to everyone.

PDA Technical Report No. 68, (TR 68) Risk Based Approach for Prevention and Management of Drug Shortages 2014. 54 pages. *Digital: Item No. 43517*

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**

Points to Consider for Aseptic Processing: Part 2, May 2016 *2016. 58 pages.*

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

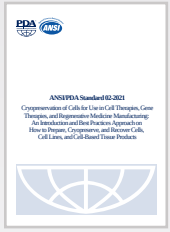
Points to Consider for Aseptic Processing: Part 1, January 2015 *2015. 65 pages.*

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

Points to Consider for Aseptic Processing - PDA Journal of Pharmaceutical Science and Technology: 2003 Supplement Volume 57 Issue 2 *2003. 72 pages.*

Digital: Item No. 42148

ANSI/PDA Standard 02-2021: Cryopreservation of Cells for Use in Cell Therapies, Gene Therapies, and Regenerative Medicine Manufacturing: An Introduction and Best Practices Approach on How to Prepare, Cryopreserve, and Recover Cells, Cell Lines, and Cell-Based Tissue Products.

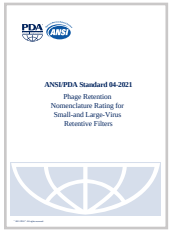


This new standard provides guidance on how to establish suitable procedures for the cryopreservation and recovery of biological cells for use in cell and gene therapy products and regenerative medicine manufacturing either as an intermediate step or when cryopreservation is the final step. The guide 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

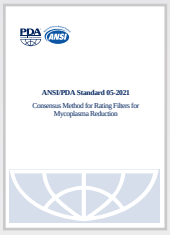


This new standard addresses virus-removal filters that retain viruses by a size-exclusion mechanism. It is intended to provide filter suppliers with an approach to standardizing methodology and nomenclature for large- and small-virus retentive filters using bacteriophage as a model and to assist users/manufacturers 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

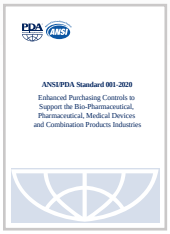


This standard describes a filter challenge test for standardizing test parameters across laboratories using 47 mm discs and using A. laidlawii as the test organism. While this standard is primarily to educate users and filter manufacturers about best practices for mycoplasma reduction filtration, this 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 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 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

M **$180** | NM **$325** | G **$180**

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

M **$150** | NM **$325** | G **$150**

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

M **$150** | NM **$325** | G **$150**

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

M **$150** | NM **$325** | G **$150**

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**

PDA Survey: 2014 PDA Process Validation Survey

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**

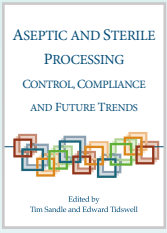
PDA Technical Books

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**



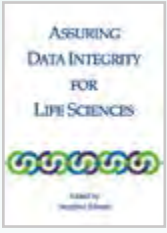
Aseptic and Sterile Processing: Control, Compliance and Future Trends takes a current and future approach to two vital processing procedures – aseptic and sterile manufacturing. *2017. 930 pages.*

Digital: Item No. 18038

M **$260** | NM **$325** | G **$240**

Assuring Data Integrity for Life Sciences

EDITOR: **Siegfried Schmitt**



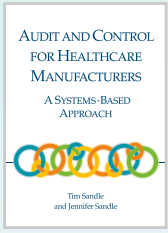
This book provides a truly global perspective on data integrity and the solutions available to address this serious issue. It includes two main sections: the regulatory and historic background of data integrity, and practical advice on how to prevent or rectify data integrity breaches. *2016. 408 pages.*

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**



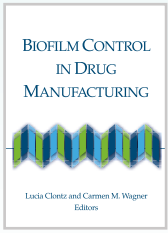
Audits are an important part of quality assurance and the quality management system. With the help of PDA's book, *Audit and Control for Healthcare Manufacturers: A Systems-Based Approach,* you can ensure the quality and effectiveness of your processes, systems, and personnel is maintained throughout 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~~ $192 | NM ~~$299~~ $239 | G ~~$190~~ $152

Biological Indicators for Sterilization Processes

EDITORS: **Margarita Gomez and Jeanne Moldenhauer**

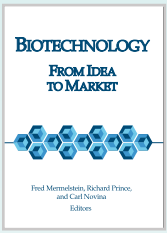
2008. 536 pages. Hardcover: Item No. 17268

M ~~$280~~ $196 | NM ~~$349~~ $245 | 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**



BESTSELLER 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**

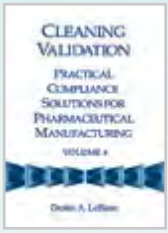
Cleaning and Cleaning Validation is a series of volumes presenting current knowledge and approaches to cleaning and cleaning validation of pharmaceuticals, medical devices, and associated products, consistent with current regulatory documents and expectations. Case studies presented throughout the volumes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

Digital: Item No. 17987

M ~~$535~~ $428 | NM ~~$670~~ $536 | G ~~$465~~ $372

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~~ $508 | NM ~~$790~~ $632 | G ~~$435~~ $348

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~~ $212 | NM ~~$329~~ $263 | G ~~$180~~ $144

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.

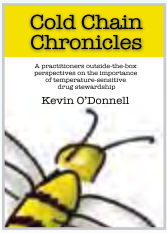
2014. 600 pages.

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**



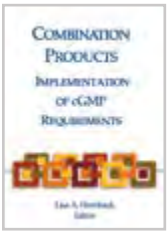
Noted pharmaceutical cold-chain expert Kevin O'Donnell relates a series of engaging stories carefully crafted to elevate awareness, understanding, and criticality of temperature-sensitive drug products throughout the supply chain, not only for the stakeholders involved, but also for the consumer in us 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**



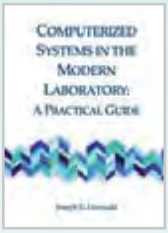
This book explores the unique aspects and considerations for implementation of cGMP in a combination product environment. It includes comprehensive information from leaders in the industry regarding the unique requirements for several common combination products situations. *2013. 200 pages.*

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~~ $212 | NM ~~$329~~ $263 | G ~~$210~~ $168

Confronting Variability: A Framework for Risk Assessment

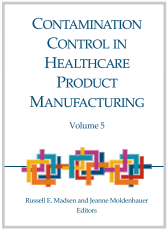
EDITORS: **Diane Petitti and Richard Prince**

2007. 222 pages. Hardcover: Item No. 17244

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

Contamination Control in Healthcare Product Manufacturing, Volume 5

EDITORS: **Russell E. Madsen and Jeanne Moldenhauer**



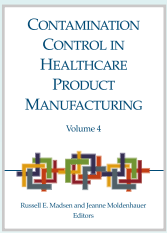
The fifth volume in PDA's popular series, *Contamination Control in Healthcare Product Manufacturing*, explores practical approaches to leverage environmental monitoring data to improve performance, how to design a risk-based environmental monitoring program for non-sterile manufacturing, the clinical 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**

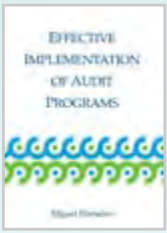
This first-of-two volume release takes an in-depth look at the digital technologies that are impacting the pharmaceutical and healthcare landscape now and into the future. It explores what each technology does, the potential use of the technology and the practical aspects for its implementation, along 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**



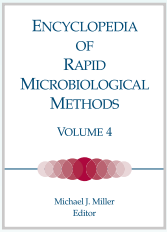
This well-researched text is a must have for personnel involved in the implementation and execution of critical programs, auditors, auditees, and outsourcing providers! *2017. 390 pages.*

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**



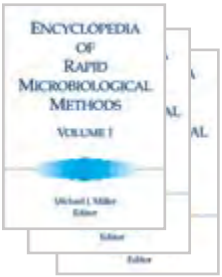
This volume complements the author's previous three volumes by offering new techniques, case studies, new equipment, and much more. Details about quality control, choosing appropriate methods, future use and technologies, and mass spectrometry are included. *2013. 608 pages.*

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

M ~~$335~~ $268 | NM ~~$419~~ $335 | G ~~$290~~ $232

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

EDITOR: **Michael J. Miller**



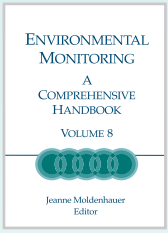
Introductory volumes of the *Encyclopedia of Rapid Microbiological Methods* series describes the rapid methods currently available and focuses on regulatory initiatives currently in place that will help pharmaceutical microbiologists begin the journey of implementing rapid microbiological methods in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

Digital: Item No. 17989

M ~~$795~~ $636 | NM ~~$989~~ $791 | G ~~$685~~ $548

Environmental Monitoring: A Comprehensive Handbook, Volume 8

EDITOR: **Jeanne Moldenhauer**



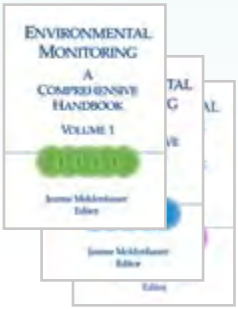
Volume 8 of the *Environmental Monitoring Handbook* series is a mixture of new topics and new takes on previously discussed topics. In this Volume, you will find information about regulatory/compendial updates, testing methods, risk methods and tools, and routine (and non-routine) monitoring. This Volume 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**



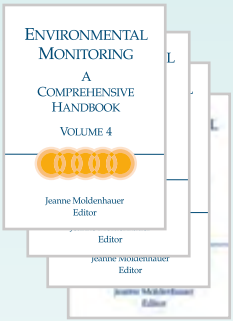
Regulatory bodies worldwide have all established standards and guidelines for environmental control. Unfortunately, the requirements are not equivalent across documents and nations. These three volumes describe methods for developing and operating an appropriate, sustainable microbiological program for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

Digital: Item No. 18007

M ~~$800~~ $640 | NM ~~$1,000~~ $800 | 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 ~~$1,070~~ $856 | NM ~~$1,340~~ $1,072 | G ~~$930~~ $744

Environmental Monitoring: A Comprehensive Handbook, Volumes 4, 5, 6, and 7 items for Individual Purchase, Volumes 1-7

Volume 1 *(Digital: Item No. 17977) Hardcover is not available*
Volume 2 *(Digital: Item No. 17978) Hardcover is not available*
Volume 3 *(Digital: Item No. 17979) Hardcover is not available*
Volume 4 *(Hardcover: Item No. 17291 Digital: Item No. 18008)*
Volume 5 *(Hardcover: Item No. 17299 Digital: Item No. 18009)*
Volume 6 *(Digital: Item No. 18010) Hardcover is not available*
Volume 7 *(Hardcover: Item No. 17325 Digital: Item No. 18011)*

M ~~$335~~ $268 | NM ~~$419~~ $335 | G ~~$290~~ $232

Protocol CD in PDF format *(Item No. 18056)*

M ~~$75~~ $60 | NM ~~$89~~ $71 | G ~~$45~~ $36

Essential Microbiology for QP Candidates

AUTHOR: **Nigel Halls**

2007. 314 pages.

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

M ~~$250~~ $175 | NM ~~$309~~ $220 | G ~~$180~~ $130

Ethylene Oxide Sterilization Validation and Routine Operations Handbook

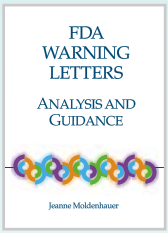
AUTHOR: **Anne F. Booth**

2007. 203 pages. Digital: Item No. 17942

M **$225** | NM **$279** | G **$180**

FDA Warning Letters: Analysis and Guidance

AUTHOR: **Jeanne Moldenhauer**



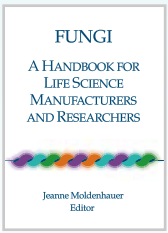
BESTSELLER The best way to handle Warning Letters issued by the U.S. FDA is to prevent them. This text identifies and discusses those Letters recently issued, offers analysis, and provides guidance to help readers avoid receiving such a letter. *2020. 578 pages.*

Hardcover: Item No. 17356 | Digital: Item No. 18065

M **$195** | NM **$239** | G **$185**

Fungi: 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**

Global Sterile Manufacturing Regulatory Guidance Comparison

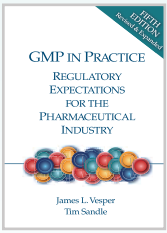
The *Global Sterile Manufacturing Regulatory Guidance Comparison – With link to Comparison Spreadsheet* compares regulatory guidance documents issued by the U.S. FDA, the EU, the Pharmaceutical Inspection Convention/Scheme, and the World Health Organization. *2016. 99 pages.*

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**



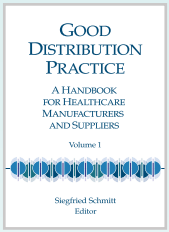
BESTSELLER *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fifth Edition, Revised and Expanded* examines 34 elements that are typically included in a modern pharmaceutical quality system, including Data Integrity. Each quality system element has an overview section, some risk-related 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

EDITOR: **Siegfried Schmitt**



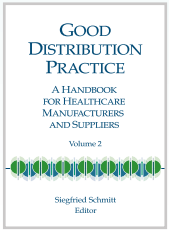
BESTSELLER Following an introduction to the subject of Good Distribution Practice (GDP), the first volume of this book covers key topics related to five main points: the applicable GDP regulations worldwide, including serialization; an overview of the requirements of Qualified Persons and Responsible 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

EDITOR: **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**~~ **$87** | NM ~~**$179**~~ **$108** | G ~~**$80**~~ **$48**

Introduction to Environmental Monitoring in Pharmaceutical Areas

AUTHOR: **Michael Jahnke**

2001. 114 pages. Digital: Item No. 17925

M **$72** | NM **$93** | G **$51**

Laboratory Design: Establishing the Facility and Management Structure

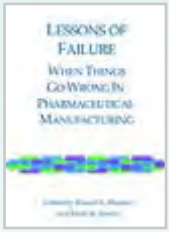
AUTHOR: **Scott Sutton**

2010. 391 pages. Digital: Item No. 18002

M **$196** | NM **$245** | G **$140**

Lessons of Failure: When Things Go Wrong in Pharmaceutical Manufacturing

EDITORS: **Russell E. Madsen and Maik W. Jornitz**



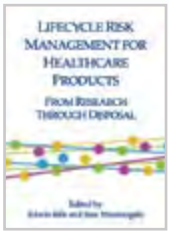
In *Lessons of Failure When Things Go Wrong in Pharmaceutical Manufacturing,* world-renowned experts share their global work experiences to highlight root cause analysis and problem solving. The stories are not only examples of what can go wrong, but also contain key points to take away and apply. For those who provide GMP and quality training, this book is a goldmine. *2015. 299 pages.*

Digital: Item No. 18013

M **$210** | NM **$259** | G **$190**

Lifecycle Risk Management for Healthcare Products: From Research through Disposal

EDITORS: **Edwin Bills and Stan Mastrangelo**



This book provides current information on the risk management process as it applies to health and safety of health products, drugs and biologics, and medical devices and products that are a combination of two or more of these. The application of the processes will help manufacturers of these products to create and maintain products that are at an acceptable level of safety for society through the product lifecycle. *2016. 295 pages.*

Hardcover: Item No. 17338 | Digital: Item No. 18019

M **$225** | NM **$279** | G **$190**

Media Fill Validation Environmental Monitoring During Aseptic Processing

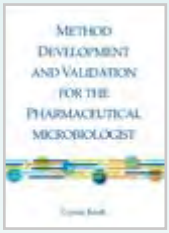
AUTHOR: **Michael Jahnke**

2001. 114 pages. Digital: Item No. 17924

M ~~$120~~ $72 | NM ~~$155~~ $93 | G ~~$85~~ $72

Method Development and Validation for the Pharmaceutical Microbiologist

AUTHOR: **Crystal Booth**



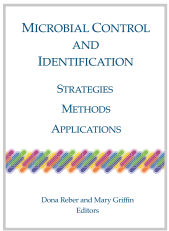
The purpose of this book is to inspire ideas and provide recommendations regarding method development and validation strategies for pharmaceutical microbiologists. The book may also aid microbiologists who are starting new facilities or validating equipment. This is a must-have resource for anyone engaged in the many aspects of method development and validation in pharmaceutical microbiology. *2017.*

Hardcover: Item No. 17339 | Digital: Item No. 18022

M **$210** | NM **$259** | G **$190**

Microbial Control and Identification: Strategies Methods Applications

EDITORS: **Dona Reber and Mary Griffin**



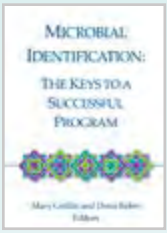
The Editors of this book assembled a team of subject matter experts who share their expertise on microbial identifications (IDs) in this thoughtfully edited volume. This invaluable book includes details about viral and mycoplasma ID methods, challenges and case studies on fungal IDs, use of science-based risk assessment for objectionable organisms, microbial IDs for medical devices and cosmetics, and much more. *2018. 592 pages.*

Digital: Item No. 18043

M **$240** | NM **$299** | G **$220**

Microbial Identification: The Keys to a Successful Program

EDITORS: **Mary Griffin and Dona Reber**



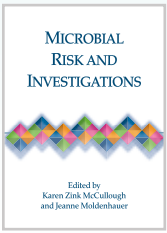
The Editors of this book assembled a team of subject matter experts who share their expertise on microbial identifications (IDs) in this thoughtfully edited volume. This invaluable book includes details about viral and mycoplasma ID methods, challenges and case studies on fungal IDs, use of science-based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

Digital: Item No. 17953

M ~~$240~~ $192 | NM ~~$299~~ $239 | G ~~$190~~ $152

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**

Microbial Risk Assessment in Pharmaceutical Clean Rooms

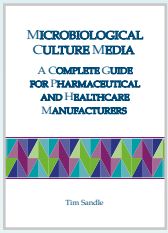
AUTHORS: **Berit Reinmueller and Bengt Ljungqvist**

2001. 17 pages. Digital: Item No. 17920

M **$95** | NM **$119** | G **$75**

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

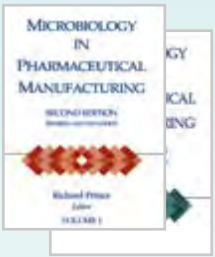
AUTHOR: **Michael Jahnke**

2002. 70 pages. Digital: Item No. 17919

M **$120** | NM **$149** | G **$95**

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

M ~~$375~~ $300 | NM ~~$465~~ $372 | G ~~$250~~ $200

Available for Individual Purchase

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

M ~~$235~~ $188 | NM ~~$289~~ $231 | G ~~$155~~ $124

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

M **$150** | NM **$250** | G **$120**

PDA Technical Series: Pharmaceutical Glass

The *PDA Technical Series: Pharmaceutical Glass* is a collection of articles previously published in the *PDA Journal of Pharmaceutical Science and Technology*. This compilation organizes 19 articles on glass published between 2007 and 2017 into four categories: Overview, Material Composition, Delamination, and Quality Methods.

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

M **$150** | NM **$250** | G **$120**

Pharmaceutical Contamination Control: Practical Strategies for Compliance

EDITOR: **Nigel Halls**

2007. 289 pages. Hardcover: Item No. 17246

M ~~$280~~ $196 | NM ~~$349~~ $245 | G ~~$190~~ $140

Pharmaceutical Legislation of the European Union, Japan and the United States of America - An Overview, Updated and Expanded Second Edition

EDITOR: **Barbara Jentges**

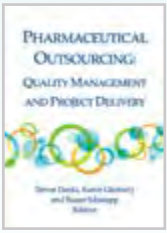
The book presents a condensed overview of the regulatory systems and processes for marketing a drug product in the three major global regions: Japan, the United States, and the European Union. *2016. 164 pages.*

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

EDITOR: **Richard Prince**

2004. 758 pages. Hardcover: Item No. 17207

M ~~$320~~ $225 | NM ~~$399~~ $280 | G ~~$210~~ $150

Pharmaceutical Quality Control Microbiology: A Guidebook to the Basics

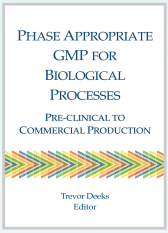
AUTHOR: **Scott Sutton**

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

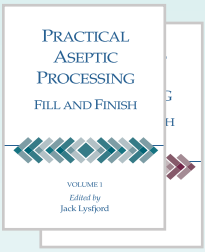
2018. 525 pages.

Digital: Item No. 18042

M **$240** | NM **$299** | G **$220**

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

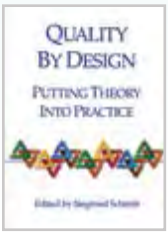
Available for Individual Purchase

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 ~~$210~~ $168 | NM ~~$259~~ $207 | G ~~$155~~ $124

Radiation Sterilization: Validation and Routine Operations Handbook

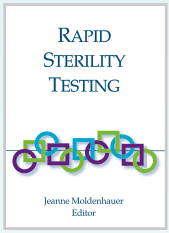
AUTHOR: **Anne F. Booth**

2008. 183 pages. Hardcover: Item No. 17277

M ~~$225~~ $158 | NM ~~$279~~ $200 | G ~~$180~~ $130

Rapid Sterility Testing

EDITOR: **Jeanne Moldenhauer**



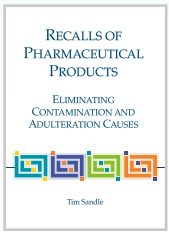
In this book, you will find a history of the sterility test methodology and detailed discussions that provide the regulatory requirements and allowances for gaining approval of rapid sterility test methods. *2011. 501 pages.*

Hardcover: Item No. 17302 | Digital: Item No. 17994

M ~~$250~~ $200 | NM ~~$309~~ $247 | G ~~$200~~ $160

Recalls of 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 ~~$280~~ $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. 18018

M **$240** | NM **$299** | G **$210**

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**

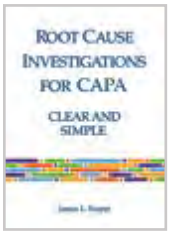
This book offers a systematic, 10-step approach, from the decision to validate to the assessment of the validation outcome, for validating configurable, off-the-shelf computer software that generates data or controls information about products and processes subject to binding regulations. *2006. 183 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**



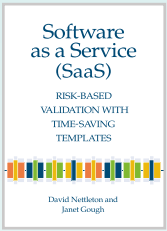
This text, based on workshops led by instructor and author James Vesper, provides practical tools for both a thorough understanding of risk-based CAPA investigations and regulatory acceptable applications. *2020. 332 pages.*

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**



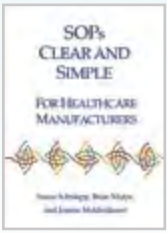
BESTSELLER From this book, you will learn a systematic, step-by-step approach for validating configurable off-the-shelf software that generates data or controls information about products and processes subject to regulations. *2020. 182 pages.*

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.

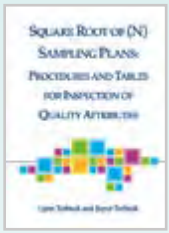
Upon finishing this book, you'll be able to not only write out SOPs but also follow them to fully maintain compliance. *2019. 177 pages.*

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~~ $168 | NM ~~$259~~ $207 | G ~~$170~~ $136

Steam Sterilization: A Practitioner's Guide

EDITOR: **Jeanne Moldenhauer**

2002. 740 pages. Hardcover: Item No. 17183

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~~ $192 | NM ~~$299~~ $239 | G ~~$210~~ $168

Systems Based Inspection for Pharmaceutical Manufacturers

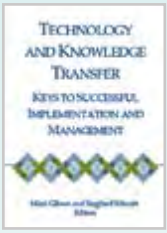
EDITOR: **Jeanne Moldenhauer**

2007. 398 pages. Digital: Item No. 17972

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.

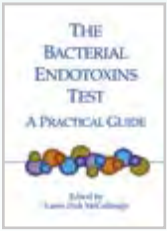
2014. 474 pages.

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 External Quality Audit

AUTHORS: **Janet Gough and Monica Grimaldi**

2001. 122 pages. Digital: Item No. 17922

M **$145** | NM **$179** | G **$85**

The Internal Quality Audit

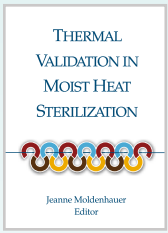
AUTHORS: **Monica Grimaldi and Janet Gough**

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**

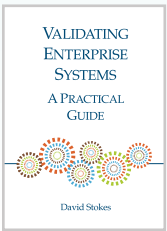
This book is for pharmaceutical professionals working in product discovery, development, manufacturing, quality assurance, and quality control. It presents a basic introduction to data, trend, and out-of-trend definitions and proposes terminology to clarify the use of the word "control" in several contexts. 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~~ $180 | NM ~~$279~~ $223 | 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

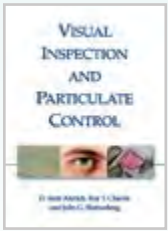
AUTHOR: **Stephan Krause**

2007. 174 pages. *Digital: Item No. 17971*

M **$280** | NM **$349** | G **$200**

Visual Inspection and Particulate Controls

AUTHORS: **D. Scott Aldrich, Roy T. Cherris, and John G. Shabushnig**



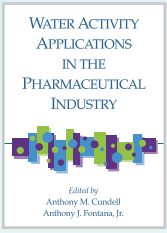
BESTSELLER This book is a practical guide for the control of visible defects and contamination in pharmaceutical products. It is intended for product inspectors and lab support personnel and for those who use inspection results or are responsible for inspection operations. Meant to educate seasoned inspectors 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**

Water Activity Applications in the Pharmaceutical Industry

EDITORS: **Anthony M. Cundell, Anthony J. Fontana, Jr.**



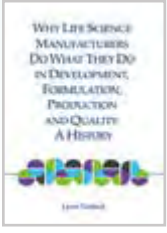
This book examines the fundamentals and relationships of water activity, ranging from the measurement of moisture content, water activity, and water sorption isotherms, to ways in which water activity affects microorganisms, chemical reaction rates, drug product formulation and processing and physical 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 Drug 483s: 2015-2019

AUTHOR: **Jeanne Moldenhauer**

This publication provides a summary and analysis of publicly available yearly observation data for drug product manufacturers from the U.S. FDA and presents it in a more useful, digestible format. It includes an analysis of trends in observations and a breakdown of the most common observations from the past five years. *2020. 126 pages.*

Digital: Item No. 18078

M **$129** | NM **$159** | G **$119**

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 sanitization 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.

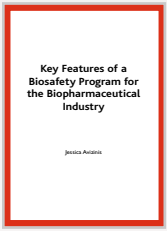
2018. 37 pages.

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

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

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

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

Managing the Pharmaceutical Cold Chain

AUTHOR: **Steve Winyard**

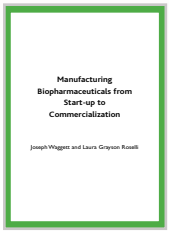
This chapter is reprinted and available individually from *Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1*, edited by Siegfried Schmitt, a text that collects in one place invaluable and comprehensive regulatory, manufacturing, and distribution guidance and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

Digital: Item No. 18075

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

Manufacturing Biopharmaceuticals From Start-Up to Commercialization

AUTHOR: **Joseph Waggett and Laura Roselli**



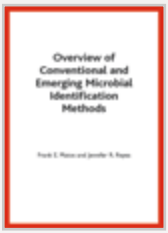
The magnitude of knowledge and experience required to have a meaningful impact on biotechnology product approvals and market success is monumental. For the first time, this expertly crafted chapter is reprinted from *Biotechnology: From Idea to Market,* edited by Fred Mermelstein, Richard Prince, and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

Digital: Item No. 18068

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

Overview of Conventional and Emerging Microbial Identification Methods

AUTHOR: **Frank E. Matos, Jennifer R. Reyes**



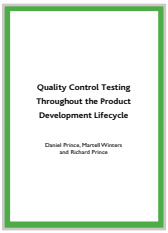
This reprint from *Microbial Control and Identification: Strategies, Methods, and Applications,* edited by Dona Reber and Mary Griffin, demonstrates how microbial identification knowledge is a cornerstone in the concept of microbial and contamination control programs. *2020. 47 pages.*

Digital: Item No. 18071

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

Quality Control Testing Throughout the Product Development Lifecycle

AUTHOR: **Daniel Prince, Martell Winters, Richard Prince**



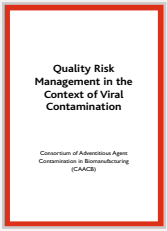
The magnitude of knowledge and experience required to have a meaningful impact on biotechnology product approvals and market success is monumental. For the first time, expertly crafted chapter is reprinted from *Biotechnology: From Idea to Market,* edited by Fred Mermelstein, Richard Prince and Carl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

Digital: Item No. 18069

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

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**

Regulatory Affairs Role in Product Development

AUTHOR: **David L. Rosen**

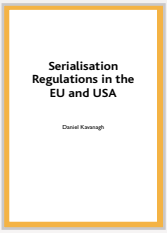
The magnitude of knowledge and experience required to have a meaningful impact on biotechnology product approvals and market success is monumental. For the first time, this expertly crafted chapter is reprinted from *Biotechnology: From Idea to Market,* edited by Fred Mermelstein, Richard Prince, and 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**

Serialisation Regulations in the EU and USA

AUTHOR: **Daniel Kavanagh**



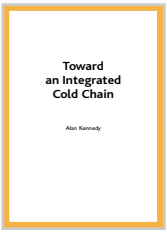
This chapter is reprinted and available individually from *Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1,* edited by Siegfried Schmitt, a text that collects in one place invaluable and comprehensive regulatory, manufacturing and distribution guidance and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

Digital: Item No. 18073

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

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

M **$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

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