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#PDABooks

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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**.

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**

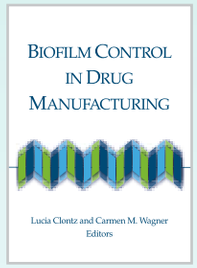
BESTSELLER *Aseptic and Sterile Processing: Control, Compliance and Future Trends* takes a current and future approach to two vital processing procedures – aseptic and sterile manufacturing. *2017. 930 pages.*

Hardcover: Item No. 17342 | Digital: Item No. 18038

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

Biofilm Control in Drug Manufacturing

EDITORS: **Lucia Clontz and Carmen M. Wagner**



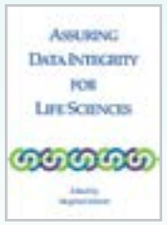
This book provides guidance for preventing and controlling biofilm contamination in pharmaceutical and biopharmaceutical processing. *2012. 496 pages.*

Digital: Item No. 17986

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

Assuring Data Integrity for Life Sciences

EDITOR: **Siegfried Schmitt**



BESTSELLER 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**

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 ~~$198~~ $140

LEGEND: M **= Member Pricing** | NM **= Nonmember Pricing** | G **= Government Pricing**

Cleaning and Cleaning Validation, Volumes 1 and 2

EDITOR: **Paul L. Pluta**

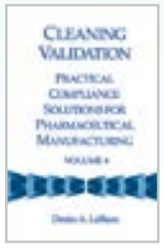
Cleaning and Cleaning Validation is a series of volumes presenting current knowledge and approaches to cleaning and cleaning validation of pharmaceuticals, medical devices, and associated products, consistent with current regulatory documents and expectations. Case studies presented throughout the volumes 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**

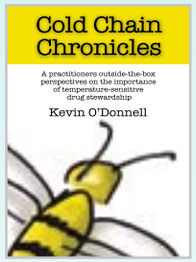
BESTSELLER This book is about cleanrooms and controlled environments in relation to the pharmaceutical and healthcare sectors. With its focus on cleanroom microbiology, this book is applicable to both the sterile and non-sterile pharmaceutical sectors. *2014. 600 pages.*

Hardcover: Item No. 17326 | 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**

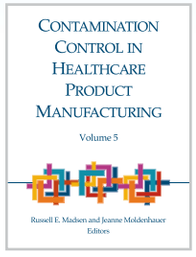
2007. 222 pages

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**



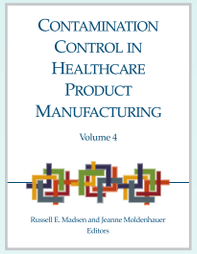
NEW The fifth volume to PDA's popular series, *Contamination Control in Healthcare Product Manufacturing,* explores practical approaches to leverage environmental monitoring data to improve performance, how to design a risk-based environmental monitoring program for non-sterile manufacturing, the clinical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



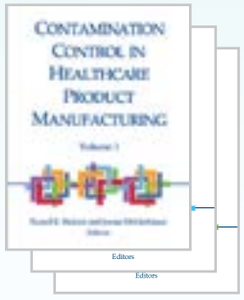
This book is an essential complement to any contamination control library! Volume 4 is a useful reference guide when combined with the previous three volumes. *2016. 402 pages.*

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 *(Hardcover: Item No. 17311 Digital: Item No.17952)*
Volume 2 *(Hardcover: Item No. 17317 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**

NEW 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**

Effective Implementation of Audit Programs

AUTHOR: **Miguel Montalvo**

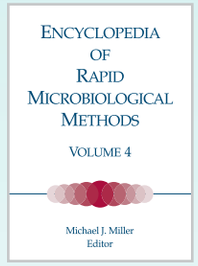
This well-researched text is a must have for personnel involved in the implementation and execution of critical programs, auditors, auditees, and outsourcing providers! *2017. 390 pages.*

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**



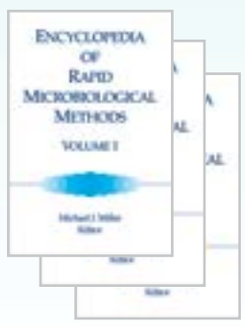
This volume complements the author's previous three volumes by offering new techniques, case studies, new equipment, and much more. Details about quality control, choosing appropriate methods, future use and technologies, and mass spectrometry are included. *2013. 608 pages.*

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**



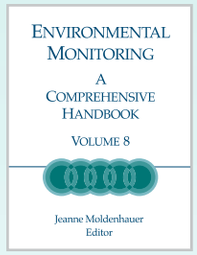
Introductory volumes of the *Encyclopedia of Rapid Microbiological Methods* series describes the rapid methods currently available and focuses on regulatory initiatives currently in place that will help pharmaceutical microbiologists begin the journey of implementing rapid microbiological methods in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



BESTSELLER 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**

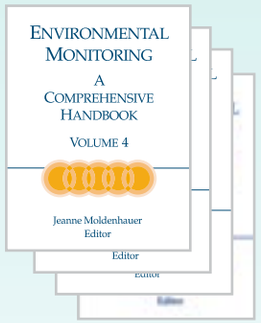
Regulatory bodies worldwide have all established standards and guidelines for environmental control. Unfortunately, the requirements are not equivalent across documents and nations. These three volumes describe methods for developing and operating an appropriate, sustainable microbiological program for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

Volume 1 *(Digital: Item No. 17977) Hardcover is not available*

Volume 2 *(Digital: Item No. 17978)*

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)*

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

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.*

Softcover: Item No. 03006

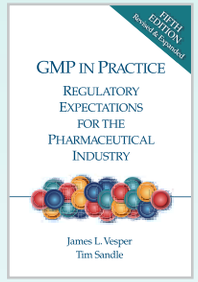
M $250 | NM $375 | G $250

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**



NEW 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

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**

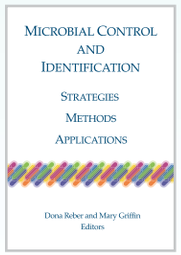
BESTSELLER The purpose of this book is to inspire ideas and provide recommendations regarding method development and validation strategies for pharmaceutical microbiologists. The book may also aid microbiologists who are starting new facilities or validating equipment. This is a must-have resource for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



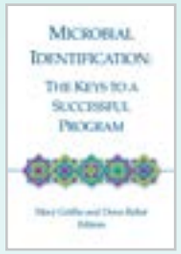
NEW BESTSELLER In PDA's latest release, expert microbiologists and biopharmaceutical industry leaders explore the role of microbial identification knowledge as a cornerstone in the concept of microbial and contamination control programs. This book is an excellent reference for new microbiologists and seasoned professionals alike. Each chapter illustrates how microbial control programs for facilities, equipment, and personnel can have a positive impact on products and ultimately, patients. *2018. 592 pages.*

Hardcover: Item No. 17347 | 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**

BESTSELLER 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 *(Hardcover: Item No. 17279 Digital: Item No. 18052)*

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

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

PDA Technical Series: Pharmaceutical Glass

NEW 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 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**

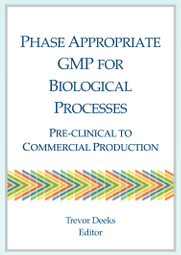
2007. 205 pages

Hardcover: Item No. 17242 | 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**



NEW 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

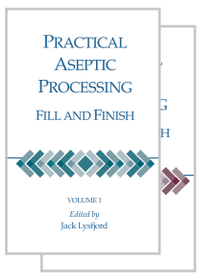
2018. 525 pages.

Hardcover: Item No. 17346 | 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

Practical Aseptic Processing Fill and Finish, Volumes 1 and 2 *(continued)*

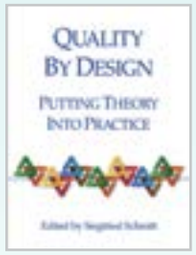
Available for Individual Purchase

Volume 1 *(Digital: Item No. 18036)*
Volume 2 *(Hardcover: Item No. 17255 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**

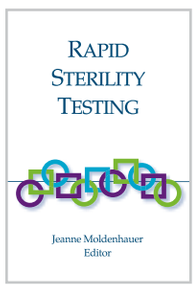
2008. 183 pages.

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

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**

BESTSELLER 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.*

Hardcover: Item No. 17337 | 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.*

Hardcover: Item No. 17256

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

SOPs Clear and Simple: For Healthcare Manufacturers

AUTHORS: **Susan Schniepp, Brian Matye and Jeanne Moldenhauer**

NEW 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.

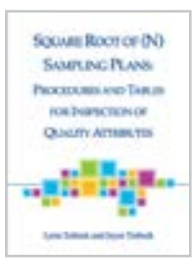
Upon finishing this book, you'll be able to not only write out SOPs but also follow them to fully maintain compliance. *2019. 177 pages.*

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**

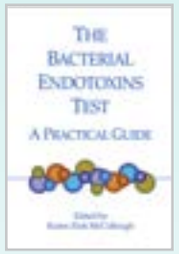
Written by global subject matter experts, this book offers the practical experience needed to obtain a competitive edge. This book will help companies take a proactive approach to streamlining and optimizing their technology transfer processes to ensure successes. *2014. 474 pages.*

Hardcover: Item No. 17318 | Digital: Item No. 17984

M **$265** | NM **$329** | G **$210**

The Bacterial Endotoxins Test: A Practical Guide

EDITOR: **Karen Zink McCullough**



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.

Hardcover: Item No. 17297 | 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**

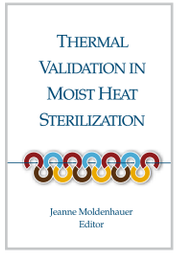
The Internal Quality Audit

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**



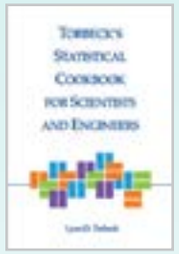
The various authors cited in this book have a wealth of practical experience in thermal validation of moist heat sterilization processes. This book is an essential reference guide for managers, supervisors, and all others concerned with preparing validation plans acceptable to regulators worldwide. *2011. 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**

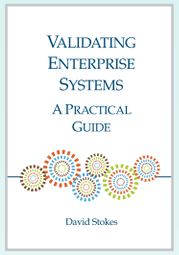
BESTSELLER This book is for pharmaceutical professionals working in product discovery, development, manufacturing, quality assurance, and quality control. It presents a basic introduction to data, trend, and out-of-trend definitions and proposes terminology to clarify the use of the word "control" in 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.

Hardcover: Item No. 17330 | 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**

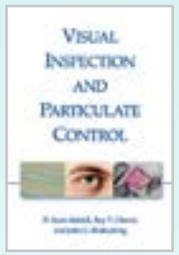
Validation of Analytical Methods for Biopharmaceuticals: A Guide to Risk-Based Validation and Implementation Strategies

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.

Hardcover: Item No. 17334 | Digital: Item No. 18015

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

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

PDA Booklets contain one chapter from a larger publication, chosen for the relevance of content, expertise of the author, and industry demand.

Cleaning SOPs: Five Proven and Validated SOPs

AUTHOR: **Anne Marie Dixon-Heathman**

NEW 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.

Digital: Item No. 18057

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

Biopharmaceutical Validation and Technical Transfer

AUTHOR: **Russell E. Madsen**

NEW 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**

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. Our newest compendium offers 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

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

Environmental Monitoring, Volume 2: Practical Approaches

EDITOR: **Jeanne Moldenhauer**

Learn about rapid microbiological monitoring, environmental monitoring for sterility test isolators, and how to present environmental monitoring data to internal and external stakeholders. *2017. 92 pages.*

Digital: Item No. 18032

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

Sterilization: Establishing the Process

AUTHOR: **Tim Sandle**

Navigate compliance aspects of sterility testing, containment system sterility, and sterility test failure investigations.

2017. 193 pages

Digital: Item No. 18029

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

Sterilization: Practical Approaches

AUTHOR: **Tim Sandle**

Explore practical approaches to sterility testing, gamma irradiation for single-use disposables, ophthalmic preparations, and contamination control.

2017. 106 pages

Digital: Item No. 18030

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

NEW Pharmaceutical and Biopharmaceutical Manufacturing: Understanding Your Process Series Risk Management Library

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

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

Risk Management Library Volume 1: Lifecycle Risk Management

EDITORS: **Edwin Bills and Stan Mastrangelo**

Written by experienced authors, this Volume offers insight into the risk management processes, management considerations, and strategies in product development, implementation of risk management for non-product software, and the future of risk management. *2018. 126 pages.*

Digital: Item No. 18044

M **$100** | NM **$125** | G **$100**

Risk Management Library Volume 2: Practical Approaches to Risk-Based Compliance

AUTHOR: **Siegfried Schmitt**

This Volume offers guidance in implementing process analytical technology (PAT), discusses the challenges and pitfalls of applying a science and risk-based approach in research and manufacturing, and presents documented evidence for risk-based compliance.

2018. 92 pages.

Digital: Item No. 18045

M **$100** | NM **$125** | G **$100**

Risk Management Library Volume 3: Practical Approaches to Risk Assessment and Management

AUTHOR: **James L. Vesper**

In this Volume, well-respected global experts give an overview of the risk management process and the tools required, including risk-related documents and records and techniques for auditing a risk management program. *2018. 56 pages.*

Digital: Item No. 18046

M **$100** | NM **$125** | G **$100**

Risk Management Library Volume 4: Practical Approaches to Risk Assessment and Management Problem Solving: Tips and Case Studies

AUTHOR: **Tim Sandle**

Receive expert guidance on major topics, such as regulatory perspectives on risk and five insightful case studies to help develop the best approaches to problem solving based upon the "What if" and "five whys" method.

2018. 150 pages.

Digital: Item No. 18047

M **$100** | NM **$125** | G **$100**

Risk Management Library Volume 5, Risk Problem Solvers: Failure to Follow Established Procedures

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

Sometimes even well-designed systems are thwarted by human behavior, causing a series of blunders that common sense says could not have happened. In this Volume, you'll find 10 examples and solutions to problems arising from failure to follow established procedures.

2018. 56 pages.

Digital: Item No. 18048

M **$100** | NM **$125** | G **$100**

Risk Management Library Volume 6, Risk Problem Solvers: Lack of Process Understanding

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

This Volume discusses diagnosis and corrective actions to common problems, such as incorrect batch records, contaminated product complaints, contamination, environmental monitoring, and many other subjects.

2018. 102 pages.

Digital: Item No. 18049

M **$100** | NM **$125** | G **$100**

Risk Management Library *(continued)*

Risk Management Library Volume 7, Risk Problem Solvers: Inadequate Facilities, Procedures and Process Contro

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

This Volume describes 24 problems and offers solutions regarding everything from bioburden contamination in a contained water system to filter integrity, customer complaints, process control failures, and many more real-world problems that were solved with adequate investigations. *2018. 122 pages.*

Digital: Item No. 18050

M **$100** | NM **$125** | G **$100**

API Residues and Cleaning

AUTHOR: **William Hall**

2013. 22 pages.

Digital: Item No. 17954

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

Application and Insights for Lyophilization of Parenteral Products

AUTHOR: **Edward Trappler**

2009. 31 pages.

Digital: Item No. 17932

M **$55** | NM **$69** | G **$30**

Aseptic Process Validation and Aseptic Process Simulation Studies

AUTHOR: **Harold Baseman**

2009. 31 pages.

Digital: Item No. 17934

M **$55** | NM **$69** | G **$30**

Auditing the CMO

AUTHORS: **Thomas Thorpe and Jessica Walker**

2013. 28 pages.

Digital: Item No. 17955

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

Best Practices in Environmental Monitoring Automation

AUTHORS: **Robert Toal, Michael Goetter, Susan Harrison, Jeremy Tanner, Timothy A. Coleman, and Robert Lutskus**

2009. 21 pages.

Digital: Item No. 17941

M **$55** | NM **$69** | G **$30**

Best Practices in Implementing Quality Agreements

AUTHOR: **Kenneth Drost**

2013. 22 pages.

Digital: Item No. 17956

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

Caveats of Bacterial Endotoxin Testing

AUTHOR: **Kevin Williams**

2007. 35 pages.

Digital: Item No. 17938

M **$55** | NM **$69** | G **$30**

Cleaning Agents and Cleaning Chemistry

AUTHORS: **Nancy Kaiser and George Verghese**

2009. 22 pages.

Digital: Item No. 17957

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

Cleaning and Disinfection

EDITORS: **Russell Madsen and Jeanne Moldenhauer**

2014. 150 pages.

Digital: Item No. 17969

M **$145** | NM **$179** | G **$110**

CMOs for Early Phase Biologicals Production: Contract Manufacturing and Control

AUTHORS: **John Conner, Bill Minshall, and Rabi Prusti**

2013. 53 pages.

Digital: Item No. 17958

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

Contamination Risk Assessment

EDITORS: **Russell Madsen and Jeanne Moldenhauer**

2014. 210 pages.

Digital: Item No. 17968

M **$145** | NM **$179** | G **$110**

Designing a Contamination Control Program

AUTHOR: **Sandra Lowery**

2004. 67 pages.

Digital: Item No. 17902

M **$105** | NM **$129** | G **$45**

Designing and Controlling Water Systems

EDITORS: **Russell Madsen and Jeanne Moldenhauer**

2014. 145 pages.

Digital: Item No. 17966

M **$145** | NM **$179** | G **$110**

Environmental Impact on Media Fills

AUTHOR: **John Lindsay**

2005. 36 pages.

Digital: Item No. 17914

M **$55** | NM **$69** | G **$30**

Implementing Process Analytical Technology: The Challenges and Pitfalls of Applying a Science and Risk-Based Approach in Research and Manufacturing

AUTHORS: **Siegfried Schmitt and Jennifer Thompson**

2008. 15 pages.

Digital: Item No. 17935

M **$35** | NM **$45** | G **$25**

Microbiological Validation Master Plan

AUTHOR: **Trevor Deeks**

2004. 42 pages.

Digital: Item No. 17904

M **$75** | NM **$89** | G **$35**

Mold and Fungal Contamination

EDITORS: **Russell Madsen and Jeanne Moldenhauer**

2014. 110 pages.

Digital: Item No. 17967

M **$145** | NM **$179** | G **$110**

Particulate Matter in Injectable Drug Products

AUTHOR: **Stephen Langille**

2014. 37 pages.

Digital: Item No. 17965

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

Pharmaceutical Microbiology Laboratories Proficiency and Competency

AUTHOR: **Jerry Tjernagel**

2009. 12 pages.

Digital: Item No. 17940

M **$35** | NM **$45** | G **$25**

Practical Aspects of Thermal Validation for Moist Heat Sterilization

AUTHORS: **Angela Coon and Michael Sadowski**

2011. 58 pages.

Digital: Item No. 17949

M **$85** | NM **$105** | G **$45**

Practical Things to Improve Aseptic Process Equipment System Operation, Reduce Interventions and Reduce Product Risk

AUTHOR: **Jack Lysfjord**

2010. 14 pages.

Digital: Item No. 17933

M **$35** | NM **$45** | G **$25**

QbD and Process Validation — Complementary Lifecycle Approaches

AUTHOR: **Paul Pluta**

2011. 50 pages.

Digital: Item No. 17961

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

Regulatory Background to Aseptic Processing

AUTHORS: **Gordon Farquharson and Richard Johnson**

2009. 16 pages.

Digital: Item No. 17931

M **$35** | NM **$45** | G **$25**

Risk Management for Combination Products

AUTHOR: **Edwin Bills**

2013. 38 pages

Digital: Item No. 17962

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

Sources and Control of Contamination

EDITORS: **Russell Madsen and Jeanne Moldenhauer**

2014. 250 pages.

Digital: Item No. 17970

M **$200** | NM **$250** | G **$150**

Steam Sterilization Process Validation

AUTHOR: **James Agalloco**

2011. 42 pages

Digital: Item No. 17950

M **$60** | NM **$75** | G **$35**

Training and Learning Critical Contributors to Quality

AUTHOR: **James L. Vesper**

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