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Ponemos a su disposición los siguientes títulos de su interés, a precios preferenciales y descuentos en la compra de 5 libros o más:

Computerized Systems in the Modern Laboratory: A Practical Guide (H0625)
by: Joseph Liscouski
The Bio/Pharmaceutical industry is at an interesting crossroads regarding the use of electronic technologies in laboratories. Laboratory management and staff must often evaluate tools that they don't completely understand, while facing pressure from vendors trying to make a sale. Furthermore, regulatory agencies are requiring senior management to justify the application of scientific electronic technology. Computerized Systems in the Modern Laboratory will provide laboratory staff and managers 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.
Date of Publication: Mar 2015 ISBN Number: 193372286X
Number of Pages: 434 PDA Item No: Hardcover: 17329.

Validating Enterprise Systems: A Practical Guide (H0626)
Author: David Stokes
Here is a book that one peer reviewer called "brilliant." Written by a well-know subject matter expert, this book describes the latest tools, techniques and regulatory information needed to validate enterprise systems. Subjects covered include challenges, acquisition and procurement, developing and documenting user requirements, validation planning, governance, data migration, prototyping pilots, test strategies, electronic records, customization, risk management, SOPs, validating in the cloud and much, much more.
Date of Publication: Feb 2015 ISBN Number: 1933722614
Number of Pages: 471 PDA Item No: Hardcover: 17303

Environmental Monitoring: A Comprehensive Handbook, Volume 7 (Hardcover) (H0649)
Edited by Jeanne Moldenhauer
This is volume 7 of the Environmental Monitoring Handbook series. Each volume of this series discusses different aspects of environmental monitoring. One of the first topics discussed in this volume is the topic of cleanrooms and ways to prevent contamination. Subject matter experts Dr. Tim Sandle, Jan Eudy, Jim Polarine, John Lindsay and others describe new and/or better ways to do things.
The second section of the book describes various environmental monitoring techniques and methods and includes informative chapters from Ryan Burke, Allan Marinelli, Dr. Andrew Sage, Tim Cser, Sean Toler, Claire Fritz Briglia and others.
The third section of the book deals with changes to standards. Memarzadeh and DeBerandinis explain the changes that occurred for ANSI Standard 29.14 and how this is applicable in pharmaceutical environments and the last section of this volume talks about new technologies and aids that can be used in evaluating these methods with chapters from Dr. Sage and Dr. JP Jiang. There is a wealth of useful information that you can use in establishing, maintaining and updating your environmental monitoring program!
Date of Publication: Jan 2015 ISBN Number: 1933722851
Number of Pages: 388 PDA Item No: 17325

Assuring Data Integrity for Life Sciences (Hardcover) (H0654)
Editor. Siegfried Schmitt
This new 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.
Each chapter is written by renowned, highly experience subject matter experts in the fields of compliance and data integrity and includes a "how to" section with practical, implementable advice. Content is up to date with the latest regulations and guidances, making this the most relevant reference source of its kind. Useful checklists and aide memoirs can be customized by the discerning reader. This book should be equally useful for the quality unit professional, operations manager, validation experts and regulators.
The modular structure allows readers to pick chapters of special interest without having to reach the chapters in order. However, given the usefulness and universal application the "nuggets of wisdom" and advice provided, it is anticipated that readers will want to read the publication in its entirety.
Date of Publication: Mar 2016 ISBN Number: 1933722975
Number of Pages: 408 PDA Item No: Hardcover: 17335

Contamination Control in Healthcare Product Manufacturing, Volume 4 (Hardcover) (H0658)
Editor Jeanne Moldenhauer
ISO 14644 Parts 1 and 2 — The Revised Cleanroom Standard and Contamination Control by Tim Sandle Updates to the ISO Bioburden Standard P.S. What Happened to the Micro-biologists? by Martell Winters Risk AssessmentRisk of Microbiological Spores, Prevention Measures and Disinfection Strategies by Tim Sandle How Issues Related to Utilities, Surfaces and Practices Impact Cleanroom Environments by Jim Polarine and Beth Kroeger Gowning and Cleanroom Behavior Cleanroom Gowning by Crystal M. Booth Handwashing in the Pharmaceutical Industry by Jeanne Moldenhauer Investigations Investigation of Microbiological Contamination in Water Systems: A Case Study by Walid El Azab
The Fight Against Contamination is Difficult but not lost by Olivier Chancel Environmental Monitoring Microbial Monitoring in Cleanrooms: Use of Contamination Recovery Rates (USP<1116>), Real Time Monitoring, and the State of Contamination Control by Claudio Denoya and Gilberto Dalmaso Approaches to Charting and Setting Control Limits for Environmental Monitoring Microbial Data by Raphael Bar A Practical Approach to Investigating Environmental Monitoring Excursions by Robert Westney Risk Based Environmental Monitoring in Aseptic Processing, in the Era of Big Data by Parsa Famili, Susan Cleary and Marsha Hardiman Identification Systems

Pros and Cons of Using Maldi-TOF MS For Microbiological Identification by Elvira Engelmann and Frank Kugler
Published May 2016 ISBN 1933722983 Pages 403
PDA Item Number Hardcover: 17336

Method Development and Validation for the Pharmaceutical Microbiologist (H0659)
The book primarily focuses on parenteral products and the excipients, but the methodology can transfer to other areas of microbiology as well. The book also provides advice on programs and special studies that might be performed in the pharmaceutical microbiology laboratory. 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 when 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.
Published Feb 2017 ISBN 9781942911029
Pages 406 PDA Item Number Hardcover: 17339 | Digital: 18022

Method Development and Validation for the Pharmaceutical Microbiologist (Hardcover) (H0720)
Editor. Crystal Booth
The book primarily focuses on parenteral products and the excipients, but the methodology can transfer to other areas of microbiology as well. The book also provides advice on programs and special studies that might be performed in the pharmaceutical microbiology laboratory.
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 when 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.
Date of publication: Feb 2017. Number of Pages: 406. ISBN: 9781942911029. PDA Item No: 17339.

Aseptic and Sterile Processing: Control, Compliance and Future Trends (H0729)
The Editors realized that there was an urgent imperative for the relevant subjects to be reassessed and represented. To achieve this objective, along with many subject matter experts, they produced a book that is foremost practical. It has been designed for those involved with aseptic and sterile processing to take away many learning points and apply these principles to aseptic and sterile processing within the pharmaceutical and healthcare sectors.
Drawing on experience, they made every effort to incorporate sound science into the practices described, not least to emphasize why new paradigms are required but to provide wide-ranging guidance and offer depth and scope. This is why chapters on human error, risk assessment, depyrogenation, bioburden testing and so on, are extensively covered. It is the aim of the Editors to help readers reassess legacy definitions and historical understandings and move them toward concepts that will help them think in new ways about equipment and processes that will reach the highest standards and evaluate them through science-based risk assessments.
Ublished Jul 2017 ISBN 9781942911128
Pages 931 PDA Item Number Hardcover: 17342 | Digital 18038

Environmental Monitoring: A Comprehensive Handbook, Volume 8 (Hardcover) (H0730)
Editor. Jeanne Moldenhauer
Volume 8 of the Environmental Monitoring Handbook series is a mixture of new topics and 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.
Date of Publication: Aug 2017 ISBN Number: 9781942911135
Number of Pages: 257 PDA Item No: Hardcover: 17343

Torbeck`s Statistical Cookbook for Scientists and Engineers (Hardcover) (H0731)
Edited: Lynn 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.
These modules were developed based upon years of experience in the field and training at many facilities, including the U.S. FDA, and are intended to fill a niche that is not currently addressed by other statistical books. Each module uses the same format with modifications. Where helpful, a worked example is presented in a parallel format to the procedure.
Scientists and engineers engaged in healthcare as well as other industrial manufacturing will find this text an invaluable resource.
Date of Publication: Oct 2017 ISBN Number: 9781942911142
Number of Pages: 241 PDA Item No: Hardcover: 17344.

Contamination Control in Healthcare Product Manufacturing, Volume 5 (Hardcover) (H0736)
Edited by: Russell Madsen, Jeanne Moldenhauer.
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! Edited by global subject matter experts, the fifth volume of PDA's Contamination Control series includes valuable updated information on a variety of contamination control topics such as: Contamination control strategies, Low Endotoxin Recovery (LER), Environmental monitoring, Regulatory expectations, Contamination control in the real world.
Date of Publication: 2018. Number of Pages: 510. ISBN Number: 9781942911326. Hardcover: 17350.

Microbial Control and Identification: Strategies Methods Applications (H0741)
By: Dona Reber
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.
The three sections will focus on the following topics:

- Strategies: Regulation, regulatory expectations, and strategies for trending, risk assessments, and risk management.
- Methods: Current best practices for microorganism identification methods, both conventional and emerging rapid methods for bacteria, viruses, mycoplasma, and fungi.
- Applications: Microbiology laboratory training for identifications, use of environmental and control microorganisms, disinfectant effectiveness and best practices, and biosafety for laboratories, manufacturing facilities, and personnel.

Date of Publication: May 2018 ISBN Number: 9781942911272
Number of Pages: 592 PDA Item No: Hardcover: 17347

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fifth Edition, Revised & Expanded (H0742)
Have you ever asked yourself, "Where in the Good Manufacturing Practices (GMPs) does it say I have to do _____?" If so, look no further than PDA's *GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, fifth edition, Revised and Expanded.*
As companies strive to harmonize global requirements for quality systems, the 5th edition of this text provides an overview of the 34 essential global cGMP requirements that are typically included in a modern pharmaceutical quality system, including data integrity and how they have evolved. Explore risk-related questions, delve into several expectations for each quality system element encompasses, and review real-world examples from cGMP regulations from the US FDA, Health Canada, the European Union, the World Health Organization, and the International Conference on Harmonization (ICH).
If you're looking for an enhanced understanding of GMP in practice, this text is a must-have for your reference collection.
Published Jul 2018 ISBN 9781942911289
Pages 690 PDA Item Number Hardcover: 17349 | Digital: 18054

Audit and Control for Healthcare Manufacturers: A Systems-Based Approach (Hardcover) (H0751)
By Jennifer Sandle, Tim Sandle
Audits are an important part of quality assurance and the quality management system. With the help of PDA's newest 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!.
Date of Publication: Apr 2019 ISBN Number: 9781942911364
Number of Pages: 862 PDA Item No: Hardcover: **17351**

SOPs Clear and Simple: For Healthcare Manufacturers (Hardcover) (H0752)
Edited Brian Matye, Jeanne Moldenhauer, Susan Schiniepp
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, straight forward 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.
Date of Publication: Jan 2019 ISBN Number: 9781942911333
Number of Pages: 177 PDA Item No: Hardcover: 17348

Biotechnology: From Idea to Market (Hardcover) (H0771)
Edited by Fred Mermelstein, Carl Novina, Richard Prince
PDA's latest professional resource, Biotechnology: From Idea to Market, is 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 this 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.
Expertly conceived and crafted by co-editors Fred Mermelstein, Richard Prince, and Carl Novina, with a foreword by Nobel Laureate Philip Sharp, this book features 22 chapters written by renowned subject matter experts in their respective fields. Collectively, these chapters illuminate and unify the healthcare products innovation process, spanning from academia to industry, from research to commercialization. Chapters are organized into five sections:

- Section 1: Due Diligence (Chapters 1-6)
- Section 2: Financing (Chapters 7-9)
- Section 3: Operationalization (Chapters 10-16)
- Section 4: Legal (Chapters 17-19)
- Section 5: Commercialization (Chapters 20-22)

Gain a more integrative understanding of product development and commercialization and get all the information you need to become a successful biotechnology entrepreneur!
Date of Publication: Aug 2019 ISBN Number: 9781942911371

Number of Pages: 1064 PDA Item No: Hardcover: 17352

Fungi: A Handbook for Life Science Manufacturers and Researchers (Hardcover) (H0772)
Edited By: Jeanne Moldenhauer
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.
Date of Publication: Dec 2019 ISBN Number: 9781942911401
Number of Pages: 813 PDA Item No: 17355

FDA Warning Letters: Analysis and Guidance (Hardcover) (H0782)
By Jeanne Moldenhauer
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.
In addition to the Warning Letter summaries there is discussion of U.S. FDA's authority to perform and approach to inspections, some analysis of the types of observations, and guidance on how to deal with adverse findings if you have them.
As an added benefit, this text also includes instructions and suggestions for those who were unable to avoid getting a warning letter to help resolve matters as quickly as possible.
Date of Publication: Feb 2020 ISBN Number: 9781942911418
Number of Pages: 578 PDA Item No: Hardcover 17356

Recalls of Pharmaceutical Products: Eliminating Contamination and Adulteration Causes (Hardcover) (H0783)
Edited. Dr. 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.
Date of Publication: Mar 2020 ISBN Number: 9781942911425
Number of Pages: 728 PDA Item No: **17357**

Software as a Service (Saas): Risk-Based Validation with Time-Saving Templates. (H0784)
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. You will also get access to templates the authors have used as training tools for more than 1,000 companies and components of more than 300 validation projects. These tools and knowledge will assist you in establishing a compliant, timely, and successful program.
Date of Publication: Apr 2020. Bumber of Pages: 182. ISBN Number: 9781942911494. PDA Item No: Hardcover: 17358.

Root Cause Investigations for CAPA: Clear and Simple. (H0786)
Edited James 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.
Beginning with topics such as why and how much investigations matter, regulatory requirements, roles and responsibilities, the text then progresses to the big picture. It discusses the initial discovery, applying risk-based thinking to quality events and deviations, and moves on to specifics discussing:

- Models used in describing incidents
- Human Errors and Human Factors
- Methods and Tools
- Interviews
- Immediate actions and corrections
- Corrective actions and preventive actions
- Procedures

The author then explains training as a corrective action, evaluation of techniques, writing the report, review and approval, and communication and management responsibilities. It is the perfect companion for your library shelf or computer or, perhaps, both.
"Understanding how to properly plan and perform investigations, how to decide on effective means to address the outcome of such investigations, and how to use the knowledge gained from the experience are key to process reliability and improvement. That makes this book so important and the approaches presented in it so valuable. Enjoy the book. Learn from the journey".
Date of Publication: Jun 2020. Number of pages: 332. ISBN Number: 9781942911500. PDA Item No: Hardcover: 17359.

Digital Transformation and Regulatory Considerations for Biopharmaceutical and Healthcare Manufacturers: Digital Technologies for Automation and Process Improvement (Hardcover) (H0789)
By: Tim Sandle
This first-of-two volume release from prolific author Tim Sandle fills an important void by taking an in-depth look at the way digital technologies are impacting the pharmaceutical and healthcare landscape both now and into the future. He explores how companies have been embracing digital technologies as part of the transformation of their business models.
The disruption caused by the digital transformation of pharmaceuticals and healthcare is not static; it is evolving, and it will continue to evolve. Across the informative and substantive

chapters, this book takes stock of the current technological landscape, where it is likely to develop, and the challenges that adopters face, in terms of practicalities and in maintaining GMP compliance. It explores what each technology does, the potential use of the technology, and the practical aspects for its implementation.

Yet, digital transformation is not just about technology. The process also concerns changes to culture and structure, the understanding of which is presented in this book and is critical for those working in the pharmaceutical sector.

The themes covered in this first volume are process-centric and include blockchain and track and trace technology, fostering the digital pharmaceutical company, and building efficiencies through real-time metrics and Process Analytical Technology. The second volume will address the digitization of the laboratory and a survey of data handling issues.

Date of Publication: Oct 2020 ISBN Number: 9781942911524
Number of Pages: 378 PDA Item No: Hardcover: 17361

Quality by Design - An Indispensable Approach to Accelerate Biopharmaceutical Product Development (H0791)

PDA's book, *Quality by Design — An Indispensable Approach to Accelerate Biopharmaceutical Product Development*, edited by industry experts Cristiana Campa, Vaccines Technical R&D, GSK, and M. Amin Khan , Vaccines R&D, GSK, 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.

More than 60 authors have contributed to this influential text emphasizing the importance of QbD to product development and commercialization. Several case studies covering biotherapeutics and vaccines are shared by several major companies and well-recognized academic institutions. These case studies illustrate that QbD is a key strategic approach to decide what should be prioritized, enabling both fast product, process, and analytical development, ensuring product safety and efficacy; and phase-appropriate control strategy and comparability, focused on patient needs.

In addition, this book demonstrates how Prior Knowledge is useful to inform QbD-driven risk assessment and focus on non-redundant activities, fostering tailored innovation. Examples of how the use of modelling can be a powerful asset to ensure the streamlined execution of experimental activities (e.g., process, stability, and analytical space) are included.

Published Mar 2021 ISBN 9781945584220

Pages 514 PDA Item Number Hardcover: 13013 | Digital: 48005

Conducting Compliant Investigations (Hardcover) (H0793)

By: Jeanne Moldenhauer

In this book 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.

Date of Publication: Mar 2021 ISBN Number: 9781942911579
Number of Pages: 504 PDA Item No: Hardcover: 17363

Digital Transformation and Regulatory Considerations for Biopharmaceutical and Healthcare Manufacturers, Volume 2: Digital Data, Insights, Metrics and Analytics (Hardcover) (H0794)

By: Tim Sandle

This second of two volumes details how pharmaceutical and healthcare manufacturers have ben embracing digital technologies as part of the transformation of their business models. It contextualizes current developments and future advancements in terms of the COVID-19 situation of 2020 and specific measures that were taken.

Topics and laboratory functions that will be explored include:

- New model healthcare
- Ways to use digital data, including root cause investigations
- Office technology
- Protecting ownership security
- E-learning and virtual inspections
- And many more

The first volume of this two-part collection addresses building a digital company, big data analytics, advances in Process Analytical Technology electronic batch records, Block Chain, and more. Taken together, these volumes provide a clear picture of where things currently stand, where they are likely to develop, and the challenges that digital technology adopters face, in terms of practicalities and in maintaining GMP compliance.

Date of Publication: Jan 2021 ISBN Number: 9781942911531
Number of Pages: 420 PDA Item No: Hardcover: 17362

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Horario: 09:00-18:00 LUNES A VIERNES HORA DE LA CIUDAD DE MÉXICO

Para mayor agilidad en el registro de sus datos y preparación de la cotización, mencione el número de ejemplares que quiere y el código "H" que aparece entre paréntesis.