GRUPO TERRA FARMA, DISTRIBUYE PUBLICACIONES DE LA PDA (PARENTERAL DRUG ASSOCIATION).

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

Assuring Data Integrity for Life Sciences (Hardcover) (H0626)
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

Audit and Control for Healthcare Manufacturers: A Systems-Based Approach (Hardcover) (H0579)
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**

Biotechnology: From Idea to Market (Hardcover) (H0571)
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

Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 3 (Hardcover)
Author: Destin LeBlanc
In Destin LeBlanc's Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Vol. 3 pharmaceutical manufacturers and upper management are encouraged to meet the challenges of the science-based and risk-based approaches to cleaning validation.

Volume 3, a complement to Destin's two earlier books on the same subject, presents modifications and updates of his monthly Cleaning Memos originally published from January 2009 through December 2012. Each Cleaning Memo is presented as a chapter, with the chapters then organized by common topics. For example, topics related to setting limits are in one section, those related to sampling in another section, and so forth. An appendix with a list of acronyms is included as well.
Date of Publication: May 2017 ISBN Number: 1933722681
Number of Pages: 251 PDA Item No: Hardcover: 17310

Cleanroom Microbiology (Hardcover) (H0582)
Author: Tim Sandle, R. Vijayakumar
While there are books on cleanrooms available, these focus almost entirely on the physical and rarely address microbiological risks. Similarly, there are various books on microbiology (even a few about pharmaceutical microbiology), yet these books rarely mention cleanrooms, or, where they do, give controlled environments limited coverage.
To the authors of Cleanroom Microbiology, these two domains, normally separated by different functions, are inseparable. This book is about cleanrooms and controlled environments in relation to the pharmaceutical and healthcare sectors and is applicable to both the sterile and non-sterile pharmaceutical sectors with its focus on cleanroom microbiology.
Date of Publication: Jan 2015 ISBN Number: 1933722843
Number of Pages: 588 PDA Item No: Hardcover: 17326

Cold Chain Chronicles: A practitioners outside-the-box perspectives on the importance of temperature-sensitive drug stewardship (H0583)
Author: Kevin O`Donnell
This book is quite different from the typical prescriptive PDA/DHI "how-to" publication. 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 for the consumer in us all. O'Donnell deftly blends his cold-chain storytelling with charm and wit, history and science, and the wisdom of a practitioner's 35 years' experience. These thought-provoking narratives convey to the reader heuristic lessons that underscore the risks involved and the impending need to improve the processes that ensure these fragile pharmaceutical products arrive to their destinations — and to the patients who need them — in a safe, controlled way.
As an added bonus for both new and experienced colleagues, the World Health Organization has granted permission allowing readers to access, either by URL or QR codes available in the book, training videos they have prepared on the subject.
Date of Publication: Jan 2015 ISBN Number: 1933722827
Number of Pages: 184 PDA Item No: Hardcover: 17323

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.

Contamination Control in Healthcare Product Manufacturing, Volume 5 (Hardcover) (H0650)
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.

Effective Implementation of Audit Programs. (H0631)
Editor. Miguel Montalvo
Written by Miguel Montalvo, who has more than 32 years of extensive experience in the areas of cGMP compliance, quality operations/systems and validation functions/responsibilities, this book applies recent developments and perspectives from regulators and industry experts.
This well-researched text is a must have for personnel involved in the implementation and execution of critical programs, auditors, auditees and outsourcing providers!
Date of Publication: Feb 2017 ISBN Number: 9781942911036
Number of Pages: 390 PDA Item No: Hardcover: 17340

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

Environmental Monitoring: A Comprehensive Handbook, Volume 8 (Hardcover) (0632)
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

Fungi: A Handbook for Life Science Manufacturers and Researchers (Hardcover)

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) (H0646)
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

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry, Fifth Edition, Revised and Expanded (H0633)
Editor. James L. Vesper
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.
Date of Publication: Jul 2018.

Global Sterile Manufacturing Regulatory Guidance Comparison (Softcover) (H470)
Within the document, you will find analysis and comparison tables that are easy-to-use references for companies that need to adhere to the four regulatory documents; the spreadsheet allows companies to do their own assessment of their status for each element.
Date of Publication: Feb 2016 ISBN Number: 9780939459834
Number of Pages: 99 PDA Item No: Softcover: 03006.

Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1 (Hardcover) (H0572)
Edited by Siegfried Schmitt
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.
This text and its companion Volume 2 will help drive down costs and improve efficiency
Date of Publication: Oct 2019 ISBN Number: 9781942911388
Number of Pages: 578 PDA Item No: Hardcover: 17353

Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 2.
Edited by Siegfried Schmitt
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.
Date of Publication: Oct 2019 ISBN Number: 9781942911395
Number of Pages: 420 PDA Item No: Hardcover: 17354

Lifecycle Risk Management for Healthcare Products: From Research Through Disposal (Hardcover) (H0634)
Editor. Edwin Bills, 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, 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 though the product lifecycle.
This book has been divided into two parts, part one covers healthcare risk management processes and frameworks and part two covers special topics.
In the first part, the editors provide a historical perspective of the risk management framework as well as management and its responsibilities for implementation of risk management in health product companies. You will also find an overview of combination products, use of risk traceability, criteria for risk acceptability and production and post-product risk management in this section.
In the second part, specific applications of health product risk management are examined, including clinical trials, quality system software and in vitro diagnostic devices.

Date of Publication: 2016. Number of Pages: 295. ISBN Number: 19781942911012. PDA Item No: 17338.

Method Development and Validation for the Pharmaceutical Microbiologist (Hardcover) (H0635)

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.

Microbiological Culture Media: A Complete Guide for Pharmaceutical and Healthcare Manufacturers (Hardcover) (H0636)

Editor. Tim Sandie

Taking into account that 90 percent of quality control microbiology remains reliant upon culturebased 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.

Date of Publication: Nov 2017. Number of Pages: 582. ISBN: 9781942911159. PDA Item No: 17345.

Microbial Risk and Investigations (H0632)

Edited by: Jeanne Moldenhauer, Karen McCullough

The Barr Decision (Barr, 1993) forever changed how pharmaceutical companies look at data that is out-of-specification (OOS). Following issue of this legal decision, many companies and regulators worked to determine how this decision affects microbiological test results. Date of Publication: Apr 2015. Number of Pages: 866. ISBN Number: 1933722894. PDA Item No: Hardcover: 17328.

Phase Appropriate GMP for Biological Processes: Pre-clinical to Commercial Production (Hardcover) (H0622)

Edited by Trevor Deeks

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.

Date of Publication: Feb 2018 ISBN Number: 9781942911173

Number of Pages: 525 PDA Item No: Hardcover: 17346

Pharmaceutical Legislation of the European Union, Japan and the United States of America - An Overview, Updated and Expanded Second Edition (Hardcover) (H0641)

Editor. Barbara Jentges.

Whether you are a student, a newcomer to the pharmaceutical industry or a seasoned professional, the second edition of this book has something for everyone. 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.

Content for each chapter has been updated and expanded by authors with significant regulatory and pharmaceutical experience. Two new chapters have been added that cover regional requirements for CTD-Module 1 and post-approval changes.

Subject matter is written in an easy-to-read style with added figures and tables which make it easy to compare differences in complex regulatory systems and key legislation. Suggested guidances are given throughout for further reading. Filled with useful information, this book is a great resource for any level of expertise.

Date of Publication: 2016. Number of Pages: 161. ISB: 9780939459858. PDA Item No: Hardcover: 13011.

Point to Consider for Aseptic Processing: Part 1 (H0565)

Edited Cristiana Campa, Mohammed Amin Khan

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.
All of these aspects are covered in the four comprehensive sections of the book, which are organized under the following topics:

- Part I- Product Understanding
- Part II- Process Understanding and Modeling
- Part III- Analytical Strategy and Modeling
- Part IV- Platform Knowledge

Date of Publication: Mar 2021. Number of Pages: 514. ISBN Number: 9781945584220. PDA Item No: Hardcover: 13013.

Rapid Sterility Testing (Hardcover) (H0637)
Edited Jeanne Moldenhauer
The current compendial sterility test methodology has been fully harmonized for Europe, Japan and the United States for many years. In spite of having a fully harmonized test methodology, in reality, the test methodology is only effective in detecting gross contamination in a batch of product. Manufacturers are now focused on how their aseptically processed products might achieve a shortened time to product release as part of the sterility test. To date regulatory support has not been gained to support a program of parametric release for aseptically filled products. This results in many companies looking at rapid sterility testing methods to reduce the time to release for aseptically-filled products.
In this book you will find a history of the sterility test methodology as well as detailed discussions that provide the regulatory requirements and allowances for gaining approval of rapid sterility test methods. Compendial requirements for validation and implementation of these methods in the United States and Europe are also discussed. Subject matter experts provide information on the types of methods that can be considered for aseptic sterility testing and discuss issues such as the statistical methods used to validate these methods, especially since many of the new technologies are superior to the conventional methods. Last, there are a substantial number of case studies describing how various companies have approached selecting, validating and implementing new methodologies for sterility testing at their site.
Book written in October, 2011
Date of Publication: Feb 2015 ISBN Number: 1933722568
Number of Pages: 505 PDA Item No: Hardcover: 17302

Recalls of Pharmaceutical Products: Eliminating Contamination and Adulteration Causes (Hardcover)
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**

Risk Assessment and Management for Healthcare Manufacturing: Practical Tips and Case Studies (Hardcover) (H0638)
Edited Tim Sandle
Avoidance of hazards and assessment of risk have long been part of the manufacture of pharmaceuticals and healthcare products. A high-quality drug product must be free from contamination and reliably deliver the intended therapeutic dose as stated on the label and to achieve this manufactures must always be mindful of risk.
Tim Sandle's newest book incorporates regulatory perspectives, scientific methods and practical examples to describe approaches to problem solving when assessing, managing and reviewing risk. The book is divided into four sections that present a formal approach to risk. The first section provides a look at risk assessments and hazards, exploring the origins, looking at key concepts and philosophies and assessing the regulatory perspective. An overview of available tools for risk assessment and problem solving leads into specific 'soft skills' that can help to run an effective meeting, oversee a project and report root cause analysis and risk outcomes. The book concludes with an extensive set of case studies to show real-world applications of the tools and techniques presented. The wide range of topics presented throughout the four sections includes risk considerations for aging pharmaceutical facilities, application of quality risk management to cleanroom design and process incident investigation.
Date of Publication: Sep 2016. ISBN Number: 1933722991
Number of Pages: 730 PDA Item No: Hardcover: 17337

Root Cause Investigations for CAPA: Clear and Simple. (H0403)
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.

SOPs Clear and Simple: For Healthcare Manufacturers (Hardcover) (H0629)
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

Square Root of (N) Sampling Plans: Procedures and Tables for Inspection of Quality Attributes (H0575)
Edited: Lynn Torbeck, Joyce Torbeck
The goal of Lynn and Joyce Torbeck's book, Square Root of (N) Sampling Plans: Procedures and Tables for Inspection of Quality Attributes, is to show that the sqrt (N) plans are statistically correct and can be used in applications that minimize risk to the patient. This book presents technical and practical information for the correct use of the three sqrt (N) attribute sampling plans.
While the book is oriented to the domestic and international pharmaceutical industry, the material is general enough to be adapted to other industries and applications.
July 2013. Hardcover. 127 PÁGINAS. ISBN Number: 1933722738

Software as a Service (Saas): Risk-Based Validation with Time-Saving Templates. (H403)
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.

Square Root of (N) Sampling Plans: Procedures and Tables for Inspection of Quality Attributes. (H0450)
Edited: Lynn Torbeck and Joyce Torbeck
The goal of Lynn and Joyce Torbeck's book, Square Root of (N) Sampling Plans: Procedures and Tables for Inspection of Quality Attributes, is to show that the sqrt (N) plans are statistically correct and can be used in applications that minimize risk to the patients.
This book presents technical and practical information for the correct use of the three sqrt (N) attribute sampling plans.
While the book is oriented to the domestic and international pharmaceutical industry, the material is general enough to be adapted to other industries and applications.
Date of Publication: Jan 2015. Number of Pages: 130. ISBN Number: 1933722738. PDA Item No: Hardcover: 17314.

Torbeck`s Statistical Cookbook for Scientists and Engineers (Hardcover) (H0648)
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.

Validating Enterprise Systems: A Practical Guide (H0578)
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

Why Life Science Manufacturers Do What They Do in Development, Formulation, Production and Quality: A History (Hardcover) (H432)
by: Lynn 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. Because this book is not organized in a linear fashion, Torbeck encourages readers to dip into any chapter that is of interest. This book is not a statistics text per se; however, it shares the author's passion and decades of experience for statistics applied to pharmaceutical quality by showing how they can be used in real-world pharmaceutical quality problems.
Date of Publication: 2015. Number of Pages: 455. ISBN Number: 1933722924. PDA Item No: Hardcover: 17333.

PARA MAYORES INFORMES Y COTIZACIONES FAVOR DE CONTACTAR:

www.grupoterrafarma.com
E-mail:
info@grupoterrafarma.com
o telefónicamente a:

MÉXICO: (+5255) 56509274 / 56487482

Whatsapp: (+52-55) 45480411 / 29064357

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.