



## **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:

### **Environmental Monitoring: A Comprehensive Handbook, Volume 4 (Hardcover) (H0563)**

The past decade has seen a global emphasis on environmental monitoring. Regulatory bodies worldwide have all established standards and guidelines for environmental control. Unfortunately, the requirements are not equivalent among documents and nations. The Environmental Monitoring series edited by Jeanne Moldenhauer provides guidance through the ins and outs of the multitudinous aspects of compliance. This book, Volume 4 in the series, contains perspectives from global subject matter experts and includes:

Designing and Validating a Contamination Control Program  
Real-Time Trending of Environmental Monitoring Data  
The Use of Risk Management in Environmental Monitoring  
Lean Microbiology Laboratories  
Observations in Support of Lean Microbial Identification  
Dealing with Contamination: What is the Risk to the Product?  
Collection Efficiency of Microbiological Impaction Air Samplers  
Microbiological Excursions in Environmental Monitoring: A Risk Based Approach in Sterile Production  
Overview of Recent Warning Letters for Environmental Monitoring  
Long-Term Microbiological Air Monitoring  
Rapid, Simple and Cost-Efficient Environmental Monitoring of Microorganisms by Fourier-Transform Infrared Spectroscopy  
This book is a must have for anyone involved in any way with environmental monitoring concerns.

Published May 2010, ISBN 1933722452, Pages 234, PDA Item Number 17291

### **Cleaning Validation: Practical Compliance Solutions for Pharmaceutical Manufacturing, Volume 3 (Hardcover)**

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.

**Published May 2013 ISBN 933722681**

**Pages 248 PDA Item Number 17310**

### **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

### **Good Distribution Practice: A Handbook for Healthcare Manufacturers and Suppliers, Volume 1 (Hardcover)**

**Dr 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 9781942911388

Pages 578 PDA Item Number 17353

### **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

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