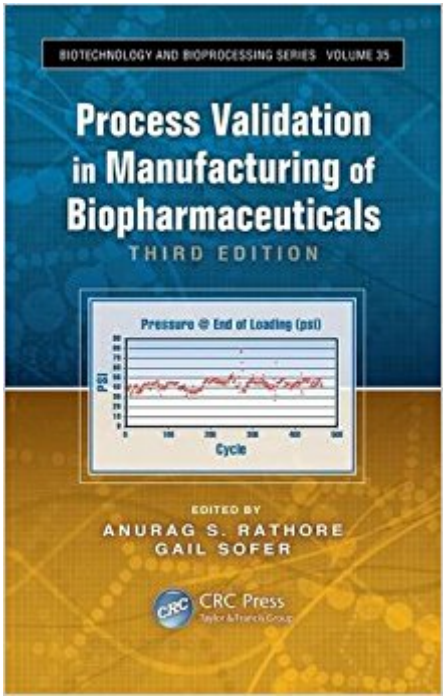
Ebook Directory
the best source of ebook

The book was found

Process Validation In Manufacturing Of Biopharmaceuticals, Third Edition (Biotechnology And Bioprocessing)



PDF
Adobe
DOWNLOAD EBOOK

Synopsis

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

Book Information

Series: Biotechnology and Bioprocessing (Book 35)
Hardcover: 532 pages
Publisher: CRC Press; 3 edition (May 9, 2012)
Language: English
ISBN-10: 1439850933
ISBN-13: 978-1439850930
Product Dimensions: 6.1 x 1.1 x 9.2 inches
Shipping Weight: 1.9 pounds (View shipping rates and policies)
Average Customer Review: 3.9 out of 5 stars 4 customer reviews
Best Sellers Rank: #582,097 in Books (See Top 100 in Books) #168 inÃ Â Books > Science & Math > Chemistry > Analytic #424 inÃ Â Books > Engineering & Transportation > Engineering > Bioengineering > Biotechnology #478 inÃ Â Books > Textbooks > Medicine & Health Sciences > Medicine > Basic Sciences > Pharmacology

Customer Reviews

ANURAG S. RATHORE is a consultant of Biotech CMC Issues. He is also a faculty at the Department of Chemical Engineering, Indian Institute of Technology, Delhi, India. His previous roles included management positions at Amgen Inc., Thousand Oaks, California and Pharmacia Corp., St. Louis, Missouri. His areas of interest include process development, scale-up, technology transfer, process validation, process analytical technology and quality by design. He has authored more than 180 publications and presentations in these areas. He is presently serving as the Editor-in-Chief of Preparative Biochemistry and Biotechnology and serves on the Editorial Advisory Boards for Biotechnology Progress, BioPharm International, Pharmaceutical Technology Europe and Separation and Purification Reviews. Dr. Rathore has edited books titled Quality by Design for Biopharmaceuticals: Perspectives and Case Studies (2009), Elements of Biopharmaceutical Production (2007), Process Validation (2005), Electrokinetic Phenomena (2004) and Scale-up and Optimization in Preparative Chromatography (2003). He has a Ph.D. in Chemical Engineering from Yale University. Ã Â Gail Sofer: After serving as the director of Regulatory Services at BioReliance for 6 years, Dr. Sofer has recently joined GE Healthcare (formerly Amersham Biosciences) as the director of Regulatory Compliance in a new consulting team. Her publications include numerous articles and book chapters on downstream processing, virus inactivation, and validation. She has also coedited and authored several books. She serves on the Science Advisory Board of PDA, the Editorial Advisory Boards of BioPharm, BioQuality, and BioProcess International, and the Scale-Up Advisory Board of Genetic Engineering News. She chairs a PDA task force on virus filters and is cochair of the ASTM subcommittee on Adventitious Agents for Tissue Engineered Medical Products. She holds an M.S. degree in biochemistry from the University of Miami.

Excellent reference resource; perhaps you need a deep understanding of validation to follow it. My suggestion is to include examples (483's, approval letters etc...) or to design activities you can use with prospective students that are required to use it as a textbook for a process validation course.Excellent purchasing experience...

The third edition of Process Validation in Manufacturing of Biopharmaceuticals is a mix of new and updated chapters. I particularly enjoyed reading the chapters on new US FDA guidance on process validation, risk based validation and process validation with a CMO. Overall, I felt the book remains THE reference on the subject of process validation, particularly for biotech therapeutics and is a timeless reference and guide on the subject and is applicable to any drug manufacturing process that employs chromatography. Kudos to the editors and authors for such a great job!

The content of this book is almost identical to the book entitled Process Validation in manufacturing of Biopharmaceuticals edited by Anurag Singh Rathore and Gail Sofner From Informa. Only a few title is newly added. I have no idea other titles are revised or updated because I have no intention to purchase this kind of repetition book.

I got a item. Good Quick delivery service thank you so much. Have a nice day.I hope buy return to other item.

Download to continue reading...

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing) A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry (Biotechnology and Bioprocessing) Handbook of Process Chromatography, Second Edition: Development, Manufacturing, Validation and Economics Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs Biopharmaceuticals: Biochemistry and Biotechnology Biopharmaceuticals (Biotechnology Revolution) Building Biotechnology: Biotechnology Business, Regulations, Patents, Law, Policy and Science The Ethics of Biotechnology (Biotechnology in the 21st Century)**OUT OF PRINT** Third Eye: Third Eye Activation Mastery, Easy And Simple Guide To Activating Your Third Eye Within 24 Hours (Third Eye Awakening, Pineal Gland Activation, Opening the Third Eye) Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation (Publication / United States Catholic Conference) ISO 11135:2014, Second Edition: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices Pharmaceutical Process Validation, Second Edition (Drugs and the Pharmaceutical Sciences) Bioprocessing Piping and Equipment Design: A Companion Guide for the ASME BPE Standard (Wiley-ASME Press Series) Handbook of Process Chromatography: A Guide to Optimization, Scale Up, and Validation Additive Manufacturing Technologies: 3D Printing, Rapid Prototyping, and Direct Digital Manufacturing Supply Chain Management in Manufacturing + Inventory Control in Manufacturing: 2 Books in 1 ISO 22716:2007, Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices Applied Biopharmaceutics & Pharmacokinetics, Sixth Edition (Shargel, Applied Biopharmaceuticals & Pharmacokinetics) Applied Biopharmaceutics & Pharmacokinetics, Fifth Edition (Shargel, Applied Biopharmaceuticals & Pharmacokinetics) Quality by Design for Biopharmaceuticals: Principles and Case Studies