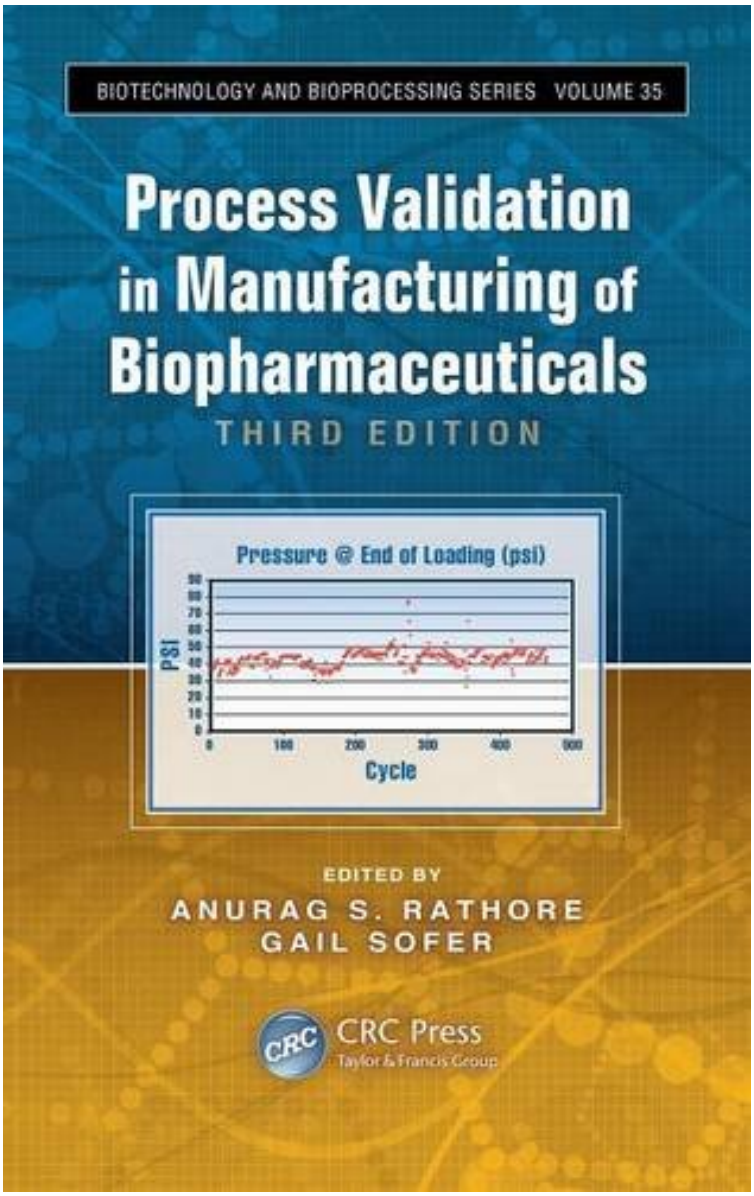
# Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing)

*From Brand: CRC Press*
*ePub | *DOC | audiobook | ebooks | Download PDF*






#184278 in Books CRC Press 2012-05-09Original language:EnglishPDF # 1 9.21 x 1.13 x 6.14l, 1.95 #File Name: 1439850933532 pages | File size: 34.Mb

**From Brand: CRC Press : Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing)** before purchasing it in order to gage whether or not it would be worth my time, and all praised Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and

Bioprocessing):

0 of 0 people found the following review helpful. Review for the book- Porcess Validation in Manufacturing of Biopharmaceuticals, 2012By Hugo RomanExcellent 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...1 of 1 people found the following review helpful. Process Validation in Manufacturing of Pharmaceuticals, Third Edition (Biotechnology and Bioprocessing)By Chris PThe 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!3 of 3 people found the following review helpful. The content is almost identical to the existing bookBy Hideharu ShintaniThe 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.

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.

About the AuthorANURAG 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 s. 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. 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.