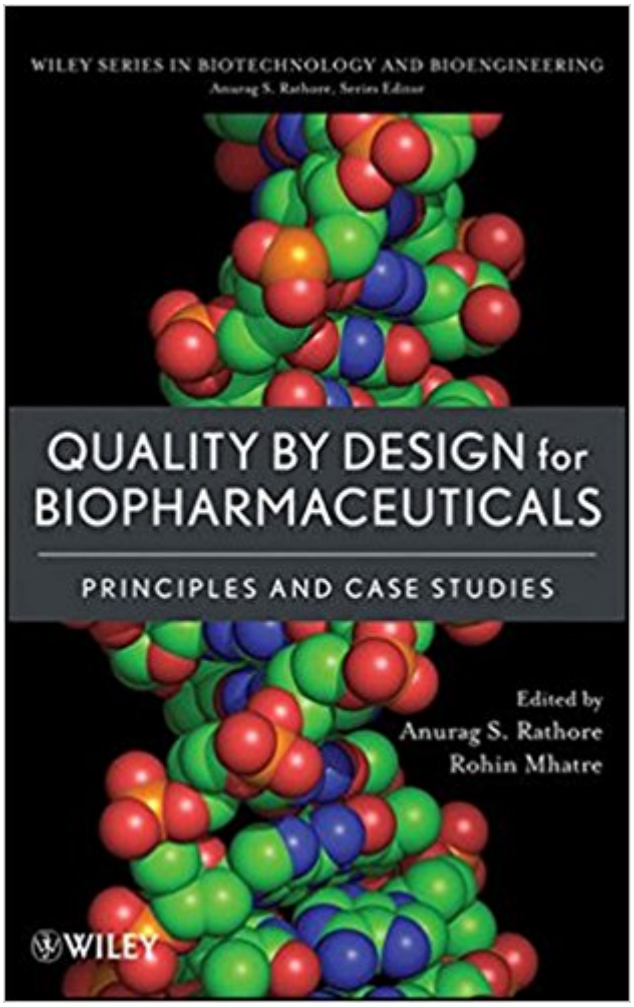
Quality By Design For Biopharmaceuticals: Principles And Case Studies



Synopsis

The concepts, applications, and practical issues of Quality by Design Quality by Design (QbD) is a new framework currently being implemented by the FDA, as well as EU and Japanese regulatory agencies, to ensure better understanding of the process so as to yield a consistent and high-quality pharmaceutical product. QbD breaks from past approaches in assuming that drug quality cannot be tested into products; rather, it must be built into every step of the product creation process. Quality by Design: Perspectives and Case Studies presents the first systematic approach to QbD in the biotech industry. A comprehensive resource, it combines an in-depth explanation of basic concepts with real-life case studies that illustrate the practical aspects of QbD implementation. In this single source, leading authorities from the biotechnology industry and the FDA discuss such topics as: The understanding and development of the product's critical quality attributes (CQA) Development of the design space for a manufacturing process How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates to QbD Relevant PAT tools and applications for the pharmaceutical industry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) to QbD Filled with vivid case studies that illustrate QbD at work in companies today, Quality by Design is a core reference for scientists in the biopharmaceutical industry, regulatory agencies, and students.

Book Information

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Customer Reviews

Wiley Series in Biotechnology and bioengineering Anurag S. Rathore, Series Editor Quality by Design for Biopharmaceuticals Principles and Case Studies Edited by Anurag S. Rathore Rohin Mhatre

Anurag S. Rathore received his PhD in chemical engineering from Yale University and is the Director of Process Development, Amgen Inc. 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 100 publications and presentations in these areas and serves on the editorial advisory boards for Biotechnology Progress, BioPharm International, Pharmaceutical Technology Europe, Journal of Biochemical and Biophysical Methods, and Separation and Purification Reviews. Rohin Mhatre is a Senior Director in the BioProcess Development department at Biogen Idec, Cambridge, Massachusetts, and has been with the company since 1996. His group is responsible for development of analytical methods and product characterization to support the process and formulation development of early and late stage clinical programs. Mhatre is also leading the QbD initiative within Biogen Idec. He has authored several publications and been an invited speaker to numerous scientific meetings.

Worth reading, and has good coverage of topics. It does begin getting thin towards the end, but if you are reading this review you probably already know you should buy this book.

As a QbD evangelist myself, I highly recommend this book as a must-read to those starting QbD in Biopharmaceuticals.The Book covers: (Chapters)1. QbD: Basic Concepts (Terminologies)2. Considerations for Biotech Product in QbD (Steven Kozlowski, OBP of FDA is a co-author)3. Molecular Design of malaria vaccines4. Risk Assessment to determine criticality of product quality attributes5. Design Space for a Microbial Fermentation Step6. QbD for Tangential Flow Filtration7. Design Space for Purification Process8. Viral Clearance: QbD and Design Space9. Formulation: QbD, Risk Assessment and Design Space10. Biologics: Fomulation and Process Development11. QbD for Raw Materials12. PAT Tools for Biologics13. Evolution and Integration of QbD and PATCons:Since each chapter is written by different co-authors, quality varies chapter-by-chapter. (This may be a pro)Even the way each author applied QbD tools (risk assessment, design space, etc.) varies much.Just like any other field, the practice of QbD has been rapidly evolving since 2009.Therefore some suggestions in the book seem outdated.Pros: (Far Outweigh the Cons)Nevertheless, Anurgag and Mohin did a fantastic job of covering a wide range of key QbD

topics in Biologics.I would use the book as case studies and not a manual.QbD in large molecules is not as straightforward as with small molecules so this reference is highly useful to those in Biologics.I liked the book so much that I made presentation slides based on the book and share them with my colleagues.I also began following up with the authors and share their latest thoughts on QbD. If you want the slides and interviews you can get them at QbDWorks.I highly recommend this Book to any QbD professional.

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