



Quality by Design for Biopharmaceuticals: Principles and Case Studies

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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.

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Quality by Design for Biopharmaceuticals: Principles and Case Studies From Brand: Wiley-Interscience Bibliography

- Sales Rank: #1511539 in Books
- Brand: Brand: Wiley-Interscience
- Published on: 2009-06-22
- Original language: English
- Number of items: 1
- Dimensions: 9.50" h x .75" w x 6.30" l, 1.30 pounds
- Binding: Hardcover
- 328 pages

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From the Inside Flap

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Quality by Design for Biopharmaceuticals

Principles and Case Studies

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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*.

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