Quality by Design for Biopharmaceuticals: Principles and Case Studies (Wiley Series in Biotechnology and Bioengineering)

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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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