Pharmaceutical Quality by Design: A Practical Approach
Walkiria S. Schlindwein (Editor), Mark Gibson (Editor)

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**DESCRIPTION**

*A practical guide to Quality by Design for pharmaceutical product development*

*Pharmaceutical Quality by Design: A Practical Approach* outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product.

Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource:

- Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development
- Puts the focus on the industrial aspects of the new QbD approach
- Includes several illustrative examples of applications of QbD in practice
- Offers advanced specialist topics that can be systematically applied to industry
Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

ABOUT THE AUTHOR

Editors

Walkiria S. Schlindwein is Associate Professor of Pharmaceutics at the School of Pharmacy, De Montfort University. Walkiria is the programme leader of two Postgraduate courses in Pharmaceutical Quality by Design.

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