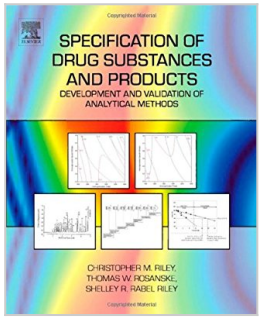

Specification of Drug Substances and Products: Development and Validation of Analytical Methods

From Elsevier

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Specification of Drug Substances and Products: Development and Validation of Analytical Methods is a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development and validation of analytical methods. This book is intended as more than a review of new regional guidelines, existing regulatory guidance, and industry practices. It provides a hands-on guide to understanding and applying these in practice. The authors discuss critical issues, novel approaches, and future directions while also providing insight into how International Guidelines were developed and the rationale behind them.

- Guide to industry best practices of analytical methodologies used in the specification of new drug substances and products (e.g. DOE, QbD)
- Critical assessment of the application of ICH guidelines on method validation and specification setting, written by experts involved in the development and application of the guidelines to aid understanding of requirements and what is expected by regulatory authorities
- Direct applicability to the day-to-day activities in drug development and the potential to increase productivity

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Editorial Review

Review

"...a valuable addition to a pharmaceutical scientists' library….relevant and of interest to various "stake-holders" in the drug development arena, including chemists, analysts, and programme managers. I can recommend it."--***Organic Process Research & Development Journal,*** **Sep-14**

*"Its main role is to explain how to meet the most recent International Conference on Harmonization guidelines for drug development. The book is organized to offer a critical and comprehensive account of the approaches used to identify the key determinants of quality production that affect the safety, effectiveness, and marketability of a drug."--****ProtoView.com,*** **April 2014**

From the Back Cover

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Key features

Includes extensive information on Residual Solvents, Inorganic impurities, Solid-state characterization, Chiral Methods, Extractables and Leachables, Pharmacopeial Methods and Tests, and more. **Christopher M. Riley** is President of Riley and Rabel Consulting Services. He was Vice President of Analytical R&D at DuPont Pharmaceutical Company, and Vice President of ChemPharm at ALZA (a division of Johnson and Johnson) as well as a member of the ICH Expert Working Group on Impurities. **Thomas W. Rosanske** is the Director of Business Development at Acceleration Laboratory Services, Incorporated. He has previously held scientific and senior management positions at The Upjohn Company, Marion Laboratories, Marion Merrell Dow, Hoechst Marion Roussel, Quintiles, Eli Lilly, Beckloff Associates, and PPD. He currently serves on a Small Molecule USP Expert Committee. **Shelley R. Rabel Riley** is an Assistant Professor of Chemistry in the Department of Natural Sciences at Northwest Missouri State University, as well as Vice-President of Riley and Rabel Consulting Services. She has previously held Principal Scientist positions at DuPont Pharmaceutical Company and ALZA (a division of Johnson and Johnson), and served as Director of Small Molecule Pharmaceutics at Amgen.About the Author
President of Riley and Rabel Consulting Services. Former Vice President of Analytical R&D at DuPont Pharmaceutical Company, and Vice President of ChemPharm at ALZA (a division of Johnson and Johnson) as well as a member of the ICH Expert Working Group on Impurities.

Director of Business Development at Acceleration Laboratory Services, Incorporated. He has previously held scientific and senior management positions at The Upjohn Company, Marion Laboratories, Marion

Merrell Dow, Hoechst Marion Roussel, Quintiles, Eli Lilly, Beckloff Associates, and PPD. He currently serves on a Small Molecule USP Expert Committee.

Assistant Professor of Chemistry in the Department of Natural Sciences at Northwest Missouri State University, as well as Vice-President of Riley and Rabel Consulting Services. She has previously held Principal Scientist positions at DuPont Pharmaceutical Company and ALZA (a division of Johnson and Johnson), and served as Director of Small Molecule Pharmaceutics at Amgen. Users Review**From reader reviews:**

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