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Principles of Parenteral Solution Validation: A Book Review

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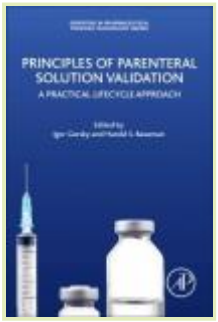

Principles of Parenteral Solution Validation, A Practical Lifecycle Approach, edited by Igor Gorsky and Harold S. Baseman

INTRODUCTION

This review describes the recently-published Principles of Parenteral Solution Validation, A Practical Lifecycle Approach, edited by Igor Gorsky and Harold S. Baseman. This book is part of the Expertise in Pharmaceutical Process Technology series published by Academic Press (Elsevier) and edited by Michael Levin. Igor Gorsky is a member of the Editorial Advisory Board of the IVT Network.

This review describes the book purpose, target audience, and technical content. Specific book characteristics are highlighted.

This book provides an excellent and comprehensive review of a complex subject. Content in this book will be useful to all involved in sterile product manufacturing and validation. This book would be a valuable addition to the personal library of pharma product practitioners and a valuable reference in the workplace environment.

Book Purpose

The stated goal of this book is to provide parenteral drug manufacturers with a volume that helps with their implementation of comprehensive process validation programs as well as to becoming a “go-to” reference on this important subject.

Target Audience

The primary audience for the Expertise in Pharmaceutical Process Technol series comprises pharmaceutical personnel from low-level R&D and production technicians to team leaders and department heads – an extensive range of readers from doers to management. In addition to these various activity levels, industry practitioners in sterile product validation include a wide range of disciplines including engineers, microbiologists, pharmacists, chemists, and other technical fields. The authors also

surveyed industry experts when designing book content and addressed recommended subjects. These recommendations, e.g., FDA guidance applications, risk management, experimental study design, scale-up and technology transfer, and case studies demonstrate the range of topics addressed in this book.

Book Type

Technical books may be categorized into various general types, e.g., user manuals, teaching books, reference books, procedures, questions, and answers (FAQ), general discussions, and several others. Principles of Parenteral Solution Validation Technology addresses part or all of these categories in its various chapters. Although the book subtitle explicitly states A Practical Lifecycle Approach and the stated emphasis of the Expertise in Pharmaceutical Process Technology series is to be a practical guide for practitioners, this book provides much more that practical content. Validation of parenteral solution products is a complex subject. Practitioners described above represent a variety of technical disciplines. The content of this book provides useful information to all who are involved in parenteral product validation and supporting functions.

CONTENT

The content of this book directly addresses a lifecycle approach to sterile solution product validation and is logically organized in its presentation.

Sterile product validation was the initial area of validation to be addressed by FDA in the 1970's. The Introduction section of Principles of Parenteral Solution Validation provides a comprehensive review of the sequence of activities leading to the current practice of sterile product validation. After this historical introduction, the book provides comprehensive technical content in three general sections.

The first section (six chapters) describes fundamental technical information basic to sterile products. "Process Validation: Design and Planning" is consistent with FDA's approach to pharmaceutical product manufacturing – firms must understand their product and process. "Aseptic Process Validation: Aseptic Process Simulation Design" discusses testing of the aseptic manufacturing process; content in this chapter is useful to manufacturing technicians, microbiologists, equipment engineers, and other technical groups; this process involves all of the aforementioned disciplines. This chapter provides comprehensive discussion of all aspects of media fills including an instructive case study. Two chapter discussing risk management follow. Risk management is a critical topic in all pharmaceutical manufacturing and quality systems; these chapters discuss ICH Q9, risk assessments, and applications to real-life manufacturing situations. Cleaning validation is next discussed including determination of residue limits. The use of statistics in process validation, also specifically requested by FDA, closes the introductory section of chapters. A practical approach to using statistics in process validation is described.

The second section (three chapters) of the book describes the lifecycle approach to process validation applied to parenteral product process validation. The lifecycle approach comprises three stages of validation activities. Stage 1 addresses parenteral process design and demonstrates the practical application of process understanding previously discussed in "Process Validation Design and Planning; a case study with statistical analysis is also provided. Stage 2 comprises Process Performance Qualification (PPQ); this chapter describes related equipment qualification as well as actual PPQ. Stage 3 comprises post-validation Continued Process Verification including statistical process control, statistical analysis and case studies.

The final book section(four chapters) addresses miscellaneous topics relevant to sterile product validation. These include sterilizing filter testing, environmental monitoring, isolators, and terminal sterilization. Sterile filtration is fundamental to sterile product manufacturing. Environmental monitoring addresses facility control. Isolators are relatively new equipment useful for highly potent drugs and aging facilities; their use requires unique and specialized procedures. Terminal sterilization is applicable for drugs able to withstand associated thermal treatment. Each of these chapter are specialized topics with engineering, microbiological, operational, and technical aspects for good understanding. Example data and cases are again provided in these chapter.

Discussion

The content of this book directly reflects it title and purpose. The table of contents provides section details; the book also provide a comprehensive index. The content is clearly expressed and understandable to all. Tables, figures, charts, and other graphic enhancements are well executed. Data presentations and case studies demonstrate relevance and application of the subject matter. The book is well referenced and footnoted as appropriate. Its content provides comprehensive review

of critical and contemporary topics. Content is technical with practical applications – a very useful and relatable book. In summary, this book is highly recommended and will be valuable to all involved in sterile solution manufacturing, pharmaceutical product compounding, and product/process validation.

BOOK AUTHORS

Primary authors of this book are:

- Igor Gorsky, Senior Consultant, Concordia ValSource LLC, USA and
- Harold S. Baseman, Chief Operating Officer and Principle, ValSource LLC and Concordia ValSource LLC, Jupiter, FL, USA.

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Table of Contents

BOOK DATA

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