

Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality (Drugs and the Pharmaceutical Sciences)

By Michael J. Akers

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Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality (Drugs and the Pharmaceutical Sciences) By Michael J. Akers

Sterile Drug Products: Formulation, Packaging, Manufacturing, and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms. The author has 38 years of experience in the development and manufacture of sterile dosage forms including solutions, suspensions, ophthalmics and freeze dried products. This book is based on the courses he has delivered for over three decades, to over 3000 participants, and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common.

This is an ideal reference book for those working directly and indirectly with sterile dosage forms, be it product development (formulation, package, process, analytical), manufacturing, quality control, quality assurance, regulatory, purchasing, or project management. This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools, providing basic knowledge and principles in four main areas of parenteral science and technology:

- Product development, including formulation, packaging, and process development.
- Manufacturing, including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control.
- Quality and regulatory, including the application of good manufacturing practice regulations, aseptic processing guidelines, and unique quality control testing methods for the sterile dosage form
- Clinical aspects, including administration, potential hazards, and biopharmaceutics of sterile products in a clinical setting.

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Editorial Review

About the Author

Michael J. Akers Ph.D. is Senior Director of Pharmaceutical Research and Development at Baxter and leads the Baxter Lyophilization Center of Excellence in Bloomington, Indiana. Dr. Akers received his B.A. degree from Wabash College and Ph.D. degree in Pharmaceutics from the University of Iowa College of Pharmacy, and has previously been employed at Searle Laboratories, Alcon Laboratories, University of Tennessee, and Eli Lilly and Company. Dr. Akers is active in the Parenteral Drug Association and is a Fellow of the American Association of Pharmaceutical Scientists. He is editor-in-chief of *Pharmaceutical Development and Technology*, and author or editor of six books, including *Parenteral Quality Control: Sterility, Pyrogen, Particulate, and Packaging Integrity Testing, Third Edition*, 2002.

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