

Sterile Pharmaceutical
Products

Process Engineering Applications

Drug Manufacturing
Technology Series

Edited by
Kenneth E. Avis



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manufacturing and lyophilization of protein pharmaceuticals are discussed Includes a case study on blow fill seal processing technology and a chapter on economic and cost factors for bioprocess engineering **Sterile Drug Products** Michael J. Akers, 2016-04-19 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 **Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition** Stephen P. Denyer, Rosamund M. Baird, 2006-12-26 Microbiological matters continue to exercise considerable influence on product quality In both the pharmaceutical and medical device industries products of greater sophistication along with evolving regulatory requirements are elevating the challenges related to maintaining microbiological integrity Updated to reflect technological and regulatory changes the Guide to Microbiological Control in Pharmaceuticals and Medical Devices Second Edition covers those principal aspects of microbiology that are relevant to the preformulation formulation manufacturing and license application stages involved with the production of pharmaceuticals and medical devices In recognition of the diverse disciplines involved in pharmaceutical and medical device production this work provides a brief introduction to microbiology geared towards the nonmicrobiologist Covering good manufacturing practice in the control of contamination the text explores quality control the preservation of formulations and principles of sterilization including microbiological specific considerations for biotechnological products and other medical devices It also provides additional materials on package integrity and contamination risks in clean rooms The editors have produced a companion text the Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices see reverse which when paired with the Guide offers a complete theoretical and practical treatment of microbiological control This book provides a comprehensive distillation of information concerning methodology and regulations that would otherwise remain scattered throughout the literature It allows scientists from many fields to address potential problems in advance and implement suitable strategies at the earliest stages of development **Clean-In-Place for Biopharmaceutical Processes** Dale A. Seiberling, 2007-10-15 An invaluable source instruction on the principles instrumentation design implementation operation and maintenance of an effective clean in place system CIP this guide illustrates best practices and successful applications of CIP in both pharmaceutical and biotechnology facilities Offering reader friendly descriptions of the various types of equipment and materials found in typical CIP processes Clean In Place For Biopharmaceutical Processes will take the guess work out of CIP development and illustrate all one needs to know for the establishment and optimal functioning of a CIP system **Tissue and Cell Processing** Deirdre Fehily, Scott A. Brubaker, John N. Kearney, Lloyd Wolfinbarger, Jr., 2012-06-11 By presenting the latest technological advances and growing national and international regulation this new book explores state of the art developments in the challenging field of tissue and cell processing It provides a guide to easier and safer practice in operational principles of

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