Sterile Pharmaceutical Products

Process Engineering Applications

Drug Manufacturing Technology Series

Edited by Kenneth E. Avis



Sterile Pharmaceutical Products Process Engineering Applications

Kenneth E. Avis, Carmen M. Wagner, Vincent L. Wu

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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 thoseprincipal 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

The Encyclopedia of Bioprocess Technology Michael C. Flickinger, Stephen W. Drew, 1999 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 preservation decontamination and sterilization Nearly half of the book is devoted completely to tissue or cell specific issues relating to processing With lists of learning points and case studies which consist of sample processing protocols descriptions of where processing went wrong sample risk assessments or validation studies the authors help you find specific information fast

Encyclopedia of Bioprocess Technology Michael C. Flickinger, 1999

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