

DRUGS AND THE PHARMACEUTICAL SCIENCES

VOLUME 142

Microbial Contamination Control in the Pharmaceutical Industry



edited by
Luis Jimenez

Microbial Contamination Control In Parenteral Manufacturing Drugs And The Pharmaceutical Sciences

Tim Sandle



Microbial Contamination Control In Parenteral Manufacturing Drugs And The Pharmaceutical Sciences:

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Microbial Contamination Control in the Pharmaceutical Industry Luis Jimenez, 2004-08-30 This authoritative reference presents an up to date review of the testing methods emerging technologies and analytical systems and procedures used to prevent the microbial contamination of pharmaceutical processes products and environments It identifies new tools for sample analysis and evaluation and the impact of these advancements on the company

Microbiological Contamination Control in Pharmaceutical Clean Rooms Nigel Halls, 2016-04-19 Contamination control in pharmaceutical clean rooms has developed from a jumble of science and engineering knowledge of what has worked well or badly in the past dependent upon the technology available at the time the clean room was built and subsequent technological developments Surrounding it all is a blanket of regulations Taking a multidisciplinary approach

Biocontamination Control for Pharmaceuticals and Healthcare Tim Sandle, 2024-01-28 Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio burden control and reduction at each transition in classified areas of a facility The first edition of the book covered many of the aspects of the strategy but the new official guidance signals that a roadmap is required to fully comply with its requirements Completely updated with the newest version of the EU GMP EN17141 the new edition expands the coverage of quality risk management and new complete examples to help professionals bridge the gap between regulation and implementation Biocontamination Control for Pharmaceuticals and Healthcare offers professionals in pharma quality control and related areas guidance on building a complete biocontamination strategy Includes the most current regulations Contains three new chapters including Application of Quality Risk Management and its Application in Biocontamination Control Designing an Environmental Monitoring Programme and Synthesis An Anatomy of a Contamination Control Strategy Offers practical guidance on building a complete biocontamination strategy

Active Pharmaceutical Ingredients, Second Edition Samuel H Yalkowsky, Yan He, Parijat Jain, Sanford Bolton, Charles Bon, Stefan Wellek, Ronald M Atlas, Donghern Kim, Leland J Cseke, Peter B Kaufman, William Wu, 2009-12-23 Equivalence testing has grown significantly in importance over the last two

decades especially as its relevance to a variety of applications has become understood Yet published work on the general methodology remains scattered in specialists journals and for the most part it focuses on the relatively narrow topic of bioequivalence assessment With a far broader perspective Testing Statistical Hypotheses of Equivalence provides the first comprehensive treatment of statistical equivalence testing The author addresses a spectrum of

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

Hygienic Design of Food Factories John Holah, Huub L. M. Lelieveld, 2011-10-26 Food safety is vital for consumer confidence and the hygienic design of food processing facilities is central to the manufacture of safe products Hygienic design of food factories provides an authoritative overview of hygiene control in the design construction and renovation of food factories The business case for a new or refurbished food factory its equipment needs and the impacts on factory design and construction are considered in two introductory chapters Part one then reviews the implications of hygiene and construction regulation in various countries on food factory design Retailer requirements are also discussed Part two describes site selection factory layout and the associated issue of airflow Parts three four and five then address the hygienic design of essential parts of a food factory These include walls ceilings floors selected utility and process support systems entry and exit points storage areas and changing rooms Lastly part six covers the management of building work and factory inspection when commissioning the plant With its distinguished editors and international team of contributors Hygienic

design of food factories is an essential reference for managers of food factories food plant engineers and all those with an academic research interest in the field An authoritative overview of hygiene control in the design construction and renovation of food factories Examines the implications of hygiene and construction regulation in various countries on food factory design Describes site selection factory layout and the associated issue of airflow [Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals](#) Tim Sandle,2025-08-01 Sterility Sterilisation and Sterility Assurance for Pharmaceuticals Technology Validation and Current Regulations Second Edition is an in depth guide to the world of pharmaceutical sterilization This new edition has been updated to reflect the latest standards and regulations ensuring alignment with current practices It explores emerging methods and techniques complemented by new case studies that provide practical examples Readers will gain comprehensive knowledge about sterilization s critical role in healthcare and pharmaceutical manufacturing highlighting the importance of controlling microbial challenges to ensure product safety and patient well being The book discusses sterility sterilization methods such as gamma radiation e beam dry heat steam gas vapor filtration and new techniques like X ray sterilization liquid phase sterilization ultraviolet light supercritical gases and sterilization assurance governance It covers biopharmaceutical manufacturing processes including aseptic filling container and packaging design and cleanroom environments This edition is essential for professionals in pharmaceuticals healthcare and medical device manufacturing providing the knowledge needed to comply with current standards and regulations Includes nine new chapters with many new case studies Offers coverage on the most current standards and regulations Provides full coverage of novel sterilization methods **Endotoxin Detection and Control in Pharma, Limulus, and Mammalian Systems** Kevin L. Williams,2019-07-24 Endotoxin detection and control is a dynamic area of applied science that touches a vast number of complex subjects The intersection of test activities includes the use of an ancient blood system from an odd living fossil Limulus It is used to detect remnants of the most primitive and destructive forms of life prokaryotes as contaminants of complex modern systems mammalian and Pharma Recent challenges in the field include those associated with the application of traditional methods to new types of molecules and manufacturing processes The advent of at will production of biologics in lieu of harvesting animal proteins has revolutionized the treatment of disease While the fruits of the biotechnology revolution are widely acknowledged the realization of the differences in the means of production and changes in the manner of control of potential impurities and contaminants in regard to the new versus the old are less widely appreciated Endotoxin as an ancient dynamic interface between lifeforms provides a singular perspective from which to view the parallel development of ancient and modern organisms as well as the progress of man in deciphering the complexity of their interactions in his efforts to overcome disease *Endotoxins* Kevin L. Williams,2007-02-23 This source expertly examines the discovery biological structure control and continued clarification of endotoxin from a parenteral manufacturing perspective with in depth discussion of state of the art technologies involving Limulus amebocyte lysate LAL such as assay

development automation depyrogenation Completely revised and expanded
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
Russell, Hugo and Ayliffe's Principles and Practice of Disinfection, Preservation and Sterilization Adam P. Fraiese, Jean-Yves Maillard, Syed Sattar, 2013-02-18 The new edition of this established and highly respected text is THE definitive reference in its field It details methods for the elimination or prevention control of microbial growth and features New chapters on bioterrorism and community healthcare New chapters on microbicide regulations in the EU USA and Canada Latest material on microbial resistance to microbicides Updated material on new and emerging technologies focusing on special problems in hospitals dentistry and pharmaceutical practice Practical advice on problems of disinfection and antiseptics in healthcare A systematic review of sterilization methods with uses and advantages outlined for each Evaluation of disinfectants and their mechanisms of action with respect to current regulations The differences between European and North American regulations are highlighted throughout making this a truly global work ideal for worldwide healthcare professionals working in infectious diseases and infection control
Pharmaceutical Microbiological Quality Assurance and Control David Roesti, Marcel Goverde, 2020-01-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks

Disinfection and Decontamination Jeanne Moldenhauer, 2018-11-20 This book describes various methods of decontamination and how the methods work There is a discussion of the various cleaning and disinfection methods utilized along with details of how to qualify these methods It also describes new technologies that may be useful in the battle for decontamination across industries Finally this book provides a single resource on how one can address contamination issues for a variety of manufacturing processes and industries Explores new technologies that may be useful in the battle for decontamination Examines various methods of decontamination and how the methods work Addresses contamination issues for a variety of manufacturing processes and industries Describes how to detect contaminants as well as how to deal with contaminants that are present Includes methods for both decontamination reaction and preventing contamination proactive

An Introduction to Pharmaceutical Sciences Jiben Roy, 2011-07-25 This textbook is written as a unified approach to various topics ranging from drug discovery to manufacturing techniques and technology regulation and marketing The key

theme of the book is pharmaceuticals what every student of pharmaceutical sciences should know from the active pharmaceutical ingredients to the preparation of various dosage forms along with the relevant chemistry this book makes pharmaceuticals relevant to undergraduate students of pharmacy and pharmaceutical sciences This book explains how a particular drug was discovered and then converted from lab scale to manufacturing scale to the market It explains the motivation for drug discovery the reaction chemistry involved experimental difficulties various dosage forms and the reasoning behind them mechanism of action quality assurance and role of regulatory agencies After having a course based on this book the student will be able to understand 1 the career prospects in the pharmaceutical industry 2 the need for interdisciplinary teamwork in science 3 the techniques and technology involved in making pharmaceuticals starting from bulk drugs and 4 different dosage forms and critical factors in the development of pharmaceutical formulations in relation to the principles of chemistry A few blockbuster drugs including atorvastatin sildanefil ranitidine ciprofloxacin amoxicillin and the longest serving drugs such as aspirin and paracetamol are discussed in detail Finally the book also covers the important current pharmaceutical issues like quality control safety counterfeiting and abuse of drugs and future prospects for pharmaceutical industry Unified approach explaining drug discovery bulk drug manufacturing formulation of dosage forms with pharmacological and therapeutic actions Manufacturing processes of representative active pharmaceutical ingredients and their chemistry plus formulation of dosage forms presented in this book are based on actual industrial processes Covers many aspects relevant to students of the pharmaceutical sciences or newly employed pharmaceutical researchers employees It contains summary information about regulatory agencies of different countries *Principles of Parenteral Solution Validation* Igor Gorsky, Harold S. Baseman, 2019-11-27 Principles of Parenteral Solution Validation A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product By using a lifecycle approach this book discusses the latest technology compliance developments and regulatory considerations and trends from process design to divesting As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin this book incorporates numerous case studies and real world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area *CleanRooms*, 2008-02 A central resource of technology and methods for environments where the control of contamination is critical *A Textbook of Microbiology*: Dubey R.C. & Maheshwari D.K., 2023 This new edition of *A Textbook of Microbiology* continues to provide a comprehensive coverage on the basic principles of the subject with its focus on the concepts of ecology of microorganisms The book has been written in lucid and easily understandable language for students Each chapter has self test exercise at the end of the book Besides fulfilling the needs of undergraduate students this book would also be useful for postgraduate students as well as aspirants of various competitive examinations *A Textbook of Microbiology (Library Hardback Edition)* Dubey R.C. & Maheshwari D.K., This textbook is for University College Students in India Abroad Ecology of microorganisms especially soil water and air microbial

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