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Pharmaceutical Technology: Concepts and applications
Microbial Limit and Bioburden Tests
Fundamentals of Design, Testing and Operation
A Primer Based on Best Practices
Materials for Medical Application
Isolation Technology
Production and Processes
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A Practical Guide
Clean Room Technology in ART Clinics
Pharmaceutical Manufacturing Handbook
Contamination and ESD Control in High-Technology Manufacturing
Pharmaceutical Isolators
Cleanroom Technology
Sterilization of Medical Devices
Sterilisation of Polymer Healthcare Products
Environmental Monitoring for Cleanrooms and Controlled Environments
Quality Assurance of Pharmaceuticals
Cleanrooms and associated controlled environments. Part 3, Test methods (ISO 14644-3:2019, corrected version 2020-06)
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PN-EN ISO 14644-3
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A Practical Guide, Second Edition
Applications, Processes, and Controls, Second Edition
Precision Engineering

SHEPPARD ASHLEY

Pharmaceutical Technology: Concepts and applications Bentham Science Publishers
Pharmaceutical Technology – Concepts and Applications articulates on the various pharmaco-technological concepts associated with industrial pharmacy. The book not only focuses on providing comprehensive information on formulation development and affiliated areas but also emphasizes on their industrial applications. With a plethora of examples that illustrate important concepts, the book equips students of pharmacy to rise to the requirements of the industry.
Microbial Limit and Bioburden Tests William Andrew
This book is meant to be a guide to all who want to learn about a highly regulated industry. My approach is to give you, the reader, an example of a fictitious device, and we will take it from a conceptual idea all the way to launch and beyond. My intention is to incorporate the best experiences that I and other contributors have had into this book and convert them into laymans terms for those who are in need. These experiences can and will be indispensable to beginners and professionals alike who are trying their hand in the medical device industry and to those who have not been out of their silo to help see how each of the systems relate to each as a whole. However, it should be noted that the contents of this book should be taken only as information and is not intended to demonstrate how companies can be in compliance. In some instances, there are multiple ways to go through the maze of regulations that are documented and made by agencies because the regulations are pretty much made and designed to be flexible and high level so that companies can adopt their systems, which are solely designed for their purposes. Therefore, this book will try to avoid complicated words and complex technical details of engineering and statistics. This book will strive to be an embodiment of the honest-to-goodness, everyday experiences and issues that folks experience while working in the medical device industry.
Fundamentals of Design, Testing and Operation Springer
Contamination control is being used by more and more industries where the highest level of cleanliness and hygiene is of vital importance. This book covers the basic principles of contamination control and cleanroom technology from a holistic point of view. It deals with cleanliness and hygiene and their effects on the outcome of a process, reflecting the latest results from both scientific and practical points of view. The following topics are covered: contaminants and how they are measured cleanrooms and clean zones cleaning and decontamination cleanroom clothing the impact of people on cleanliness. Intended as an introduction to the area of contamination control, the text is also an excellent source of knowledge for people with both theoretical and practical experience. The Swedish version has been used for a long time within the Nordic countries as a basic training textbook within the pharmaceutical, microelectronics, food and beverage, optics and many other industries.
A Primer Based on Best Practices John Wiley & Sons
Decontamination in Hospitals and Healthcare brings an understanding of decontamination practices and the development of technologies for cleaning and control of infection to a wide audience interested in public health, including healthcare specialists, scientists, students or patients. Part one highlights the importance and history of decontamination in hospitals and healthcare before exploring the role of standards in decontamination, infection control in Europe, and future trends in the area. Part two focuses on decontamination practices in hospitals and healthcare. It considers the role of the nurse in decontamination, the issues of microbial biofilm in waterlines, control of waterborne microorganisms, and the use of gaseous decontamination technologies. Further chapters explore decontamination of prions, the use of protective clothing, no-touch automated room disinfection systems, and controlling the presence of microorganisms in

hospitals. Part three discusses practices for decontamination and sterilization of surgical instruments and endoscopes. These chapters examine a range of guidance documents, including the choice framework for local policy and procedures for decontamination of surgical instruments, as well as novel technologies for cleaning and detection of contamination. Decontamination in Hospitals and Healthcare provides a reference source on decontamination for public health professionals and students concerned with healthcare. It is particularly useful for scientists in microbiology and disinfection/decontamination laboratories, healthcare workers who use disinfectants, students in microbiology, clinicians, members of the Institute of Decontamination Sciences/Central Sterilising Club, and those employed in the Central Sterile Services departments of healthcare facilities. Discusses decontamination processes in Europe Provides an in-depth understanding into decontamination in healthcare settings, specifically hospitals and dental practices Examines the decontamination of surgical equipment and endoscopes

Materials for Medical Application Academic Press

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is ‘current good manufacturing practice (CGMP)’’, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

Isolation Technology Pearson Education India

Modular construction can dramatically improve efficiency in construction, through factory production of pre-engineered building units and their delivery to the site either as entire buildings or as substantial elements. The required technology and application are developing rapidly, but design is still in its infancy. Good design requires a knowledge of modular production, installation and interface issues and also an understanding of the economics and client-related benefits which influence design decisions. Looking at eight recent projects, along with background information, this guide gives you coverage of: generic types of module and their application vertical loading, stability and robustness dimensional and spacial planning hybrid construction cladding, services and building physics fire safety and thermal and acoustic performance logistical aspects – such as transport, tolerances and safe installation. A valuable guide for professionals and a thorough introduction for advanced students.

Production and Processes Smithers Rapra

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. This key part of controlling risk escalation can lead to the contamination of medicinal products, hence necessary tracking precautions are essential. Regulatory authorities have challenged pharmaceutical companies, healthcare providers, and those in manufacturing practice to adopt a holistic approach to contamination control. New technologies are needed to introduce barriers between personnel and the environment, and to provide a rapid and more accurate assessment of risk. This book offers guidance on building a complete biocontamination strategy. Provides the information necessary for a facility to build a complete biocontamination strategy Helps facilities understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements Provides insight into developing an environmental monitoring program Covers the types of rapid microbiological monitoring methods now available, as well as current legislation

Regenerative Medicine and Tissue Engineering CRC Press

A critical technology in the science of contamination control, environmental monitoring is a technique that provides important data on the quality of a process, processing environment, and final product, which can aid scientists in identifying and eliminating potential sources of contamination in cleanrooms and controlled environments. In response

Design in Modular Construction Pharmaceutical Press

Here comes ISO 14644. There has never been a ISO 14644 Guide like this. It contains 28 answers, much more than you can imagine; comprehensive answers and extensive details and references, with insights that have never before been offered in print. Get the information you need--fast! This all-embracing guide offers a thorough view of key knowledge and detailed insight. This Guide introduces what you want to know about ISO 14644. A quick look inside of some of the subjects covered: ISO 14644-4, ISO 14644-9, Institute of Environmental Sciences and Technology - International standards, IEST, Kennedy Space Center - Facilities, ISO 14644-6, University of Texas, Dallas - Research, ISO 14644-5, Cleanroom suitability, ISO 14644-3, ISO 14644-1, ISO 14644-8, ISO 14644-2, Cleanroom - Cleanroom classifications, ISO 14644-7, ISO 1750 - ISO 10000 - ISO 14999, FED-STD-209E, Cleanroom suitability - Testing, The University of Texas at Dallas - Research, List of International Organization for Standardization standards - ISO 10000 - ISO 14999, and much more...

CRC Press

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

A Practical Guide World Health Organization

The collection of topics in the second volume of this book challenges the reader to think beyond standard methods and question why certain current procedures remain static while technological advances abound in other aspects of sterilisation technology. By small means, better practices may come to pass to help answer some of the residual healthcare sterilisation and nosocomial infection queries: What are some of the current challenges in healthcare sterilisation, and how can they be handled? What are some of the acceptable current non-traditional sterilisation methods, challenging alternatives, and novel modalities? What are some of the packaging, validation and statistical considerations of sterilisation practices? How does design-of-product and packaging interrelate with sterilisation processing? Are the current sterility media and practices optimal for recovery of more modified and more resistant viable organism entities and product? Are there increased sterility and product quality needs with new types of implantables and technological advances within the three dimensional combinations of diagnostics, drug release and challenging medical devices?

Clean Room Technology in ART Clinics John Wiley & Sons

Applications, Processes, and Controls is the second volume in the Handbook for Critical Cleaning, Second Edition. Should you clean your product during manufacturing? If so, when and how? Cleaning is essential for proper performance, optimal quality, and increased sales. Inadequate cleaning of product elements can lead to catastrophic failure of the entire system and serious hazards to individuals and the general public. Gain a competitive edge with proven cleaning and contamination-control strategies A decade after the bestselling original, the Handbook for Critical Cleaning, Second Edition helps manufacturers meet today’s challenges, providing practical information and perspective about cleaning chemistries, equipment, processes, and applications. With 90% new or revised chapters plus supplementary online material, the handbook has grown into two comprehensive volumes: Cleaning Agents and Systems, and Applications, Processes, and Controls. Helping manufacturers become more efficient and productive, these books: Show how to increase profitability and meet both existing and expected product demand Clarify the sea of print and Internet information about cleaning chemistries and techniques Address challenges of performance, miniaturization, and cost, as well as regulatory and supply chain pressures Offer clearly written guidance from the viewpoints of more than 70 leading industry contributors in technical, management, academic, and regulatory disciplines Overview chapters by the editors, industry icons Barbara and Ed Kanegsberg, meld the different viewpoints and compile and critique the options. The result is a complete, cohesive, balanced perspective that helps manufacturers better select, implement, and maintain a quality, value-added cleaning process. The second volume, Handbook for Critical Cleaning: Applications, Processes, and Controls, addresses how to implement, validate, monitor, and maintain a critical cleaning process. Topics include cleanrooms, materials compatibility, worker safety, sustainability, and environmental constraints. The book shows readers how to draw from diverse disciplines—including aerospace, art conservation, electronics, food, life sciences, military, optics, and semiconductors—to achieve superior productivity.

Pharmaceutical Manufacturing Handbook CRC Press

The Pharmaceutical Engineering Series is a comprehensive reference for the pharmaceutical professional covering all aspects from quality, documentation and validation through manufacturing processes to facility design and management. In 'Quality', Dr Kate McCormick provides the reader with comprehensive coverage of this vital subject, including the quality life cycle, management and cost of quality, GMP, auditing and inspections. This book with the others in the series will become a unique source of reference and educational material for the readership. Case studies and examples make the book of direct practical relevance to the professional in the pharmaceutical industry Find the answers you are looking for quickly and easily with clear indexing and referencing Reference to international standards and practice mean this book will be useful wherever you are working

Contamination and ESD Control in High-Technology Manufacturing CRC Press

A practical "how to" guide that effectively deals with the control of both contamination and ESD This book offers effective strategies and techniques for contamination and electrostatic discharge (ESD) control that can be implemented in a wide range of high-technology industries, including semiconductor, disk drive, aerospace, pharmaceutical, medical device, automobile, and food production manufacturing. The authors set forth a new and innovative methodology that can manage both contamination and ESD, often considered to be mutually exclusive challenges requiring distinct strategies. Beginning with two general chapters on the fundamentals of contamination and ESD control, the book presents a logical progression of topics that collectively build the necessary skills and knowledge: Analysis methods for solving contamination and ESD problems Building the contamination and ESD control environment, including design and construction of cleanrooms and ESD protected environments Cleaning processes and the equipment needed to support these processes Tooling design and certification Continuous monitoring Consumable supplies and packaging materials Controlling contamination and ESD originating from people Management of cleanrooms and ESD protected workplace environments Contamination and ESD Control in High-Technology Manufacturing conveys a practical, working knowledge of contamination and ESD control strategies and techniques, and it is filled with case studies that illustrate key principles and the benefits of contamination and ESD control. Moreover, its straightforward style makes the material, which integrates many disciplines of engineering and science, clear and accessible. Written by three leading industry experts, this book is an essential guide for engineers and designers across the many industries where contamination and ESD control is a concern.

Pharmaceutical Isolators Butterworth-Heinemann

A self-contained and practical book providing step-by-step guidance to the design and construction of cleanrooms, appropriate testing methodologies, and operation for the minimization of contamination... This second edition has been comprehensively revised and includes extensive updates to the two chapters that contain information on cleanroom standards and guidelines. The chapter on risk management has been extensively revised, especially the section on risk assessment. Other new subjects that have been added to the various chapters are those on clean-build, determination of air supply volumes for non-unidirectional airflow cleanrooms, RABS (Restricted Access Barrier Systems), contamination recovery test methods, entry of large items into a cleanroom, glove allergy problems, and how to develop a cleanroom cleaning programme. Used for in-house training and a textbook in colleges, this volume is for cleanroom personnel at all levels. It provides novices with an introduction to the state-of-the-art technology and professionals with an accessible reference to the current practices. It is particularly useful in the semiconductor, pharmaceutical, biotechnology and life sciences industries. William Whyte is an international authority in cleanrooms, with over 45 years experience in research, teaching and consulting in the electronic, healthcare and pharmaceutical industries. He is a member of British and International standards committees writing the International Cleanroom standards, and has received numerous awards for his work in Cleanroom Technology. A comment on the first edition: "...extremely useful and helpful...very well-written, highly organized, easy to understand and follow..." (Environmental

Geology, 2003)
Cleanroom Technology John Wiley & Sons
In this series Rajiv Kohli and Kash Mittal have brought together the work of experts from different industry sectors and backgrounds to provide a state-of-the-art survey and best-practice guidance for scientists and engineers engaged in surface cleaning or handling the consequences of surface contamination. The expert contributions in this volume cover important fundamental aspects of surface contamination that are key to understanding the behavior of specific types of contaminants. This understanding is essential to develop preventative and mitigation methods for contamination control. The coverage complements the treatment of surface contamination in vol.1, Fundamental and Applied Aspects. This volume covers: Sources and Generation of Particles; Manipulation Techniques for Particles on Surfaces; Particle Deposition and Rebound; Particle Behavior in Liquid Systems; Biological and Metallic Contamination; and includes a comprehensive list of current standards and resources. Comprehensive coverage of innovations in surface contamination and cleaning Written by established experts in the contamination and cleaning field Each chapter is a comprehensive review of the state of the art Case studies included
Sterilization of Medical Devices Woodhead Publishing
This book offers practical applications addressing the specifics of contamination, including particle origination, characterization, identification, and elimination, with a special focus on quality considerations. Written by an industry expert, this material offers a clear and concise understanding of particle populations and their control in stability, efficacy, and predictability in the manufacture of healthcare products. Complete with a full-color insert of micrographs illustrating commonly encountered particulate matter and over eighty figures, tables, and charts. Features
Sterilisation of Polymer Healthcare Products Walter de Gruyter GmbH & Co KG
Sterilisation has always been challenging but sterilisation of healthcare products and polymers, especially together is an even greater challenge - how do you sterilise without adversely affecting the end use or the end user? This book discusses all the sterilisation methods used for polymeric healthcare products both traditional and new.
Environmental Monitoring for Cleanrooms and Controlled Environments Emereo Publishing
Manufacturing generates wealth, whereas high-precision manufacturing is even more lucrative. Mechanical engineers, professionals and students can turn to Precision Engineering for an in-depth understanding on manufacturing of optical, electronic and mechanical products. Starting with an introduction to precision engineering, the book describes theory and design of precision machines as well as mechanics of ultra-precision machining. It also discusses manufacturing based on atomic bit processes as well as topics like atomic force, scanning, electron and optical microscopy, surface finish and clean rooms. The book is designed as per the syllabi of NTU Singapore, UTM Johor Bahru, Malaysia and MMU Melaka, Malaysia.
Quality Assurance of Pharmaceuticals John Wiley & Sons
In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

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