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Decontamination in Hospitals and Healthcare
Cleanrooms and Associated Controlled Environments
Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition
Pharmaceutical Technology: Concepts and applications
Pharmaceutical Manufacturing Handbook
Mosby's Sterile Compounding for Pharmacy Technicians
Introduction to Contamination Control and Cleanroom Technology
Regenerative Medicine and Tissue Engineering
Compounding Sterile Preparations
Healthcare Sterilisation
Exposure to Microbiological Agents in Indoor and Occupational Environments
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Cleanroom Technology
Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook
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Journal of the IEST
Developments in Surface Contamination and Cleaning, Volume 4
Quality Assurance of Pharmaceuticals
CleanRooms
Reinraumtechnik
Control of Particulate Matter Contamination in Healthcare Manufacturing
Environmental Monitoring for Cleanrooms and Controlled Environments
Isolation Technology
Text Book of Industrial Pharmacy
WHO Expert Committee on Specifications for Pharmaceutical Preparations

Microbial Contamination Control in Parenteral Manufacturing
Handbook of Pharmaceutical Manufacturing Formulations
Medical Device
Handbook for Critical Cleaning
The Certified Pharmaceutical GMP Professional Handbook
Microbial Limit and Bioburden Tests
Pharmaceutical Isolators
Sterilization of Medical Devices
Handbook of Validation in Pharmaceutical Processes, Fourth Edition
DIN EN ISO 14644-3, Reinräume und zugehörige Reinraumbereiche. Teil 3, Prüfverfahren (ISO 14644-3:2019, korrigierte Fassung 2020-06)
Biocontamination Control for Pharmaceuticals and Healthcare
Quality
Materials for Medical Application

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DALTON HAMMOND

Decontamination in Hospitals and Healthcare Academic Press
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.
Cleanrooms and Associated Controlled Environments Bentham Science Publishers
Gain a complete introduction to institutional pharmacy practice and efficiently prepare for the new sterile compounding certification exam! Comprehensively covering sterile products, aseptic technique, and the workings of the sterile compounding facility, Mosby’s Sterile Compounding for Pharmacy Technicians: Principles and Practice, 2nd Edition, focuses on safe and accurate practice. This edition has expanded and updated coverage to address preparation, processing, medications, technique, and documentation, with review, analysis, and application of , , and and additional content on waste management, workflow, safety and compliance, billing and reimbursement, and emergency management. Illustrations abound, and content is brought to life with an updated art program, step-by-step procedures, and technician notes and alerts. Certification review questions are included with each chapter, and online student and instructor resources round out the offering. Competency forms, lab activities, and sample compounding orders allow you to perform basic, hands-on aseptic manipulations in the lab. Mini-case scenarios promote critical thinking and application. Tech Notes, Tech Alerts, and Did You Know? boxes offer key information on-the-job success. Content modeled after ASHP curriculum for technician training. Chapter quizzes and an online sample exam offer student practice and exam preparation. Instructor support materials online, including lesson plans, PowerPoint slides, a test bank, student handouts, answer keys, an image collection, and chapter pretests. NEW! Expanded and updated content on all aspects of preparation, processing, medications, techniques, and documentation plus new content on the sterile environment; , , and ; hazardous materials and waste management; workflow, quality control; safety and compliance; billing and reimbursement; and emergency and disaster planning. NEW! Procedure boxes with step-by-step instructions, technique photos, and rationales. NEW and EXPANDED! Updated art program focuses on the sterile environment, equipment and supplies, and skills. NEW! Chapter quiz questions and a sample exam prepare students for classroom exams or the new certification credentialing exam.
Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition World Health Organization
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 Technology: Concepts and applications William Andrew

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.

Pharmaceutical Manufacturing Handbook 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 *Mosby's Sterile Compounding for Pharmacy Technicians* iSmithers Rapra Publishing
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.
Introduction to Contamination Control and Cleanroom Technology John Wiley & Sons
Revised to reflect significant advances in pharmaceutical production and regulatory expectations, Handbook of Validation in Pharmaceutical Processes, Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive. This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions. As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years, this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio-pharmaceutical production processes. Handbook of Validation in Pharmaceutical Processes, Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals. Key Features: Provides an in-depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program, and suggests the newest and most advanced solutions Explores distinctive and specific process steps, and identifies critical process control points to reach acceptable results New chapters include disposable systems, combination products, nano-technology, rapid microbial methods, contamination control in non-sterile products, liquid chemical sterilization, and medical device manufacture
Regenerative Medicine and Tissue Engineering Woodhead Publishing
Decontamination in Hospitals and Healthcare, Second Edition, enables users to obtain detailed knowledge of decontamination practices in healthcare settings, including surfaces, devices, clothing and people, with a specific focus on hospitals and dental clinics. Offers in-depth coverage of all aspects of decontamination in healthcare Examines the decontamination of surgical equipment and endoscopes Expanded to include new information on behavioral principles in decontamination, control of microbiological problems, waterborne microorganisms, pseudomonas and the decontamination of laundry

Compounding Sterile Preparations CRC Press
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.
Healthcare Sterilisation John Wiley & Sons
This reference surveys emerging trends, concepts, and procedures used in the characterization and control of contaminants; the sterile production of traditional drugs and biologics; the design, construction, and validation of new parenteral facilities; and the monitoring of clean environments-vividly illustrating the routes by which products, proce
Exposure to Microbiological Agents in Indoor and Occupational Environments CRC Press
The most significant changes in isolation technology during the past five years have not been in the technology itself but in its increased acceptance. This acceptance is clearly demonstrated by the series of monographs, guidelines, and standards produced by regulatory bodies to describe best practice in the design and operation of isolators. Thoroughly revised and updated, Isolation Technology: A Practical Guide, Second Edition provides an in-depth overview of new standards and new technology. Here's what's new in the Second Edition: " Descriptions of and comments on new guidelines and standards " Technological advances - such as the new breed of sanitizing gas generators " Updates that reflect current thinking and new information Drawing on his vast experience in this field, the author delineates practical ways to improve product standards, increase operator productivity, efficiency and safety, and cut costs. Carefully designed for easy understanding by readers from multiple fields, the book reviews the how-tos for setting up clean rooms and techniques for maintaining sterility, and includes case studies, resource listings, and numerous photographs. The combination of up-to-date information and the author's clear writing style make this the ideal resource for both experienced and beginning professionals.
Clean Room Technology in ART Clinics Smithers Rapra

No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, particularly the new line of small protein products, joining the long list of proven sterile products, the technology of manufacturing ster

Cleanroom Technology DIN EN ISO 14644-3, Reinräume und zugehörige Reinraumbereiche. Teil 3, Prüfverfahren (ISO 14644-3:2019, korrigierte Fassung 2020-06)Environmental Monitoring for Cleanrooms and Controlled Environments Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Butterworth-Heinemann

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensusbuilding process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating ventilation and air-conditioning systems (HVAC) ? illustrative part; Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

Sterilisation of Polymer Healthcare Products 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.

Contamination and ESD Control in High-Technology Manufacturing AG PUBLISHING HOUSE (AGPH Books)

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

Journal of the IEST CRC Press

A central resource of technology and methods for environments where the control of contamination is critical.

Developments in Surface Contamination and Cleaning, Volume 4 World Health Organization

Dieses in kürzester Zeit zum Standardwerk der Reinraumtechnik avancierte Fachbuch wurde in der vorliegenden Auflage durch neueste Ergebnisse und aktuellste Entwicklungen ergänzt. Die Darstellung der Regelwerke wurde wieder auf neuesten Stand gebracht. Das Thema der Reinraum-Automation wird erstmals in einem neu aufgenommenen Kapitel dargestellt. Ausgehend von reinraumtechnischen Problemstellungen werden die Grundlagen und Anwendungen beschrieben und aktuelle Lösungen dargestellt. Für alle wichtigen Aspekte der Kontaminationskontrolle werden Methoden, Reinraumsysteme und deren Leistungsgrenzen behandelt. Eine Besonderheit des Buches liegt in der systematischen Verknüpfung von Grundlagen, Problemstellungen und deren praktischer Umsetzung. Die Herausgeber gelten als Nestoren der Reinraumtechnik. Für ihre Arbeiten innerhalb der Industrie wie für technisch-wissenschaftliche Gremien wurden sie wiederholt ausgezeichnet.

Quality Assurance of Pharmaceuticals CRC Press

Quality, second edition, provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing. It is an excellent resource for practitioners, those pursuing pharmaceutical related certifications, and for students trying to learn more about pharmaceutical manufacturing. This book provides the background theory, applied descriptions of the guidelines and concepts, plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts. In this book the authors share their combined 60+ years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system. This book provides real-life examples from industry and guidelines for practical application of tools that can be referenced by operators, engineers, and management.This book is fully revised, updated, and expanded with new content in areas such as QbD, Lean, Six Sigma, basic data analysis, and CAPA tools. Fully revised, updated, and expanded new edition Features new topics such as QbD,

Lean, Six Sigma, basic data analysis, and CAPA tools Includes end-of-chapter summaries and end-of-chapter question and/or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply

Springer-Verlag

This book gives an introduction to the highly interdisciplinary field of biomaterials. It concisely summarizes properties, synthesis and modification of materials such as metals, ceramics, polymers or composites. Characterization, in vitro and in vivo testing as well as a selection of various applications are also part of this inevitable guide.

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