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Environmental Management System ISO 14001: 2004 Createspace Independent Publishing Platform
Failure to adequately control any microbial challenge associated within process or product by robust sterilisation will result in a contaminated marketed product, with potential harm to the patient. Sterilisation is therefore of great importance to healthcare and the manufacturers of medical devices and pharmaceuticals. Sterility, sterilisation and sterility assurance for pharmaceuticals examines different means of rendering a product sterile by providing an overview of sterilisation methods including heat, radiation and filtration. The book outlines and discusses sterilisation technology and the biopharmaceutical manufacturing process, including aseptic filling, as well as aspects of the design of containers and packaging, as well as addressing the cleanroom environments in which products are prepared. Consisting of 18 chapters, the book comprehensively covers sterility, sterilisation and microorganisms; pyrogenicity and bacterial endotoxins; regulatory requirements and good manufacturing practices; and gamma radiation. Later chapters discuss e-beam; dry heat sterilisation; steam sterilisation; sterilisation by gas; vapour sterilisation; and sterile filtration, before final chapters analyse depyrogenation; cleanrooms; aseptic processing; media simulation; biological indicators; sterility testing; auditing; and new sterilisation techniques. Covers the main sterilisation methods of physical removal, physical alteration and inactivation Includes discussion of medical devices, aseptically filled products and terminally sterilised products Describes bacterial, pyrogenic, and endotoxin risks to devices and products

Handbook of Validation in Pharmaceutical Processes, Fourth Edition John Wiley & Sons
This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.
Validation of Pharmaceutical Processes CRC Press
A textbook which is both comprehensive and comprehensible and that offers easy but scientifically sound reading to both students and professionals Now in its 12th edition in its native German, Voigt's Pharmaceutical Technology is an interdisciplinary textbook covering the fundamental principles of pharmaceutical technology. Available for the first time in English, this edition is produced in full colour throughout, with a concise, clear structure developed after consultation with students, instructors and researchers. This book: Features clear chapter layouts and easily digestible content Presents novel trends, devices and processes Discusses classical and modern manufacturing processes Covers all formulation principles including tablets, ointments, capsules, nanosystems and biopharmaceutics Takes account of legal requirements for both qualitative and quantitative composition Addresses quality assurance considerations Uniquely relates contrasting international pharmacopeia from EU, US and Japan to formulation principles Includes examples and text boxes for quicker data assimilation Written for both students studying pharmacy and industry professionals in the field as well as toxicologists, biochemists, medical lab technicians, Voigt’s Pharmaceutical Technology is the essential resource for understanding the various aspects of pharmaceutical technology.
Compounding Sterile Preparations CRC Press
Includes as many case studies as the contributors could identify, with the goal of answering questions that arise as a result of conducting day-to-day sterilization activities. Discussion of the theory of microbial inactivation and the philosophy of sterilization validation is followed by practical information on methods of interest to a broad audience. Chapters on special considerations for ethylene oxide, packaging of sterile products, contract sterilization, and regulations complete the coverage. Annotation copyright by Book News, Inc., Portland, OR
Healthcare Sterilisation CRC Press
Microbiologists working in both the pharmaceutical and medical device industries, face considerable challenges in keeping abreast of the myriad microbiological references available to them, and the continuously evolving regulatory requirements. The Handbook of Microbiological Quality Control provides a unique distillation of such material, by providing a wealth of microbiological information not only on the practical issues facing the company microbiologist today, but also the underlying principles of microbiological quality assurance. All the chapters have been written by leading experts in this field. The Handbook of Microbiological Quality Control provides guidance on safe microbiological practices, including laboratory design and sampling techniques. The design storage, use and quality control of microbiological culture is considered in depth. Principles of enumeration and identification of micro-organisms, using both traditional and rapid methods as well as the pharmacopoeial methods for the detection of specified organisms, are elaborated in detail. Guidance is given on laboratory methods supporting the sterility assurance system: sterility testing, bioburden testing, the

use of biological indicators and environmental monitoring methods, as well as methods for detecting and quantifying endotoxins. Pharmacopoeial methods for microbiological assay and preservative efficacy testing are reviewed. Problems for those involved in disinfection and cleansing techniques and microbiological audit are discussed from a practical viewpoint. Finally, a number of pertinent case studies and worked examples illustrate problems highlighted in the text. The Handbook of Microbiological Quality Control is the essential reference source for the professional microbiologist.

Disinfection and Decontamination Marcel Dekker

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Introduction & Standard Practices, Volume 1 John Wiley & Sons

Empower your staff to improve safety, quality and compliance with the help of new guidelines and standards. We've updated every chapter of this popular review of the fundamentals of preparing sterile products in hospital, home-care, and community pharmacy settings to reflect the most recent revisions to USP . Included are the latest guidelines for the compounding process, quality assurance methods, and comprehensive coverage of all aspects of the dispensing process. Comprehensive documentation for the guidelines is included in the appendices.Chapters new to this edition focus on: Gap analysis and action plans Safe use of automatic compounding devices Cleaning and disinfecting Radiopharmaceuticals as CSPs Allergen extracts as CSPs.

Formulation, Process, Quality and Regulatory Considerations Woodhead Publishing

The effective sterilisation of any material or device to be implanted in or used in close contact with the human body is essential for the elimination of harmful agents such as bacteria. Sterilisation of biomaterials and medical devices reviews established and commonly used technologies alongside new and emerging processes. Following an introduction to the key concepts and challenges involved in sterilisation, the sterilisation of biomaterials and medical devices using steam and dry heat, ionising radiation and ethylene oxide is reviewed. A range of non-traditional sterilisation techniques, such as hydrogen peroxide gas plasma, ozone and steam formaldehyde, is then discussed together with research in sterilisation and decontamination of surfaces by plasma discharges. Sterilisation techniques for polymers, drug-device products and tissue allografts are then reviewed, together with antimicrobial coatings for 'self-sterilisation' and the challenge presented by prions and endotoxins in the sterilisation of reusable medical devices. The book concludes with a discussion of future trends in the sterilisation of biomaterials and medical devices. With its distinguished editors and expert team of international contributors, Sterilisation of biomaterials and medical devices is an essential reference for all materials scientists, engineers and researchers within the medical devices industry. It also provides a thorough overview for academics and clinicians working in this area. Reviews established and commonly used technologies alongside new and emerging processes Introduces and reviews the key concepts and challenges involved in sterilisation Discusses future trends in the sterilisation of biomaterials and medical devices

Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics Marcel Dekker Incorporated

The field of medical instrumentation is inter-disciplinary, having interest groups both in medical and engineering professions. The number of professionals associated directly with the medical instrumentation field is increasing rapidly due to intensive penetration of medical instruments in the health care sector. In addition, the necessity and desire to know about how instruments work is increasingly apparent. Most dictionaries/encyclopedias do not illustrate properly the details of the bio-medical instruments which can add to the knowledge base of the person on those instruments. Often, the technical terms are not covered in the dictionaries. Unless there is a seamless integration of the physiological bases and engineering principles underlying the working of a wide variety of medical instruments in a publication, the curiosity of the reader will not be satisfied. The purpose of this book is to provide an essential reference which can be used both by the engineering as well as medical communities to understand the technology and applications of a wide range of medical instruments. The book is so designed that each medical instrument/ technology will be assigned one or two pages, and approximately 450 medical instruments are referenced in this edition.

A Practical Handbook CRC Press

The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences, also highlighting key developments, research and future opportunities. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of the product development phase of drug discovery and drug development. Each chapter covers fundamental principles, advanced methodologies and technologies employed by pharmaceutical scientists, researchers and the pharmaceutical industry. The book focuses on excipients, radiopharmaceuticals, and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice (GMP) guidelines. Researchers and students will find this book to be a comprehensive resource for those working in, and studying, pharmaceuticals, cosmetics, biotechnology, foods and related industries. Provides an overview of practical information

for clinical trials Outlines how to ensure an environment that follows Good Manufacturing Practice (GMP) Examines recent developments and suggests future directions for drug production methods and techniques

Voigt's Pharmaceutical Technology Smithers Rapra

Presenting authoritative and engaging articles on all aspects of drug development, dosage, manufacturing, and regulation, this Third Edition enables the pharmaceutical specialist and novice alike to keep abreast of developments in this rapidly evolving and highly competitive field. A dependable reference tool and constant companion for years to com

Practical Aseptic Processing CRC Press

Environmental Management System ISO 14001:2004 provides the information and practical know-how required to facilitate a smooth adoption and incorporation of the latest revisions and enhancements put forth by the International Organization for Standardization. This unique work shows how to adopt or transition to the documentation procedures required

Sterile Drug Products Elsevier

This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.

The Biologics and Biotechnology Handbook for Engineers Elsevier

The ways of sterilisation begin as far back as biblical and roman times, from early beginnings to standardization. Sterilisation evolution has gone through a series of trials and wizardry before it achieved the status of science. And even with a scientific approach, some of its modalities frequently has been referred to as an art (an imaginary focus), while most have achieved a certain scientific standardization. This book provides a drawbridge between history, terminology, environmental and fundamentals of sterilisation that beginners to sterilisation should recognize, but continues with advancements, which supervisors and managers should know and apply. So while providing historical and current sterilisation information, the book also provides interfacial areas with design practices, development, environmental control, material compatibility, microbiology, packaging, process selection, statistics, technical information and validation. This book consists of two volumes (Healthcare Sterilisation, Introduction and Standard Practices: Volume 1, and Healthcare Sterilisation, Challenging Practices: Volume 2). Volume 1 provides an introduction, and an overview of sterilisation on early and classical sterilisation principles such as absolutism and overkill, and steadfast and standard methods. It will help answer some healthcare sterilisation queries such as: what are the origins and evolution of sterilisation? How does environmental control and microbiology affect sterilisation? What are some of the classical as well as standard sterilisation methods? What are the most consistent and reliable sterilisation methods? Is sterilisation in your future? An ounce of prevention is worth a pound of cure. Without sterilisation, infectious disease and contamination would run rampant. Consequently, sterilisation has tremendous value and disease control, and this book provides a three dimensional view of it.

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals Lippincott Williams & Wilkins

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)

Fill and Finish Springer Science & Business Media

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 book is based on the courses he has delivered for over three decades, to over 3000 participants, and is intended to remain relevant for the indefinite future even as new technologies and new applications of old technologies become common. This is an ideal reference book for those working directly and indirectly with sterile dosage forms, be it product development (formulation, package, process, analytical), manufacturing, quality control, quality assurance, regulatory, purchasing, or project management. This book is also intended as an educational resource for the pharmaceutical and biopharmaceutical industry and pharmacy schools, providing basic knowledge and principles in four main areas of parenteral science and technology: Product development, including formulation, packaging, and process development. Manufacturing, including basic teaching on all the primary unit operations involved in preparation of sterile products and the underlying importance of contamination control. Quality and regulatory, including the application of good manufacturing practice regulations, aseptic processing guidelines, and unique quality control testing methods for the sterile dosage form Clinical aspects, including administration, potential hazards, and biopharmaceutics of sterile products in a clinical setting.

Endotoxin Detection and Control in Pharma, Limulus, and Mammalian Systems Lippincott Raven

Prevention is the first line of defence in the fight against infection. As antibiotics and other antimicrobials encounter increasing

reports of microbial resistance, the field of decontamination science is undergoing a major revival. A Practical Guide to Decontamination in Healthcare is a comprehensive training manual, providing practical guidance on all aspects of decontamination including: microbiology and infection control; regulations and standards; containment, transportation, handling, cleaning, disinfection and sterilization of patient used devices; surgical instrumentation; endoscopes; and quality management systems. Written by highly experienced professionals, A Practical Guide to Decontaminationin Healthcare comprises a systematic review of decontamination methods, with uses and advantages outlined for each. Up-to-date regulations, standards and guidelines are incorporated throughout, to better equip healthcare professionals with the information they need to meet the technical and operational challenges of medical decontamination. A Practical Guide to Decontaminationin Healthcare is an important new volume on state-of-the-art decontamination processes and a key reference source for all healthcare professionals working in infectious diseases, infection control/prevention and decontamination services.

Remington Parenteral Drug Association

For over 100 years, Remington has been the definitive textbook and reference on the science and practice of pharmacy. This Twenty-First Edition keeps pace with recent changes in the pharmacy curriculum and professional pharmacy practice. More than 95 new contributors and 5 new section editors provide fresh perspectives on the field. New chapters include pharmacogenomics, application of ethical principles to practice dilemmas, technology and automation, professional communication, medication errors, re-engineering pharmacy practice, management of special risk medicines, specialization in pharmacy practice, disease state management, emergency patient care, and wound care. Purchasers of this textbook are entitled to a new, fully indexed Bonus CD-ROM, affording instant access to the full content of Remington in a convenient and portable format.

Technology, Validation and Current Regulations Springer

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.

Sterile Product Development CRC Press

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