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Handbook of Validation in Pharmaceutical Processes, Fourth Edition - James Agalloco 2021-10-18

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

Block's Disinfection, Sterilization, and Preservation - Gerald McDonnell 2020-06-26

With more international contributors than ever before, Block's Disinfection, Sterilization, and Preservation, 6th Edition, is the first new edition in nearly 20 years of the definitive technical manual for anyone involved in physical and chemical disinfection and sterilization methods. The book focuses on disease prevention—rather than eradication—and has been thoroughly updated with new information based on recent advances in the field and understanding of the risks, the technologies available, and the regulatory environments.

Plastics in Medical Devices - Vinny R. Sastri 2010-03-05

No book has been published that gives a detailed description of all the types of plastic materials used in medical devices, the unique requirements that the materials need to comply with and the ways standard plastics can be modified to meet such needs. This book will start with an

introduction to medical devices, their classification and some of the regulations (both US and global) that affect their design, production and sale. A couple of chapters will focus on all the requirements that plastics need to meet for medical device applications. The subsequent chapters describe the various types of plastic materials, their properties profiles, the advantages and disadvantages for medical device applications, the techniques by which their properties can be enhanced, and real-world examples of their use. Comparative tables will allow readers to find the right classes of materials suitable for their applications or new product development needs.

Springer Handbook of Medical Technology - Rüdiger Kramme 2011-10-02

This concise, user-oriented and up-to-date desk reference offers a broad introduction to the fascinating world of medical technology, fully considering today's progress and further development in all relevant fields. The Springer Handbook of Medical Technology is a systemized and well-structured guideline which distinguishes itself through simplification and condensation of complex facts. This book is an indispensable resource for professionals working directly or indirectly with medical systems and appliances every day. It is also meant for graduate and post graduate students in hospital management, medical engineering, and medical physics.

Validation of Pharmaceutical Processes - James P. Agalloco 2007-09-25

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

Sterilisation of Biomaterials and Medical Devices - Sophie Lerouge 2012-09-27

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

Clinical Research in Oral Health - William V. Giannobile 2009-12-09

Clinical Research in Oral Health surveys the essentials of clinical research in oral health, anchoring these principles within the specific context of the oral health arena. Addressing research questions exclusively applicable to dentistry and oral health, the book thoroughly illustrates the principles and practice of oral health clinical research. Clinical Research in Oral Health also clarifies the framework of regulatory issues and presents emerging concepts in clinical translation, relating the research principles to clinical improvement.

Pharmaceutical Microbiology Glossary - Dr Tim Sandle 2013-09-08

An A-Z of pharmaceutical microbiology terms and definitions. This book relates to pharmaceuticals, healthcare and contamination control. The book will appeal to the student and as a reference guide for the more experienced professional.

Medical Technology Management Practice - Anthony Y. K. Chan 2003

Such readers may include but are not limited to health administrators, technology planners, biomedical engineers and technologists, and supervisors and managers of technology-intensive departments."--BOOK JACKET.

Perioperative Standards and Recommended Practices - Aorn 2011-01-01

This concise reference provides definitions of scope of practice and recommended practices. the recommended practices section is very specific and includes

information on aseptic practice, equipment and product safety, patient care, and sterilization and disinfection. It gives clear concise direction to promote optimal patient care. It also has a comprehensive section with a wide collection of sample policy and procedure documents, customizable to an individual facility to assist in compliance with accreditation standards.

Sterile Services Department - NHS Estates 2004

Provides guidance to help health planners, estates and facilities managers, sterile services managers and capital planning and design teams to plan and design a sterile services department. It discusses the objectives of a sterile services department (SSD) and service requirements, particularly focusing on: raising standards in decontamination services by optimising the built environment: service requirements strategy: calculating the optimum capacity of an SSD to eradicate bottlenecks: determining the most appropriate location of an SSD. Design guidance based on the above service objectives is outlined. Finally, the finer details of the individual spaces within an SSD are discussed.

The Secret Life of Germs - Philip M. Tierno 2004-01-06

Traces the history of germs, discussing how germs have been viewed and treated throughout time and explains why germs now pose an even greater risk to mankind than ever before.

Sterilization Manual for Health Centers - Silvia I. Acosta-Gnass 2010

This updated sterilisation manual informs health workers about the simple protocols and procedures that have been developed to prevent hospital-acquired infections both inside and outside the sterilisation plant. The guidelines included in this manual show the steps to follow

in cleaning, preparing, sterilizing, storing and transporting hospital equipment so as to obtain sterile material. It is very important to be aware of this information in order to provide patients with safe health care.

Assurance of Sterility for Sensitive Combination Products and Materials - Byron J. Lambert 2019-12-12

Assurance of Sterility for Sensitive Combination Products and Materials: New Paradigms for the Next Generation of Medical Devices and Pharmaceuticals discusses the medical device industry and existing challenges regarding the exciting new world of sensitive combination products (SCPs) and their terminal sterilization. This book reassesses the current assumptions to assure the patient's best interests are met in the development of increasingly rigorous sterilization methods used to counteract MRSA and other 'super-bugs'. In addition, the book discusses the special challenges faced with implantable medical devices, sterilization requirements and further methods needed for material selection and the design process. This book is unique in taking a holistic, end-to-end approach to sterilization, with a particular focus on materials selection and product design. Introduces sterilization principles at the material selection and design stages Addresses the industry need for new sterilization processes for new medical devices and biomaterials Provides guidance to select the appropriate sterilization technique for newly developed sensitive combination products Examines forward thinking tactics for matching new developments in material compatibility with possible regulatory and QSR strategies

Guidelines for Design and Construction of Hospital and

Health Care Facilities - AIA Academy of Architecture for Health 2001

Reflecting the most current thinking about infection control and the environment of care, this new edition also explores functional, space, and equipment requirements for acute care and psychiatric hospitals; nursing, outpatient, and rehabilitation facilities; mobile health care units; and facilities for hospice care, adult day care, and assisted living. [Editor, p. 4 cov.]

Managing Medical Devices within a Regulatory Framework - Beth Ann Fiedler 2016-09-10

Managing Medical Devices within a Regulatory Framework helps administrators, designers, manufacturers, clinical engineers, and biomedical support staff to navigate worldwide regulation, carefully consider the parameters for medical equipment patient safety, anticipate problems with equipment, and efficiently manage medical device acquisition budgets throughout the total product life cycle. This contributed book contains perspectives from industry professionals and academics providing a comprehensive look at health technology management (HTM) best practices for medical records management, interoperability between and among devices outside of healthcare, and the dynamics of implementation of new devices. Various chapters advise on how to achieve patient confidentiality compliance for medical devices and their software, discuss legal issues surrounding device use in the hospital environment of care, the impact of device failures on patient safety, methods to advance skillsets for HTM professionals, and resources to assess digital technology. The authors bring forth relevant challenges and demonstrate how management can foster increased clinical and non-clinical

collaboration to enhance patient outcomes and the bottom line by translating the regulatory impact on operational requirements. Covers compliance with FDA and CE regulations, plus EU directives for service and maintenance of medical devices Provides operational and clinical practice recommendations in regard to regulatory changes for risk management Discusses best practices for equipment procurement and maintenance Provides guidance on dealing with the challenge of medical records management and compliance with patient confidentiality using information from medical devices

Good Hospital Practice - 1988

Training Manual for Health Care Central Service Technicians - ASHCSP (American Society for Healthcare Central Services Professionals) 2006-02-17

The Training Manual is the premier reference and review publication for individuals preparing for examinations given by The Certification Board for Sterile Processing and Distribution. It is a concise, applicable tool that can be used for orientation, training, and instructional programs in health care facilities and in institutions for learning. The Fifth Edition of the manual is the largest and most comprehensive to date.

Laparoscopic Cholecystectomy - Michael Jugenheimer 2009-01-09

The Operation Primer provides excellent photographic step-by-step guidance to the surgical procedure. It has been produced to describe the operation in the simplest manner possible without over-symplifying. The core of the Operation Primer is the section on the Nodal Points where the surgical key steps are described in detail. This surgical guide book proves essential reference material to surgeons wishing to update in this specific area. The Operation Primer

Laparoscopic Cholecystectomy provides one means of understanding and learning the now largely standardized procedure of laparoscopic cholecystectomy through a series of clearly defined individual steps (the so-called Nodal Points). Following this systematic procedure is an important step towards the avoidance of complications.

ANSI/AAMI St79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities - Aami 2013-10-01

The AAMI recommended practice, Comprehensive guide to steam sterilization and sterility assurance in health care facilities, is a breakthrough standard in terms of its scope. AAMI has updated ST79 with the release of ST79:2010/A4:2013. Of particular importance, A4:2013 provides four new figures demonstrating the wrapping of items for steam sterilization and adds an annex focused on Moisture assessment. As of Oct. 25, 2013, purchasers of ST79 will receive ANSI/AAMI ST79:2010 and A1:2010 and A2:2011 and A3:2012 and A4:2014 as a single consolidated document. Among other changes from the 2006 edition of ST79, this revised and expanded second edition of ST79 includes guidance on the use and application of Class 6 emulating indicators, a chemical monitoring device fairly new to the United States. Because ST79 essentially consolidates five AAMI steam sterilization standards (whose content was reviewed and updated to reflect current good practice prior to being incorporated into ST79), it truly is a comprehensive guideline for all steam sterilization activities in healthcare facilities, regardless of the size of the sterilizer or the size of the facility, and provides a resource for all healthcare personnel who use steam for sterilization.

Biocompatibility and Performance of Medical Devices - Jean-Pierre Boutrand 2019-11-21
Biocompatibility and Performance of Medical Devices, Second Edition, provides an understanding of the biocompatibility and performance tests for ensuring that biomaterials and medical devices are safe and will perform as expected in the biological environment. Sections cover key concepts and challenges faced in relation to biocompatibility in medical devices, discuss the evaluation and characterization of biocompatibility in medical devices, describe preclinical performance studies for bone, dental and soft tissue implants, and provide information on the regulation of medical devices in the European Union, Japan and China. The book concludes with a review of histopathology principles for biocompatibility and performance studies. Presents diverse insights from experts in government, industry and academia Delivers a comprehensive overview of testing and interpreting medical device performance Expanded to include new information, including sections on managing extractables, accelerating and simplifying medical device development through screening and alternative biocompatibility methods, and quality strategies which fasten device access to market

Central Service Technical Manual - IAHCSMM 2016-01-01

Small Steam Sterilizers - British Standards Institute Staff 1914-12-31
Test methods, Medical equipment, Equipment safety, Sterilizers, Dental equipment, Steam sterilizers, Performance, Sterilization (hygiene)

Consultants and Consulting Organizations Directory - Janice W. McLean 1988
Indexes are arranged by

geographic area, activities, personal name, and consulting firm name.

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.

Sterile Product Development - Parag Kolhe 2013-10-12

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.

Standard Test Methods for Metal Powders and Powder - 2012

Healthcare Sterilisation - Wayne J Rogers 2014-06-09

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?

A Practical Guide to Decontamination in Healthcare - Gerald McDonnell 2012-05-17
Prevention is the first line of defence in the fight againstinfection. As antibiotics and other antimicrobials encounterincreasing reports of microbial resistance, the field ofdecontamination science is undergoing a major revival. APractical Guide to Decontamination in Healthcare is acomprehensive training manual, providing practical guidance on allaspects of decontamination including: microbiology and infectioncontrol; regulations and standards; containment, transportation,handling, cleaning, disinfection and sterilization of patient useddevices; surgical instrumentation; endoscopes; and qualitymanagement systems. Written by highly experienced professionals, A PracticalGuide to Decontaminationin Healthcare comprises asystematic review of decontamination methods, with uses andadvantages outlined for each. Up-to-date regulations,standards and guidelines are incorporated throughout, to betterequip healthcare professionals with the information they need tomeet the technical and operational challenges of medicaldecontamination. A Practical Guide to Decontaminationin Healthcareis an important new volume on state-of-the-art decontaminationprocesses and a key reference source for all healthcareprofessionals working in infectious diseases, infectioncontrol/prevention and decontamination services.
Federal Register - 2012-03

Decontamination in Hospitals and Healthcare - Jimmy Walker 2014-02-13
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

Guidelines for Design and Construction of Hospitals and Outpatient Facilities 2014 - Facility Guidelines Institute 2014-01-01

This product of the Facility Guidelines Institute (FGI) provides minimum standards for design and construction of hospitals and outpatient facilities. The standards for long- term care facilities will appear in a new document for 2014; please see the entry for Guidelines for Design and Construction of Residential Health, Care, and Support Facilities. Included in the Guidelines for Hospitals and Outpatient Facilities is information on the planning, design, construction, and commissioning process and facility requirements for both hospitals and outpatient facilities. Included are general hospitals, psychiatric hospitals, and rehabilitation facilities as well as new chapters on children's and critical access hospitals. Outpatient facilities covered include primary care facilities; outpatient surgery facilities; birth centers; urgent care centers; mobile units; outpatient psychiatric and rehabilitation centers; facilities for endoscopy, dialysis, and cancer treatment; and a new chapter on dental facilities. In addition, the 2014 Guidelines includes new material on safety risk assessments and medication safety zones; increased requirements for commissioning infrastructure systems; and updated requirements for surgery, imaging, endoscopy, and dialysis facilities as well as primary care facilities and freestanding emergency facilities.

X-ray Repair - Joseph J. Panichello 2005

"This unique book is intended to be used as a field guide and reference manual for field service engineers and in-house biomedical engineers when servicing radiographic equipment. The text is further enhanced with many helpful illustrations and charts. In addition to serving as a universal manual for x-ray service and biomedical engineers, the book will also be valuable to radiologists and radiology administrators."--BOOK JACKET.Title Summary field provided by Blackwell North America, Inc.