Iso 17665

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Moist Heat. Guidance on the application of ISO 17665-1. Directives relatives à l'application de l'ISO 17665-1

SOLIS WESTON

CRC Press
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
Guidance on the Application of ISO 17665-1 Woodhead Publishing
The new edition of this established and highly respected text is THE definitive reference in its field. It details methods for the elimination or prevention/control of microbial growth, and features: New chapters on bioterrorism and community healthcare New chapters on microbicide regulations in the EU, USA and Canada Latest material on microbial resistance to microbicides Updated material on new and emerging technologies, focusing on special problems in hospitals, dentistry and pharmaceutical practice Practical advice on problems of disinfection and antiseptics in healthcare A systematic review of sterilization methods, with uses and advantages outlined for each Evaluation of disinfectants and their mechanisms of action with respect to current regulations The differences between European and North American regulations are highlighted throughout, making this a truly global work, ideal for worldwide healthcare professionals working in infectious diseases and infection control.
Two Volume Set Woodhead Publishing
With this book, you get a really complete seminar for the new Regulations on medical devices and IVDs in the EU, ready at hand, at any time. These EU regulations create new rules for medical technology and laboratory diagnostics in Europe. Concise regulatory know-how is now required to keep or reposition medical devices and in vitro diagnostics on the European market, from syringes, contact lenses, medical device apps, pregnancy tests, nuclear magnetic resonance tomography to cancer tests, genetic diagnostics, HIV tests, hip implants, heart catheters, artificial spinal discs, stents and pacemakers. Concise regulatory training and further education of employees in companies and health care facilities is the order of the day. This also applies to biomedical and medical technology students at universities of applied sciences and biomedical universities, start-ups and spin-offs, who must make use of this know-how from the initial product idea through the further stages of product development to market access. The book provides a thorough, compact course on the new regulations, starting with perfect overview and easy navigation and going into depth where you need it: this book will make you fit and confident for the new European challenges! 344 pages; 47 col. figures; 26 tables
Innovation from Concept to Market Elsevier Health Sciences
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
BioSensing, Theranostics, and Medical Devices CRC Press
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.
Sterilization of Health Care Products CRC Press
This second updated edition of the Encyclopaedia of Medical Physics contains over 3300 cross-referenced entries related to medical physics and associated technologies. The materials are supported by over 1300 figures and diagrams. The Encyclopaedia also includes over 600 synonyms, abbreviations and other linked entries. Featuring over 100 contributors who are specialists in their respective areas, the encyclopaedia describes new and existing methods and equipment in medical physics. This all-encompassing reference covers the key areas of x-ray diagnostic radiology, magnetic resonance imaging (MRI), nuclear medicine, ultrasound imaging, radiotherapy, radiation protection (both ionising and non-ionising) as well as related general terms. It has been updated throughout to include the newest technologies and developments in the field, such as proton radiotherapy, phase contrast imaging, multi-detector computed tomography, 3D/4D imaging, new clinical applications of various imaging modalities, and the relevant regulations regarding radiation protection and management. Features: Contains over 3300 entries with accompanying diagrams, images, formulas, further reading, and examples Covers both the classical and newest elements in medical imaging, radiotherapy, and radiation protection Discusses material at a level accessible to graduate and postgraduate students in medical physics and related disciplines as well as medical specialists and researchers
Medical devices - Quality management systems - Guidance on the application of YY/T 0287-2017 [After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net] John Wiley & Sons
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.

3D Printing for the Radiologist, E-Book CRC Press

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.

Medical Devices and IVDs Elsevier

The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 exam Body of Knowledge (BoK) and reference list for ASQ□s Certified Biomedical Auditor program. It includes updates and corrections to errors and omissions in the second edition. Most notably it has been re-organized to align more closely with the BoK.

Fit for the new EU-Regulations: Your complete seminar for projekt, study and job Springer Nature

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.

Medical Device Design Academic Press

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?

Sterilisation of Health Care Products - Moist Heat Elsevier

Medical equipment, Sterilization (hygiene), Steam, Verification, Quality control, Quality assurance, Acceptance (approval), Installation, Performance, Maintenance, Personnel, Medical instruments, Sterilizers, Steam sterilizers

Artech House

This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.

Bioresorbable Polymers for Biomedical Applications Academic Press

Bioresorbable Polymers for Biomedical Applications: From Fundamentals to Translational Medicine provides readers with an overview of bioresorbable polymeric materials in the biomedical field. A useful resource for materials scientists in industry and academia, offering information on the fundamentals and considerations, synthesis and processing, and the clinical and R and D applications of bioresorbable polymers for biomedical applications. Focuses on biomedical applications of bioresorbable polymers Features a comprehensive range of topics including fundamentals, synthesis, processing, and applications Provides balanced coverage of the field with contributions from academia and industry Includes clinical and R and D applications of bioresorbable polymers for biomedical applications

Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices ; First Edition (ISO 17665-1 - 2006-08-15) Academic Press

Microbiological matters continue to exercise considerable influence on product quality. In both the pharmaceutical and medical device industries, products of greater sophistication, along with evolving regulatory requirements, are elevating the challenges related to maintaining microbiological integrity. Updated to reflect technological and regulatory changes, the Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition covers thoseprincipal aspects of microbiology that arerelevant to the preformulation, formulation, manufacturing, and license application stages involved with the production of pharmaceuticals and medical devices. In recognition of the diverse disciplines involved in pharmaceutical and medical device production, this work provides a brief introduction to microbiology geared towards the nonmicrobiologist. Covering good manufacturing practice in the control of contamination, the text explores quality control, the preservation of formulations, and principles of sterilization, including microbiological-specific considerations for biotechnological products and other medical devices. It also provides additional materials on package integrity and contamination risks in clean rooms. The editors have produced a companion text, the Handbook of Microbiological Quality Control in Pharmaceuticals and Medical Devices (see reverse), which when paired with the Guide offers a complete theoretical and practical treatment of microbiological control. This book provides a comprehensive distillation of information concerning methodology and regulations that would otherwise remain scattered throughout the literature. It allows scientists from many fields to address potential problems in advance and implement suitable strategies at the earliest stages of development.

Sterilization of Health Care Products ISO 17665-1:2006(E)Sterilization of Health Care ProductsMoist Heat. Guidance on the application of ISO 17665-1. Directives relatives à l'application de l'ISO 17665-1Sterilization of Health Care Products - Moist HeatRequirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices ; First Edition (ISO 17665-1 - 2006-08-15)Sterilization of Health Care Products - Moist HeatGuidance on the Application of ISO 17665-1A Practical Guide to Decontamination in Healthcare

The revised edition of the renowned and bestselling title is the most comprehensive single text on all aspects of biomaterials science from principles to applications. Biomaterials Science, fourth edition, provides a balanced, insightful approach to both the learning of the science and technology of biomaterials and acts as the key reference for practitioners who are involved in the applications of materials in medicine. This new edition incorporates key updates to reflect the latest relevant research in the field, particularly in the applications section, which includes the latest in topics such as nanotechnology, robotic implantation, and biomaterials utilized in cancer research detection and therapy. Other additions include regenerative engineering, 3D printing, personalized medicine and organs on a chip. Translation from the lab to commercial products is emphasized with new content dedicated to medical device development, global issues related to translation, and issues of quality assurance and reimbursement. In response to customer feedback, the new edition also features consolidation of redundant material to ensure clarity and focus. Biomaterials Science, 4th edition is an important update to the best-selling text, vital to the biomaterials’ community. The most comprehensive coverage of principles and applications of all classes of biomaterials Edited and contributed by the best-known figures in the biomaterials field today; fully endorsed and supported by the Society for Biomaterials Fully revised and updated to address issues of translation, nanotechnology, additive manufacturing, organs on chip, precision medicine and much more. Online chapter exercises available for most chapters

Biomedical Product and Materials Evaluation CRC Press

The fifth edition of this classic text is the definitive, clinically orientated guide to a critical area within healthcare practice, full of sound, practical advice for all those involved in the control of infection in a variety of settings. Known in previous editions as Control of Hospital Infection, the new Ayliffe's Control of Healthcare-Associated Infection has again been brought up to date and thoroughly revised to emphasise the broader range of its coverage, from the hospital setting - including the ward, operating theatres, kitchens and laundry facilities - to health care provision in the community. Returning readers will find that the content has also been restructured, improving access to related topics. Part One discusses the basic principles of infection control, including administrative issues, surveillance and reporting, sterilization, disinfection and decontamination, with an emphasis on the key area of hand hygiene. Part Two covers the specific areas of prophylaxis and treatment of infections. In Part Three prevention in different healthcare settings is presented, including issues particular to special wards and departments such as paediatric and neonatal units, intensive care, the elderly and those being treated or working within allied health areas such as x-ray, physiotherapy and the laboratory setting. Ayliffe's Control of Healthcare-Associated Infection remains essential reading for all infection control practitioners, nurses, doctors, surgeons, allied health professionals, hospital managers and administrators, and public health personnel.

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals George Mc Guire

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

From Laboratory to Point-of-Care Testing BoD – Books on Demand

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.

Moist Heat. Guidance on the application of ISO 17665-1 Smithers Rapra

Biomedical Product and Materials Evaluation: Standards and Ethics provides a much-needed overview of the procedures, issues, standards and ethical issues in the early development of biomedical products. The book covers a range of key biomedical products, from 3D printed organs and blood derived products, to stem calls and decellularized tissue products. Each chapter reviews a single product type, associated materials, biomedical applications, proven development strategies, and potential challenges. The core focus of the book is on the standardization and ethical aspects of biomedical product development, with these elements addressed and discussed in chapters dedicated to product evaluation. This is a useful reference for academics, researchers and industry professionals in R&D groups with an interest in biomaterial research and production, as well as those working in the fields of biomedical engineering, biotechnology and toxicology. Covers a variety of biomedical products, including specific biomaterials, organs-on-chips, wound care products, combinational products, and more Delves into strategies and considerations for product evaluation,

including cytotoxicity assays, microbial and blood compatibility studies Discusses standardization and ethical hurdles in biomedical product development and how to overcome them

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