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Electrospinning
Handbook of Paper and Paperboard Packaging Technology
YY/T 1511-2017 Translated English of Chinese Standard. (YYT 1511-2017, YY/T1511-2017, YYT1511-2017)
Biomedical Product and Materials Evaluation
Diagnostic target product profiles for monitoring and evaluation of soil-transmitted helminth control programs
YY/T 0326-2017 Translated English of Chinese Standard. (YYT 0326-2017, YY/T0326-2017, YYT0326-2017)
Protective Packaging for Distribution
Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals
Plastics in Medical Devices
Packaging for Terminally Sterilized Medical Devices
Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1: 2006)
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Assurance of Sterility for Sensitive Combination Products and Materials
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Silk-Based Biomaterials for Tissue Engineering, Regenerative and Precision Medicine
A Practical Guide to Decontamination in Healthcare
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Tactile Sensing and Displays
Implantable Sensor Systems for Medical Applications
Trends in Development of Medical Devices
Healthcare Sterilisation
Biomedical Engineering & Design Handbook, Volumes I and II
The Biomedical Quality Auditor Handbook, Third Edition
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Guide to Microbiological Control in Pharmaceuticals and Medical Devices, Second Edition
The ASQ Certified Medical Device Auditor Handbook
The Combination Products Handbook
Federal Register
Decontamination in Hospitals and Healthcare
In Situ Tissue Regeneration
Medical Device Regulatory Practices
WHO Expert Committee on Specifications for Pharmaceutical Preparations

SHARP RODGERS

Electrospinning Woodhead Publishing 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.

Handbook of Paper and Paperboard Packaging Technology Royal Society of Chemistry

The ASQ Certified Medical Device Auditor Handbook (formerly The Biomedical Quality Auditor Handbook) was developed by the ASQ Medical Device Division (formerly Biomedical Division) in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the medical device community. It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor (CMDA) certification exam. The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge (BoK) and reference list. The combination of this handbook with other reference materials can provide a well-rounded background in medical device auditing. Updates to this edition include: • A discussion of data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP) • Current information about federal and international regulations • New content regarding human factors and usability engineering, general safety and performance requirements, labeling, validation, risk management, and cybersecurity considerations • A thorough explanation of quality tools and techniques

YY/T 1511-2017 Translated English of Chinese Standard. (YYT 1511-2017, YY/T1511-2017, YYT1511-2017) World Health Organization

This Standard specifies performance requirements and test methods of collagen sponge. This Standard is applicable to sterile collagen sponge. This Standard is not applicable to sponge prepared with genetically engineered collagen and collagen sponge that contains other materials.

Biomedical Product and Materials Evaluation McGraw Hill Professional

Plastics in Medical Devices: Properties, Requirements, and Applications, Third Edition provides a comprehensive overview on the main types of plastics used in medical device applications. The book focuses on the applications and properties that are most important in medical device design, such as chemical resistance, sterilization capability and biocompatibility. The roles of additives, stabilizers and fillers as well as the synthesis and production of polymers are covered and backed up with a wealth of data tables. The book also covers other key aspects in detail, including regulations, compliance, purchasing controls and supplier controls, and process validation. This updated edition has been thoroughly revised with regard to new plastic materials, applications and requirements. This is a valuable resource for engineers, scientists and managers involved in the design and manufacture of medical devices. Presents detailed coverage of commercially available plastics used in medical device applications, organized by polymer type

and supported by data Includes up-to-date regulatory requirements and practical information on purchasing and supplier controls, process validation and risk management Supports the development, marketing and commercialization of medical devices and materials for use in medical devices

Diagnostic target product profiles for monitoring and evaluation of soil-transmitted helminth control programs Academic Press

The definitive industry reference on the paper and paperboard packaging sector. Now in a fully revised and updated second edition, this book discusses all the main types of packaging based on paper and paperboard. It considers the raw materials, the manufacture of paper and paperboard, and the basic properties and features on which packaging made from these materials depends for its appearance and performance. The manufacture of twelve types of paper- and paperboard-based packaging is described, together with their end-use applications and the packaging machinery involved. The importance of pack design is stressed, as well as how these materials offer packaging designers opportunities for imaginative and innovative design solutions. Environmental factors, including resource sustainability, societal and waste management issues are addressed in a dedicated chapter. The book is directed at readers based in companies which manufacture packaging grades of paper and paperboard, companies involved in the design, printing and production of packaging, and companies which manufacture inks, coatings, adhesives and packaging machinery. It will be essential reading for students of packaging technology and technologists working in food manufacturing who are users of paper and paperboard packaging products. Praise for the First Edition 'This book is a valuable addition to the library of any forward-looking company by providing in-depth coverage of all aspects of packaging which involve the most ecologically acceptable material, namely paper and paperboard.'—International Journal of Dairy Technology '...a welcome contribution to a field where coverage was previously limited to subject-specific books... or to single chapters in textbooks on broader aspects of packaging technology.'—Packaging Technology and Science

YY/T 0326-2017 Translated English of Chinese Standard. (YYT 0326-2017, YY/T0326-2017, YYT0326-2017) Smithers Rapra

This book introduces innovative and interdisciplinary applications of advanced technologies. Featuring the papers from the 10th DAYS OF BHAAAS (Bosnian-Herzegovinian American Academy of Arts and Sciences) held in Jahorina, Bosnia and Herzegovina on June 21–24, 2018, it discusses a wide variety of engineering and scientific applications of the different techniques. Researchers from academic and industry present their work and ideas, techniques and applications in the field of power systems, mechanical engineering, computer modelling and simulations, civil engineering, robotics and biomedical engineering, information and communication technologies, computer science and applied mathematics.

Protective Packaging for Distribution Elsevier

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

According to the US Food and Drug Administration (FDA), “a combination product is one composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device and a biological product.” Examples include prefilled syringes, pen injectors, autoinjectors, inhalers, transdermal delivery systems, drug-eluting stents, and kits containing drug administration devices co-packaged with drugs and/or biological products. This handbook provides the most up-to-date information on the development of combination products, from the technology involved to successful delivery to market. The authors present important and up-to-the-minute pre- and post-market reviews of international combination product regulations, guidance, considerations, and best practices. This handbook: Brings clarity of understanding for global combination products guidance and regulations Reviews the current state-of-the-art considerations and best practices spanning the combination product lifecycle, pre-market through post-market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors. Endorsed by AAMI – Association for the Advancement of Medical Instrumentation.

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals Quality Press

This book is intended to serve as a reference for professionals in the medical device industry, particularly those seeking to learn from practical examples and case studies. Medical devices, like pharmaceuticals, are highly regulated, and the bar is raised constantly as patients and consumers expect the best-quality healthcare and safe and effectiv

Plastics in Medical Devices Lippincott Williams & Wilkins

Trends in Development of Medical Devices covers the basics of medical devices and their development, regulations and toxicological effects, risk assessment and mitigation. It also discusses the maintenance of a medical device portfolio during product lifecycle. This book provides up-to-date information and knowledge on how to understand the position and benefits of new introduced medical devices for improving healthcare. Researchers and industry professionals from the fields of medical devices, surgery, medical toxicology, pharmacy and medical devices manufacture will find this book useful. The book's editors and contributors form a global, interdisciplinary base of knowledge which they bring to this book. Provides a roadmap to medical devices development and the integration of manufacturing steps to improve workflows Helps engineers in medical devices industries to anticipate the special requirements of this field with relation to biocompatibility, sterilization methods, government regulations Presents new strategies that readers can use to take advantage of rapid prototyping technologies, such as 3D printing, to reduce imperfections in production and develop products that enable completely new treatment possibilities

Packaging for Terminally Sterilized Medical Devices John Wiley & Sons

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

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1: 2006) William Andrew

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.

Block’s Disinfection, Sterilization, and Preservation John Wiley & Sons

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

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition Springer Nature

Covers chemistry, physics, engineering, and therapeutic aspects of packaging—universal to pharmaceutical, medical, and food applications This book covers the chemistry, physics, materials science, engineering, and therapeutic aspects of many different types of packaging materials, emphasizing throughout the applicability of various aspects of packaging science and technology. It also provides a simultaneous discussion of interrelated fields, and addresses the universal issues within these fields' application areas. Intended as a technical reference and as a study aid, it is relevant to anyone who studies or uses packaging or packaging materials. Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications begins with an overview of the history of the topic. It then offers chapters on the methods of obtaining raw materials, the chemistry of polymeric and non-polymeric packaging materials, physico-chemical quality parameters, and the manufacturing of packaging. Other topics look at: additives, use, suppliers, safety and environmental concerns, regulation, anti-fraud activities, new trends, and the future of packaging technology. The book also features numerous problems and worked solutions to aid student comprehension. Covers packaging and packaging materials, their properties and technologies Addresses the chemical engineering, physics, and chemistry of packaging materials, and the individual requirements for food, pharmaceutical, and medical device packaging Includes current issues such as environmental concerns and sustainability, recycling and after-use, anti-counterfeiting technology, and packaging regulations and guidelines Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications will appeal to all packaging technologists, scientists, and engineers in industry, and in regulatory agencies. It is also an excellent book for advanced students studying packaging courses, within pharmacy, pharmaceutical sciences, chemical sciences, biomedical sciences, medical sciences, engineering, product design and technology, and food science/technology.

Assurance of Sterility for Sensitive Combination Products and Materials CRC Press
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
UNE-EN ISO 11607-2:2017 CRC Press
This Standard specifies the requirements for plasmapheresis centrifuge apparatus for single use (hereinafter referred to as centrifuge apparatus) to ensure that it is compatible with the matching centrifugal automatic plasma collection machine. The plasma collected and stored by the centrifuge apparatus specified in this Standard is used for the preparation of blood products and cannot be used for clinical blood transfusion.
Silk-Based Biomaterials for Tissue Engineering, Regenerative and Precision Medicine https://www.chinesestandard.net
Silk-based Biomaterials for Tissue Engineering, Regenerative and Precision Medicine, Second Edition is a must-have reference, providing comprehensive coverage of silk-based biomaterials and their importance in translational uses and biomedicine. This new edition considers the progress made in the past eight years, featuring many new chapters, including a discussion of cutting-edge fabrication methods and techniques, new and improved blends/composites, and an expanded range of applications in tissue engineering, regenerative and precision medicine. The book holistically reviews the types, structure and properties, processing methods, and specific biomedical applications for silk-based biomaterials. This will be a vital resource for materials and tissue engineering scientists, R&D departments in industry and academia, and academics interested in biomaterials, regenerative, and precision medicine. Covers all key silk biomaterial types, including mulberry, Bombyx mori and nonmulberry/wild silk protein fibroins, sericins and spider silk, as well as their composite blends and various structures and scaffold platforms Describes the cutting-edge processing techniques for each silk type, from traditional to nonconventional methods, such as using ionic liquids and engineering nanofibers and other biomedical matrices Explores a

range of applications in tissue engineering and regenerative and precision medicine, including bioprinting, bioelectronics and medical devices

A Practical Guide to Decontamination in Healthcare Academic Press

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.

YY/T 0698.2-2009 Translated English of Chinese Standard. (YYT 0698.2-2009, YY/T0698.2-2009, YYT0698.2-2009) McGraw Hill Professional

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?

Medical Devices and In Vitro Diagnostics https://www.chinesestandard.net

This Part of YY/T 0698 provides test methods and values for materials for preformed sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

Biomedical Engineering and Design Handbook, Volume 2 Elsevier

Electrospinning is a technique used to produce nanofibres from a polymer solution using an electrostatic force. The technology is now being used to create materials for a wide variety of uses from tissue engineering and 3D printing to packaging materials and electronic sensors. This new book focusses on the recent developments in their design, process parameters and polymers-selection to enable the commercial applications of electrospinning. The initial chapters introduce the technique and then specific chapters focus on the different application areas showing the various approaches for successful implementation of this fabrication process towards commercialization from basic research and development. The book will be suitable for graduate students, academics and industrial entrepreneurs in materials science, polymer science and chemical

engineering as well as those interested in the energy and health applications of the materials.

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