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AIDAN MELISSA

Applied Human Factors in Medical Device Design Pan Amer Health Org Contextual Inquiry for Medical Device Design helps users understand the everyday use of medical devices and the way their usage supports the development of better products and increased market acceptance. The text explains the concept of contextual inquiry using real-life examples to illustrate its application. Case studies provide a frame of reference on how contextual inquiry is successfully used during product design, ultimately

producing safer, improved medical devices. Presents the ways contextual inquiry can be used to inform the evaluation and business case of technology Helps users understand the everyday use of medical devices and the way their usage supports the development of better products Includes case studies that provide a frame of reference on how contextual inquiry is successfully used during the product design process *Disposable Bioprocessing Systems* CRC Press Written by a researcher with experience designing, establishing, and validating biological manufacturing facilities worldwide, this is the first comprehensive introduction to disposable systems for biological drug manufacturing. It reviews the current state of the industry; tackles questions about safety, costs, regulations, and waste disposal; and guides readers to choose disposable components that meet their needs. This practical manual covers disposable containers, mixing systems, bioreactors, connectors and transfers, controls and sensors, downstream processing systems, filling and finishing systems, and filters. The

author also shares his predictions for the future, calling disposable bioprocessing technology a "game changer."

Medical Device Regulatory Practices

Springer Nature

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

Sterilization of Medical Devices

Washington Business Information

Surgical site infections are caused by bacteria that get in through incisions made during surgery. They threaten the lives of millions of patients each year and contribute to the spread of antibiotic resistance. In low- and middle-income countries, 11% of patients who undergo

surgery are infected in the process. In Africa, up to 20% of women who have a caesarean section contract a wound infection, compromising their own health and their ability to care for their babies. But surgical site infections are not just a problem for poor countries. In the United States, they contribute to patients spending more than 400 000 extra days in hospital at a cost of an additional US $10 billion per year. No international evidence-based guidelines had previously been available before WHO launched its global guidelines on the prevention of surgical site infection on 3 November 2016, and there are inconsistencies in the interpretation of evidence and recommendations in existing national guidelines. These new WHO guidelines are valid for any country and suitable to local adaptations, and take account of the strength of available scientific evidence, the cost and resource implications, and patient values and preferences. *The Books of Samuel* CRC Press
This recommended practice provides guidelines for the selection and use of liquid chemical sterilants (LCSs)/high-

level disinfectants (HLDs) and gaseous chemical sterilizers that have been cleared for marketing by the U.S. Food and Drug Administration for use in hospitals and other health care facilities. Included within the scope of this recommended practice are functional and physical design criteria for chemical sterilization and high-level disinfection processing areas; staff qualifications, education, and other personnel considerations ; criteria for selecting LCSs/HLDs and gaseous chemical sterilizers; safety and efficacy considerations in the use of LCSs/HLDs and gaseous chemical sterilizers; preparation of devices for processing by chemical sterilization or high-level disinfection; quality control methods; and quality process improvement. Definitions of terms and informative annexes are also provided.

Modern Textile Characterization Methods Elsevier

Stringent regulations require you to validate sterilization processes and step-by-step guidelines are needed to develop and implement a suitable validation program. Sterilization Validation and Routine Operation Handbook: Ethylene Oxide is the best practical guide available for the validation

of EtO process. The information provided complies with ANSI/AAMI/ISO 11135: 1994, Medical devices- Validation and routine control of ethylene oxide sterilization which is based on a standard developed by the European Standardizatio n Committee (CEN) entitled EN 550, Sterilization of medical devices- Validation and routine control of ethylene oxide sterilization. The text defines methods to assist you in the interpretation and understanding of the requirements in the standard and offers logical procedures for the validation and routine monitoring of your specific ethylene oxide process.

Validation of Pharmaceutic al Processes

Association for the Advancement of Medical Instrumentatio n (AAMI) UHMWPE Biomaterials Handbook describes the science, development, properties and application of of ultra-high molecular weight polyethylene (UHMWPE) used in artificial joints. This material is currently used in 1.4 million patients around the world every year for use in the hip, knee, upper extremities, and spine. Since the publication of the 1st edition there have been major advances in the development and clinical adoption of

highly crosslinked UHMWPE for hip and knee replacement. There has also been a major international effort to introduce Vitamin E stabilized UHMWPE for patients. The accumulated knowledge on these two classes of materials are a key feature of the 2nd edition, along with an additional 19 additional chapters providing coverage of the key engineering aspects (biomechanical and materials science) and clinical/biological performance of UHMWPE, providing a more complete reference for industrial and academic materials specialists, and for surgeons and clinicians who require an understanding of the biomaterials properties of UHMWPE to work successfully on patient applications. The UHMWPE Handbook is the comprehensive reference for professionals, researchers, and clinicians working with biomaterials technologies for joint replacement New to this edition: 19 new chapters keep readers up to date with this fast moving topic, including a new section on UHMWPE biomaterials; highly crosslinked UHMWPE for hip and knee replacement; Vitamin E stabilized UHMWPE for patients; clinical performance, tribology an

biologic interaction of UHMWPE State-of-the-art coverage of UHMWPE technology, orthopedic applications, biomaterial characterisation and engineering aspects from recognised leaders in the field Healthcare Sterilisation CRC Press “Companies have been implementing large agile projects for a number of years, but the ‘stigma’ of ‘agile only works for small projects’ continues to be a frequent barrier for newcomers and a rallying cry for agile critics. What has been missing from the agile literature is a solid, practical book on the specifics of developing large projects in an agile way. Dean Leffingwell’s book Scaling Software Agility fills this gap admirably. It offers a practical guide to large project issues such as architecture, requirements development, multi-level release planning, and team organization. Leffingwell’s book is a necessary guide for large projects and large organizations making the transition to agile development.” —Jim Highsmith, director, Agile Practice, Cutter Consortium, author of Agile Project Management “There’s tension between building software fast and delivering software that lasts, between

being ultra-responsive to changes in the market and maintaining a degree of stability. In his latest work, Scaling Software Agility, Dean Leffingwell shows how to achieve a pragmatic balance among these forces. Leffingwell's observations of the problem, his advice on the solution, and his description of the resulting best practices come from experience: he's been there, done that, and has seen what's worked."
—Grady Booch, IBM Fellow Agile development practices, while still controversial in some circles, offer undeniable benefits: faster time to market, better responsiveness to changing customer requirements, and higher quality. However, agile practices have been defined and recommended primarily to small teams. In Scaling Software Agility, Dean Leffingwell describes how agile methods can be applied to enterprise-class development. Part I provides an overview of the most common and effective agile methods. Part II describes seven best practices of agility that natively scale to the enterprise level. Part III describes an additional set of seven organizational capabilities that companies can master to achieve the full benefits of software

agility on an enterprise scale. This book is invaluable to software developers, testers and QA personnel, managers and team leads, as well as to executives of software organizations whose objective is to increase the quality and productivity of the software development process but who are faced with all the challenges of developing software on an enterprise scale.

ANSI/AAMI St79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities Routledge

This book constitutes the proceedings of the Workshops held in conjunction with SAFECOMP 2019, 38th International Conference on Computer Safety, Reliability and Security, in September 2019 in Turku, Finland. The 32 regular papers included in this volume were carefully reviewed and selected from 43 submissions; the book also contains two invited papers. The workshops included in this volume are: ASSURE 2019: 7th International Workshop on Assurance Cases for Software-Intensive Systems DECSoS 2019: 14th ERCIM/EWICS/ARTEMIS Workshop on Dependable Smart Embedded and Cyber-Physical

Systems and Systems-of-Systems SASSUR 2019: 8th International Workshop on Next Generation of System Assurance Approaches for Safety-Critical Systems STRIVE 2019: Second International Workshop on Safety, securiTy, and pRivacy In automotiVe systEms WAISE 2019: Second International Workshop on Artificial Intelligence Safety Engineering

Global Gidelines for the Pevention of Surgical Site Infection Springer Practical information about the complexities of biomedical technology and regulation, and their implications for manufacturers and marketers of health care devices. Written primarily for those in the industry concerned about staying competitive in light of complex and fluctuating regulatory approach The Medical Device Industry CRC Press This book, packed with real-world insights and direct experiences, is for managers who want the benefits of Agile but also must address regulatory compliance, integration of software with other disciplines, and product safety. In it, we combine our understanding of Agile development, hardware/soft

ware integration, and regulatory requirements. We know that Agile is simple but not easy; leadership is crucial to make this change spread. We aim to show how you can navigate the transition.

UHMWPE Biomaterials Handbook Wolters Kluwer India Pvt Ltd

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

Agile Methods for Safety-Critical Systems CRC 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 effective medical technologies. Obtaining marketing authorization is the first major hurdle that med techs need to overcome in

their pursuit of commercial success. Most books on regulatory affairs present regulations in each jurisdiction separately: European Union, USA, Australia, Canada, and Japan. This book proposes practical solutions for a coherent, one-size-fits-all (or most) set of systems and processes in compliance with regulations in all key markets, throughout the life cycle of a medical device. It also contains key information about international harmonization efforts and recent regulatory trends in emerging markets; important terminology needed to understand the regulators' language; and examples, case studies, and practical recommendations that bridge the gap between regulatory theory and practice.

Joining and Assembly of Medical Materials and Devices

Smithers Rapra

The Minipig in Biomedical Research is a comprehensive resource for research scientists on the potential and use of the minipig in basic and applied biomedical research, and the development of drugs and chemicals. Written by acknowledged experts in the field, and drawing on the authors' global contacts and experience with regulatory authorities

and the pharmaceutical and other industries, this accessible manual ranges widely over the biological, scientific, and practical uses of the minipig in the laboratory. Its coverage extends from the minipig's origins, anatomy, genetics, immunology, and physiology to its welfare, health, and husbandry; practical dosing and examination procedures; surgical techniques; and all areas of toxicity testing and the uses of the minipig as a disease model. Regulatory aspects of its use are considered. The reader will find an extensive amount of theoretical and practical information in the pharmacology; ADME and toxicology chapters which will help scientists and managers when deciding which species to use in basic research; drug discovery and pharmacology; and toxicology studies of chemicals, biotechnology products and devices. The book discusses regulatory uses of minipigs in the evaluation of human and veterinary pharmaceuticals, medical devices, and other classes of xenobiotics. It describes features of normal health, normal laboratory values, and common diseases. It also carefully elucidates ethical and legal

considerations in their supply, housing, and transport. The result is an all-inclusive and up to date manual about the experimental uses of the minipig that describes ‘How to’ and ‘Why’ and ’What to expect in the normal’, combining enthusiasm and experience with critical assessment of its values and potential problems.

Sterilization Technology for the Health Care Facility

Woodhead Publishing 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 **Sterilisation of Polymer Healthcare Products** CRC Press The use of polymers in medical devices is growing at a steady rate. These materials are generally relatively cheap and versatile, qualities required in many bulk applications. In more specialised medical devices, polymeric components have been developed to meet challenging property and performance requirements. This review describes the process of developing polymeric products for medical applications from design requirements through to specific examples of medical devices and packaging. An additional indexed section containing

several hundred abstracts from the Rapra Polymer Library database gives useful references for further reading.

Sterilization Manual for Health Centers

Quality Press

As medical devices become more intricate, with an increasing number of components made from a wide range of materials, it is important that they meet stringent requirements to ensure that they are safe to be implanted and will not be rejected by the human body. Joining and assembly of medical materials and devices provides a comprehensive overview of joining techniques for a range of medical materials and applications. Part one provides an introduction to medical devices and joining methods with further specific chapters on microwelding methods in medical components and the effects of sterilization on medical materials and welded devices. Part two focuses on medical metals and includes chapters on the joining of shape memory alloys, platinum (Pt) alloys and stainless steel wires for implantable medical devices and evaluating the corrosion performance of metal medical device welds. Part three moves on to

highlight the joining and assembly of medical plastics and discusses techniques including ultrasonic welding, transmission laser welding and radio frequency (RF)/dielectric welding. Finally, part four discusses the joining and assembly of biomaterial and tissue implants including metal-ceramic joining techniques for orthopaedic applications and tissue adhesives and sealants for surgical applications. Joining and assembly of medical materials and devices is a technical guide for engineers and researchers within the medical industry, professionals requiring an understanding of joining and assembly techniques in a medical setting, and academics interested in this field. Introduces joining methods in medical applications including microwelding and considers the effects of sterilization on the resulting joints and devices Considers the joining, assembly and corrosion performance of medical metals including shape memory alloys, platinum alloys and stainless steel wires Considers the joining and assembly of medical plastics including multiple welding methods, bonding strategies and

adhesives *ANSI/AAMI St58:2013: Chemical Sterilization and High-Level Disinfection in Health Care Facilities* Academic Press This Second Edition is a comprehensive resource on sterilization and disinfection of reusable instruments and medical devices Biocompatibility and Performance of Medical Devices iSmithers Rapra Publishing This work details current advances in assessing the characteristics of polymers, single fibres and fibrous systems, and associated processes based on evolving theories in the physical, chemical and mechanical sciences. It focuses on recent develpments in selected characterization methods - such as Fourier transform infrared spectroscopy, Fourier transform nuclear magnetic resonance, electron diffraction, x-ray diffraction and electron microscopy - applicatble to polymers, fibres and textiles. **Scaling Software Agility** CRC Press The validation and radiation sterilization process for biomaterials and medical devices requires careful planning to ensure regulatory compliance followed by precise accuracy in execution and documentatio

n. This in-depth guide details all steps from prevalidation planning to final report and ongoing monitoring and control. Sterilization Validation & Routine Operation Handbook: Radiation provides a framework for the validation and routine operation of an irradiation sterilization process. The guidance presented complies with ANSI/AAMI/ISO 11137: 1994, Sterilization of health care product-Requirements for validation and routine control-Radiation sterilization and the newly published AAMI substantiation of 25 kGy using VDmax procedure. The author discusses methods to aid in comprehending the requirements in these standards. She also provides practical procedures for the validation and routine monitoring and control of specific gamma and electron beam radiation sterilization processes. Background chapters provide needed information on radiation sterilization technologies, sterilization microbiology, validation approaches and working with a radiation sterilization contractor. Much of the information in this new book is presented in convenient tables and charts, with diagrams and other schematics that simply

illustrate appropriate validation methodologies . Sterilization Validation & Routine Operation Handbook: Radiation brings together in one resource information scattered throughout many documents and will be useful to all those involved in the sterilization of medical materials, drugs and devices.