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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

The field of additive manufacturing is growing dynamically as the interest is persisting from manufacturing sector, including other sectors as well. Conceptually, additive manufacturing is a way to build parts without using any part-specific tooling or dies from the computer-aided design (CAD) file of the part. Second edition of Additive Manufacturing highlights the latest advancements in the field, taking an application oriented approach. It includes new material on traditional polymer based rapid prototyping technologies, additive manufacturing of metals and alloys including related design issues. Each chapter comes with suggested reading, questions for instructors and PowerPoint slides.

Medical Device Design: Innovation from Concept to Market, Second Edition provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones; this book fills that need. It addresses medical devices' regulatory (FDA and EU) requirements, shows the essential methodologies medical designers must understand to ensure their products meet requirements, and brings together proven design protocols, thus enabling engineers and medical device manufacturers to rapidly bring new products to the marketplace. This book is unique because it takes the reader through the process of medical device development, from very early stages of conceptualization, to commercialization on the global market. This rare resource can be used by both professionals and newcomers to device design. Provides a reference to standards and regulations that have been updated, including ISO 13485:2016, FDA regulations and the European Medical Device Regulation Includes new case studies in the areas of classifying medical devices, the design process, quality, labeling, instructions for use, and more Presents additional content around software and biocompatibility concerns

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

This book will be a substantial revision, which will reflect the new version of the ISO 13485:2016. This represents the standard protocols that all medical device manufacturers must follow, in the fabrication of their products. It will focus on changes in the structure of the quality management system; change in the documentation for quality management systems and finally, present the different methods of implementation of the standard requirements within the organization. This new version was initiated in 2016, thus all appropriate enterprises using the old standard must convert to the new version, now available. The Second Edition will clarify, explain and demonstrate the new version.

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 each chapter
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.

Are you fit for the new rules in Europe? The new EU regulations on medical devices and in vitro diagnostic medical devices (IVDs) are changing the rules of the game in this important area of health care. It is now necessary to adapt quickly to the new and more demanding rules on market access in Europe. This requires a thorough knowledge of the new rules for all those responsible and employed in the sector. A sound knowledge of the new EU regulations is also indispensable for the education, training and further education of students, and for staff in research and development, in regulatory affairs and quality management. For all those who are active and responsible in the field of medical technology, biomedical and clinical engineering, e-health and related fields. The new 3rd edition gives the latest stage of regulatory corrigenda, amendments and EU-target dates and reflects the latest Guidance documents of EU on this. Don't be late: those that fail to prepare - prepare to fail! 336 pages; 38 Fig., 23 Tab. Although complex and lengthy, the process of certification for the ISO 13485 can be easily mastered using the simple method outlined in ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry. Written by an experienced industry professional, this practical book provides a complete guide to the ISO 13485 Standard certification for medical device manufacturing. Filled with examples drawn from the author's experience and spanning different sectors and fields of the medical device industry, the book translates the extra ordinary requirements and objectives of the standard into feasible activities and tasks. The book provides a full analysis of each clause and sub clause through quality perspectives: the implications on an organization, its processes, management, human resources, infrastructures, work environment, control and effectiveness, documentations and records. The book is organized like the standard itself — the table of contents is identical to the ISO 13485 Standard's table of contents — making it user friendly, familiar, and unthreatening. You can use the book as a consulting session — read it, explore it ,extract ideas — and draw on the information and knowledge that suits you and your organization, and then apply it effectively to your quality management system and processes.

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 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.

Mechanical Circulatory and Respiratory Support is a comprehensive overview of the past, present and future development of mechanical circulatory and respiratory support devices. Content from over 60 internationally-renowned experts focusses on the entire life-cycle of mechanical circulatory and respiratory support – from the descent into heart and lung failure, alternative medical management, device options, device design, implantation techniques, complications and medical management of the supported patient, patient-device interactions, cost effectiveness, route to market and a view to the future. This book is written as a useful resource for biomedical engineers and clinicians who are designing new mechanical circulatory or respiratory support devices, while also providing a comprehensive guide of the entire field for those who are already familiar with some areas and want to learn more. Reviews of the most cutting-edge research are provided throughout each chapter, along with guides on how to design new devices and which areas require specific focus for future research and development. Covers a variety of disciplines, from anatomy of organs and evolution of cardiovascular devices, to their clinical applications and the manufacturing and marketing of devices Provides engineering and clinical perspectives to assist readers in the design of a market appropriate device Discusses history, design, usage, and development of mechanical circulatory and respiratory support systems

ISO 17665-1:2006(E) Sterilization of Health Care Products Moist Heat. Guidance on the application of ISO 17665-1. Directives relatives à l'application de l'ISO 17665-1 Handbook of Humanitarian Health Care Logistics Designing the Supply Network and Managing the Flows of Information and Health Care Goods in Humanitarian Assistance during Complex Political Emergencies in low-resource settings George Mc Guire A Practical Guide to Decontamination in Healthcare John Wiley & Sons

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.

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 Decontamination in 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 Decontamination in 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. 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 those principal aspects of microbiology that are relevant 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 non-microbiologist. 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.

This book is meant to be a guide to all who want to learn about a highly regulated industry. My approach is to give you, the reader, an example of a fictitious device, and we will take it from a conceptual idea all the way to launch and beyond. My intention is to incorporate the best experiences that I and other contributors have had into this book and convert them into layman's terms for those who are in need. These experiences can and will be indispensable to beginners and professionals alike who are trying their hand in the medical device industry and to those who have not been out of their silo to help see how each of the systems relate to each as a whole. However, it should be noted that the contents of this book should be taken only as information and is not intended to demonstrate how companies can be in compliance. In some instances, there are multiple ways to go through the maze of regulations that are documented and made by agencies because the regulations are pretty much made and designed to be flexible and high level so that companies can adopt their systems, which are solely designed for their purposes. Therefore, this book will try to avoid complicated words and complex technical details of engineering and statistics. This book will strive to be an embodiment of the honest-to-goodness, everyday experiences and issues that folks experience while working in the medical device industry.

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?

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.

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

This standard provides guidelines for the application of medical device quality management system requirements in YY/T 0287-2017. This standard applies to organizations of various sizes and types, as well as suppliers or other external parties that provide products and services for them, which involves one or more stages of the life cycle of medical devices.

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.

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.

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.

Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies. The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update. This cutting-edge resource includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission. The format, specification, and technical requirements of the e-CTD, the electronic version of CTD, are also thoroughly discussed. The book is organized into six highly practical segments: Part I: CTD, eCTD, Module 1, and Environmental Risk Assessment Part II: CTD Summaries Part III: Quality Topics Part IV: Nonclinical Topics Part V: Clinical Topics Part VI: Other Topics (including drug-device combination products) This text is a must-have for those in the pharmaceutical industry determining regulatory requirements for the major world markets in Europe, the US, Canada, and Japan.

This book provides the bridge between engineering design and medical device development. There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones. It addresses medical devices' regulatory (FDA and EU) requirements--some of the most stringent engineering requirements globally. Engineers failing to meet these requirements can cause serious harm to users as well as their products' commercial prospects. This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements. It brings together proven design protocols and puts them in an explicit medical context based on the author's years of academia (R&D phase) and industrial (commercialization phase) experience. This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly. The medical device market is a multi-billion dollar industry. Every engineered product for this sector, from scalpels/stents to complex medical equipment, must be designed and developed to approved procedures and standards. This book shows how Covers US, and EU and ISO standards, enabling a truly international approach, providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products

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

The field of additive manufacturing has seen explosive growth in recent years due largely in part to renewed interest from the manufacturing sector. Conceptually, additive manufacturing, or industrial 3D printing, is a way to build parts without using any part-specific tooling or dies from the computer-aided design (CAD) file of the part. Today, most engineered devices are 3D printed first to check their shape, size, and functionality before large-scale production. In addition, as the cost of 3D printers has come down significantly, and the printers' reliability and part quality have improved, schools and universities have been investing in 3D printers to experience, explore, and innovate with these fascinating additive manufacturing technologies. Additive Manufacturing highlights the latest advancements in 3D printing and additive manufacturing technologies. Focusing on additive manufacturing applications rather than on core 3D printing technologies, this book: Introduces various additive manufacturing technologies based on their utilization in different classes of materials Discusses important application areas of additive manufacturing, including medicine, education, and the space industry Explores regulatory challenges associated with the emergence of additive manufacturing as a mature technological platform By showing how 3D printing and additive manufacturing technologies are currently used, Additive Manufacturing not only provides a valuable reference for veteran researchers and those entering this exciting field, but also encourages innovation in future additive manufacturing applications.

Comprehensive, yet concise, 3D Printing for the Radiologist presents an overview of three-dimensional printing at the point of care. Focusing on opportunities and challenges in radiology practice, this up-to-date reference covers computer-aided design principles, quality assurance, training, and guidance for integrating 3D printing across radiology subspecialties. Practicing and trainee radiologists, surgeons, researchers, and imaging specialists will find this an indispensable resource for furthering their understanding of the current state and future outlooks for 3D printing in clinical medicine. Covers a wide range of topics, including basic principles of 3D printing, quality assurance, regulatory perspectives, and practical implementation in medical training and practice. Addresses the challenges associated with 3D printing integration in clinical settings, such as reimbursement, regulatory issues, and training. Features concise chapters from a team of multidisciplinary chapter authors, including practicing radiologists, researchers, and engineers. Consolidates today's available information on this timely topic into a single, convenient,

resource.

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

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.

This book aims to give readers a basic understanding of commonly used additive manufacturing techniques as well as the tools to fully utilise the strengths of additive manufacturing through the modelling and design phase all the way through to post processing. Guidelines for 3D-printed biomedical implants are also provided. Current biomedical applications of 3D printing are discussed, including indirect applications in the rapid manufacture of prototype tooling and direct applications in the orthopaedics, cardiovascular, drug delivery, ear-nose-throat, and tissue engineering fields. Polymer-Based Additive Manufacturing: Biomedical Applications is an ideal resource for students, researchers, and those working in industry seeking to better understand the medical applications of additive manufacturing.

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

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.

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