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BLAKE JASE

Biomaterials for Spinal Surgery Woodhead Publishing
Principles of Biomedical Sciences and Industry Improve your product development skills to bring new ideas to biomedicine The development of innovative healthcare products, such as biodegradable implants, biopharmaceuticals, or companion diagnostics, requires a multi-disciplinary approach that incorporates scientific evidence with novel and innovative ideas to create new and improved products and treatments. Indeed, product development and the integration of science with commercial aspects have become key challenges for scientists working in the pharmaceutical, biotech, and medtech industries. Using a multi-pronged approach to development, Principles of Biomedical Sciences and Industry combines ideas and methodologies from four of the central areas of focus in the biomedical arena: pharmaceuticals, diagnostics, biomaterials, and medical devices. In doing so, the book covers the entire product lifecycle, from translating a scientific idea into a prototype to product development, launch, and management. Principles of Biomedical Sciences and Industry readers will also find: Several case studies from the most important product categories (pharmaceuticals, diagnostics, medical devices, combination products) Chapters dealing with toxicology and safety risks in development, as well as regulatory approval Key business aspects including how to secure funding, managing intellectual property, and price regulation in the market An ideal resource for teachers and students that conveys the information in an easily-digestible format Ideal for advanced students and young professionals pursuing a career in the biomedical and healthcare industries, Principles of Biomedical Sciences and Industry is an essential reference for those in pharmaceutical industry, biotechnologists, medicinal chemists, bio-engineers, pharma engineers, and management consultants.
Emerging Research on Bioinspired Materials Engineering Woodhead Publishing
This practical resource provides toxicologists and scientists with essential information on the regulations that govern their jobs and products. Regulatory Toxicology also covers the scientific and historical underpinnings of those regulations. Each chapter provides a grounding in the historical events that led to the development of original legislation and major subsequent changes in legislation. The major administrative divisions for regulatory agencies and their main missions and responsibilities are also detailed, as are the basic filing units or documents the agencies require of individuals to meet goals. This second edition is updated to reflect new developments in the field.
Trends in Development of Medical Devices Springer Nature
This first edition of Testing Tribocorrosion of Passivating Materials Supporting Research and Industrial Innovation: A Handbook treats in a clear, concise, and practical manner an important material degradation and protection matter. It is designed as a handbook and provides a well structured approach of the basics needed to investigate the tribocorrosion behavior of passivating materials, and to conduct in a correct way a laboratory investigation on it. It provides answers on practical and theoretical approaches of tribocorrosion phenomena to engineers and medical persons involved with material assemblies subjected to aggressive environmental and mechanical conditions. For academic researchers it is a pertinent tool assisting them in how they can perform

a tribocorrosion investigation and obtain results that are correctly interpreted and can be exchanged. Different parts of the book are illustrated with practical examples. This handbook is truly an indispensable guide for every professional who comes into contact with the complex material degradation and protection processes that take place under combined corrosion and wear conditions. Fields of interest include: transportation (aeronautics, maritime, rail, automotive), medical implants (orthopaedics, dentistry), biochemistry, food production, energy production, and machining. The coordination of this handbook writing was done by Professor Jean-Pierre Celis (Katholieke Universiteit Leuven, Belgium) and Professor Pierre Ponthiaux (Ecole Centrale Paris, France) assisted by twelve European experts who contributed jointly to the nine chapters of this handbook. Main topics dealt with are tribocorrosion phenomena in medical and industrial sectors, depassivation and repassivation phenomena, impact on synergism in tribocorrosion, specific testing techniques, coupling tribology-to-corrosion, design of a testing protocol, and normalisation.
Biocompatibility of Dental Materials Elsevier
There have been important developments in materials and therapies for the treatment of spinal conditions. Biomaterials for spinal surgery summarises this research and how it is being applied for the benefit of patients. After an introduction to the subject, part one reviews fundamental issues such as spinal conditions and their pathologies, spinal loads, modelling and osteobiologic agents in spinal surgery. Part two discusses the use of bone substitutes and artificial intervertebral discs whilst part three covers topics such as the use of injectable biomaterials like calcium phosphate for vertebroplasty and kyphoplasty as well as scoliosis implants. The final part of the book summarises developments in regenerative therapies such as the use of stem cells for intervertebral disc regeneration. With its distinguished editors and international team of contributors, Biomaterials for spinal surgery is a standard reference for both those developing new biomaterials and therapies for spinal surgery and those using them in clinical practice. Summarises recent developments in materials and therapies for the treatment of spinal conditions and examines how it is being applied for the benefit of patients Reviews fundamental issues such as spinal conditions and their pathologies, spinal loads, modelling and osteobiologic agents in spinal surgery Discusses the use of bone substitutes and artificial intervertebral discs and covers topics such as the use of injectable biomaterials like calcium phosphate for vertebroplasty and kyphoplasty
Sterilisation of Biomaterials and Medical Devices Springer Science & Business Media
Advances in molecular biology and toxicology are paving the way for major improvements in the evaluation of the hazards posed by the large number of chemicals found at low levels in the environment. The National Research Council was asked by the U.S. Environmental Protection Agency to review the state of the science and create a far-reaching vision for the future of toxicity testing. The book finds that developing, improving, and validating new laboratory tools based on recent scientific advances could significantly improve our ability to understand the hazards and risks posed by chemicals. This new knowledge would lead to much more informed environmental regulations and dramatically reduce the need for animal testing because the new tests would be based on human cells and cell components. Substantial scientific efforts and resources will be required to leverage these new technologies to realize the vision, but the result will be a more efficient, informative and less costly system for assessing the hazards posed by industrial chemicals and pesticides.
Medical Device Regulatory Practices Academic Press
This practical book provides toxicologists with essential information on the regulations that govern their jobs and products. Regulatory Toxicology, Third Edition is an up-to-date guide to required safety assessment for the entire range of man-made marketed products. Individual chapters written by experts with extensive experience in the field address requirements not only for human pharmaceuticals and medical devices (for which there are available guidances), but for the full range of man-made products. New in this edition are three chapters addressing Safety Data Sheet Preparation, Regulatory Requirements for GMOs, and Regulatory Requirements for Tobacco and Marijuana. The major administrative divisions for regulatory agencies and their main responsibilities are also detailed, as are the basic filing documents the agencies require. Coverage includes food additives, dietary supplements, cosmetics, over-the-counter drugs, personal care and consumer products, agriculture and GMO products, industrial chemicals, air and drinking water regulations and the special cases of California’s Proposition 65, requirements for safety data sheets, and oversight regulations. Both US and international requirements are clearly presented and referenced. In one volume, those who have regulatory responsibility in companies, lawyers, educators, and those selling these materials in the marketplace can learn about regulatory requirements and how to meet them.
Bone Response to Dental Implant Materials Springer
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
Design Controls for the Medical Device Industry, Second Edition John Wiley & Sons
Toxicological Aspects of Medical Device Implants provides comprehensive information on the use of medical implant and devices and the balance between the application of the devices in relation to any potential adverse effects. In order to ensure the safety and effectiveness of medical devices, many international policies, regulations, and standards have been established, and the book also discusses medical devices within this regulatory framework. The book covers a broad range of disease topics and disease-specific implants and an interdisciplinary team of experts brings a wealth of information on implants used in various disease models and associated risk factors. Toxicological Aspects of Medical Device Implants is a comprehensive resource for toxicologists, biomedical engineers, immunologists, medical staff, regulators, and manufacturers working in the field who need to be aware of the potential toxicity and device management of such a wide variety of implants and devices and their health risks. Discusses the adverse toxicological effects of medical devices Covers a broad range of disease topics and disease specific implants Offers contributions from experts from across several disciplines
WHO Expert Committee on Specifications for Pharmaceutical Preparations CRC Press
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools. The Expert Committee develops standards through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: WHO good manufacturing practices for excipients used in pharmaceutical products (revision); IAEA/WHO good manufacturing practices for in-house cold kits for radiopharmaceutical preparations (new); WHO good practices for pharmaceutical quality control laboratories (revision); WHO/UNFPA female condom generic specification (new); WHO Biowaiver List: proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release (updated), solid oral dosage forms; WHO guideline on Biopharmaceutics Classification System-based biowaivers (revision); and Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (republished). All of the above are included in this report and recommended for implementation.
Kenya Gazette World Health Organization
Signi?cant progress has been made in the development of neural prostheses for restoration of human functions and improvement of the quality of life. Biomedical engineers and neuroscientists around the world are working to improve the design and performance of existing devices and to develop novel devices for arti?cial vision, arti?cial limbs, and brain-machine interfaces. This book, Implantable Neural Prostheses 2: Techniques and Engineering Approaches, is part two of a two-volume sequence that describes state-of-the-art advances in techniques associated with implantable neural prosthetic devices. The techniques covered include biocompatibility and biostability, hermetic packaging, electrochemical techniques for neural stimulation applications, novel electrode materials and testing, thin-?lm ?exible microelectrode arrays, in situ char-terization of microelectrode arrays, chip-size thin-?lm device encapsulation, microchip-embedded capacitors and microelectronics for recording, stimulation, and wireless telemetry. The design process in the development of medical devices is also discussed. Advances in biomedical engineering, microfabrication technology, and neu- science have led to improved medical-device designs and novel functions. However, many challenges remain. This book focuses on the engineering approaches, R&D advances, and technical challenges of medical implants from an engineering p- spective. We are grateful to leading researchers from academic institutes, national laboratories, as well as design engineers and professionals from the medical device industry who have contributed to the book. Part one of this series covers designs of implantable neural prosthetic devices and their clinical applications.
Genetic Toxicology Testing Elsevier
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
Nanoparticles in the Water Cycle CRC Press
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
Haschek and Rousseaux's Handbook of Toxicologic Pathology, Volume 2 Academic Press
The Kenya Gazette is an official publication of the government of the Republic of Kenya. It contains notices of new legislation, notices required to be published by law or policy as well as other announcements that are published for general public information. It is published every week, usually on Friday, with occasional releases of special or supplementary editions within the week.
Modern Medicine CRC Press
Achieving good clinical outcomes with implanted biomaterials depends upon achieving optimal function, both mechanical and biological, which in turn depends upon integrating advances realized in biological science, material science, and tissue engineering. As these advances push back the frontiers of biomaterial medicine , the control and patterning
Handbook of Biomaterials Biocompatibility Academic Press
Genetic Toxicology Testing: A Laboratory Manual presents a practical guide to genetic toxicology testing of chemicals in a GLP environment. The most commonly used assays are described, from laboratory and test design to results analysis. In a methodical manner, individual test methods are described step-by-step, along with equipment, suggested suppliers, recipes for reagents, and evaluation criteria. An invaluable resource in the lab, this book will help to troubleshoot any assay problems you may encounter to optimise quality and efficiency in your genetic toxicology tests.

Genetic Toxicology Testing: A Laboratory Manual is an essential reference for those new to the genetic toxicology laboratory, or anyone involved in setting up their own. Offers practical and consistent guidance on the most commonly-performed tests and procedures in a genetic toxicology lab Describes standard genetic toxicology assays, their methodology, reagents, suppliers, and analysis of their results Includes guidance on general approaches: formulation for in vitro assays, study monitoring, and Good Laboratory Practice (GLP) Serves as an essential reference for those new to the genetic toxicology laboratory, or anyone involved in setting up their own lab

Biomaterials and Medical Devices CRC Press

A practical handbook rather than merely a chemistry reference, Szycher's Handbook of Polyurethanes, Second Edition offers an easy-to-follow compilation of crucial new information on polyurethane technology, which is irreplaceable in a wide range of applications. This new edition of a bestseller is an invaluable reference for technologists, marketers, suppliers, and academicians who require cutting-edge, commercially valuable data on the most advanced uses for polyurethane, one of the most important and complex specialty polymers. internationally recognized expert Dr. Michael Szycher updates his bestselling industry "bible" With seven entirely new chapters and five that are revised and updated, this book summarizes vital contents from U.S. patent literature—one of the most comprehensive sources of up-to-date technical information. These patents illustrate the most useful technology discovered by corporations, universities, and independent inventors. Because of the wealth of information they contain, this handbook features many full-text patents, which are carefully selected to best illustrate the complex principles involved in polyurethane chemistry and technology. Features of this landmark reference include: Hundreds of practical formulations Discussion of the polyurethane history, key terms, and commercial importance An in-depth survey of patent literature Useful stoichiometric calculations The latest "green" chemistry applications A complete assessment of medical-grade polyurethane technology Not biased toward any one supplier’s expertise, this special reference uses a simplified language and layout and provides extensive study questions after each chapter. It presents rich technical and historical descriptions of all major polyurethanes and updated sections on medical and biological applications. These features help readers better understand developmental, chemical, application, and commercial aspects of the subject.

Design Controls for the Medical Device Industry, Third Edition Springer Science & Business Media

Medical Modelling:?The Application of Advanced Design and Additive Manufacturing Techniques in Medicine, Third Edition?provides readers with a thorough update of the core contents, along with key information on innovative imaging techniques, additive manufacturing technologies and a range of applied case studies. This comprehensive new edition includes new coverage of advanced technologies, such as selective laser melting, electron beam melting, multi jet fusion, and more. The extensive section of peer-reviewed case studies is thoroughly updated and includes additional clinical examples, describing the practical applications of advanced design technologies in surgical, prosthetic, orthotic, dental and research applications. Finally, Medical Modelling:?The Application of Advanced Design and Additive Manufacturing Techniques in Medicine, Third Edition explores the future potential of medical modelling, such as in simulations for training, the development of new medical devices and so on. Covers the essential stages and methods of creating virtual and physical anatomical models from medical scan data Presents an overview of the main AM processes, including advantages and limitations Provides worked examples and case studies with detailed descriptions of the applications of 3D scanning, CAD, and AM to a wide variety of anatomical, surgical, prosthetic, orthotic, and associated applications

Information Resources in Toxicology, Volume 2: The Global Arena Routledge

The revised edition of this renowned and bestselling title is the most comprehensive single text on all aspects of biomaterials science. It 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. Over 29,000 copies sold, this is the most comprehensive coverage of principles and applications of all classes of biomaterials: "the only such text that currently covers this area comprehensively" - Materials Today Edited by four of the best-known figures in the biomaterials field today; fully endorsed and supported by the Society for Biomaterials Fully revised and expanded, key new topics include of tissue engineering, drug delivery systems, and new clinical applications, with new teaching and learning material throughout, case studies and a downloadable image bank

Regulatory Toxicology, Third Edition Academic Press

This new fifth edition of Information Resources in Toxicology offers a consolidated entry portal for the study, research, and practice of toxicology. Both volumes represents a unique, wide-ranging, curated, international, annotated bibliography, and directory of major resources in toxicology and allied fields such as environmental and occupational health, chemical safety, and risk assessment. The editors and authors are among the leaders of the profession sharing their cumulative wisdom in toxicology’s subdisciplines. This edition keeps pace with the digital world in directing and linking readers to relevant websites and other online tools. Due to the increasing size of the hardcopy publication, the current edition has been divided into two volumes to make it easier to handle and consult. Volume 1: Background, Resources, and Tools, arranged in 5 parts, begins with chapters on the science of toxicology, its history, and informatics framework in Part 1. Part 2 continues with chapters organized by more specific subject such as cancer, clinical toxicology, genetic toxicology, etc. The categorization of chapters by resource format, for example, journals and newsletters, technical reports, organizations constitutes Part 3. Part 4 further considers toxicology’s presence via the Internet, databases, and software tools. Among the miscellaneous topics in the concluding Part 5 are laws and regulations, professional education, grants and funding, and patents. Volume 2: The Global Arena offers contributed chapters focusing on the toxicology contributions of over 40 countries, followed by a glossary of toxicological terms and an appendix of popular quotations related to the field. The book, offered in both print and electronic formats, is carefully structured, indexed, and cross-referenced to enable users to easily find answers to their questions or serendipitously locate useful knowledge they were not originally aware they needed. Among the many timely topics receiving increased emphasis are disaster preparedness, nanotechnology, -omics, risk assessment, societal implications such as ethics and the precautionary principle, climate change, and children’s environmental health. Opens with an overview of the international toxicology scene, organizations and activities involved with both the science and regulatory framework, and a specific look at the European Union’s efforts Offers an extensive collection of chapters covering over 40 countries and their toxicological infrastructure which includes listings of major books and journals, organizations, professional societies, universities, poison control centers, legislation, and online databases Provides the Second Edition of the International Union of Pure and Applied Chemistry’s Glossary of Terms Used in Toxicology, a carefully constructed and peer reviewed collation of critical terms in the science Concludes with a potpourri of quotes concerning toxicology and their use in the arts and popular culture Paired with Volume One, which offers chapters on a host of toxicology sub-disciplines, this set offers the most comprehensive compendium of print, digital, and organizational resources in the toxicological sciences with over120 chapters contributions by experts and leaders in the field

Toxicity Testing in the 21st Century 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.