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Babiarz, J.C. Pisano, D.J. 2008 Overview of FDA and drug development FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics Pisano, D.J. Mantus, D.S. New York Informa Healthcare USA, Inc1

Regulatory affairs and testing (Chapter 12) - Mechanics of ...
and/or validate specific biomaterials for use in an eventual Advanced Therapy Medicinal Product or Medical Device. Preclinical regulatory affairs would need to be completed taking due account of current good laboratory practice (GLP) and ISO guidelines. Manufacturing processes would also

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All biomaterials and medical devices are subject to a long list of regulatory practises and policies which must be adhered to in order to receive clearance. This book provides readers with information on the systems in place in the USA and the rest of the world.

All biomaterials and medical devices are subject to a long list of regulatory practises and policies which must be adhered to in order to receive clearance. This book provides readers with information on the systems in place in the USA and the rest of the world. Chapters focus on a series of procedures and policies including topics such as commercialization, clinical development, general good practise manufacturing and post market surveillance. Addresses global regulations and regulatory issues surrounding biomaterials and medical devices Especially useful for smaller companies who may not employ a full time vigilance professional Focuses on procedures and policies including risk management, intellectual protection, marketing authorisation, university patent licenses and general good practise manufacturing

Medical device regulation in Asia has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs.

This book gives an introduction to the highly interdisciplinary field of biomaterials. It concisely summarizes properties, synthesis and modification of materials such as metals, ceramics, polymers or composites. Characterization, in vitro and in vivo testing as well as a selection of various applications are also part of this inevitable guide.

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.

In the past, life science product manufacturers were required to satisfy governmental regulatory requirements in their particular geographic area in order to receive commercialization access to that market. However, over the past ten years there has been a significant trend towards convergence of market access variables in the commercialization of life science products. Market access in global biomedical product commercialization discusses the commercialization and convergence of life science products, including medical devices, biomaterials, in vivo products and pharmaceuticals, from all global market access areas. Topics covered will include regulatory, reimbursement, pricing and health economic perspectives. Investigates the commercialization and convergence of life science products Strong focus on case studies, providing further insight into each topic Examines the differences between markets where the balance between private and public healthcare varies

In Situ Tissue Regeneration: Host Cell Recruitment and Biomaterial Design explores the body's ability to mobilize endogenous stem cells to the site of injury and details the latest strategies developed for inducing and supporting the body's own regenerating capacity. From the perspective of regenerative medicine and tissue engineering, this book describes the mechanism of host cell recruitment, cell sourcing, cellular and molecular roles in cell differentiation, navigational cues and niche signals, and a tissue-specific smart biomaterial system that can be applied to a wide range of therapies. The work is divided into four sections to provide a thorough overview and helpful hints for future discoveries: endogenous cell sources; biochemical and physical cues; smart biomaterial development; and applications. Explores the body's ability to mobilize endogenous stem cells to the site of injury Details the latest strategies developed for inducing and supporting the body's own regenerating capacity Presents smart biomaterials in cell-based tissue engineering applications—from the cell level to applications—in the first unified volume Features chapter authors and editors who are authorities in this emerging field Prioritizes a discussion of the future direction of smart biomaterials for in situ tissue regeneration, which will affect an emerging and lucrative industry

Medical Devices and Regulations: Standards and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise, practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

Despite advances in materials and sterilisation, patients who receive biomaterials of medical device implants are still at risk of developing an infection around the implantation site. This book reviews the fundamentals of biomaterials and medical device related infections and methods and materials for the treatment and prevention of infection. The first part of the book provides readers with an introduction to the topic including analyses of biofilms, diagnosis and treatment of infection, pathology and topography. The second part of the book discusses a range of established and novel technologies and materials which have been designed to prevent infection. Provides analysis of biofilms and their relevance to implant associated infections. Assesses technologies for controlling biofilms. Considers advantages and disadvantages of in vivo infection studies.

Biomaterials and Regenerative Medicine in Ophthalmology, Second Edition, focuses on an aging population and the increasing instances of eye diseases. Biomaterials continue to be used for numerous medical devices for the restoration of eyesight, improving many patients' quality of life. Consequently, biomaterials and regenerative medicine are becoming increasingly important to the advances of ophthalmology and optometry. This book provides readers with an updated and expanded look at the present status and future direction of biomaterials and regenerative medicine in this important field. Provides an integral and significant exploration of biomaterials and regenerative medicine, presenting crucial advances made in the fields of ophthalmology and optometry, such as the development of intraocular lenses and new applications for contact lens Presents a new and updated look at the future direction of biomaterials and regenerative medicine in this field Comprehensive coverage in a range of fields, including hydrogels, corneal tissue engineering, and stem cell therapies for the restoration of the ocular surface