

Regulatory Strategy Template For Medical Devices

Jack Wong, Raymond Tong

Global Medical Device Regulatory Strategy, Second Edition Susumu Nozawa, Peter Takes, 2020-09-11

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Regulatory Intelligence as the Basis for Regulatory Strategy and Global Drug Development Petra Heyen, 2011-03-14

Master's Thesis from the year 2004 in the subject Health - Miscellaneous, grade: sehr gut, University of Bonn (Mathematisch-Naturwissenschaftliche Fakultät), language: English, abstract: The Regulatory Affairs (RA) department is a key discipline in the global network of drug development. During drug development, regulatory strategy is one crucial success factor for the approval of the development candidate. Also, regulatory strategy can optimise labelling in the key countries in order to maximise the market success. No submission and approval would be possible without the appropriate dossier composition and compilation. Without adherence to the respective guidance documents and scientific advice from Health Authorities to design the optimal clinical development plan, optimal labelling would not be feasible. These two examples show some characteristics of the regulatory strategy: it is highly interactive with other disciplines and it is heavily based on a thorough intelligence work which enables the RA Manager to know the rules of the game and to develop the optimal regulatory strategy for the current development candidate. The major cornerstone for developing a regulatory strategy is regulatory intelligence. This document focuses on regulatory intelligence. The regulatory contributions to the global drug development from early research to submission are described. Strategies for generic drugs as well as detailed strategies for life-cycle management are excluded. Major components of regulatory intelligence are: - Competitor Information - Information on Regulatory Environment - Information on Legal Requirements Competitor analysis is an essential aspect of the intelligence work. Sources of competitive information as well as relevant items of competitive information are described. Sources of

information about the regulatory environment and sources of information about the legal regulatory environment are described and their tremendous impact on setting up and modify

Handbook of Medical Device Regulatory Affairs in Asia Jack Wong, Raymond Tong, 2018-03-28 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.

Medical Product Regulatory Affairs John J. Tobin, Gary Walsh, 2023-08-29 Medical Product Regulatory Affairs Hands-on guide through the jungle of medical regulatory affairs for every professional involved in bringing new products to market Based on a module prepared by the authors for an MSc course offered by the University of Limerick, Ireland, Medical Product Regulatory Affairs is a comprehensive and practical guide on how pharmaceutical and medical devices are regulated within the major global markets. The Second Edition builds on the success of the first with an even wider scope and full coverage of new EU regulations on the safe use of medical devices. Following a look at drug development, complete sections are devoted to national and EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics dealt with include CDER, CBER and marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/ Manufacturing Practices. Medical Product Regulatory Affairs includes information on: Aims and structure of regulation, covering purpose and principles of regulation, national and EU legislative processes, and pharmacopeia Regulatory strategy, covering product development and manufacturing, market vigilance, quality assurance systems, personnel, and documentation Drug discovery and development, covering prescription status, physical properties, therapeutic use, and drug discovery, development, and delivery Non-clinical studies, covering non-clinical study objectives and timing, pharmacological and pharmacodynamic studies, and bioavailability and bioequivalence Clinical trials, covering trial protocol, monitoring of trials, trial master files, and FDA communications The wide coverage of different product types and the main global markets makes Medical Product Regulatory Affairs ideal for training courses on regulatory affairs in academia and industry. It is also a valuable reference for pharmacologists, bioengineers, pharma engineers, and students in pharmacy to familiarize themselves with the topic.

Medical Device Regulatory Practices Val Theisz, 2015-08-03 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 Regulatory Affairs Jack Wong, Raymond K. Y. Tong, 2022-01-27 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. Experts from influential international regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency, Japan Pharmaceuticals and Medical Devices Agency, Saudi Food and Drug Authority, Korea Testing Laboratory, Taiwan FDA, World Health Organization, Asian Harmonization Working Party, Regulatory Affairs Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects.

Medical Device Regulations Michael Cheng, World Health Organization, 2003-09-16 The term 'medical devices' covers a wide range of equipment essential for patient care at every level of the health service, whether at the bedside, at a health clinic or in a large specialised hospital. Yet many countries lack access to high-quality devices, particularly in developing countries where health technology assessments are rare and there is a lack of regulatory controls to prevent the use of substandard devices. This publication provides a guidance framework for countries wishing to create or modify their own regulatory systems for medical devices, based on best practice experience in other countries. Issues highlighted include: the need for harmonised regulations; and the adoption, where appropriate, of device approvals of advanced regulatory systems to avoid an unnecessary drain on scarce resources. These approaches allow emphasis to be placed on locally-assessed needs, including vendor and device registration, training and surveillance and information exchange systems.

FDA and Intellectual Property Strategies for Medical Device Technologies Gerald B. Halt (Jr.), John C. Donch (Jr.), Amber R. Stiles, Lisa Jenkins VanLuvanee, Brandon R. Theiss, Dana L. Blue, 2019 This book offers comprehensive, easy to understand guidance for medical device technology innovators on how to work through the United States FDA regulatory review process, while also providing insight on the various intellectual property concerns that many medical device innovators face. In the first portion of this book, readers are introduced to important concepts concerning FDA compliance for medical devices, as well as strategies for successfully navigating the FDA regulatory review process. Specifically, the first portion discusses the expansive range of medical devices and then walks through the most common routes to market: the PMA and 510(k) application processes. In the second portion of this book, readers are introduced to the various types of intellectual property rights that are available for medical device technology inventions and innovations, and can explore ways

to overcome unique intellectual property challenges faced by many medical device technology innovators. In the third portion of the book, specific strategies are discussed to navigate the interface between the FDA regulatory process and the process of obtaining intellectual property protection. This book also includes a number of descriptive examples, case studies and scenarios to illustrate the topics discussed, and is intended for use by medical device designers, developers and innovators. Investigates the FDA approval process as it pertains to medical device technology Address some of the major FDA hurdles that medical device innovators often face while seeking approval Discusses the interplay between FDA regulatory review of medical device technology and intellectual property strategy Explores the benefits of protecting, managing and enforcing intellectual property obtained for medical device technology so that innovators can obtain the best possible commercial results from their IP ownership Uses real case studies to illustrate concepts covered.

Medical Device Quality Management Systems Susanne Manz, 2018-09-27 Medical Devices Quality Management Systems: Strategy and Techniques for Improving Efficiency and Effectiveness is written for the needs of quality, compliance, and regulatory professionals in medical device companies. It includes secrets for developing an effective, yet efficient, Quality Management System (QMS) and explains how to create a vision, strategy, and tactical plans. Author Manz shares lessons on leadership, key roles and responsibilities within a medical device company, while also exploring the concepts of process ownership, individual accountability, and how to cultivate a culture of quality and compliance. This book is useful for all executive, functional leaders, and organizations in the highly regulated medical device industry. Provides practical, real-world guidance on developing an effective and efficient Quality Management System Presents a roadmap for QMS development Covers techniques to assess current state Includes discussions on tools, such as CAPA and Six Sigma that help define vision, strategy and quality plans

Excellence Beyond Compliance William I. White, 2018-05-16 Many companies limp along from day-to-day treating the quality side of the business as a necessary evil, and doing only what is minimally necessary for compliance to regulations. This kind of approach to compliance almost always results in inefficiencies and sometimes can result in a curious kind of noncompliance. Documentation created with compliance as the sole consideration often ends up confusing the employees who must use the documentation. This book looks beyond what is necessary for compliance alone to address what makes a quality management system (QMS) both effective and efficient. This book also never forgets that real people must make any QMS work; the book provides a blueprint for creating a QMS that real people will find useful. After a review of the challenges that any medical device company faces in the world of today—the multiple sources of QMS requirements—the book poses a question: are we satisfied with the QMS we have now, or could we do better? If we want to do better, this book can help. This book offers: Advice that will lead to an effective and efficient QMS. Detailed guidance on the key decisions to be made regarding the quality system being established. Detailed ideas on how to execute those decisions. Up-to-date information on

compliance to current regulations and standards and guidance on staying up to date. Specific examples of procedures. Information regarding requirements for combination products, such as a drug + device combination. Advice on incorporating risk management in the QMS.

Medical Device Quality Assurance and Regulatory Compliance Richard C. Fries,1998-08-11 Acquaints developers of medical devices with the basic concepts and major issues of medical quality assurance and regulatory documents, describes the requirements listed in these documents, and provides strategies for compliance with these requirements.

Managing Medical Devices within a Regulatory Framework Beth Ann Fiedler,2016-09-10 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

Regulatory Data Science for Medical Devices Jeroen Bergmann,2022-04-29 Regulations that cover the legal obligations that manufacturers are bound to are essential for keeping the general public safe. Companies need to follow the regulations in order to bring their products to market. A good understanding of the regulations and the regulatory pathway defines how fast and at what cost the manufacturer can introduce innovations to the market. Regulatory technology and data science can lead to new regulatory processes and evidence in the medical field. It can equip stakeholders with unique tools that can make regulatory decisions more objective, efficient, and accurate. This book describes the latest research within the broader domain of Medical Regulatory Technology (MedRegTech). It covers concepts such as the complexity and user-friendliness of medical device regulations, novel algorithms for regulatory navigation, descriptive datasets from a health service provider,

regulatory data science techniques, and considerations of the environmental impacts within a national health service. This book brings all these aspects together to offer an introduction into MedRegTech research. In the long term, these technologies and methods will help optimize the regulatory strategy for individual healthcare innovations and revolutionize the way we engage with regulatory services.

Handbook of Medical Device Regulatory Affairs in Asia Jack Wong, Raymond Tong, 2018-03-21 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.

FDA Regulatory Affairs Douglas J. Pisano, David S. Mantus, 2008-08-11 Examines harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations as they apply to human drug and device development, research, manufacturing, and marketing. The Second Edition focuses on the new drug approval process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements. Written in

Combination Products Smita Gopaldaswamy, Venky Gopaldaswamy, 2008-04-22 The field of combination product development (products born of the integration of medical devices, biologics, and drugs) is so new that, while literature abounds on each part individually, there are very few publications, including FDA documents, available concerning the unique challenges posed by this nascent but fast-growing area. Providing

Medical Device Product Lifecycle Bernadette White, Fintan Barnette, 2022-03-11 This book is intended to provide an introduction to the application of a lifecycle approach to product design and development for medical devices. Medical Device Product Lifecycle management provides a framework to develop, design maintain user requirements and ensure the safety and performance of medical devices. Application of a Medical Device Product Lifecycle Management benefits the business aspects of manufacturing, fosters alignment across design and development teams and incorporates the voice of the customer, taking into account their needs and safety that is inherent in the design of products. The Medical Device Product Lifecycle (MDPL) relies upon several distinct quality management elements and processes in order to function effectively. These include; principles and establishment of a quality management system, regulatory processes, validation processes, engineering processes, change management and risk management processes. The MDPL process itself requires procedures

and documentation to facilitate product realization. For the reader to gain the maximum benefit from this book, the following points should be considered. To begin with-Regulations are mandatory. Medical devices range in their application (intended use and indications), technologies, principles of operation, complexity and value. However, regulation in addition to standards need to be consulted and applied within organizations. The manufacturer has a legal responsibility in this regard and the classification and commercial strategy may require regulations such as FDA 21 CFR 820, (United States), and Medical Device Regulations EU MDR (2017/745) or Regulation 2017/746 on In-Vitro Diagnostic Devices (IVDR) (in Europe). Introduction Establishing a Medical Device Product Development Process is necessary to for medical device manufacturers to meet FDA regulations and regional regulations applicable to the products for sale. Beyond the legal stipulation, an additional purpose is to realize and deliver safe and effective medical devices that meet the intended use and user needs which provides medical solutions that enhance and preserve quality of life. To achieve safe and effective products, the guiding principles and techniques not only need to be applied in the design and development stages, but maintaining and monitoring the performance through the product lifecycle is required. It is easily to compartmentalize product performance and safety as a development and design-based activity, however, an effective medical device lifecycle process must ensure design safety and continuity until product retirement and discontinuation. The introduction of new medical device products or changes to existing medical device products necessitate design and development activities in order to plan and deliver the appropriate verifications and validations to demonstrate safety and performance of products. Device manufacturers in establishing and applying a Medical Device Product Lifecycle Process must continually ensure the process is fit-for-purpose and that is fulfils its legal and regulatory obligations (e.g. meeting the requirements of 21 CFR 820.30: Medical Devices - Quality System Regulation and ISO 13485: Medical Devices- Quality Management Systems etc.) A Medical Device Product Lifecycle process must be a comprehensive, end-to-end process that encompasses the entire life cycle of a product from project initiation through to product discontinuation and retirement of a marketed product. Making a comprehensive and detailed process intuitive and easy-to-apply should also play a role in designing and maintaining a MDPL process. Structuring the process into specific stages and the use of design review or gate reviews also provides for a format that has milestones and a stage by stage approach that makes it easier for engineers to work with.

Clinical Evaluation of Medical Devices Karen M. Becker,John J. Whyte,2007-11-05 The original edition of this text, Clinical Evaluation of Medical Devices: Principles and Case Studies, provided the first overview of key principles and approaches to medical device clinical trials, illustrated with a series of detailed, real-world case studies. The book is designed as a resource for clinical professionals and regulatory specialists working in the field of new medical device development and marketing. Since the first edition of this text was published in 1997, the rapid pace of innovation in health care technologies continues to yield exciting and important new products. The regulatory landscape has also evolved, reflecting some of the

changes and needs within the medical device industry. The purpose of Clinical Evaluation of Medical Devices: Principles and Case Studies, Second Edition is to provide an updated and expanded presentation of the scientific methods and regulatory requirements applied to the study of new significant risk medical devices. The text now includes (1) new information on the requirements and process for gaining reimbursement of new products from Medicare and private insurers, with case studies of research specifically designed for this purpose as well as health care technology assessment methods; (2) information on new statistical methodologies applied to medical device trials; and (3) all new case studies, including examples of combination products, three-phase development models (i. e. , feasibility, FDA approval, Medicare reimbursement), and novel study designs.

The Challenges of Conducting Medical Device Studies Keith Summerhayes, 2005 Describing all the regulations, guidelines and directives that affect medical device studies.

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