Ghtf Sg3 Quality Management System Medical Devices

Ghtf Sg3 Quality Management System Medical Devices *Downloaded from ftp.wtvq.com by guest*

AHMED BALL

An International Handbook for Medical Devices and Healthcare Products CRC Press
Пострегистрационный надзор — это комплекс мероприятий, проводимых производителями для сбора информации об использовании медицинских изделий, обращающихся на рынке, и анализа опыта их использования, а также для определения необходимости принятия тех или иных мер. Пострегистрационный надзор является одним из важнейших инструментов, призванных обеспечить безопасность и эффективность медицинских изделий, а также принятие мер в случае, если риск, связанный с дальнейшим использованием медицинского изделия, перевешивает приносимую им пользу. Анализ опыта пострегистрационного надзора также позволяет выявить возможности для усовершенствования медицинского изделия. В настоящем документе изложены задачи и процедуры пострегистрационного надзора за медицинскими изделиями, осуществляемого производителями с помощью их экономических агентов, а также процедуры надзора за рынком, осуществляемого регулирующими органами, и роль других заинтересованных сторон, участвующих в этих процессах. В нем описаны меры, принимаемые для того, чтобы выпущенные на рынок медицинские изделия постоянно соответствовали требованиям в отношении безопасности, качества и эффективности.

WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices CRC Press
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.

Medical devices - Quality management systems - Guidance on the application of YY/T 0287-2017 [After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net] World Health Organization
This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and adoption of new and revised WHO Recommendations, Guidelines, and guidance documents. Following these discussions, WHO Guidelines on the quality, safety and efficacy of Ebola vaccines, and WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products were adopted on the recommendation of the Committee. In addition, the following two WHO guidance documents on the WHO prequalification of in vitro diagnostic medical devices were also adopted: (a) Technical Specifications Series (TSS) for WHO Prequalification - Diagnostic Assessment: Human immunodeficiency virus (HIV) rapid diagnostic tests for professional use and/or self-testing; and (b) Technical Guidance Series (TGS) for WHO Prequalification - Diagnostic Assessment: Establishing stability of in vitro diagnostic medical devices. Subsequent sections of the report provide information on the current status, proposed development and establishment of international reference materials in the areas of: antibiotics, biotherapeutics other than blood products; blood products and related substances; in vitro diagnostics; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines, and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-5). Finally, all additions and discontinuations made during the 2017 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6. The updated full catalog of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.

Collection of Scientific Articles: Philosophy, Political Science, History CRC Press
The field of mechatronics integrates modern engineering science and technologies with new ways of thinking, enhancing the design of products and manufacturing processes. This synergy enables the creation and evolution of new intelligent human-oriented machines. The Handbook of Research on Advancements in Robotics and Mechatronics presents new findings, practices, technological innovations, and theoretical perspectives on the the latest advancements in the field of mechanical engineering. This book is of great use to engineers and scientists, students, researchers, and practitioners looking to develop autonomous and smart products and systems for meeting today’s challenges.

Handbook of Medical Device Regulatory Affairs in Asia William Andrew
The Model recommends guiding principles and harmonized definitions and specifies the attributes of effective and efficient regulation to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The Model is particularly relevant for WHO Member States with little or no regulation for medical devices currently in place but with the ambition to improve this situation. It foresees that such countries will progress from basic regulatory controls towards an expanded level to the extent that their resources allow. The Model is written for the legislative, executive, and regulatory branches of government as they develop and establish a system of medical devices regulation. It describes the role and responsibilities of a country's regulatory authority for implementing and enforcing the regulations. Also, it describes circumstances in which a regulatory authority may either "rely on" or "recognize" the work products from trusted regulatory sources (such as scientific assessments, audit, and inspection reports) or from the WHO Prequalification Team. Section 2 of this document recommends definitions of the terms "medical devices" and IVDs. It describes how they may be grouped according to their potential for harm to the patient or user and specifies principles of safety and performance that the device manufacturer must adhere to. It explains how the manufacturer must demonstrate to a regulatory authority that its medical device has been designed and manufactured to be safe and to perform as intended during its lifetime. Section 3 presents the principles of good regulatory practice and enabling conditions for effectively regulating medical devices. It then introduces essential tools for regulation, explaining the function of the regulatory entity and the resources required. Section 4 presents a stepwise approach to implementing and enforcing regulatory controls for medical devices as the regulation progresses from a basic to an expanded level. It describes elements from which a country may choose according to national priorities and challenges. Also, it provides information on when the techniques of reliance and recognition may be considered and on the importance of international convergence of regulatory practice.Section 5 provides a list of additional topics to be considered when developing and implementing regulations for medical devices. It explains the relevance of these topics and

provides guidance for regulatory authorities to ensure that they are addressed appropriately. The Model outlines a general approach but cannot provide country-specific guidance on implementation. While it does not offer detailed guidance on regulatory topics, it contains references to relevant documents where further information may be found. It does not detail the responsibilities of other stakeholders such as manufacturers, distributors, procurement agencies, and health-care professionals, all of whom have roles in assuring the quality, safety, and performance of medical devices.

Medical Device Design for Six Sigma https://www.chinesestandard.net

Risk management principles are effectively utilized in many areas of business and government, including finance, insurance, occupational safety, and public health, and by agencies regulating these industries. The U.S. Food and Drug Administration (FDA) and its worldwide counterparts are responsible for protecting public health by ensuring the safety and effectiveness of the drugs and medical devices. Regulators must decide whether the benefits of a specific product for patients and users outweigh its risk, while recognizing that □absolute safety□ (or zero risk) is not achievable. Every product and every process has an associated risk. Although there are some examples of the use of quality risk management in the FDA-regulated industry today, they are limited and do not represent the full contribution that risk management has to offer. The present FDA focus on risk-based determination is requiring that the regulated industries improve dramatically their understanding and capability of hazard control concepts. In addition, the importance of quality systems has been recognized in the life sciences industry, and it is becoming evident that quality risk management is a valuable component of an effective quality system. The purpose of this book is to offer a systematic and very comprehensive approach to quality risk management. It will assist medical and food product manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples. The appropriate use of quality risk management can facilitate compliance with regulatory requirements such as good manufacturing practices or good laboratory practices. The content of this book will provide FDA-regulated manufacturers with a framework within which experience, insight, and judgment are applied systematically to manage the risks associated with their products. Manufacturers in other industries may use it as an informative guidance in developing and maintaining a risk management system and process. The two appendices add even more insight: Appendix A contains general examples of risk management, while Appendix B includes 10 case studies illustrating real examples of the quality risk management process across the medical product arena.

Sixty-eighth Report World Health Organization

Research and development on microorganisms in food has evolved from a luxury to a necessity for companies competing in the global marketplace. Whether research is conducted internally or externally through contract laboratories and universities, microbial research in foods is crucial to the safety and integrity of our food supply. Microbiological Research and Development for the Food Industry covers the technical and practical insights needed for developing and utilizing various capabilities to advance food microbiology research. Providing examples of how research data can be applied to consumer and brand protection efforts, this book: Describes the purposes and processes for conducting microbiological research and development for companies and organizations involved in food, beverage, and ingredient production and distribution Covers a broad range of topics of importance to food microbiologists in allied food industries and organizations, government, and academia Includes examples of successful research methods for food microbiology laboratories Written to walk the reader through the process of investigating microorganisms in food systems for consumer and brand protection, Microbiological Research and Development for the Food Industry provides practical understanding of the necessary mechanisms and research approaches used in the field. It fuses the business and scientific aspects of microbiological research to underscore the return on investment for beverage and food ingredient producers. This text goes beyond routine presence/absence testing of pathogens and spoilage microorganisms in foods. It describes ways data can be collected to answer more complex questions and provides examples of how such data can be applied to consumer and brand protection efforts.

Principles of Parenteral Solution Validation Plastics in Medical DevicesProperties, Requirements, and Applications

The first comprehensive guide to the integration of Design forSix Sigma principles in the medical devices development cycle Medical Device Design for Six Sigma: A Road Map for Safetyand Effectiveness presents the complete body of knowledge forDesign for Six Sigma (DFSS), as outlined by American Society forQuality, and details how to integrate appropriate designmethodologies up front in the design process. DFSS helps companiesshorten lead times, cut development and manufacturing costs, lowertotal life-cycle cost, and improve the quality of the medicaldevices. Comprehensive and complete with real-world examples, thisguide: Integrates concept and design methods such as Pugh ControlledConvergence approach, QFD methodology, parameter optimizationtechniques like Design of Experiment (DOE), Taguchi Robust Designmethod, Failure Mode and Effects Analysis (FMEA), Design for X,Multi-Level Hierarchical Design methodology, and Response Surfacemethodology Covers contemporary and emerging design methods, includingAxiomatic Design Principles, Theory of Inventive Problem Solving(TRIZ), and Tolerance Design Provides a detailed, step-by-step implementation process foreach DFSS tool included Covers the structural, organizational, and technical deploymentof DFSS within the medical device industry Includes a DFSS case study describing the development of a newdevice Presents a global prospective of medical device regulations Providing both a road map and a toolbox, this is a hands-onreference for medical device product development practitioners,product/service development engineers and architects, DFSS and SixSigma trainees and trainers, middle management, engineering teamleaders, quality engineers and quality consultants, and graduatestudents in biomedical engineering.

Disposable Bioreactors II IGI Global

The second edition of a bestseller, Design Controls for the Medical Device Industry provides a comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure your company’s design control program evolves in accordance with current industry practice. The text assists in the development of an effective design control program that not only satisfies the US FDA Quality System Regulation (QSR) and ISO 9001 and 13485 standards, but also meets today’s third-party auditor/investigator expectations and saves you valuable time and money. The author’s continual participation in FDA QSR inspections and Notified Body ISO audits is reflected in updates to all chapters and appendices of the book, now bursting at the seams with: New coverage of ISO 9001 and 13485 design control requirements More real-world examples from the medical device industry Additional detail for greater understanding and clarity Fresh templates for practical implementation Extensive references for further study The book addresses design control elements such as design planning, input, output, review, verification, validation, change, transfer, and history, as well as risk management inclusive of human factors and usability, biocompatibility, the FDA Quality System Inspection Technique (QSIT) for design controls, and medical device regulations and classes in the US, Canada, and Europe.

Orientaciones para la vigilancia poscomercialización y la vigilancia del mercado de los dispositivos médicos, incluidos los de diagnóstico in vitro Wasatch Consulting Resources LLC

Understanding and improving the CAPA system as a whole is the focal point of this book, the only of its kind dealing exclusively with this critical system within highly regulated industries. Features include: Information about the importance of the CAPA system within the quality system for the medical products regulated industry. Fully updated with current versions of regulations (U.S. FDA, EU, ISO 13485, and so on), and a new section covers the regulatory expectation of customer complaint investigations. Investigation and CAPA elements of the 2015 revision of the ISO 9001 standard. New coverage on the investigation plan and the new U.S. FDA quality metric guidance, as well as a section discussing the tight relationship between CAPAs and FMEA. A new chapter fully devoted to human errors and human factors, and their impact in the investigation and CAPA system. Discussion of a dozen of the most common pitfalls commonly encountered in the investigation and CAPA world of regulated companies. An example of an investigation and CAPA expert certification program being used for many companies. Forms and examples of the different elements (investigation report, root causes checklist, human error investigation, CAPA plan, and so on) covered in the book. Fully usable forms are also included in the companion CD in Microsoft Word format. While the first edition of this book was aimed solely at the FDA-regulated industry, the title of this second edition reflects the importance of the investigation/root cause analysis stage as the necessary preceding step of any effective corrective and preventive action system. Investigation and CAPA are concepts used in many sectors besides the FDA-regulated industry, such as: automotive, electronics, aerospace, telecommunications, process industry, and many more. This book will become an essential reference for those in these other industries.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing Quality Press

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

Microbiological Research and Development for the Food Industry Academic Press

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, Third Edition Springer Science & Business Media

Reference text on validation processes for manufacturing medical devices.

New Paradigms to Bring Innovative Healthcare Products to Patients Quality Press

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.

Plastics in Medical Devices Quality Press

How have recent changes in domestic and international regulations affected quality management in the development and marketing of medical devices in the US and abroad? Consultants Daniel and Kimmelman take a close look at the Quality System Regulation (QsReg), the ISO 13485: 2003 standard and the ISO/TR 14969: 2004 guidance document as well as a number of US Food and Drug Administration (FDA) and Global Harmonization Task Force (GHTF) guidance documents. The authors provide extensive commentary and notes an update their material to include such topics as the incorporation of principles of risk management into the medical device organizations' quality management systems (QMSs) and considerations of combination products. Daniel and Kimmelman include full coverage of the QSReg requirements, descriptions of comparable requirements in the ISO documents, excerpts of the FDA's responses to the QSReg preamble and excerpts from FDA guidance documents related to QMSs.

Plastics in Medical Devices Quality Press

Responding to the growing demand for minimally invasive procedures, this book provides a comprehensive overview of the current technological advances in image-guided surgery. It blends the expertise of both engineers and physicians, offering the latest findings and applications. Detailed color images guide readers through the latest techniques, including cranial, orthopedic, prostrate, and endovascular interventions.

WHO Expert Committee on Biological Standardization Springer Science & Business Media

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.

Sterile Manufacturing Quality Press

Neurorehabilitation Technology provides an accessible, practical overview of the all the major areas of development and application in the field. The initial chapters provide a clear, concise explanation of the rationale for robot use and the science behind the technology before proceeding to outline a theoretical framework for robotics in neurorehabilitative therapy. Subsequent chapters provide detailed practical information on state-of-the-art clinical applications of robotic devices, including robotics for locomotion; posture and balance and upper extremity recovery in stroke and spinal cord injury. Schematic diagrams, photographs and tables will be included to clarify the information for the reader. The book also discusses standard and safety issues and future perspectives.

The Medical Device Validation Handbook Anisiia Tomanek OSVČ

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.

Practical Process Validation World Health Organization

Design, development and life-cycle management of any electromechanical product is a complex task that requires a cross-functional team spanning multiple organizations, including design, manufacturing, and service. Ineffective design techniques, combined with poor communication between various teams, often leads to delays in product launches, with last minute design compromises and changes. The purpose of Design of Electromechanical Products: A Systems Approach is to provide a practical set of guidelines and best practices for driving world-class design, development, and sustainability of electromechanical products. The information provided within this text is applicable across the entire span of product life-cycle management, from initial concept work to the detailed design, analysis, and development stages, and through to product support and end-of-life. It is intended for professional engineers, designers, and technical managers, and provides a gateway to developing a product’s design history file ("DHF") and device aster record ("DMR"). These tools enable design engineers to communicate a product’s design, manufacturability, and service procedures with various cross-functional teams.