Ghtf Sg3 Quality Management System Medical Devices

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Human-Computer Interaction: Concepts, Methodologies, Tools, and Applications - Management Association, Information Resources 2015-10-02
As modern technologies continue to develop and evolve, the ability of users to interface with new systems becomes a paramount concern. Research into new ways for humans to make use of advanced computers and other such technologies is necessary to fully realize the potential of 21st century tools. Human-Computer Interaction: Concepts, Methodologies, Tools, and Applications gathers research on user interfaces for advanced technologies and how these interfaces can facilitate new developments in the fields of robotics, assistive technologies, and computational intelligence. This four-volume reference contains cutting-edge research for computer scientists; faculty and students of robotics, digital science, and networked communications; and clinicians invested in assistive technologies. This seminal reference work includes chapters on topics pertaining to system usability, interactive design, mobile interfaces, virtual worlds, and more.
YY/T 0595-2020: Translated English of Chinese Standard. (YYT 0595-2020, YY/T0595-2020, YYT0595-2020) - https://www.chinesestandard.net 2021-03-20
[After payment, write to & get a FREE-of-charge, unprotected true-PDF from: Sales@ChineseStandard.net] 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.
Introduction to Product Design and Development for Engineers - Dr. Ali Jamnia 2018-06-12
Introduction to Product Design and Development for Engineers provides guidelines and best practices for the design, development, and evaluation of engineered products. Created to serve fourth year undergraduate students in Engineering Design modules with a required project, the text covers the entire product design process and product life-cycle, from the initial concept to the design and development stages, and through to product testing, design documentation, manufacturability, marketing, and sustainability. Reflecting the author's long career as a design engineer, this text will also serve as a practical guide for students working on their capstone design projects.
Assurance of Sterility for Sensitive Combination Products and Materials - Byron J. Lambert 2019-12-12
Assurance of Sterility for Sensitive Combination Products and Materials: New Paradigms for the Next Generation of Medical Devices and Pharmaceuticals discusses the medical device industry and existing challenges regarding the exciting new world of sensitive combination products (SCPs) and their terminal sterilization. This book reassesses the current assumptions to assure the patient’s best interests are met in the development of increasingly rigorous sterilization methods used to counteract MRSA and other 'super-bugs'. In addition, the book discusses the special challenges faced with implantable medical devices, sterilization requirements and further methods needed for material selection and the design process. This book is unique in taking a holistic, end-to-end approach to sterilization, with a particular focus on materials selection and product design. Introduces sterilization principles at the material selection and design stages Addresses the industry need for new sterilization processes for new medical devices and biomaterials Provides guidance to select the appropriate sterilization technique for newly developed sensitive combination products Examines forward thinking tactics for matching new developments in material compatibility with possible regulatory and QSR strategies
Proactive Supplier Management in the Medical Device Industry - James B. Shore 2016-05-06
In order for organizations to have high confidence in the reliability of their medical devices, they must ensure that each and every component or service meets requirements, including quality requirements. In that light, supplier management is not only a regulatory requirement but also a business aspect. The intent of this book is to show readers a process of effectively selecting, evaluating, and implementing applicable controls based on the evaluation and ongoing proactive management of suppliers, consultants, and contractors in a state of compliance. These processes can be applied to all suppliers, consultants, and contractors. In writing this book, the authors made sure that readers could immediately apply its content. They provide best practices based on a combined 50+ years of quality and engineering experience, having worked with some of the best medical device companies and contract manufacturers in the world. Four icons use throughout the book help readers navigate and understand the content. The FDA and toolbox icons assist in determining whether it□s a requirement or a tool to help achieve compliance. The □Lessons from the Road□ icon indicates real-life stories and what the authors have learned throughout their careers. Lastly, the check mark icon is used to highlight key thoughts, what they feel are unique takeaways or deserve a special focus.
Plastics in Medical Devices - Vinny R. Sastri 2010-03-05
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.
DESIGN CONTROLS, RISK MANAGEMENT & PROCESS VALIDATION FOR MEDICAL DEVICE PROFESSIONALS - Vernon Geckler 2017-02-11
This handbook provides the most up to date resource currently available for interpreting and understanding design controls. This handbook is the most exhaustive resource ever written about FDA & ISO 13485 design controls for medical devices with a collection of all applicable regulations and real-world examples. Four-hundred & forty, 8.5" X 11" pages provides an extensive evaluation of FDA 21 CFR 820 and is cross-referenced with ISO 13485 to provide readers with a broad and in-depth review of practical design control implementation techniques. This handbook also covers basic, intermediate and advanced design control topics and is an ideal resource for implementing new design control processes or upgrading an existing process into medical device quality systems. This critical resource also specifically outlines key topics which will allow quality managers and medical device developers to improve compliance quickly to pass internal and external audits and FDA inspections. The author breaks down the regulation line by line and provides a detailed interpretation by using supportive evidence from the FDA design control guidance and the quality systems preamble. Numerous examples, case studies, best practices, 70+ figures and 45+ tables provide practical implementation techniques which are based on the author's extensive experience launching numerous medical device products and by integrating industry consultant expertise. In addition, bonus chapters include: explanation of medical device classification, compliance to design controls, risk management, and the design control quality system preamble. 20-40 pages are dedicated to each of the major design control topics: Design and Development Planning, Design Input, Design Output, Design Transfer, Design Verification, Design Validation, Design Change and Design History File.
WHO Expert Committee on Biological Standardization - World

Health Organization 2018-07-18
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 catalogue of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.

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.

Orientaciones para la vigilancia poscomercialización y la vigilancia del mercado de los dispositivos médicos, incluidos los de diagnóstico in vitro - 2021-05-14
La vigilancia poscomercialización consiste en el conjunto de actividades realizadas por los fabricantes para recopilar y evaluar la experiencia obtenida con los dispositivos médicos comercializados y para determinar si es necesario tomar medidas al respecto. Se trata de un instrumento crucial para asegurar la seguridad y el rendimiento de los dispositivos médicos y garantizar que se adopten medidas si los riesgos de seguir usando algún dispositivo médico superan los beneficios. La evaluación de las experiencias de vigilancia poscomercialización también puede poner de relieve oportunidades de mejora de los dispositivos médicos

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Multilingual - 2006

The ASQ Certified Medical Device Auditor Handbook, Fourth Edition - Scott A Laman 2021-02-05
The ASQ Certified Medical Device Auditor Handbook (formerly The Biomedical Quality Auditor Handbook) was developed by the ASQ Medical Device Division (formerly Biomedical Division) in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the medical device community. It principally serves as a resource to candidates preparing for the Certified Medical Device Auditor (CMDA) certification exam. The fourth edition of this handbook has been reorganized to align with the 2020 certification exam Body of Knowledge (BoK) and reference list. The combination of this handbook with other reference materials can provide a well-rounded background in medical device auditing. Updates to this edition include: • A discussion of data privacy, data integrity principles, and the Medical Device Single Audit Program (MDSAP) • Current information about federal and international regulations • New content regarding human factors and usability engineering, general safety and performance requirements, labeling, validation, risk management, and cybersecurity considerations • A thorough explanation of quality tools and techniques

Руководство по пострегистрационному надзору за медицинскими изделиями, в том числе используемыми для диагностики in vitro - 2021-05-14
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.

Medical Regulatory Affairs - Jack Wong 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.

Image-Guided Interventions - Terry Peters 2008-05-21
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.

Plastics in Medical Devices - Vinny R. Sastri 2021-10-01

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

Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics - 2020-12-09

Handbook of Medical Device Regulatory Affairs in Asia - Jack Wong 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.

Guideline on General Principles of Process Validation - 1987

Practical Process Validation - Mark Allen Durivage 2016-07-14

For the past decade, process validation issues ranked within the top six of Food and Drug Administration (FDA) form 483 observation findings issued each year. This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book. The authors will share their collective knowledge: to help organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards. The intent of this book is to provide manufacturing quality professionals working in virtually any industry a quick, convenient, and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements. It will aid quality technicians, engineers, managers, and others that need to plan, conduct, and monitor validation activities.

Introduction to Product Design and Development for Engineers - Dr. Ali Jamnia 2018-06-01

Introduction to Product Design and Development for Engineers provides guidelines and best practices for the design, development, and evaluation of engineered products. Created to serve fourth year undergraduate students in Engineering Design modules with a required project, the text covers the entire product design process and product life-cycle, from the initial concept to the design and development stages, and through to product testing, design documentation, manufacturability, marketing, and sustainability. Reflecting the author's long career as a design engineer, this text will also serve as a practical guide for students working on their capstone design projects.

Sterile Manufacturing - Sam A. Hout 2021-07-05

This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.

The Medical Device Validation Handbook - Robert Packard 2015-04-05

Reference text on validation processes for manufacturing medical devices.

Design of Electromechanical Products - Ali Jamnia 2016-12-08

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.

WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices - World Health Organization 2017-05-09

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 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 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.

The FDA and Worldwide Quality System Requirements Guidebook for Medical Devices - Amiram Daniel 2008-01-01

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.

Disposable Bioreactors II - Dieter Eibl 2013-12-17

Dynamic Single-Use Bioreactors Used in Modern Liter- and m3- Scale Biotechnological Processes: Engineering Characteristics and Scaling Up, by Christian Löffelholz, Stephan C. Kaiser, Matthias Kraume, Regine Eibl , Dieter Eibl. Orbitally Shaken Single-Use Bioreactors, by Wolf Klöckner, Sylvia Diederichs, Jochen Büchs. Therapeutic Human Cells: Manufacture for Cell Therapy/Regenerative Medicine by Christian van den Bos, Robert Keefe, Carmen Schirmaier, Michael McCaman. Fast Single-Use VLP Vaccine Productions Based on Insect Cells and the Baculovirus Expression Vector System: Influenza as Case Study by Regine Eibl, Nina Steiger, Sabine Wellnitz, Tiago Vicente, Corinne John, Dieter Eibl. Microbial High Cell Density Fermentations in a Stirred Single-Use Bioreactor by Thomas Dreher, Bart Walcarius, Ute Husemann, Franziska Klingenberg, Christian Zahnow, Thorsten Adams, Davy de Wilde, Peter Casteels, Gerhard Greller. Quorus Bioreactor: A New Perfusion-Based Technology for Microbial Cultivation by Sheena J. Fraser, Christian Endres. Cultivation of Marine Microorganisms in Single-Use Systems by Friederike Hillig, Maciej Pilarek, Stefan Junne, Peter Neubauer. Flexible Biomanufacturing Processes that Address the Needs of the Future by Bernhard Diel, Christian Manzke, Thorsten Peuker. An Approach to Quality and Security of Supply for Single-Use Bioreactors by Magali Barbaroux, Susanne Gerighausen, Heiko Hackel. A Risk Analysis for Production Processes with Disposable Bioreactors by Tobias Merseburger, Ina Pahl, Daniel Müller, Markus Tanner.

The Biomedical Quality Auditor Handbook, Third Edition - Heather Crawford 2017-09-08

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.

Robotics: Concepts, Methodologies, Tools, and Applications - Management Association, Information Resources 2013-10-31

"This book explores some of the most recent developments in robotic motion, artificial intelligence, and human-machine interaction, providing insight into a wide variety of applications and functional areas"--Provided by publisher.

Principles of Parenteral Solution Validation - Igor Gorsky 2019-11-27

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

Design Controls for the Medical Device Industry, Third Edition - Marie B. Teixeira 2019-08-02

This third edition provides a substantial comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure a company's design control program evolves in accordance with current industry practice. It assists in the development of an effective design control program that not only satisfies the US FDA Quality Systems Regulation (QSR) and 13485:2016 standards, but also meets today's Notified Body Auditors' and FDA Investigators' expectations. The book includes a review of the 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. Practical advice, methods and appendixes are provided to assist with implementation of a compliant design control program and extensive references are provided for further study. This third edition: Examines new coverage of ISO 13485-2016 design control requirements Explores proven techniques and methods for compliance Contributes fresh templates for practical implementation Provides updated chapters with additional details for greater understanding and compliance Offers an easy to understand breakdown of design control requirements Reference to MDSAP design control requirements

Quality Risk Management in the FDA-Regulated Industry - José Rodríguez Pérez 2012-06-12

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.

Handbook of Research on Advancements in Robotics and Mechatronics - Habib, Maki K. 2014-12-31

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 Investigation and Effective CAPA Systems, Second Edition - José Rodríguez-Pérez 2016-04-04

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.

Design Controls for the Medical Device Industry, Second Edition - Marie B. Teixeira 2013-11-12

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.

Medical Device - Rommel Garcia 2017-06-06

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 laymans 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.

Medical Device Design for Six Sigma - Basem El-Haik 2011-09-20

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.

The Regulatory Compliance Almanac - Les Schnoll 2008