

医疗器械质量管理体系 (ISO 13485:2016) 标准精要

高赋能质量管理模式，确保医疗器械安全有效

提升企业自身竞争能力
实现全价值链精益管理



一站式搞定质量管理体系
十二模块 PDCA循环
轻松理解质量管理体系原理

法规、体系和产品有机结合
各国法规要求 体系四大过程
产品安全性能 灵活应对

风险管理预防机制
四大要素 六大过程
风险方法 全方面运用

生产服务过程控制与确认
“人机料法环测”
实用场景“3Q”应用

管理评审与内部审核
输入输出 六大审核过程
宏观微观 系统监测体系有效性

数据分析工具灵活运用
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方法

运用系统化、深层次方法论，打造医疗器械企业核心竞争力。



核心要点

建立质量方针与目标，强化企业各方面质量管理，保证医疗器械安全有效。



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Iso 13485 2016 Implementation Bsi Group

Ilkka Juuso



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Writing In-House Medical Device Software in Compliance with EU, UK, and US Regulations Philip S.

Cosgriff, Matthew J. Memmott, 2024-03-26 This book is a comprehensive guide to producing medical software for routine clinical use It is a practical guidebook for medical professionals developing software to ensure compliance with medical device regulations for software products intended to be sold commercially shared with healthcare colleagues in other hospitals or simply used in house It compares requirements and latest regulations in different global territories including the most recent EU regulations as well as UK and US regulations This book is a valuable resource for practising clinical scientists producing medical software in house in addition to other medical staff writing small apps for clinical use clinical scientist trainees and software engineers considering a move into healthcare The academic level is post graduate as readers will require a basic knowledge of software engineering principles and practice Key Features Up to date with the latest regulations in the UK the EU and the US Useful for those producing medical software for routine clinical use Contains best practice

The Combination Products Handbook Susan Neadle, 2023-05-16 Combination products are therapeutic and diagnostic products that combine drugs devices and or biological products According to the US Food and Drug Administration FDA a combination product is one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product Examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products This handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market The authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices This handbook Brings clarity of understanding for global combination products guidance and regulations Reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors Endorsed by AAMI Association for the Advancement of Medical Instrumentation

Decontamination in Hospitals and Healthcare James T. Walker, 2019-11-26 Decontamination in Hospitals and Healthcare Second Edition enables users to obtain detailed knowledge of decontamination practices in healthcare settings including surfaces devices clothing and people with a specific focus on hospitals and dental clinics Offers in depth coverage of all aspects of decontamination in healthcare Examines the decontamination of surgical equipment and endoscopes Expanded to include new information on behavioral principles in decontamination control of microbiological problems waterborne microorganisms pseudomonas and the decontamination of laundry

Digital

Respiratory Healthcare Hilary Pinnock,Vitalii Poberezhets,David Drummond,2023-12-01 Respiratory care is undergoing a period of major change as it cautiously begins to embrace digital transformation Catalysed by the need for remote consultation in the pandemic time honoured approaches to delivering care are now being challenged by technology based initiatives This Monograph deftly guides the reader through the potential benefits and pitfalls of such change breaking the discussion down into three areas technological opportunities and regulatory challenges social benefits challenges and implications exemplars of digital healthcare Each chapter reviews contemporary literature and considers not if but how a digital respiratory future can provide optimal care The result is an authoritative balanced guide to developing digital respiratory health Design of Biomedical Devices and Systems, 4th edition Paul H. King,Richard C. Fries,Arthur T. Johnson,2018-10-03 This fourth edition is a substantial revision of a highly regarded text intended for senior design capstone courses within departments of biomedical engineering bioengineering biological engineering and medical engineering worldwide Each chapter has been thoroughly updated and revised to reflect the latest developments New material has been added on entrepreneurship bioengineering design clinical trials and CRISPR Based upon feedback from prior users and reviews additional and new examples and applications such as 3D printing have been added to the text Additional clinical applications were added to enhance the overall relevance of the material presented Relevant FDA regulations and how they impact the designer s work have been updated Features Provides updated material as needed to each chapter Incorporates new examples and applications within each chapter Discusses new material related to entrepreneurship clinical trials and CRISPR Relates critical new information pertaining to FDA regulations Presents new material on discovery of projects worth pursuing and design for health care for low resource environments Presents multiple case examples of entrepreneurship in this field Addresses multiple safety and ethical concerns for the design of medical devices and processes **Enabling and Safeguarding Personalized Medicine** Federica Casarosa,Francesca Gennari,Arianna Rossi,2025-08-28 This open access volume provides a comprehensive guide to the most pressing challenges arising from the technologies that enable personalized medicine It brings together theoretical empirical and case study based contributions that span across disciplinary boundaries to examine related problems and propose solutions critically Personalized medicine is the next frontier in scientific public health and commercial advancements By recognizing the uniqueness of each human body data driven treatments and digital robotic devices are being increasingly developed to enable patients and medical personnel to benefit from highly accurate and personalized diagnoses and therapies Healthcare customization is based on predictive preventive personalized and participatory elements each of which requires an interplay between healthcare systems medical personnel patients as well as bioengineers economists regulators lawyers and business owners If the goal of more proactive patient inclusion is to enhance the efficacy of personalized medical interventions it is also paramount to evaluate whether the adoption of customized solutions is sustainable from both economic and organizational perspectives Legal norms provide the

framework in which the development of new medical devices the sharing of data for the public good and the provision of healthcare may occur This area of research and practice is regulated by a complex mix of norms concerning personal and non personal data AI governance cybersecurity health law and liability regimes In ever evolving domains where some regulations still need to be defined approved or implemented researchers and practitioners need guidance to enable the safe by design development of medical technologies The book is organized in three sections I Facilitating and Protecting Personalized Medicine which revolves around the mechanisms that enable the sharing and reuse of health data within the Common European Data Spaces seeks to address the cybersecurity challenges posed by medical technologies and critically discusses the definition of scientific research in recent legislative efforts II Scoping Challenges Through the Players in the Personalized Medicine Ecosystem which gathers varied interdisciplinary insights from scholars and practitioners in the fields of medicine economics engineering education and compliance and III Challenges of Personalized Medicine for Liability which focuses on the challenges that personalized data driven medicine poses for traditional and novel liability regimes

Inspection of Medical Devices Almir Badnjević, Mario Cifrek, Ratko Magjarević, Zijad Džemić, 2023-11-26 This comprehensive guide invites nations worldwide to embark on a transformative journey implementing independent third party verification systems that ensure medical devices comply with both international and national regulations Prepare to be captivated as we delve into the intricate processes unveil essential procedures and illuminate the paramount importance of establishing traceability for medical device measurements Imagine a world where medical devices undergo rigorous independent safety and performance verification guaranteeing the utmost reliability for patient diagnoses and treatment This book takes you on a compelling exploration of precisely that vision Focusing on cutting edge diagnostic and therapeutic devices it captures the very essence of the latest international directives and regulations ensuring you stay ahead of the curve This new edition goes beyond the conventional delving into the realms of innovation and progress Unveiling in depth maintenance regimes within healthcare institutions we provide you with invaluable insights into post market surveillance As the world embraces the transformative potential of artificial intelligence we pave the way for evidence based management of medical device maintenance a concept poised to reshape the healthcare landscape Imagine a future where medical devices are seamlessly integrated into the legal metrology system while fully operational national laboratories for medical device inspection set new standards of excellence This book vividly illustrates how such a powerful union can elevate the reliability of medical devices in diagnosis and patient care Brace yourself for a paradigm shift that not only enhances efficacy but also leads to significant cost reductions within your country's healthcare system Join us on this extraordinary journey as we unveil the untapped potential of medical device inspection With our innovative approach and unrivaled expertise together we can revolutionize healthcare transforming the lives of countless patients worldwide Get ready to be inspired informed and empowered welcome to the future of healthcare

Trends in Development of Medical Devices Prakash Srinivasan

Timiri Shanmugam, Logesh Chokkalingam, Pramila Bakthavachalam, 2020-01-25 Trends in Development of Medical Devices covers the basics of medical devices and their development regulations and toxicological effects risk assessment and mitigation It also discusses the maintenance of a medical device portfolio during product lifecycle This book provides up to date information and knowledge on how to understand the position and benefits of new introduced medical devices for improving healthcare Researchers and industry professionals from the fields of medical devices surgery medical toxicology pharmacy and medical devices manufacture will find this book useful The book s editors and contributors form a global interdisciplinary base of knowledge which they bring to this book Provides a roadmap to medical devices development and the integration of manufacturing steps to improve workflows Helps engineers in medical devices industries to anticipate the special requirements of this field with relation to biocompatibility sterilization methods government regulations Presents new strategies that readers can use to take advantage of rapid prototyping technologies such as 3D printing to reduce imperfections in production and develop products that enable completely new treatment possibilities

Insights in cardiovascular imaging: 2022 Christos Bourantas, Sebastian Kelle, Grigorios Korosoglou, 2023-07-21

A Practical Field Guide for ISO 13485:2016 Erik V. Myhrberg, Joseph Raciti, Brandon L. Myhrberg, 2019-11-06 The purpose of this expanded field guide is to assist organizations step by step in implementing a quality management system QMS in conformance with ISO 13485 2016 whether from scratch or by transitioning from variations of the ISO 13485 family In keeping with ISO 9000 2015 s definition of quality as the degree to which a set of inherent characteristics fulfills requirements Myhrberg Raciti and Myhrberg have identified the requirements and inherent characteristics distinguishing features for this expanded field guide Within the guide each subclause containing requirements is the focus of a two page visual spread that consistently presents features that fulfill the requirements listed below This guide will Provide a user friendly guide to ISO 13485 2016 s requirements for implementation purposes Identify the documents documentation required along with recommendations on what to consider retaining adding to a QMS during ISO 13485 2016 implementation Guide internal auditor s regarding what to ask to verify that a conforming and effective QMS exists Direct management on what it must do and should consider to satisfy ISO 13485 2016 s enhanced requirements as well as on the responsibilities for top management Depict step by step in flowchart form what must occur to create an effective conforming QMS

Developing an ISO 13485-Certified Quality Management System Ilkka Juuso, 2022-03-20 Developing an ISO 13485 Certified Quality Management System An Implementation Guide for the Medical Device Industry details the lessons learned from a real world project focusing on building an ISO 13485 2016 Quality Management System QMS from scratch and then having it officially certified It is a practical guide to building or improving your existing QMS with tried and tested solutions The book takes a hands on approach first teaching the top 25 lessons to know before starting to develop a QMS and then walking you through the process of writing the quality manual and the standard operating procedures training the staff on the QMS organizing an

internal audit executing a management review and finally passing the necessary external audits and obtaining certification It helps you to progress from one task to the next and provides all the essential information to accomplish each task as quickly and efficiently as possible It does not attempt to replicate the standard but instead drills into the standard to expose the core of each section of the standard and reorganize its contents into a practical workflow for developing maintaining and improving a Lean QMS The book includes a wealth of real world experience both from the author s personal dive into quality management and from the experiences of other companies in the field and provides handy checklists for ensuring key documents and processes are fit for use the emphasis here is to help ensure you have considered all relevant aspects In addition the book is not intended as a cheat sheet for the standard or as a review of the standard that only adds lengthy commentary on each of the clauses Instead the book fixes easy misunderstandings regarding QMS provides insight into why the various clauses are written the way they are and provides a great base to both understanding ISO 13485 QMS and developing your own QMS The book is intended to serve both experts and novices audiences it provides special insight on the most crucial and effective aspects of QMS

ISO 13485:2016 Itay Abuhav,2018-05-11 Summary This book provides valuable effective guidance for understanding interpreting and implementing ISO 13485 2016 standard requirements Despite its more than 800 page length the author has specifically designed its contents to maximize usability for the reader with a table of contents identical to that of the ISO standard itself which enables easy navigation and orientation Pragmatic in style and down to earth in tone this book draws real life examples and case studies from the author s many years of experience in consulting to illustrate even the most complex of ISO 13485 2016 standard requirements and their implementation Identifying relevant requirements and how they harmonize with quality management systems developing processes for design and development as well as product realization and validation are just a few of the issues covered in depth by this publication In addition the author constantly reviews the distinctive characteristics and aspects of the medical device manufacturing industry so that the reader can also appreciate the subject of this book in an everyday context Features A pragmatic and down to earth approach towards the reader s understanding of ISO 13485 2016 standard requirements implementation Uses examples and cases from real life based on the author s many years of experience in quality management A table of contents structured identically to that of ISO 13485 2016 itself allowing easier navigation and orientation for the reader Emphasises guidance for ISO 13485 2016 standard requirements which are difficult to interpret and implement Constantly reviews the aspect of medical device industry characteristics and distinctive so the reader can reflect the content with its daily work

A Practical Field Guide for ISO 13485 Erik V. Myhrberg,Joseph A Raciti,2019-11-06 The purpose of this expanded field guide is to assist organizations step by step in implementing a quality management system QMS in conformance with ISO 13485 2016 whether from scratch or by transitioning from variations of the ISO 13485 family In keeping with ISO 9000 2015 s definition of quality as the degree to which a set of inherent characteristics fulfills

requirements Myhrberg Raciti and Myhrberg have identified the requirements and inherent characteristics distinguishing features for this expanded field guide Within the guide each subclause containing requirements is the focus of a two page visual spread that consistently presents features that fulfill the requirements listed below This guide will Provide a user friendly guide to ISO 13485 2016 s requirements for implementation purposes Identify the documents documentation required along with recommendations on what to consider retaining adding to a QMS during ISO 13485 2016 implementation Guide internal auditor s regarding what to ask to verify that a conforming and effective QMS exists Direct management on what it must do and should consider to satisfy ISO 13485 2016 s enhanced requirements as well as on the responsibilities for top management Depict step by step in flowchart form what must occur to create an effective conforming QMS

A Practical Field Guide for ISO 13485:2016 Erik V. Myhrberg, Joseph Raciti, Brandon L. Myhrberg, 2019 The purpose of this expanded field guide is to assist organizations step by step in implementing a quality management system QMS in conformance with ISO 13485 2016 whether from scratch or by transitioning from variations of the ISO 13485 family In keeping with ISO 9000 2015 s definition of quality as the degree to which a set of inherent characteristics fulfills requirements Myhrberg Raciti and Myhrberg have identified the requirements and inherent characteristics distinguishing features for this expanded field guide Within the guide each subclause containing requirements is the focus of a two page visual spread that consistently presents features that fulfill the requirements listed below This guide will Provide a user friendly guide to ISO 13485 2016 s requirements for implementation purposes Identify the documents documentation required along with recommendations on what to consider retaining adding to a QMS during ISO 13485 2016 implementation Guide internal auditor s regarding what to ask to verify that a conforming and effective QMS exists Direct management on what it must do and should consider to satisfy ISO 13485 2016 s enhanced requirements as well as on the responsibilities for top management Depict step by step in flowchart form what must occur to create an effective conforming QMS

Medical Devices -- Quality Management Systems -- Requirements for Regulatory Purposes (ISO 13485:2016), 2017

Guidance on the Relationship Between en ISO 13485 British Standards Institute Staff, 1918-03-21 Management Diagnostic equipment medical Quality management Medical equipment Information management *Implementing an Iso 13485 Quality Management System for Medical Devices* Ann Goodall, British Standards Institute Staff, 1914-04-04 Medical equipment Medical instruments Medical technology Quality management Quality assurance systems Acceptance approval Management Quality and Management **ISO 13485:2016**, 2017 **ISO 13485 for Engineers** Priscilla Browne, 2021-12 This book is written to provide Quality engineers medical engineers device engineers with a practical and insightful companion to understand ISO 13485 Quality Management system for medical devices It provides a straight to the point perspective which should assist in the interpretation of the standard and provide a benchmark for what is expected in the application of the standard and compliance for industry ISO 13485 2016 is an international standard for the quality

management of medical devices It is of value and applicable to a number of business areas that are involved in the various stages of a medical device and its product lifecycle It may be applied by a design company manufacturer raw material supplier calibration service sterilization services or distributor The scope of the standard covers design and development production storage and distribution installation servicing if required decommissioning and disposal In particular manufacturers of medical devices and typically mandated by regulatory bodies to comply with ISO 13484 and must demonstrate compliance and application of the standard subject to certification and an audit process FDA 21 CFR Part 820 is another example of a Quality Management system While its official designation is a Quality System QS it serves a similar purpose to ISO 13485 Quality management system for medical devices However there is an important distinction 21 CFR Part 820 has a regulatory standing in the United states While many competent authorities require the application of ISO 13485 the framework of ISO 13485 is a standard opposed to a regulation Revised in 2016 ISO 13485 2016 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements The scope of the standard can apply to any organisation or company involved throughout the life cycle of a product including design and or development production storage and distribution installation or servicing of a medical device and design and development or provision of technical or professional services The 2016 revision is designed to address recent developments in quality management and other updated regulations that relate to the industry Improvements in the new version of the standard include broadening its applicability to include all organisations involved in the life cycle of the product from the concept stage to end of life along with greater alignment with regulatory requirements and post market surveillance including complaint handling Overview of Content Introduction to ISO 13485 Directives and Standards Competent Authorities Notified Bodies How ISO 13485 differs to ISO 9001 ISO TR 14969 Terms Definitions Process Approach Plan Do Check Act PDCA Quality Management System Introduction Regulatory Requirements Risk Based Approach Changes within the QMS Documentation Quality Manual Control of Records Management Responsibility Management Commitment Customer Focus Quality Policy Planning Management Review Resource Management Provision of resources Human resources Infrastructure Work environment contamination control Product realization Planning of Product Realization Design and Development Production and service provision Ctrl of monitoring measuring equipment Measurement Analysis PART 2 Good Documentation Practices Introduction Quality Management Systems PART 3 Validation Introduction Equipment and Software Validation Software Validation Process Validation Packaging Validation Implementing ISO/IEC 17025:2017 Bhavan (Bob) Mehta,2019-02-21 The focus of this book is to demystify the requirements delineated within ISO IEC 17025 2017 while providing a road map for organizations wishing to receive accreditation for their laboratories AS9100 ISO 9001 2015 and ISO 13485 2016 are standards that have been created to support the development and implementation of effective approaches to

quality management and are recognized blueprints for the establishment of a quality management system QMS for many diverse industries Similar to these recognized QMS standards ISO IEC 17025 2017 for laboratory accreditation serves a unique purpose It is not unusual for laboratories to retain dual certification in ISO 9001 2015 and ISO IEC 17025 2017 However ISO IEC 17025 2017 contains requirements specific to the laboratory environment that are not addressed by ISO 9001 2015 This book highlights those differences between ISO 9001 2015 and ISO IEC 17025 2017 while providing practical insight and tools needed for laboratories wishing to achieve or sustain accreditation to ISO IEC 17025 2017 For those currently or formerly accredited to the 2005 version of ISO IEC 17025 an appendix outlines the changes between the 2005 and 2017 versions of the standard

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