



# Quality manual, ISO 13485 and MDR, free template

By Guillaume Promé

Sep. 24, 2021 • ISO 13485, Regulation (EU) 2017/745

The European regulation for medical devices requires manufacturers to **write and maintain a quality manual** that documents the quality management system implemented, as specified in Regulation (EU) 2017/745, Chapter L2.2 and Annex XLA.6.2 :

“ All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

In this article, you will find a **quality manual template** conforming to the requirements of **Regulation 2017/745** and **EN ISO 13485:2016 + A11:2021**.

👉 This quality manual template can be set up according to your activities and products, using Qualitio online templates.

## What is quality manual?

The quality manual is a document that presents the measures taken by an organization to meet the requirements applicable to its quality management system.

## What is the purpose of quality manual?

The quality manual allows to understand the functioning of a company and its environment and to communicate its objectives. It is often presented to auditors and



# Quality Manual Template Iso 13485 Medical Devices

**G.R Higson**



## **Quality Manual Template Iso 13485 Medical Devices:**

**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

**Medical Devices** Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo, 2015-08-18 Medical Devices and Regulations Standards and Practices will shed light on the importance of regulations and standards among all stakeholders bioengineering designers biomaterial scientists and researchers to enable development of future medical devices Based on the authors practical experience this book provides a concise practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

**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 13495 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

**ISO 9001:2000 Quality Management System Design** Jay J. Schlickman, 2003 Provides a set of design rules for creating a quality management system that will naturally translate into successful ISO 9001 2000 certification The book identifies the key documentation components and supplies guidelines for outlining and writing the quality manual standard operating procedures work instructions forms and records Two case studies illustrate the upgrade and recertification of a corporation from ISO 9001 1994 to ISO 9001 2000 and the creation of a company s first quality management system The author is an auditor certified by the ASQ ANSI registrar accreditation board Annotation copyrighted by Book News Inc Portland OR

**Biocompatibility and Performance of Medical Devices** Jean-Pierre Boutrand, 2019-11-21 Biocompatibility and Performance of Medical Devices Second Edition provides an understanding of the biocompatibility and performance tests for ensuring that biomaterials and medical devices are safe and will perform as expected in the biological environment Sections cover key concepts and challenges faced in relation to biocompatibility in medical devices discuss the evaluation and characterization of biocompatibility in medical devices describe preclinical performance studies for bone dental and soft tissue implants and provide information on the regulation of medical devices in the European Union Japan and China The book concludes with a review of histopathology principles for biocompatibility and performance studies Presents diverse insights from experts in government industry and academia Delivers a comprehensive overview of testing and interpreting medical device performance Expanded to include new information including sections on managing extractables accelerating and simplifying medical device development through screening and alternative biocompatibility methods and quality strategies which fasten device access to market

**Medical Device Safety** G.R Higson, 2001-10-29 Medical Device Safety The Regulation of Medical Devices for Public Health and Safety examines the prospects for achieving global harmonization in medical device regulation and describes a possible future global system Unresolved difficulties are discussed while solutions are proposed An essential book for all those involved in health physics

en     **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

**Devices and Wearables Using Smart Actuator** Ermira Junita Abdullah, Dayang Laila Abdul Majid, Kittikhun Thongpull, 2025-02-03 The new generation of devices and wearables requires state of the art technology to provide seamless solutions for the users This tutorial style book on circuits and systems introduces the latest devices and wearables using smart materials for compact and lightweight design It provides an overview on the fundamental theory of shape memory alloy materials designing shape memory alloy actuation for different applications as well as highlighting current devices and wearables using shape memory alloy Shape memory alloy is a type of smart material that has huge potential to replace conventional actuators due to its high force to weight ratio The book also includes other examples of medical devices that have been developed It is targeted for researchers technical staff engineers and students focusing on devices and wearables

**Medical Device Design** , 2012-12-17 This book provides the bridge between engineering design and medical device development There is no single text that addresses the plethora of design issues a medical devices designer meets when developing new products or improving older ones It addresses medical devices regulatory FDA and EU requirements some of the most stringent engineering requirements globally Engineers failing to meet these requirements can cause serious harm to users as well as their products commercial prospects This Handbook shows the essential methodologies medical designers must understand to ensure their products meet requirements It brings together proven design protocols and puts them in an explicit medical context based on the author s years of academia R D phase and industrial commercialization phase experience This design methodology enables engineers and medical device manufacturers to bring new products to the marketplace rapidly The medical device market is a multi billion dollar industry Every engineered product for this sector from scalpels stents to complex medical equipment must be designed and developed to approved procedures and standards This book shows how Covers US and EU and ISO standards enabling a truly international approach providing a guide to the international standards that practicing engineers require to understand Written by an experienced medical device engineers

and entrepreneurs with products in the from the US and UK and with real world experience of developing and commercializing medical products      **MDD Compliance Using Quality Management Techniques** Ray

Tricker,2012-04-27 The Medical Devices Directive MDD is an all encompassing document legislating for the manufacture of any medical device or material used either temporarily or permanently on or in the human body To achieve its main objectives the MDD requires the manufacturer of all products covered by the Directive to possess a fully auditable Quality Management System consisting of Quality Policies Quality Procedures and Work Instructions based on the ISO 9000 standard The book is based on the sound principles of ISO 9000 and will guide to the reader if required to eventually set up an ISO 9000 fully compliant system MDD Compliance using Quality Management Techniques consists of the following A brief guide to the Medical Devices Directive explaining the main requirements of the directive translating legal Eurospeak into everyday language An overview of ISO 9000 and how the MDD links in with these international requirements A Quality Manual will provide a template for a complete Quality Management System that can be used by any product being produced under the requirements of the MDD CD ROM containing a software copy of the Quality Manual A User manual consisting of clear instructions and flow charts on how to set up and use the Quality Management System described in the Quality Manual

## Whispering the Techniques of Language: An Mental Journey through **Quality Manual Template Iso 13485 Medical Devices**

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