



# 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



# Iso 13485 Quality Manual Template

**L Cohen**



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

**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 *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

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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

**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     **ISO 13485** Itay Abuhav,2011-10-20 Although complex and lengthy the process of certification for the ISO 13485 can be easily mastered using the simple method outlined in ISO 13485 A Complete Guide to Quality Management in the Medical Device Industry Written by an experienced industry professional this practical book provides a complete guide to the ISO 13485 Standard certification for medical device manufacturing Filled with examples drawn from the author s experience and spanning different sectors and fields of the medical device industry the book translates the extra ordinary requirements and objectives of the standard into feasible activities and tasks The book provides a full analysis of each clause and sub clause through quality perspectives the implications on an organization its processes management human resources infrastructures work environment control and effectiveness documentations and records The book is organized like the standard itself the table of contents is identical to the ISO 13485 Standard s table of contents making it user friendly familiar and unintimidating You can use the book as a consulting session read it explore it extract ideas and draw on the information and knowledge that suits you and your organization and then apply it effectively to your quality management system and processes     **ISO 9001 Sample Quality Manual** Harold J. Steudel,1992     How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements Stephanie L. Skipper,2015-10-14 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system     **ISO 9000 Quality**

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**ISO 17025-2017 Sample Quality Manual for Testing Lab** M. NAVEED,Kranti DHARKAR,Ramesh LAKHE,2018-12-17 This book is specially useful for the laboratories preparing Quality Manual as per ISO 17025 2017 Lab Quality Management System It includes the index release authorisation amendment sheet explanation of how lab complies with clause requirements references to procedures and records for each clause as an evidence The book is also useful to all the professionals associated with laboratory quality management as reference for preparing the lab for accreditation

**Easy ISO 13485** Jahangir Asadi,2021-10-17 If your document can answer these 6 questions then you have developed a completely effective document no matter that it is a quality manual procedure SOP work instruction see page 34 for more details

**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     ISO 9001:2000 Harold J. Steudel,Terry M. Mann,2000     *Weights and Measures Division ... Type Evaluation Laboratory Quality Manual Template ...*, Nistir 7028 ... *U.s. Department of Commerce* National Institute of Standards and Technology (U.S.),2004\*     MDD Compliance Using Quality Management Techniques Ray Tricker,2000 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 Easy to follow guide to MDD Written in clear no nonsense format Quality manual will provide template for any product being produced under MDD

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identify what type of data you want to gather if you want to observe a child s socialization skills schedule the observation while the child is at a playdate with friends if you want to observe a child in the school setting schedule the observation on a weekday when the child is in class

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the example of observation report rusnadi ali kasan after about 20 minutes passed the teacher this is interesting that the teacher tried to then shared and distributed a feedback collaborate the students by asking them to form to the student and also gave me one

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for example a school psychologist is nearly finished with an sld evaluation in spite of this she is obligated to visit the classroom during ongoing instruction and make note of the student s behavior see table 8 1 in this school district the idea observation requirement is delegated to the school psychologist

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for instance while drawing a picture she told me i am drawing a foot then she wrote foot similarly while making the same drawing she said the eyes are smiling at you and she wrote eyes child a displays improving cognitive development skills her

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