MEDQDOC
QMS TEMPLATES

Supporting your medical device compliance to ISO 13485 and QSR

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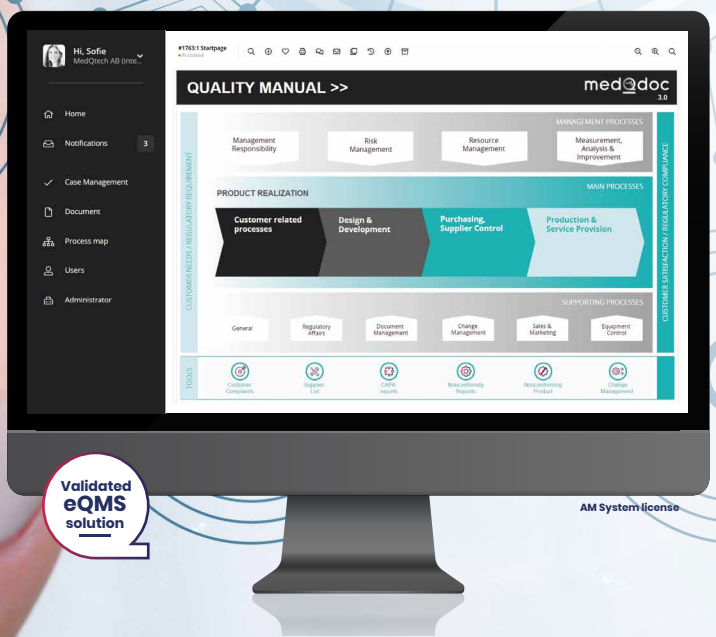
A QUALITY MANAGEMENT SYSTEM (eQMS) DESIGNED FOR THE MEDICAL DEVICE INDUSTRY

Connecting quality and regulatory compliance with a human touch

COMPLY EASILY WITH

- ISO 13485
- ISO 14971
- MDR 2017/745
- IVDR 2017/746



Validated eQMS solution

AM System license

MedQdoc offers Quality Management System (QMS) templates to help your organisation meet regulatory requirements for medical devices.

In this document, you will find a list of MedQdoc's QMS templates that can be used to ensure your medical device complies with ISO 13485 and FDA 21 CFR 820 (QSR).

Table of contents

1. Introduction

MedQdoc includes QMS templates to help your organisation comply with:
+ EN ISO 13485:2016 + EN ISO 14971:2019 + QSR 21 CFR part 820

1.1 Definitions

Each document/record in MedQdoc is grouped by document type:

CASE
Case management forms, for example CAPA, Complaints and Change

Policy
High level requirements to comply with applicable regulations & standards

SOP
Standard operating procedure

WI
Work instruction

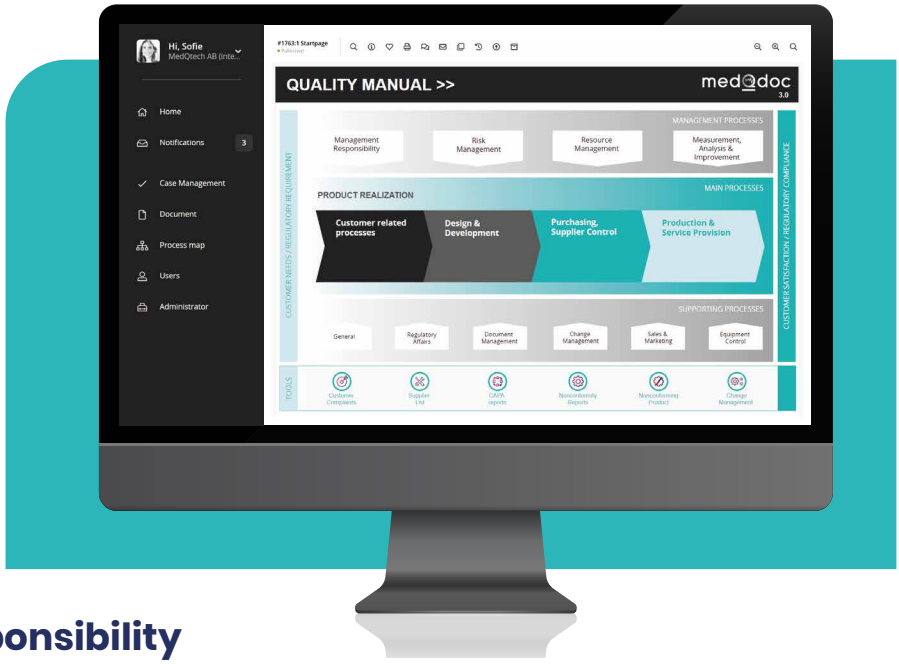
REC
Record – all documents that are not controlled documents are shown with the prefix REC

Template
Available templates in the template library

2. MedQdoc Start page

This is the start page of MedQdoc – your quality management system.

Content for each chapter in the Quality Manual is listed below.



2.1 Management Responsibility

Type	Title	ISO 13485	21 CFR part 820
SOP	Change Management	4.1 General requirements 7.3.9 Control of design and development changes	820.20 Management responsibility
SOP	Management Review	5.6 Management review	820.20 Management responsibility
SOP	Communication, Internal/External	5.5 Responsibility, authority and communication	820.20 Management responsibility
SOP	Management Responsibility	5.1 Management commitment	820.20 Management responsibility
SOP	Functions, Roles and Job Descriptions	5.5.1 Responsibility and authority	820.20 Management responsibility
Policy	Quality Policy	5.3 Quality policy	820.20 Management responsibility
REC	Example of Quality Plan & Objectives	5.4 Planning	820.20 Management responsibility
REC	Example of Organization Chart	5.5 Responsibility, authority and communication	820.20 Management responsibility
Template	Management Review Agenda/ Protocol	5.6 Management review	820.20 Management responsibility
Template	Quality Objectives, Planning - Period YEAR 20XX/20XX	5.4 Planning	820.20 Management responsibility
CASE	Change Management	4.1 General requirements	820.20 Management responsibility

2.2 Risk Management

Type	Title	ISO 14971
SOP	Product Risk Management	ISO 14971:2019
Policy	Risk Management Policy	ISO 14971:2019
Template	Risk Management Plan	ISO 14971:2019
Template	Risk Management Report	ISO 14971:2019
Template	Risk Analysis	ISO 14971:2019
Template	Risk Analysis with Attachment	ISO 14971:2019
Template	Checklist - ISO/TR 24971:2020, Annex A	ISO/TR 24971:2020

2.3 Resource Management

Type	Title	ISO 13485	21 CFR part 820
SOP	Resource Management	6.1 Provision of resources	820.20 Management responsibility
SOP	Competence & Training	6.2 Human resources	820.25 Personnel
SOP	Infrastructure & Work Environment	6.3 Infrastructure, 6.4 Work environment and contamination control	820.70 Production and process controls
Template	Training Record	6.2 Human resources	820.25 Personnel
Template	Personnel CV Upload	6.2 Human resources	820.25 Personnel
Template	Introduction Program	6.2 Human resources	820.25 Personnel
Template	Performance & Development Review	6.2 Human resources	820.25 Personnel

2.4 Measurement, Analysis & Improvement

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Nonconforming Process	8.1 General 8.2 Monitoring and measurement 8.3 Control of nonconforming product	820.90 Nonconforming product 820.198 Complaint files
SOP	Post Market Surveillance	8.2 Monitoring and measurement 8.2.1 Feedback MDR, Annex III	820.198 Complaint files
SOP	Customer Complaints	8.1 General 8.2.2 Complaint handling	820.198 Complaint files
SOP	Reporting to Authorities	8.1 General 8.2 Monitoring and measurement 8.2.3 Reporting to regulatory authorities	820.198 Complaint files
SOP	Internal Audit	8.1 General 8.2 Monitoring and measurement 8.2.4 Internal audit	820.22 Quality audit
SOP	Analysis of Data	8.4 Analysis of data 8.2.5 Monitoring and measurement of processes 8.2.6 Monitoring and measurement of product	820.250 Statistical techniques
SOP	CAPA – Corrective and Preventive Action	8.5 Improvement	820.100 Corrective and preventive action

Type	Title	ISO 13485	QSR 21 CFR part 820
Template	Post Market Surveillance Plan	8.2.1 Feedback MDR, Annex III	N/A
Template	Post Market Surveillance Checklist (Article 83)	8.2.1 Feedback MDR, Article 83	N/A
Template	Post Market Surveillance Report	8.2.1 Feedback MDR, Annex III	N/A
Template	Periodic Safety Update Report	8.2.1 Feedback MDR, Article 86	N/A
Template	Internal Audit Program	8.2 Monitoring and measurement 8.2.4 Internal audit	820.22 Quality audit
Template	Internal Audit Plan/ Agenda	8.2 Monitoring and measurement 8.2.4 Internal audit	20.22 Quality audit
Template	Internal Audit Report	8.2 Monitoring and measurement 8.2.4 Internal audit	20.22 Quality audit
CASE	Nonconformity (General)	8.1 General 8.2 Monitoring and measurement	820.22 Quality audit 820.198 Complaint files
CASE	Nonconforming Product	8.3 Control of nonconforming product	820.90 Nonconforming product
CASE	Customer Complaint	8.2.2 Complaint handling	820.198 Complaint files
CASE	CAPA	8.5 Improvement	820.100 Corrective and preventive action

2.5 Product Realization

2.5.1 Customer Related Processes (Sales & Marketing)

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Customer Related Process	7.2 Customer related processes	N/A
Template	Customer Order	7.2 Customer related processes	N/A

2.5.2 Design & Development

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Design and Development	7.3 Design and development	820.30 Design control
SOP	Design Reviews	7.3 Design and development review	820.30 Design control
Template	Design Review	7.3 Design and development review	820.30 Design control
Template	Product Concept Report	7.1 Planning of product realization	820.30 Design control
Template	Design & Development Plan	7.3.2 Design and development planning	820.30 Design control
Template	Design & Development Verification Plan	7.3.6 Design of development verification	820.30 Design control

Type	Title	ISO 13485	QSR 21 CFR part 820
Template	Design & Development Validation Plan	7.3.7 Design of development validation	820.30 Design control
Template	Design & Development Validation Report	7.3.7 Design of development validation	820.30 Design control
Template	Design Transfer Plan/ Report	7.3.8 Design and development transfer	820.30 Design control
Template	Design Input & Output Matrix	7.3.3 Design and development inputs 7.3.4 Design and development outputs	820.30 Design control
CASE	Change Management	7.3.9 Control of design and development changes	820.30 Design control

2.5.3 Purchasing, Supplier Control

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Purchasing	7.4 Purchasing	820.50 Purchasing control
SOP	Supplier Control	7.4 Purchasing	820.50 Purchasing control
WI	Using Case Management for Supplier Control	7.4 Purchasing	820.50 Purchasing control
Template	Purchase Order	7.4 Purchasing	820.50 Purchasing control
Template	Supplier Audit Plan/Report	7.4 Purchasing	820.50 Purchasing control
Template	SCAR	7.4 Purchasing	820.50 Purchasing control
CASE	Supplier Questionnaire	7.4 Purchasing	820.50 Purchasing control
CASE	Supplier Registration & Evaluation	7.4 Purchasing	820.50 Purchasing control
CASE	Supplier Performance Review	7.4 Purchasing	820.50 Purchasing control
CASE	Change Management	7.4 Purchasing	820.50 Purchasing control
CASE	Supplier List	7.4 Purchasing	820.50 Purchasing control

2.5.4 Production & Service Provision

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Production & Service Provision	7.5 Production and service provision	820.70 Production and process control 820.130 Device packaging
SOP	Process Validation	7.5 Production and service provision	820.75 Process validation
SOP	Identification & Traceability	7.5 Production and service provision	820.60 Identification 820.65 Traceability
SOP	Device Master Record - DMR	7.5 Production and service provision	820.182 Device master control
SOP	Warehousing	7.5 Production and service provision	820.140 Handling 820.150 Storage 820.160 Distribution
Template	Device Master Record Checklist	7.5 Production and service provision	820.182 Device master control
Template	Production Quality Plan	7.5 Production and service provision	820.70 Production and process control
Template	Notification to customer about changes on his/her property	7.5 Production and service provision	N/A

2.6 General

Type	Title	ISO 13485	21 CFR part 820
QM	Quality Manual	4.1 General requirements 4.2 Document requirements	820.5 Quality system 820.20 (e) Management responsibility
SOP	Computerized Software Validation	4.1 General requirements	11.10 Controls for closed system 11.30 Controls for open system
SOP	QMS Processes, Risk Based Approach	4.1 General requirements	N/A
Policy	IT-Policy	4.1 General requirements	11.10 Controls for closed system 11.30 Controls for open system
REC	Master Validation List - Computerized Software	4.1 General requirements	820.75
REC	Risk Analysis for QMS Processes	4.1 General requirements	N/A
Template	Risk Analysis for Computerized Software System	4.1 General requirements	N/A

2.7 Regulatory Affairs

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Regulatory Compliance MDR	MDR article 10, sec. 9 (a)	N/A
SOP	Regulatory Compliance IVDR	IVDR article 10, sec. 9 (a)	N/A

2.8 Document Management

Type	Title	ISO 13485	21 CFR part 820
SOP	Document Control	4.1 Control of documents 4.2 Control of records	820.40 Document control 820.180 General requirements 820.182 Device master control 820.184 Device history records 820.186 Quality system record
SOP	List of External Requirements	4.1 Control of documents	820.40 Document control
SOP	Translation	MEDDEV 2.5/5 Rev. 3	820.40 Document control
SOP	Archiving	4.2 Control of records	820.182 Device master control 820.184 Device history records 820.186 Quality system record
SOP	Product Related Information Material	4.2 Control of records	820.182 Device master control 820.184 Device history records 820.186 Quality system record
WI	Responsibility, Authority and Archive of Documents	4.1 Control of documents	820.40 Document control
WI	System Owner	4.1 Control of documents 4.2 Control of records	820.40 Document control
Template	Create new SOP within eQMS	4.1 Control of documents	820.40 Document control

2.9 Change Management

Type	Title	Reference	21 CFR part 820
SOP	Change Management	4.1 General requirements 7.3.9 Control of design and development changes	820.20 Management responsibility
CASE	Change Management	4.1 General requirements	820.20 Management responsibility

2.10 Equipment Control

Type	Title	ISO 13485	QSR 21 CFR part 820
SOP	Control of Monitoring & Measuring Equipment	7.6 Control of monitoring and measuring equipment	820.72 Inspection, measuring, and test equipment
REC	List of Monitoring & Measuring Equipment	7.6 Control of monitoring and measuring equipment	820.72 Inspection, measuring, and test equipment
Template	Calibration Protocol	7.6 Control of monitoring and measuring equipment	820.72 Inspection, measuring, and test equipment

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To arrange a consultative approached video meeting, or if you have questions about eQMS, please reach out.