MEDQDOC QMS TEMPLATES

Supporting your medical device compliance to ISO 13485 and QSR

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Connecting quality and regulatory compliance with a human touch

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

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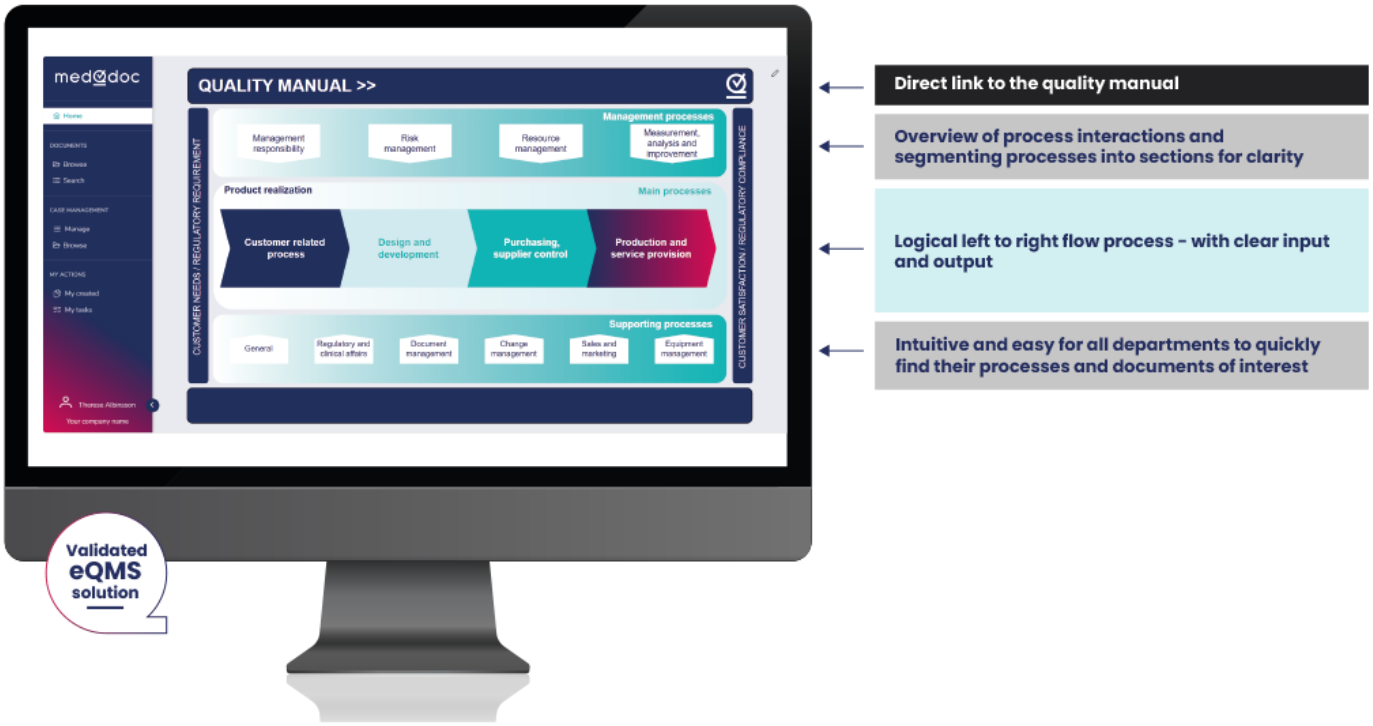
1 MedQdoc Start Page

MedQdoc provides over 160 templates to support you in compiling the QMS and the technical documentation your medical device, to meet regulatory requirements.

The MedQdoc configuration is built around the QMS start page and includes a predefined structure to help your ogranisation meet regulatory requirements for medical devices. n 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).



2 QMS Templates and related records

2.1 Management Responsibility

Type	Title
QM	Quality Manual
Policy	Quality Policy
Policy	IT Policy
SOP	Management Responsibility
SOP	Management Review
SOP	Responsibility and authority
SOP	Internal and External Communication
FC	Management review process
TEMPLATE	Management review agenda, Protocol
TEMPLATE	Organisation chart
TEMPLATE	Quality plan and Objectives

2.2 Risk Management

Type	Title
Policy	Risk Management Policy
SOP	Product Risk Management
SOP	QMS Risk Management
FC	Product risk management process
FC	QMS risk management process
FC	Risk management figure
TEMPLATE	Checklist ISO/TR 24971:2020, annex A
TEMPLATE	Risk management plan
TEMPLATE	Risk management report
TEMPLATE	Risk analysis for computer software
TEMPLATE	Risk analysis for QMS processes
TEMPLATE	Risk analysis and hazard and traceability matrix

2.3 Resource Management

Type	Title
SOP	Resource management
SOP	Infrastructure and work environment
SOP	Competence and training
TEMPLATE	Introduction program
TEMPLATE	Performance and development review
TEMPLATE	Training record

Type	Title
SOP	Nonconformity and CAPA
SOP	Nonconforming product and CAPA
SOP	Customer complaint
SOP	Reporting to authorities (Vigilance and FSCA)
SOP	Post market surveillance
SOP	Internal audit
SOP	Analysis of data
FC	Nonconformity and CAPA process
FC	Nonconforming product and CAPA process
FC	Customer complaint process
FC	Reporting to authorities (Vigilance and FSCA) process
LOG	Customer complaint
LOG	Nonconformity and CAPA
TEMPLATE	Analysis of data plan/report
TEMPLATE	Internal audit plan/agenda
TEMPLATE	Internal audit program
TEMPLATE	Internal audit report
TEMPLATE	Nonconforming product
TEMPLATE	Nonconformity
TEMPLATE	CAPA
TEMPLATE	Customer complaint
TEMPLATE	Periodic safety update report
TEMPLATE	Post market surveillance checklist
TEMPLATE	Post market surveillance plan
TEMPLATE	Post market surveillance report
TEMPLATE	Post market clinical follow-up plan

2.4 Customer related process

Type	Title
SOP	Customer related process
FC	Customer related process
TEMPLATE	Customer Order

2.5 Design and Development

Type	Title
SOP	Design and development control
SOP	Design and development review

SOP	Usability engineering process
SOP	Software development process
FC	Design and development control process
FC	Usability engineering process
FC	Software development process
TEMPLATE	Design and development plan
TEMPLATE	Design and development validation plan
TEMPLATE	Design and development validation report
TEMPLATE	Design and development verification plan
TEMPLATE	Design and development verification report
TEMPLATE	Design traceability matrix
TEMPLATE	Design review
TEMPLATE	Design transfer plan/report
TEMPLATE	Formative/summative evaluation test report
TEMPLATE	Formative/summative test protocol
TEMPLATE	Product concept report
TEMPLATE	Software development plan
TEMPLATE	Usability engineering report
TEMPLATE	User interface evaluation plan
TEMPLATE	User interface specification

2.6 Supplier Management

Type	Title
SOP	Supplier control
SOP	Purchasing
FC	Supplier control process
LOG	Supplier approval list
TEMPLATE	Purchase order
TEMPLATE	SCAR - Supplier corrective action request
TEMPLATE	Supplier audit plan/report
TEMPLATE	Supplier evaluation plan/report
TEMPLATE	Supplier questionnaire
TEMPLATE	Verification of purchased materials products

2.7 Production and Service provision

Type	Title
SOP	Production and service provision
SOP	Warehousing
SOP	Identification and traceability
SOP	Device master record (DMR)
SOP	Device master record (DMR)
SOP	Process validation
FC	Process validation process
TEMPLATE	Device master record checklist
TEMPLATE	Notification to customer about changes on his/her property
TEMPLATE	Production quality plan

2.8 Change Management

Type	Title
SOP	Change Management
FC	Change Management Process
LOG	List of Changes
TEMPLATE	Change Request and Order

2.9 Sales and Marketing

Type	Title
SOP	Sales and Marketing Process

2.10 Document Management

Type	Title
SOP	Document control
SOP	Archiving
SOP	List of external requirements
SOP	Product related information material
SOP	Translation
WI	Authority and location of QMS records
WI	Authority and location of technical documentation
FC	Document Control Process
FC	Product related information material process
TEMPLATE	Create new SOP within MedQdoc

2.11 Regulatory and Clinical Affairs

Type	Title
SOP	Regulatory compliance MDR
SOP	Regulatory compliance IVDR
SOP	Unannounced audits
SOP	Clinical evaluation
FC	Conformity assessment rout MDR
FC	Conformity assessment rout IVDR
FC	Regulatory compliance MDR process
FC	Regulatory compliance IVDR process
FC	Unannounced audits process
FC	Decision steps qualification MDSW
FC	UDI Process
TEMPLATE	Appointment letter - Person responsible for regulatory compliance (PRRC)
TEMPLATE	Checklist - Information required in the label and in the IFU
TEMPLATE	Clinical evaluation plan
TEMPLATE	Clinical evaluation report
TEMPLATE	EU declaration of conformity
TEMPLATE	Example of label specification
TEMPLATE	General product description IVDR
TEMPLATE	General product description MDR
TEMPLATE	General safety and performance checklist IVDR, Annex I
TEMPLATE	General safety and performance checklist MDR, Annex I
TEMPLATE	Instruction for use (IFU), example
TEMPLATE	IVDR codes
TEMPLATE	MDR codes
TEMPLATE	Qualification and classification IVDR
TEMPLATE	Qualification and classification MDR
TEMPLATE	Qualification of MD as software IVDR
TEMPLATE	Qualification of MD as software MDR
TEMPLATE	Regulatory strategy IVDR
TEMPLATE	Regulatory strategy MDR
TEMPLATE	Summary technical documentation IVDR
TEMPLATE	Summary technical documentation MDR
TEMPLATE	Technical documentation checklist MDR

2.12 Equipment Management

Type	Title
SOP	Production and service provision
SOP	Warehousing
SOP	Identification and traceability
LOG	List of monitoring and measuring equipment
TEMPLATE	Calibration protocol

2.13 General

Type	Title
SOP	Production and service provision
SOP	Warehousing
SOP	Identification and traceability
LOG	Master validation list for computer software
TEMPLATE	Electronic records and signature awareness
TEMPLATE	MedQdoc implementation plan
TEMPLATE	Certification Letter to FDA
TEMPLATE	List of MedQdoc templates