Quality Manual, Policy and Objectives

ISO 13485:2016 Section	Document Section
4.1.1	1.
4.1.2	4.
4.2.1 b)	(All)
4.2.2	(All)
5.3	2.
5.4.1	2.

Summary

The Quality Manual describes the scope of the Quality Management System, its documented procedures and a description of their interactions.

1. Scope

The QMS described in this Quality Manual applies to all products of *<your company name>*.

Role of Company

> Other roles besides manufacturer are: Authorized representative, distributor.

<your company name> is a manufacturer of Medical Devices.

Applicable Standards

The following table only gives an overview of the most relevant regulation and standards. For a comprehensive overview, see the list of applicable standards (reference here).

Standard / Regulation / Law	Why Applicable?
MDR (2017/745)	Regulation for all Medical Device Manufacturers in the EU
EN ISO 13485:2016	QMS required by essential requirements of MDD/MDR
EN ISO 14971:2019	Risk management for medical devices
IEC 62304:2006	Software development for medical devices
IEC 62366-1:2015	Usability evaluation for medical devices

Exclusions

The following sections of ISO 13485:2016 will be excluded due to the product being stand-alone software:

- 6.4.2 Contamination control
- 7.5.2 Cleanliness of product
- 7.5.5 Particular requirements for sterile medical devices
- 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems
- 7.5.9.2 Particular requirements for implantable medical devices
- 7.5.11 Preservation of product

2. Quality Policy & Objectives

Quality Policy

Describe what your company is about, specifically, its mission and things which are important for it. Maybe you're developing software for patients with a certain disease and your goal is to improve their lives.

In addition, the policy should include a commitment to meet legal requirements, keep the QMS up to date and define quality objectives to work towards.

Quality Objectives

Whatever policy you outlined above, now you need to make it measurable by defining objectives which can be tracked. Those objectives should not (only) refer to the quality of your devices but the quality of your QMS and the overall work of your organization. Typical examples are: hiring excellence in staff, providing, best-of-class device performance, high standards of customer satisfaction, etc.

Key Performance Indicators (KPIs)

Auditors might ask you: how do you keep track of a quality objective, to see if it was achieved or not? The answer is: Key Performance Indicators. As part of your management review, you have to review all QMS processes plus your quality policy and objectives at least annually. Now, you can meet both requirements at the same time by defining KPIs for your QMS processes. You can then argue that by achieving your KPIs, you make sure that your processes run well, which also meets your quality objectives.

These are your action items: 1. Make sure to define at least one KPI for each QMS process. 2. Make sure each quality objectives translates into at minimum one process KPI. Where there's no corresponding

process for a quality objective, you define additional KPIs that are not process-related. 3. You can document those KPIs either in each SOP or in a separate overview sheet. For example, you can use the template for a management review report for that purpose.

Also see regulatory requirements: ISO 13485, para. 4.1.3.a (process KPIs) and para. 5.6.2 (management review input).

In this section here, describe where you define your KPIs and how you keep track of them. For example, say that you define KPIs in every single SOP or reference to a separate, central overview sheet. Ideally, KPIs are tracked by each process owner independently.

3. Roles

Describe the roles of the people in your company. Typically this is done by drawing an organigram (you could use draw.io for that). Or, you just use a table like below.

Minimum requirement information: required qualification and description of tasks related to QMS process involvement If applicable, add: report / authority, access rights, etc.

Role	People
CEO	Steve Jobs
CTO	Steve Wozniak
Product Manager	Ada Lovelace
QMO	Oliver Eidel

All C-level roles (CEO, CTO, CMO) are referred to as the Management. Management is generally responsible to define responsibilities and authorities, to define and communicate Quality Policy and Goals and to ensure that the whole organization is oriented towards them.

See ISO 13485, para. 5.1, para. 5.5.1

The Quality Management Officer (QMO) is responsible for:

- ensuring that processes needed for the company's quality management system are documented
- reporting to top management on the effectiveness of the quality management system and any need for improvement
- ensuring the promotion of awareness of applicable regulatory requirements and QMS requirements throughout the organization.

Required qualification for this role:

- Fluent in German and English language

- At minimum one year of professional experience in the fields of quality management and regulatory affairs

  See ISO 13485, para. 5.1, para. 5.5.2

Person Responsible for Regulatory Compliance (PRRC) Responsibilities of the PRRC are in accordance with Art. 15 MDR as follows:

- Ensure (review / release) the conformity of the devices is appropriately checked in accordance with the QMS before a device is released (also see Art. 10 Para. 9 MDR)
- Ensure (review / release) that the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date for all medical devices (also see Art. 10 Para. 4 and Art. 6 MDR)
- Ensure (review / release) that obligations for post-market surveillance are complied with in accordance with Art. 10 Para. 10 MDR
- Ensure (review / release) that the reporting obligations of Articles 87 to 91 MDR are fulfilled (FSCA / incidents, also see Art. 10 Para. 13 MDR)
- Ensure that, in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV MDR is issued.

The PRRC shall not be subjected to Management instructions while carrying out his/her responsibilities specified above. His/her tasks may be delegated to other roles as long as it is ensured that final responsibility stays with the PRRC. She or he has the power and authority to represent the company in the scope of his/her responsibilities, e.g. in communicating with state authorities.

Required qualification for this role:

- Fluent in English language
- Knowledge of the role and responsibilities of a 'Person Responsible for Regulatory Compliance' according to Art. 15 MDR
- Higher education degree in law, medicine, pharmacology or engineering
  - OR: four years of professional experience in the fields of quality management and regulatory affairs
- At minimum one year of professional experience in the fields of quality management and regulatory affairs

4. Processes

List all your SOPs here. This list is highly company-specific and might therefore be currently incomplete.

Important Note:

Also mention if one of these processes is outsourced to a third party (typical examples: internal auditing or clinical evaluation done by a regulatory consultant, software development done by an external agency; see ISO 13485:2016, para. 4.1.5 for more context).

SOP	Process Category	Internal / Outsourced
SOP Corrective and Preventive Action	Management	Internal
SOP Clinical Evaluation	Core	Outsourced (?)
SOP Product Certification and Registration	Core	Internal
SOP Change Management	Core	Internal
SOP Deployment	Core	Internal
SOP Document and Record Control	Support	Internal
SOP Integrated Software Development	Core	Internal
SOP Feedback Management	Core	Internal
SOP Internal Auditing	Management	Outsourced (?)
SOP Management Review	Management	Internal
SOP Post-Market Surveillance	Management	Internal
SOP Problem Resolution	Core	Internal
SOP Software Validation	Support	Internal
SOP Update of Regulations	Support	Internal
SOP Vigilance	Core	Internal