



QUALITY MANUAL
Alias the Quality Bible or
the Quality DNA

**Interactive Quality Manual Creator
and the GAP Report Tool**

IT ALL STARTS WITH YOUR **QUALITY MANUAL** AND qmsWrapper.

If you are developing medical device, know that MedTec is a highly regulated industry, and the **FDA** and **EU** (European Union) take compliance very seriously. Whether you're aiming for 501K or CE mark clearance, a **Quality Manual is required**.

But where to start?

Start with qmsWrapper, it includes an Interactive Quality Manual Creator Tool that helps you create your company's Quality Manual, that is fully integrated with your QMS processes or workflows, all in accordance with ISO 13485:2016 and U.S.QSR (21CFR 820).

As a bonus, qmsWrapper includes a GAP Report Tool to help you reveal any "holes" between "what you currently do", and "what the Compliance Standards and your Quality Manual are expecting", to help you identify missing reports, incomplete processes - before the ISO auditors do!

Get on track with your ISO and FDA compliance and focus on getting your product to market.



The Quality Manual

Various ISO standards and FDA QSR's require that you have a Quality Manual. A QMS Manual is essential not only for your own team, but also because both your suppliers and your customers use it as the basic measure to determine and evaluate if your company meets your quality commitment.

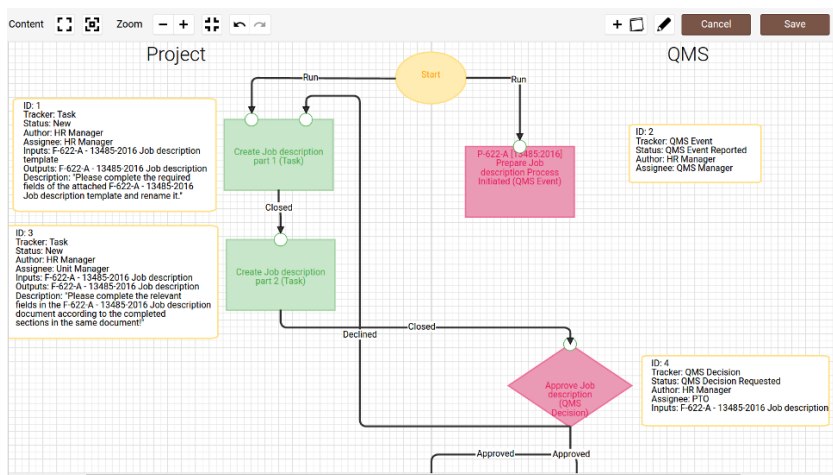
THE QUALITY MANUAL SHOULD INCLUDE THE FOLLOWING:

- Process interaction diagram

1.Lower Level contains support processes such as Document control and Training

2.Middle level contains core processes such as Design and development, Purchasing and Manufacturing

3.Top level contains the Management processes such as Management review, Internal audit and CAPA)



- Statements of the applicable processes and their implementation

6.4.2 Contamination control

Please remove the whole section if it is not applicable for the Company. Additionally please use the following sentence

☐ Not applicable

There is no contamination issues related to the company's product / service, therefore this section is not applicable.

☒ Applicable

In order to prevent contamination of other product, the work environment, or personnel, special arrangement to control contaminated or potentially contaminated product is a documented process.

Please remove the following section if you do not develop or produce sterile medical devices

☒ The company has documented requirements for the product related to the control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes, please refer to

* P-622-B 13485 -2016 Competence training and awareness *

process.

For QSR 820.70, controlled conditions relating to requirements for environmental control, personnel and contamination control are outlined in the procedure

* P-622-B 13485 -2016 Competence training and awareness *

Save Cancel

- List of excluded processes and the reason of exclusion

1.2 Application

This section pertains to ISO 13485 Clause 1 Scope, allowing for claiming exclusions from certain requirements of the standard. The most applicable sections are listed below but you can also exclude other requirements that do not apply, for example, 7.5.10, Customer property.

Note that in some countries you may be able to exclude design control requirements even when you design products. Contact your registrar or regulatory agency to find out if this would apply in your situation.

The Company has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

Please do not remove sections that are applicable for your company or product/service. You can add more sections from the standard from the chapters 6, 7 and 8

Please add some justification for each excluded section -- in most of the cases it might be very simple, for example: the company's product is software only product therefore cleanliness of product and contamination control does not apply.

Select what is applicable:

☒

Does not have cleanliness of product and contamination control (7.5.2)

Justification ^{*}

☐

Does not perform installation (7.5.3) or servicing (7.5.4)

Justification ^{*}

☐

Does not have particular requirements for sterile medical devices. (7.5.5 and 7.5.7)

Justification ^{*}

☐

Does not have particular requirements for active implantable medical devices and implantable medical devices (7.5.9.2)

Justification ^{*}

- Organizational chart

6.3 Infrastructure

Please replace the indicated positions with the relevant ones in your company

The Company provides the infrastructure necessary to achieve conformity to product requirements. During the budgeting and strategic planning processes, buildings, equipment, workspace, and associated utilities are evaluated and provided. When new personnel are added, hiring managers coordinate activities to ensure appropriate process equipment including hardware and software if required and supporting services such as telephones, computers, etc.

The

☒ CEO

☒ President

☒ Product manager

☒ Project manager

☒ PTO

+

☐ has

☒ have

overall responsibility for identifying, providing and maintaining the resources needed to achieve product conformance, prevent product mix-ups, ensure orderly handling of product including workspace, associated facilities, equipment, hardware and software, and supporting services.

- Quality objectives

5.4.1 Quality objectives

Quality objectives are established to support our company efforts in achieving our quality policy and reviewed

Review Frequency ^{*}

for suitability.

Objectives are established at relevant functions and levels within the company. Quality objectives are consistent with the quality policy, measurable, concrete and take into account applicable requirements, relevant to conformity of products to enhancement of customer satisfaction, monitored, communicated and updated as required refer to

Please provide the location and title of the document where the company's Quality objective resides

Location ^{*}

Save

Cancel

- Quality policy

1.3 Quality policy statement

Please uncheck the default Policy text and create your own if your company has got other quality objectives or other means to deliver these to the target groups. The main principle is that the Quality policy has to be short, concrete and understandable to all employees

The Company is committed to customer satisfaction by meeting quality

✓ and delivery

expectations through continual improvement of the quality objectives.

Our quality objectives are to:

- Provide a framework for establishing, reviewing, understanding and communicate quality objectives,
- Ensuring that we comply, with all applicable internal & external requirements,
- Ensuring continuous improvement with the intent to improve processes, product and our customer's total experience
- Maintain the effectiveness of our Quality Management Systems.

Add more items as appropriate

✓ This policy insures that the Company maintains the effectiveness of the established quality system and complies with customer and product requirements. It has been formulated and approved by the executive staff of the Company. The policy is explained and discussed at orientation training given to all existing and new employees.

Add text

- References to relevant documents such as Work instructions, process descriptions and forms

4.2.3 Control of documents

Documents required by the QMS shall be controlled according to the "Document Control Procedure"

Please put reference here to the appropriate Process description

Text about the reference

Records are special type of document (see 4.2.4) and shall be controlled according "Control Quality Records Procedure"

Please put reference here to the appropriate Process description

Text about the reference

- The quality policies and procedures your company should follow, how quality will be measured, defined risks

5.2 Customer focus

Executive management ensures that customer requirements are determined and met with the goal of increasing customer satisfaction. Customer requirements are determined and satisfaction is measured through our product realization and measurement, analysis and improvement processes and procedures.

Executive management shall ensure that product conformity and on-time delivery are measured and that appropriate actions are taken if planned results are not or will not be, achieved.

5.3 Quality policy

Our quality policy expresses our commitment to meet or exceed customer requirements and expectations by maintaining the effectiveness of our quality system. The policy establishes a framework by which we establish and review quality objectives, and is periodically reviewed by executive management to ensure its continuing suitability. Executive management ensures that the policy is communicated and understood throughout the organization.

5.4 Planning

5.4.1 Quality objectives

Quality objectives are established to support our company efforts in achieving our quality policy and reviewed annually for suitability.

- CAPA procedures

8.5.2 Corrective action ✕

The Company takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

P-850 CAPA process description

defines requirements for:

- reviewing nonconformities (including customer complaints);
- determining the causes of nonconformities;
- evaluating the need for action to ensure that nonconformities do not recur;
- determining and implementing action needed;
- reviewing the effectiveness of the corrective action taken;
- flowing down corrective action requirements to a supplier, when it is determined that the supplier is responsible for the nonconformity;
- specific actions where timely and/or effective corrective actions are not achieved;
- determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required;
- verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product;
- Records of the results of action taken (see 4.2.4).

Save Cancel

- The various Roles that defines who is responsible for what and

5.5.2 Management representative ✕

The

* ☐ CEO
☐ PTO
☐ CTO
☒ Project manager
☐ Product manager
☐ Quality manager
☐ else

Please enter the name

has been appointed by the executive management as the Company's management representative. As Management Representative,

* ☐ he
☒ she
☐ they

has the following responsibility and authority:

- acting as executive management's agent in establishing, implementing and maintaining the effectiveness of – as well as improving - the quality management system;
- reporting related to the performance of the QMS system to the executive management for review and as a basis for improvement;

- Your security policy, etc

8.5.3 Preventive action ✕

The Company determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

P-850 CAPA process description

defines requirements for:

- determining potential nonconformities and their causes;
- evaluating the need for action to prevent occurrence of nonconformities;
- determining and implementing action needed;
- verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the product;
- reviewing the effectiveness of the preventive action taken, and
- Records of results of action taken (see 4.2.4).

Save Cancel

It's not an easy task to keep your Quality Manual current and up to date, it's not just challenging but time-consuming, qmsWrapper Quality Manual Creator can simplify this process.

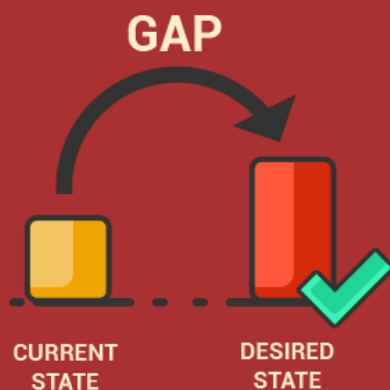


The GAP Report

Here's the critical element - the Quality Manual drives the GAP Report. The Gap Report will identify the differences between what you are currently doing and what the Standard is expecting. "The GAP" is what you are missing, have not started or not completed! The Gap will show you what processes you are using and which ones you are not using – based on what is appropriate for your product's characteristics, the structure and size of your company and your main activities.

Use qmsWrapper GAP Report tool to identify missing reports, incomplete processes - before the ISO auditors do!

The GAP Report additionally serves as a template to help implement the QMS system in the company, in a logical and structured manner.



GAP Report					Generate GAP Report	Export GAP Report to PDF
5	P-420 Document Approval	In Progress	2016-10-20	N/A		
5	P-420 Document Approval	Closed	2016-10-20	2017-01-19		
5	P-430 13485-2016 Process cancel	Not started	N/A	N/A		
5	P-540 Re-Check the Quality Plan	Not started	N/A	N/A		
6	010 wrong branching	In Progress	2017-04-04	N/A		

← GAP
← GAP

Simplify the Process of Establishing a **Quality Manual**

qmsWrapper is unique in that the Quality Manual Creator and the GAP Report tool are an integral part of qmsWrapper. The Quality Manual is not only included, but defined by the policies and processes you select in qmsWrapper. This greatly simplifies the process of creating, and maintaining a Quality Manual.

Demonstrate your company's commitment to Quality and prove your compliance with qmsWrapper!

When you purchase qmsWrapper you can choose optional add-ons, like the QMS Manual and the GAP Analysis Module (checklist). Not only does this represent a huge saving in costs, they can be very pricy to buy directly, the real cost however is in time – yours and your teams.

What you document in the Quality Manual is reflected in qmsWrapper, in particular through the Quality Workflow processes. So, what's in the manual is executed in the QMS Workflow processes.



qmsWrapper not only saves time and effort, but gives you a clear overall insight into your quality management system, so you can concentrate on compliance and make quality a priority.