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# CXO Guide Document for Implementing QMS in Medical Device Startups

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## *What is a QMS*

A QMS or a Quality Management System is a document and process control paradigm within an organization, with particular focus towards a predetermined set of outcomes. Most commonly, QMS in device companies revolve around Good Manufacturing Services (GMP).

The purpose of a QMS is multi-fold.

It helps us to

- Document design, development and manufacturing principles
- Define and document processes for quality control, personnel management, sales and event handling
- Assign responsibility for tasks and events, as well as identify key stakeholders in sub-processes
- Optimize workflows to minimize errors and inefficiencies

There exist several open and proprietary QMS standards for adhering to GMP. The most widely accepted standard for general manufacturing is ISO 9001 (Latest iteration: ISO 9001:2015), with several specialty sectors having their dedicated QMS standards, notably ISO 13485 (Latest iteration: ISO 13485:2016) for medical devices.

ISO 13485:2016 has evolved from and supersedes multiple earlier standards and documents:

- EN 46001:1997, *Specification for application of EN ISO 9001 to the manufacture of medical devices*
- EN 46002:1997, *Specification for application of EN ISO 9002 to the manufacture of medical devices*
- ISO 13485:1996 and 2003, *earlier iterations of the standard*, and,
- ISO 13488:1996, *Quality systems. Medical devices. Particular requirements for the application of EN ISO 9002*

As can be seen, ISO 13485:2016 is largely based on ISO 9001:2015, although they have some key differences.

ISO 13485:2016 has

- More comprehensive risk management requirements
- Detailed training paradigms
- Supervision pathways
- Extensive documentation
- Direct monitoring of customer requirements and fulfilment
- Focus on stability over lifecycle of product, as opposed to continuous improvement in ISO 9001.

## FDA 820 vs ISO 13485:2016

To label and sell a device as a medical device in the USA, it needs to be certified by the Food and Drug Administration (FDA) as compliant. Section 820 of FDA regulations outlines document and process control requirements for conformity as a medical device. Complying with section 820 is a legal requirement, as opposed to ISO 13485, which is a voluntary, albeit recommended, best-practices outline, and although the two sets of guidelines are closely aligned, the certification is not interchangeable, and inter-compatibility is not guaranteed.

Key differences between FDA CFR Title 21, Section 820, and ISO 13485:2016 include:

- FDA 21 CFR § 820 requirements for outlining quality objectives are lower than in ISO 13485:2016
- FDA 21 CFR § 820 and ISO 13485:2016 have divergent schedules and responsibilities for executing internal audits
- FDA 21 CFR § 820 has stronger device control requirements than ISO 13485:2016
- FDA 21 CFR § 820 and ISO 13485:2016 weigh on-the job training and prior expertise differently
- FDA 21 CFR § 820 handles complaints and reporting more stringently than ISO 13485:2016
- FDA 21 CFR § 820 deals exclusively with requirements for the US market and has no legal bearing on other jurisdictions, while ISO 13485:2016 is used as a reference for medical device regulations in several markets, despite being neither regulation, nor law.

## Pathways to get QMS up and running

The ISO 13485:2016 standard specified what documentation and procedural control is required. It does not, however, specify or designate the execution paradigm to implement the standard. For example, while a quality control document must meet certain requirements, the exact structure and content of the document itself, as well as its revision schedule is largely discretionary, albeit within the bounds of compliance.

Preparing for and certification of compliance to ISO 13485:2016 is an expensive proposition, both in time and money, yet it continues to get more desirable to acquire for businesses and products in the medical device space.

There are several ways to ensure initial and continuing compliance:

- Outsourcing process control to an external consultant
- Internal process and document control, with inputs from external consultants regarding conformity
- Internal process and document control with eQMS tools

- Internal process and document control with own tools designed directly based on product requirements and the ISO 13485:2016 specification

Of course, a more esoteric mix of the various approaches discussed above may be more suitable for a particular organization or product, depending on team prowess, product readiness, timeline of execution, available budget and product complexity.

Once the necessary document record and process control is in place, one can get audited, and certified by any qualified registrar, subject to regular audit and control schedules.

## *Summary of popular eQMS tools*

Included below are some popular eQMS platforms, with their features and pricing, in no particular order. These platforms have a particular focus on ISO 13485:2016 compliance.

| Name/Link | Cost | List of offerings (sourced from provider) |
|---|---|---|
| SoftExpert Excellence Suite (SE Suite)<br>https://www.softexpert.com/solucao/iso-13485 | Quote-based | Manage<br>• documents,<br>• processes,<br>• risks,<br>• audits,<br>• non-conformances,<br>• customer complaints,<br>• KPIs,<br>• product data |
| Conformio + ISO 13485:2016 Documentation Toolkit<br>https://advisera.com/13485academy/iso-13485-documentation-toolkit/<br>https://advisera.com/conformio/#pricing-table | US$797/yr. (up to 6 users) | • 76 document templates – all documents required for ISO 13485 certification, plus commonly used non-mandatory documents<br>• Unlimited email support<br>• Expert review of a document<br>• One hour of live one-on-one |

| | | |
|---|---|---|
| | | online consultations with an ISO 13485 expert<br>• 12 months of free access to Conformio, the leading online compliance software |
| MasterControl Spark<br>https://www.mastercontrol.com/spark/ | $109-199/user/month | • Documents<br>• PDF Publishing<br>• CAPA<br>• Training<br>• Audit<br>• Risk<br>• BOM |
| ETQ Reliance 2019<br>https://www.etq.com/iso-13485-software/ | Quote-based | • ETQ Reliance Platform<br>• Nonconformance Handling<br>• Supply Chain Quality<br>• Health and Safety<br>• Environmental Management<br>• Enterprise Risk Management<br>• Complaints Management for Life Sciences<br>• Quality by Design |
| Almir Live 2.0<br>http://www.almir.biz/software/pricing/ | $69-$99/month (total team) | • Quality Management Dashboards<br>• Asset Management<br>• Continuous Improvement Process (CIP)<br>• Document Control<br>• Training Management |

## *Documents required*

The actual documents required may vary, but a list of required documents should be prepared to ensure compliance. Here is a brief overview of document types that need to be maintained for conformity to ISO 13485:2016

| ISO 13485:2016 Section | Recommended Documents |
|---|---|
| 4. Quality Management System | • List of documents<br>• List of records<br>• Quality Manual<br>• Project Plan |
| 5. Management Responsibility | • Quality Policy<br>• Quality Objectives<br>• Management Review Procedure/Record |
| 6. Resource Management | • Human Resources<br>• Personnel Record<br>• Training Program<br>• Training Record<br>• Infrastructure and Work Environment |
| 7. Product Realization | • Risk Management Procedure<br>• Risk Management Records<br>• Design and Development Procedure<br>• Design Review<br>• Product Requirements<br>• Product Specifications<br>• Sales Procedure<br>• Supplier and Purchasing Procedure/Record<br>• Record of Traceability |

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|---|---|
| | • Record of Installation<br>• Record of Servicing<br>• Software Validation<br>• Software Documentation<br>• Procedure for Sterile Devices |
| 8. Measurement, Analysis & Improvement | • Data Analysis Conformity Procedure/Record<br>• Customer Feedback<br>• Record of complaints<br>• Conformity Procedure/Record<br>• Adverse Event Handling Procedure/Record<br>• Corrective Actions Procedure/Record<br>• Preventive Actions Procedure/Record |

## *Conclusion*

Although ISO 13485:2016 is a voluntary standard, it significantly improves project development and error mitigation. It is therefore useful is acquiring compliance, as well as in minimizing non-conformity and failure modes. Implementation of a QMS also assists in gap analysis and resource allocation, there maximizing efficiency and efficacy.

Hence, implementation of ISO 13485:2016 standard is strongly recommended early in the life-cycle of medical device design, development, manufacture and sale.