Beginners guide through ISO 13485

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QMS wrapper™

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ISO 13485 is an international standard for establishing quality management in the medical device industry. The practice of implementing a QMS is a long-term tactical decision that, once in place, works to guide the medical device company to meet standards constantly, improve general performance, and to provide a basis for maintainable development initiatives. A QMS also gives assurance to customers that the requirements for quality have been met. I've noticed that the medical device industry is missing an obvious interpretation of the ISO 13485 requirements, so I've written this guide and translate the requirements into plain English.

The industry's best-practice is implementing electronic quality management. eQMS is a system that is very easy to maintain, it makes all information available online to audit easily, and any recent changes can be communicated quickly to all staff members. qmsWrapper is a ready-to-use eQMS for medical device companies. It is interconnected Quality Management software for companies focused on regulatory issues, and quality requirements specific to these companies.

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1. What is an ISO 13485?

ISO 13485 is an **international standard** for establishing **quality management in the medical device industry**. It is an effective explanation to meet the comprehensive requirements for a QMS in the medical device industry.

The other well-known QMS requirements to follow come from the US, as the **FDA** requires that the medical device company complies with **21 CFR part 820**.

2. What is the current version of ISO 13485?

The latest revision of ISO 13485 for QMS in medical device companies is from **March 2016**.

3. Does ISO 13485:2016 only apply to medical devices?

ISO 13485 was specifically created for companies working on the medical device field. It can be applied to organizations involved in one or more stages of the life-cycle, including **design and development, production, storage and distribution, installation, servicing or final decommissioning of a medical device, disposal of medical devices, and design and development or provision of associated activities** (e.g. technical support).

The Standard can also be used by suppliers or external parties that provide products, including QMS-related services to such organizations.
The supplier or external party can voluntarily choose to conform to the requirements of the Standard or can be required by contract to conform.

4. The company received ISO 13485 certification; does it mean it can place the medical device at the market?

No. ISO certification doesn't mean automatic regulatory clearance for the product, it simply means you have a **compliant QMS**, which is the first step in getting regulatory clearance for the device. Various jurisdictions have different processes for regulatory clearance for medical devices.

5. Why should medical device companies have a QMS?

The practice of implementing a QMS is a long-term tactical decision that, once in place, works to guide the company to constantly meet standards, **improve general performance**, and to **provide a basis for maintainable development initiatives.** A QMS also gives **assurance to customers** that the requirements for quality have been met.

Understand ISO 13485

Lesson 1

Let's say you have an idea of placing an innovative medical device on the market. That's great, but you already know that going from idea to actual realization is not the whole picture, just the tip of the iceberg. Yes, there is a much larger part below the surface to know about, and it has the name, it's called **ISO 13485**.

"ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements." – as stated on its official website.

Or shortly: ISO 13485 2016 is a quality management standard for medical devices. It's not a product standard, but a process standard. Therefore, it's not enough to establish a QMS that complies with ISO 13485, you also need to comply with relevant product and service-oriented technical standards and regulations.

What this means and everything else in the standard, we will do our best to simplify it for you through this content step by step.

What are the QUALITY MANAGEMENT STANDARDS

The aim of these standards is to provide help to any organization that wants to meet product and customer requirements on a severer level. This way

organization will be compliant with all regulatory and statutory requirements.

There are various definitions, but the essence is the same. You can look at it through many frames.

A **quality management system (QMS)** is a set of interconnected elements like:

- **Using a process approach**
- **Handling the evidence to make decisions**
- **Managing your corporate relationships**
- **Encouraging improvement**
- **Engaging and involving staff**
- **Providing leadership in the organization**
- **Focusing on customers and involved parties**

> "qmsWrapper supports process and team-focused approach to QMS that ensures everyone works together towards desired quality outcomes.
>
> The processes approach can reduce errors, forgotten paperwork, missed QMS reports. Your team is not guessing what to do next for compliance, it's defined for them, monitored and managed by management automatically.
>
> The continuous improvement, tracking and measuring of your operations inevitably lead to an increase in productivity and efficiency!"

Organizations can implement these to create **quality policies** and **quality objectives**. It can be used to establish the **processes** needed for ensuring policies are followed and these objectives are achieved.

It's a system that supposed to if implemented right in the organization, improves your business processes, reduces your waste, lowers your costs, and much more. Simultaneously, it's focused on **customer satisfaction**. We can say it's a set of interconnected activities that guide to the desired quality of products, customer and organization's requirements.

ISO 13485:2016 – introduction

This is a standalone standard but it's principally based on the structure of ISO 9001:2015. The ISO 13485:2016 additionally includes specific requirements like **traceability, risk analysis and sterile manufacturing**. Every organization involved in the **MedDev industry** must prove the ability to deliver medical devices and associated services that consistently meet customer and applicable regulatory requirements.

This **Quality Management System compliant with ISO 13485 standard** is mandatory for medical devices sold in the **US, Europe, Canada, and other countries.**

Purpose of the standard

The purpose of this quality management standard is to support medical device creators to need both: customer expectation and regulatory requirements.

Medical device organizations are using this standard to establish a quality management system for the design, development, production, and installation of medical devices and related services. The point is to prove their quality management processes and ensure the best practice in everything they do.

5 top benefits of implementing ISO 13485:2016

1. INCREASING YOUR COMPANY'S CREDIBILITY AND BRAND IMAGE

It shows clients and customers that your company takes quality very seriously and that you have a system in place to ensure it.

2. IMPROVING DECISION-MAKING

When you use facts and data to drive your decisions tend to be better aligned with the strategic goals of your company.

3. INCREASING CUSTOMER SATISFACTION

Standard itself is a set of Quality management principles, one of which is ensuring customer satisfaction.

4. BETTER EMPLOYEE ENGAGEMENT

The more your employees understand their roles in delivering quality products and services, the more engaged they are, which leads to increased efficiency and productivity.

5. IMPROVING YOUR PROCESS

You'll be able to identify and eliminate waste within and between processes, reduce errors, and avoid rework - facilitating greater efficiency and cost savings.

Every ISO standard has the system of requirements and each one of them is described in segments.

In general requirements, it's established what is meant by:

- Developing and documenting QMS – **Establish QMS**
- Defining your QMS processes – **Clarify the structure**
- Supporting them – **Support processes**
- Managing QMS process changes – **Manage changes**
- Controlling your QMS outsourcing – **Control outsourcing**
- Validating your QMS software – **Validate software**

QMS establishment

The key point with QMS establishment is to be done in accordance with the requirements described in this exact standard. And by requirements freely think in terms of procedures, activities, and work instructions. The aim is to demonstrate by development and documentation that your QMS is being carried out and followed.

Structure clarification

Based on your business you will determine the processes that you need for your **QMS**, by having in mind their application throughout your organization.

Every process has its own risk, so you will also apply a **risk-based approach** to get easier control of processes and determine their interaction and order.

Supporting processes

Every so often, QMS processes without explanation don't worth much. For better understanding the processes themselves, this requirement is not less important than the others. You need to, for each QMS process, explain a method and criteria to ensure a certain operation is effective. Plus, you have to make sure that every information necessary that supports the operation is available. By supporting processes is equally considered that you have to monitor measure as appropriate and analyze these processes.

qmsWrapper includes ready-made process workflows as a step-by-step sequence of tasks with adequate explanations.

Processes are defined according to the ISO 13485 requirements.

Imagine how easy will be to report and track non-conformities, documenting your CAPAs, or performed training through a few simple steps!

Managing changes

In case of any changes made to any of these processes, you will have to evaluate their impact on set QMS, including the impact on a medical device produced under this QMS. Goes without saying that any **changes have to be controlled** as well.

Control outsourcing

If you choose to outsource any development process of your device, those processes have to be monitored and your organization has to provide adequate control over it. You are responsible for every outsourced process, for its conformity to the standard. The level of control should be equivalent to the **risk** involved and the ability of the external party to meet the requirements. You will have to include written quality requirements.

Validated software

You might choose a modern solution for your QMS instead of paper-based and use an **eQMS**. In that case, you have to make sure that the software you have chosen to implement and/or develop your QMS is validated.
What does that mean?
Validation of software is an important and obligatory part of the process when you are using **eQMS**.

"qmsWrapper is validated according to ISO/TR 80002-2 Medical device software – Part 2: Validation of software for medical device quality systems.

The outcome of the validation process is the Validation Documentation Set that will help subscribed clients to validate our software for its intended use."

Such software applications supposed to be validated prior to initial use and, as appropriate, after changes to such software or its application. With the assistance of software validation, you know you're using reliable and secure software.

Every activity associated with software validation and revalidation will be proportionate to the risk. The risk must be related to the use of the software and of course, it will be documented as it's required by the standard.

Essentials of Documentation requirements in ISO 13485

Lesson 3

You will see in the end, it's all about documentation. If not in this part then by the end you will perceive the importance of documenting practically everything. Everything has to be documented, so it can be tracked. In this QMS world, there is an already known saying that says: ***"...if it isn't documented like it didn't happen."***

In essence, everything revolves around documenting statements, required procedures, and records, including all the essential documents for planning, operation, and control of the organization's process. **Documentation is key for objective evidence.** Objective evidence to support your personnel through the design, development, manufacturing, and support of medical devices.

There are few methodical requirements that act as a driving force for the establishment and implementation of the **Quality Management System**. And the essential element is the Quality Manual.

Quality Manual

It's the primary guide for your company. It represents the quality culture of the organization, as well it has the role to outline the structure of the documentation used in QMS. It moreover has the duty to delineate authorities, inter-relationships, and responsibilities other personnel for performing within the system.

"qmsWrapper 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."

Medical Device File

It's your documented guideline. By **ISO 13485:2016** you have to establish one or more Medical Device Files. That implies for each medical device type or medical device family. The File should obtain the certificate of conformity or any document that shows that all processes in the design, production, packing, storage, and handling suffice are compliant to the requirements of the standard.

Make sure the files contain the **procedure for quality control**, the critical factors of the products, and the type of instruments that will be allocated to confirm the critical points of the product.

Keep in mind the **Medical Device File** can help you improve the production time and make you avoid process duplication, even reduce shipment damage throughout the manufacturing and shipment processes.

Document Control

It's your obligation to control the documents, in every possible way. Your organization has to ensure that all changes done to documents are **reviewed and approved**. It includes defining a period for which at least one copy of outdated documents will be retained.

The point is that documents, as per which medical devices have been manufactured and tested, be available for at least the lifetime of the **medical device**.

"qmsWrapper's Document Management includes all the high-end features you'd expect of a comprehensive document control system required to support compliance. It includes version control, detailed file histories, approvals, file tracking, source, tagging, comments and authority control."

Control of Records

Not to get confused with documents, imagine these records are a particular type of documents. They represent a type of proof. They provide evidence of conformity to requirements and the effective operation of the QMS.

Standard requires from organization to define and implement methods for protecting confidential health information contained in records.

What are the Management Responsibilities according to ISO 13485

Lesson 4

Management has an absolute responsibility to foster the **quality policy, confirm its alignment, and communicates the mission to employees**. They have a responsibility to plan, delegate authority, and communicate effectively. They are also in charge of a periodic review of operations and improvement within the organization, known as the **Management review**.

Management Commitment

Some of the management job within an organization is to **develop goals, the company's policy, strategic plans, and make decisions on the course of the business**. Practically, to be involved in almost everything. It goes without saying that management has to participate in the implementation and maintenance of the QMS.

But this part of the standard tries to point out how necessary is to provide proof of its **commitment to quality**. It can be demonstrated through:

- **Established objectives**
- **Management reviews**
- **Available resources**
- **Focusing on the customers' requirements**

The focus must be on customers as well

For medical device companies, the customers are patients and users of medical devices and technologies designed, developed, and manufactured by their organization.
Organizations should always do what is best for their patients and that should become the guiding force for **true quality**.

Quality policy as all-embracing vision

It's a document that states about commitment to customers and meeting their needs. As well as ensuring that applicable regulatory and statutory requirements are met, through effective implementation of QMS.

You also can see it as a strategy or kind of a guideline. In a certain way, it's the backbone to ensuring the effectiveness of your quality management system.

There are a few more things to keep in mind when it comes to **Quality Policy**.

Quality Policy is also the responsibility of the **top management**. They have to make sure it complies with all the requirements of the companies QMS without neglecting the company's interests, and its strategic direction should be covered.

The Quality Policy is meant to be periodically reviewed within the framework of management reviews of the QMS.

Remember: Creating a purposeful, meaningful quality management policy statement is more than just writing a slogan.

What is considered by QMS planning in ISO 13485

Lesson 5

This part of the standard explains why is planning so influential. Because without planning it's impossible to build quality into your medical device and company since the start. It's necessary to plan in such a way to ensure your QMS will be and remain effective. One of the ways you can assure that is through setting **quality objectives/goals**.

When planning, there are two things to keep in mind:

1. **Formulate quality objectives**
2. **Plan quality management system**

Purpose of Quality Objectives

Quality objectives are specific, measurable goals. They are like transitional steps to realistically achieve specific goals listed in your quality policy and defined statements for planned improvements.

Its purpose is to directly impact on QMS effectiveness because, without quality objectives, medical device company cannot promote some of the ISO 13485 Standard primary goals. The objectives are shaped for every level of the company, including a single objective for the QMS as a whole, and individual objectives for each process or product that supports it.

It's really important to make quality objectives measurable and well-defined. The objectives created for products or processes are known as **Key Performance Indicators**, they represent the main indicators for showing that individual processes are working as planned, and it helps in the measurement of the general QMS objectives.

Key Elements of Quality Planning

Planning is here to help you to determine how those objectives will be achieved. Quality plans are carefully documented plans that outline quality policies, procedures, SOPs, and guidelines for projects and/or facilities while establishing quality expectations and metrics. It's frequently considered a critical phase in the design of the **ISO 13485**.

But do not worry, by choosing the right eQMS software you will be led in the appropriate direction.

When you do **quality planning**, make sure it included all the relevant aspects and parts, such as **design and manufacturing, sales, service, and customer support**.

To make it even easier, qmsWrapper provides you various ready to go templates that are defined per ISO 13485 requirements!
To further more improve flexibility, they are editable if necessary. Of course, the "Quality Plan" template included.

Quality plans are usually written with a concise, explicit scope and sometimes are used as a checklist. That's an effective way to ensure that a process or project is meeting set quality requirements.

Quality plans generally include information on:

- Introduction of the project or process with included all possible details
- Organization chart, including external vendors
- Described responsibility for each team member
- List of the qualified supplier and standards for they have to meet before than bid on a contract
- Quality control procedures
- Audits
- Training
- CAPAs and person responsible for these actions
- Required notification and all other references including performance rating or performance report.

Responsibility, authority, and communication in ISO 13485

Lesson 6

Responsibility and Authority

Top management is in charge of appointing responsibilities to other staff and management to ensure that the QMS is being met. They also need to be responsible for communicating internally.

One of the musts for them is to establish the pyramid of decision making to accomplish the quality objectives. ISO 13485 emphasizes the fact that they have to identify the training and qualifications needed for each function.

In every medical device company, there must be an organizational structure. It describes roles, functions, and relations it shows who reports to whom. Every defined role must have a **job description** in which will be defined its **responsibilities and authorities**.
Naturally, top management has to ensure every employee is aware of its duties and responsibilities.

Management Representative

Top management is moreover in charge to appoint a member of management who has the **authority and responsibility to**:

- **ensure the processes needed for the QMS are documented**
- **report to top management on the effectiveness of the QMS**
- **ensure promotion and awareness of the QMS throughout the organization**

By all means, he is in charge of the entire QMS. He/She is like a living spine of the system and will undertake the ultimate responsibility for its effectiveness. It's expected that person has the most knowledge of the **ISO 13485 standard** in the company. It is his/her duty to ensure the documentation is compliant with the requirements of the standard.

It is important to bear in mind that the **Management Representative** does not have to be dedicated only to quality, specifically the standard notes they may have other responsibilities.

Internal Communication

It's one of the vital factors, and it has one of the most important roles in any organization. In other words, it's effectiveness.

Effective communication will allow the efficient flow of data.

Internal communication regarding the quality management system flows **two ways**:

• The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

• The organization communicates to the management information and data regarding quality performance and the effectiveness of the quality system.

Management sets **Quality Objectives** and has to communicate those. These objectives have metrics and targets (e.g. scrap, customer complaints per month, resolution time for complaints) and potentially some kind of charting/graphing/tracking over time.

For all team members to work towards the same objectives and targets, management has to communicate those to every team member and explain how they can contribute to reaching these targets (example: daily team meetings, newsletters, an information board in the break room, walk-about board).

The effectiveness of the QMS is determined by meeting the targets.

Any information can be communicated through:

• Paper or electronic documents, such as manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.;
• E-mails, memos, and meetings;
• Bulletin boards and the intranet site and newsletter;
• Training and awareness programs; and
• Employee suggestions, surveys and, feedback.

qmsWrapper's chat is a purpose-built Team Collaboration that maintains compliance built into its DNA to help foster and support team based regulatory compliance.

Also, assigning tasks between members of a certain project in qmsWrapper is a way of communication that addresses a certain assignment.

All about Management Review in ISO 13485

Lesson 7

The main goal to conduct a management review is to allow top management from time to time **to examine** the quality management system. That is done usually not less than **once in a year.**

Commonly, it's done through **the meetings**. Various topics can be covered and Top management will check if there is any need for **their improvement and changes or any other complex decision or intervention is needed**.

Not to neglect the importance of quality objectives since it's the main reason for management review.

ISO 13485 always emphasizes that you must document all decisions, records, and outputs according to standard. For easier document management and maintenance, you can **create a form** for the matter that will consist:

- **Discussed issues**
- **The participants**
- **The date and the location where the review took place**
- **Evidence or reference to the evidence**
- **Results, agendas, and responsibilities for implementation**

qmsWrapper comes with default processes made based on ISO 13485 requirements, including the "Management review meeting" that will make it easier to record all inputs and decisions.

Management Review Input

Accordingly, one of the first things is to compare the current performance with the **quality objectives**. A list of inputs is meant to be reviewed by top management. Inputs reflect on the aspects of **performance, control, consulting, changes, improvements, and risks**.

ISO 13485 has a **minimum list of 12 inputs** that Top management needs to review to assess the health of the QMS. **It includes feedback, complaint handling, audits, reporting to regulatory, process monitoring and measurement, corrective and preventive actions, follow-ups, any changes, or any other regulatory requirement.**

The aim is to all processed inputs assist in a certain way in determining the achievement of planned results. The challenge here is to identify the sources of data, collect them in an orderly manner, and acceptably present them.

Management Review Output

The review outputs are meant to assist the efficiency of the QMS and its processes.

Outputs can be seen as **decisions and actions.** They have to be carried out as a reaction to the data that were presented and discussed during the review. In practice, they are related to opportunities for the improvement and/or changes of the QMS.

Bear in mind, all the decisions of the output review will increase the competence of the medical devices and promote the ability of the manufacturer to meet requirements, regulations, and customers. Including that in the next review, you are required to assess the success of those decisions. For example, instead of declaring ***"we must enhance our customers' satisfaction"*** try "***we should enhance customers' satisfaction during installation activities"***.

What is Resource Management in the medical device world

Lesson 8

As a requirement within **ISO 13485**, **the management must ensure that adequate resources** are available to perform continuous work by the organization. Providing resources can refer to personnel, infrastructure, consumables, equipment, etc.

Human resources

In this part, the standard focuses on the improvement of human resources by making sure they can provide **quality work**. It's very important the connection between qualified employees, the implementation of QMS, and maintenance of its effectiveness. For success, a medical device company has to combine human resources and knowledge, in other words, the training of employees is unavoidable. Auditors and FDA inspectors are usually asking for evidence of it. That's why there is a saying: ***"if it's not documented, it's as it didn't happen"***.

Some elements and job characteristics must be **defined and documented,** as ISO 13485 obliges, like education, regulatory requirements, experience, certification, and training.

When we come to **training**, you have to know that every type of training has a specific goal that supports or/and promotes the organization's values. Also, training has to fill the gaps between the current skills and the desired skills. The organization can provide training in several ways like frontal, e-learning, external, or even visits to suppliers' facilities.

At the end of the training, it's always necessary to evaluate its effectiveness. It has to be done periodically and should include physical examinations.

qmsWrapper comes with default made processes based on ISO 13485 requirements, including the “Competence, training and awareness”.
That will make it easier to record training requirements, proving it’s held, and to perform effectiveness evaluation as the final step.

Infrastructure

This part includes **the building, workspaces, process equipment, software to support business operations and support services.** They are expected to be appropriate and are properly maintained to achieve conformity to product requirements.

Maintenance of buildings and facilities is performed by external contractors. This includes regular checking on lighting systems, air conditioning, and heating systems.

Using qmsWrapper’s Custom form feature it is easy to build the template for recording the maintenance activities. It will be obvious that who and when performed it, therefore it’s easier to follow up when the next interval of maintaining certain activities shall be done.

Here is also important to note that the medical device company must document the requirements of their infrastructure to achieve conformity to product requirements and prevent product mix-ups ensuring orderly product handling.

Work environment and contamination control according to ISO 13485

Lesson 9

Work environment and contamination control are important and critical for effective and compliant medical device business run.

Definition of the Working Environment

Work conditions and environments must be under **effective control**. And by the ISO 13485 standard, it undoubtedly means, it must be **documented**.

It's expected that the working environment will be in the proper conditions and realization processes that have a direct influence on the successful production of the medical devices. But the work environment is not just buildings, but equipment and materials used during production. It's important to **monitor working conditions** in case you want to keep it on a certain level.

In most cases, the **work environment consists of**:

- **Elements that may influence the processes and activities**
- **Physical elements of workspaces**
- **Resources invested in the processes or operate the activities in the workspaces**

It's critical to thoroughly understand the relationship between the product, employees, and facilities. By properly understanding these connections, it's going to be easier to properly identify the work environment. The following step is to **review it**. It means questioning and observations of employee's activities, the analysis of their tasks, performance, efforts.

Clean environment - in this part ISO 13485 explains that is required to maintain documents for cleanliness or contamination control requirements

for devices that are cleaned. The controls of the workplace and human resources have to be planned to correlate with these requirements. It has to support cleanliness goals.

Determination of the Contamination Control

In the medical device, the industry is expected that sterile medical products will come out from the manufacturer. If that wouldn't be the case, the patient's health could be endangered. Even potential contamination could cause serious harm to product performance, quality, and safety. That's why the ISO 13485 standard emphasizes the importance of **establishing, documenting, and maintaining contamination control**.

There should be a specific procedure for all returned devices to avoid **cross-contamination**. Plus, they should be revalidated that they are in the identical condition as a new product, before being submitted to the work environment – intact and unharmed, and a package sealed and complete. The purpose is to ensure the status of these products is acceptable and that there is no risk of contaminating other products, work environments, or employees.

Contamination control must be planned, defined, and maintained using documented measures. Contamination control is usually managed by proper ventilation systems, dust collectors, and monitored through air quality tests.

What is considered by the planning of your product realization as per ISO 13485

Lesson 10

Naturally, planning goes ahead of realization. And this part of the standard explains how important is for you to be consistent in planning throughout all parts of your quality management system. Plus, it refers to all phases of the life-cycle of your medical device.

Quality Plan

This requirement of the ISO 13485 is fulfilled by defining the quality plan. Therefore, first you will make a quality plan that looks like a list of activities that you obliged to follow, according to requirements.

The objective of defining the quality plan is to:

- **identify all required processes for product realization.**
- **define relations between processes.**
- **define the required resources.**
- **define acceptance criteria.**
- **define validation and verification for product and processes, required monitoring and measurement, inspection and testing, handling, storage, distribution, and traceability.**

Processes with which the manufacturer realizes the product should be addressed in the quality plan. This includes defining methods, activities, techniques, practices, responsibilities, documentation and specific records that will provide evidence for these processes.

Regulatory Requirements

Regulatory requirements have a crucial role in the designing stage during the planning product realization. You have to review the applicable national, local, and international regulation directives and standards that may apply to your medical device.
Besides this, you need to cover all the **verification and validation activities, packaging and labeling, clinical evaluation, examinations and quality assurance**. These are elements that you need to provide as evidence that requirements are met.

The required resources for production should be defined, and it consists of raw material, required machinery, work instructions, human resources, etc.

Verification and validation of the product

Later on, a medical device must go through the **verification process**, to see if your product requirement is fulfilled. The verification process can be done through **quality tests, calculations, output reviews, etc.** The point is that the quality plan defines which verification activities are needed, which parts, components, and activities are to be verified including acceptance criteria as well. **After verification, you need to validate it**. What does that mean? Validation can be seen as approval of the requirements for a specific intended use or application that has been fulfilled. Each medical device company has to describe the activities that would evaluate the compatibility of the product and what are the acceptance criteria.

The quality plan shall define the **labeling and identification requirements** for products throughout the realization processes. The content of the labeling will depend on the type of medical device and may include warnings, safety notices, etc.

Traceability is also one of the crucial requirements of ISO 13485:2016. You must define a method for handling traceability. It must include the realization process and documented procedures.

Moreover, customer requirements should be taken into account. All their functional,technical requirements, and performance specifications may

influence your planning product realization. Not to forget, even this has to be documented.

In the quality plan, you need to specify or mention the suitable instructions concerning **which documents are expected and where the records are stored**. For each activity, there must be recorded evidence.

Finally, ISO 13485 requires the **planning of the** risk management process. Why? Because successful implementation of risk management will obtain the organization a systematic method for identifying risks, evaluating, and controlling them.

The Standard refers us to the ISO 14971 for the guidance of developing, planning, and implementing a risk management system, that suggests an effective way on how to handle risk.

qmsWrapper has an integrated Risk Management Module that is built according to the ISO 14971 guidance and it makes it possible for risk managers with little experience to appropriately perform their risk-related tasks.
It has everything you need to effectively identify, evaluate, and mitigate risks through the single matrix interface.

Customer - related processes

Lesson 11

Depending on the medical device type you can assume who are potential users of the same. After you define that, you will easier understand this chapter of ISO 13485.

Determination of the requirements related to the product

There is a standardized method to identify the inputs that supposed to form and determine the device. As a medical device company, you can precisely determine what the product specifications are and evaluate whether it can meet these specifications. Including the customer's expectations of the medical device, it's easier to come to the definition of the end product.

Of course, everyone is aware achieving all customers' requirements is almost impossible, but some areas don't leave room for compromise – such as **regulatory and safety requirements**.

The organization should develop the method of capturing all inputs and distributing them to appropriate business units. There are no standard methods for such, but it may include: customer files, checklists, order forms, etc.

Review of requirements

ISO 13485 always points out how important is for medical device companies to keep to a high standard when it comes to the products and services they offer to customers. Very important is to **clarify and understand customer's requirements**, translate them into organizational terms, and ensure the organization can meet them.

By reviewing is meant to filter requirements through **risk management, product specifications, regulation, and functionality**. The point is that the

review assures the company can commit to supply the product to the customer.

It's possible that customers might change their minds and needs, and the **ISO 13485** Standard is aware of that. Because of this, a medical device company must maintain control over the realization and effectiveness of the requirements. Customer requirements have to be reviewed on several viewpoints that might affect the medical device.

Communication

ISO 13485 clearly states that every medical device company has to have a documented system for communication with customers. Also, the way how you will communicate with your customer depends on the type of your device. The reason for communication can be required product information, inquiries, contracts or order handling, or customer feedback that includes complaints as well.

Be aware, that **you have to inform the customer about all updates, changes, and improvements of the medical device**. Also, to maintain the effectiveness of the communication channels, you have to define the roles for each type of customer communication. Each role will be responsible for managing the communication channel according to the definition related to the specific case.

The **customers' feedback** provides you an objective point of view on whether your medical device company supplied the device according to the requirements. It's advantageous to get an early warning about potential quality problems. This process effectively creates inputs for improvement and initiates the necessary **corrective and preventive actions**.

From A to Z about Design and Development of medical device ISO 13485:2016

Lesson 12

The **design and development of the medical device** are one of the most crucial parts of the ISO 13485 standard due to its complexity compared to other industries. The design and development process for medical devices has to deal with product safety, risk controls, relevant regulations, and customer needs. On one hand, it's a continuation of the previous lesson based on customer needs and requirements that you included in the D&D process. The point is that if you as a medical device company fail to meet regulatory design requirements, it won't be able to reach the market.

Because Design and development processes include planning, inputs, outputs, review, verification, validation, transfer, control of D&D changes, and design and development files.

Design and development planning

The first and most important stage is **planning** because good planning will take you through with no additional costs or delays through the development of your medical device. For reason, it's said good planning is the first step to success. In this planning phase, you will set your goals of the design and development of your product, set certain activities that will include risk management. Point is to implement quality control through the design and development process as well.

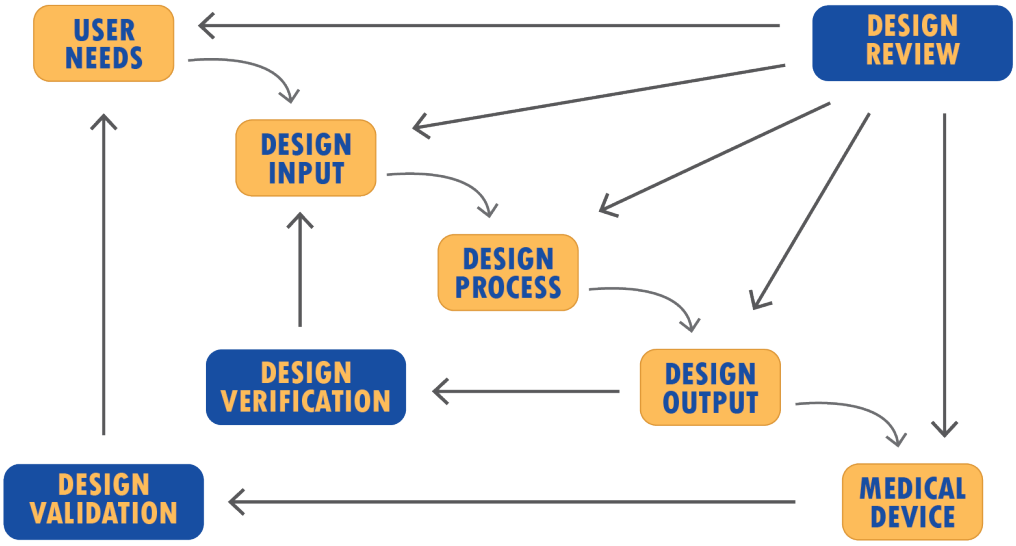
The tactic is to examine whether the development advances within measured steps according to prior planning. It is important to update the plan as the development advances and to change the plan according to what is required.

Someone with expertise must be appointed who will be managing the process. The **planning process additionally should include verification, validation, and design transfer including traceability design and development activities.**

Design and development inputs

If there are quality inputs, there will be quality outputs. Simple as that. It's crucial to adequately evaluate the needs of the customers and **determine the inputs for the medical device** carefully. Things like: intended application, past complaints, risk control, physical features, safety factors, etc. should be included while collecting inputs as well.

The ISO 13485 standard requires functionality, performance, and safety according to the intended use. Plus, they must be reviewed and approved by appropriate resources for accuracy and completeness.



Design and development outputs

Outputs now should carry out input requirements. It's expected they will provide appropriate information for purchasing, production, and service provision. Moreover, it should specify the characteristics of the product that are essentials for its safe and proper use. To clarify, design output is a drawing or specification or manufacturing instruction. It consists of **described parts, pieces, and components of the medical device**.

As required from the ISO 13485 standard, any output of design and development stages naturally has to be **properly documented and approved**.

Design and development review

Design and development **review practically should be performed after each step in the Design Controls**. In a certain way, it should be synchronized with design and development planning. The aim is to evaluate the design and development results if they meet the requirements and to identify and propose necessary actions. For the success of medical device development, reviews in these stages are crucial. On top of that, the level of complexity and formality of the review will be determined according to the nature of the medical device. The most important is that records of the results of the review and necessary actions are maintained.

Design and development verification

If you have done everything so far right, in this stage demonstrate you will demonstrate that you have designed your medical device correctly. How? By conducting some **tests, inspections, comparisons, or analysis** to show your design and development outputs met design and development inputs. **Verification** is a mandatory requirement and the records on verification results should be maintained.

Design and development validation

Validation means demonstrating that you have designed the product you intended to. Validation indicates that your **outputs and resulting product meet the specification of functionality, performance, safety, and intended use**. It should ensure the medical device satisfies its user's needs. Of course, validation activities should be recorded along the process.

Design and development transfer

The transfer of a product design into a manufacturing environment requires a detailed set of processes to organize many tasks at the same time. The keys to an effective transition are **experience, well-defined, then executed procedure, and cautious review**. This should ensure the transfer of a medical device product and related processes from the development phase to manufacturing in advance of product launch and commercialization.

Control of design and development changes

Changes are likely to happen during the design and development process, and the medical device companies are required to **establish a way to control such changes**. Every change should be evaluated based on the impact on all aspects of the medical device. The goal is that change is introduced throughout the entire development process. Records on any change, its review, and necessary actions should be maintained.

Design and development files

This is the so-called **DHF or Design History File** as per the **FDA**. As per this standard is the design and development Files. This part of the standard again shouts out that everything, but everything needs to be documented. It always has to be up to date so it can represent the current product including all changes. The file may include reference records of conformity to design requirements, records of review, verification, validation, and changes.

qmsWrappers Traceability Matrix has an innovative and unique approach to manage complex medical device products, where users can have a quick and clear overview of their medical device life-cycle. The importance of the Traceability Matrix stems from the fact that it connects requirements and uses cases to design inputs, outputs, verification, validation, and Risk Management. It's central to the development of safe medical devices and, when it's done right, it's the foundation of your FDA Design History File (DHF) and your CE Mark Technical File (TF).

What is Purchasing process in Design and Development in ISO 13485

Lesson 13

In the medical device industry, it's not just purchasing. ISO 13485 standard has some strict rules when it comes down to purchase from suppliers. The main factors that influence this process should be addressed, and the main suppliers.

ISO 13485 requires you to document your purchasing procedure to ensure purchased products adheres to stated purchasing information. What does that mean? So, you are expected to create criteria for the evaluation and selection of suppliers.

The main point is that **the medical device company describe how it will ensure the products will:**

- **Meeting predefined requirements and specifications**
- **Determining the appropriate controls over the suppliers**
- **Ensure the manufactured medical device is safe and effective as the standard requires**

When it comes to the supplier evaluation, you need to establish a set of criteria for the selection and evaluation of new or existing suppliers, and also to evaluate the supplier's ability to solve the non-fulfillment of an agreed purchase order.

The objective is to establish an ongoing control process over the supplier to foresee events that might become nonconformities or quality problems.

After you have evaluated the supplier, and have provided them with your feedback, you should, after a defined period, reevaluate whether or not they have improved their performance.

Purchasing information

The ability to transfer clear specifications regarding the product requirements to the supplier is essential. So, it should be ensured the information will contain the required details before delivery to the supplier.

The purchasing information must be reviewed and verified. It is necessary to **determine a method for reviewing the purchasing information** before submitting it to the supplier for execution. So, it should be ensured the information is **clear, correct, and complete**. The check should be carried out by an authorized person.

ISO 13485:2016 addresses the requirement to include written agreement notification by the supplier when it comes to the changes in the product that provides to the company. When your supplier needs to perform changes on the product, it must notify you in advance, and receive your approval. The issue should be discussed and agreed upon on an agreement or contract level.

Verification of purchased information

Consequently, you should verify the received product against what was agreed with the supplier. Your medical device company will define which product requirements will be controlled, specifications, characteristics, which areas, or issues on the purchased product are to be tested, controlled, evaluated, verified, etc.

The methods for conducting control activities can include **testing, reviews, sampling, evaluation of services, etc**. The point is that the selected method ensures the purchased product fulfill defined specifications and requirements, and that won't be included in the realization process if it does not.

qmsWrapper provides a process for purchasing controls, that make sure non-step will be missed when it comes to this quality event. It will ensure the purchase order contains all relevant data and it is approved, the purchased product is verified against defined criteria and ready to be released.

Medical device Production and service provision in ISO 13485

Lesson 14

ISO 13485 standard intends to cover a wide range of manufacturing, therefore, it's a bit generalized when it comes to defining applicable **requirements and service provision** processes.

This section of the standard might be confusing for many, but we will try to divide it down into simple and understandable pieces. Exactly 11 sections.

Control of production and service of provision

Control means your medical device company has to **plan, carry out, monitor, and control the production.** It is to ensure your medical device meets the set of specifications and that you have the necessary processes and environment to support its realization. It's recommended to apply a **risk-based approach** towards control of production.

Control is expected to be achieved through documenting procedures and methods. The qualification of infrastructure is also taken into consideration. For example, a situation where the infrastructure can affect the conformity of your device. Depending on the production process, your medical device company has to implement **monitoring and measuring** activities too. Plus, to identify requirements for **labeling and packaging**.

And once your medical device is manufactured, you need to define and perform activities for **product release, delivery, and post-delivery**, if the nature of the product requires it.

Cleanliness of product

In case your product requires a certain level of cleanliness, you need to document that requirement too. It is required to have a detailed procedure

that indicated employees' behavior and operations with materials, products, parts, or components. **The cleaning process has to be verified, validated, and monitored.**

Installation activities

In case your medical device requires a certain type of installation, then you need to include acceptance criteria and provisions to verify correct installation. In case when the installation activities are meant to be outsourced you need to provide documented information for the installation and verification to the outsourced partner. The purpose is to ensure the medical device will function properly in terms of functionality, performance, safety, and intended use.

Servicing activities

You have to define servicing activities if they are required too. That means any **requirements, specifications, and procedures must be recorded** and become part of your medical device file. The point is to define the type, interval, intensity, or complexity of provided service activities, and to set up roles and responsibilities.

Particular requirements for sterile medical devices

If your medical device requires to be sterilized, you will define it during the design and development process, and ISO 13485 defines that sterilization process parameters should be defined.

All sterilization records have to be **traceable** to each production batch of your medical device production.

Validation of processes for production and service provision

This is only used in case your medical device company is unable to verify the output of a process later on. When this is the case, you validate your process to make sure it achieves the planned results and this is, of course, very pecific to the processes in the company.

Particular requirements for validation of processes for sterilization and sterile barrier systems

Validation of sterilization processes – you have to develop a procedure to address the validation of sterilization processes. Validation will be necessary if there is a change or addition to a process or a product.

Validation of sterile barrier system – A sterile barrier system is a system that includes minimum adequate barriers to protect medical devices from microorganism contamination.

Identification and traceability

And yet again, you need to document the procedure for identification and traceability to identify the product throughout product realization. Things like **materials, components, sub-assemblies, inventory, work in process, finished goods** have to be identified by your Medical device company with the prime objective to eliminate mixing together the products, parts, or material with different status at all stages of the material flow.

Traceability is giving you valuable information about your product in the event of any relevant quality events – **it traces the history, location, or status by recorded identification.**

Customer property

Customer's property is good of a different kind, that is delivered to the manufacturer by the customer for further processing, for use during

the realization process. So **the owner is the customer**.

The point is to set the processes on **how to identify, verify, safeguard, and protect certain customer property**. You need to control it from unintended use. Maintain records of such events is an absolute must.

Preservation of product

Preserving of product is one of the requirements of the ISO 13485. Protecting medical devices during processing, storage, handling, and distribution are falling under this section.

All factors that can harm the medical device should be identified.

To summarize

Be aware that that any requirement in the medical device realization section of the standard might be excluded from a quality management system if they do not apply to your business.

Knowing your medical device and what is required for it is the first step in assuring successful provision activities for creating and delivering the product or service.

Using qmsWrapper's Custom form feature it is easy to build the template for recording any of the above-mentioned activities – servicing, installation, sterilization, etc.
It will be obvious that who and when performed it, and record will be maintained in the system. It can be exported, too!

Control of monitoring and measuring equipment in the medical device industry

Lesson 15

The ISO 13485 standard treats monitoring and measuring devices very seriously. Every medical device company must have had plenty of various equipment for measuring and monitoring. According to the ISO 13485 Standard, they are considered as an important element of the realization process. Therefore, the requirements are quite specific and logical.

If you want your data or results to be valid, **measuring equipment must contain the following elements:**

- **Has to be calibrated or verified before their use**
- **Has to be adjusted or readjusted, as necessary**
- **Has to be identified to determine its calibration status**
- **Has to be safeguarded from any potential risk or damage that might cause invalidation of the measuring result**

Every medical device company has to have a documented procedure for equipment calibration or verification. Those have to be maintained regularly.

The Standard that covers this part is **ISO 10012:2003** - Measurement management systems — Requirements for measurement processes and measuring equipment

Advice:

Record the equipment ID in every test related to incoming, in-process, and final inspections. Add guidelines in your SOP for equipment calibration and verification. Having the set procedure for this clause will make your life much easier.

Define how measurement activities will be determined. Refer to issues like instructions, frequencies, areas, measured material, products, and processes. The procedure will define how the manufacturer sets the criteria for measurement results; for example, tolerances, limits, expected test results, customer requirements, regulatory requirements.

The issue of monitoring and measuring processes and products is one of the tools for the implementation of controls of risks and the measurement of their effectiveness.

Every so often you will have to trace back and recall products for remeasurement where the issue was critical.

The ISO 13485 takes the issue one step further and expects there to be guiding principles regarding the implementation and control of measurement and monitoring devices.

Monitoring and measuring equipment is a key role in their approval. According to the measurement result, it is decided whether the product met its requirements or not.

However, you better prepare yourself for the possibility that monitoring and measuring devices will be found to be defective, inaccurate, with a malfunction, or not calibrated. This means there is a possibility that products that were released, based on measurements made with the defective devices, do not meet their requirements and specifications. When such a situation occurs, the manufacturer must evaluate the effect of the inaccurate measurement on the quality of the product.

Using qmsWrapper's Custom form feature it is easy to build the template for recording the calibration activities.
It will be obvious that who and when performed it, therefore it's easier to follow up when the next interval of calibration shall be done.

How ISO 13485 explains Measurement, analysis, and improvement

Lesson 16

Your medical device and its quality process must be measured, monitored, analyzed, reported, and reviewed. It's done by using a system of **measurement-analysis-improvement** that is designed to strategically manage the 'quality' of the Quality Management System (QMS).

The processes that ensure t**he effectiveness of the measurement, analysis, and improvement requirements are:**

- **Performing improvement processes;**
- **Monitoring and measuring quality;**
- **Controlling nonconforming products;**
- **Analyzing quality information;**
- **Taking the required improvement actions.**

It's one of the most challenging parts of the whole QMS process. Measurement is the process to determine a value. And the measuring process is to **collect, analyze, and report data** that are relevant to the medical devices and realization process.

3 Main Objectives

The analysis is here to support the processes and maintain the effectiveness of your quality management system, as well as the quality of the medical devices. These measures will collect data through a defined period of time.

With measurement and analysis, you will collect the necessary data for improvement throughout your medical device company. In other words, performing the above will generate improvement.

Remember that the ISO 13485 standard requires to maintain effectiveness rather than just implementing and measuring it.

When you want to define controls over the processes to measure analysis and improvement you have to:

- **Determine an appropriate method of control, such as statistical tools or techniques for each process or product**
- **Determine the scope or extent of the control – what, when, and how many will be measured.**
- **Determine the means with which the control will be implemented and utilized throughout the company**

Conclusion:

ISO 13485 Standard is telling you to plan how your medical device company will monitor, measure, and how it will use analytical processes to ensure effectiveness and conformity. It then asks you to establish feedback methods and procedures and to investigate complaints, take action, and report results. In addition to this, you are **required to**

- **Plan and perform internal audits**
- **Find out whether processes are achieving planned results**
- **Monitor and measure medical device characteristics**
- **Prevent the unintended delivery or use on nonconforming products**
- **Analyze data about your MedDev's QMS for evaluation of suitability and effectiveness**
- **Take corrective and preventive action**
- **Make any changes necessary for product safety and performance.**

Monitoring and measurement according to ISO 13485

Lesson 17

What mostly reflects the effectiveness of the Quality Management System is monitoring and measurement focus on the quality of your medical device.

The ISO 13485 Standard defines several sections in which monitoring and measurement should be emphasized highly addressed.

Feedback

The ISO 13485 Standard requires the evaluation of feedback regarding the use of the medical device. The aim is to identify early as possible any quality problem or warning related to the medical device. Standard recommends you to plan the systematic method for achieving early identification.

Feedback is here to practically define, document, and implement methods for monitoring and controlling the medical device. The best way to achieve that is to use data that were collected in the postproduction phase, or utilizing post-market surveillance to detect quality problems. In case of quality problem identification, there is a procedure for handling and submitting for further improvement process.

Feedback doesn't need to be only negative; it could be positive or suggestive regarding your medical device. Bear in mind that the data collected via feedback methods are to be used at later stages as inputs for processes of analysis of data.

Complaint handling

Complaint handling is just another way of receiving a sort of feedback. But it's still unique because it's the only **quality process** where you communicate directly with the customer. One of the key challenges is to implement a proper management strategy for **tracking and monitoring** all

complaints that you receive. In most cases, every complaint concerns a specific product of your company and must be treated as a singular event – a problem reported by a customer for a single type of product.

But it's good to keep in mind that some complaints must be reported to authorities, therefore they will require further investigation and notification of regulatory authorities.

Reporting to regulatory authorities

You have to report to regulatory authorities when a complaint is considered to reach the criteria of a field safety notice. It must be reported promptly and documented. Your medical device company should incorporate regulatory guidelines for field safety notices as part of the complaint-handling procedure.

Internal audit

It's known as an activity that comes out as the most effective action taken regarding monitoring, analyzation, control, and improvement of your QMS. Its aim is about status reports regards your QMS.
The audits evaluate whether the activities are performed and how well they are performed.

Of course, it's expected that your medical device company will define periodic intervals for conducting internal audits.

Monitoring and measurement of processes

Measuring processes are mentioned many times throughout the ISO 13485 standard – quality manual, quality objectives, management responsibility and control of production, etc. This part of the standard is saying you have to establish and implement appropriate methods for monitoring processes of your QMS, and where is relevant to apply defined methods.
When monitoring quality processes, you are required not only to verify they are defined and have been performed but also to evaluate the results and whether processes have achieved their goals.

qmsWrapper provides a Search and Report tool that allows you to track the progress of all processes initiated in your company, and it will make monitoring on them very easy. You can check whether certain process achieves planned results, and to take appropriate actions in time, if determined it doesn't.

Monitoring and measurement of the product

Monitoring and measuring activities of products are the necessary controls to ensure the medical device performs as intended. It's expected that you are doing it throughout the different realization processes at adequate levels.

Control of nonconforming products in ISO 13485

Lesson 18

The ISO 13485 covers all phases of the medical device lifecycle and one that must be covered is also the control of nonconforming products. It's a product or a medical device that does not fulfill its specified requirements like customer or regulatory requirements. It's important to be identified as soon as possible. Plus, **ISO 13485:2016** addresses the management of **non-conformity in a medical device** even after its use or after its delivery.

The purpose is to separate every medical device from other conforming medical devices. When you separate it, you have to:

- Identify it
- Separate it
- Exclude it or not to deliver it

It's expected from your medical device company to have a **predefined procedure** for cases such as nonconformity. A documented procedure that will indicate controls, authorities, and responsibilities must be set when treating non conformed medical devices.

Actions in response to nonconforming product detected before and after delivery

Communication is crucial. It's recommended to set a person or more in each phase of development product to keep an eye on any nonconformity. The main thing is to detect them. Be aware that it can occur in raw material, components, or finished medical devices. For the whole process to be effective, you have to implement systematic controls.

After it was **identified, it must be evaluated, investigated, and documented**.

Documenting non-conforming product

All gathered info about non-conformity should be in a way to help you out with mapping the problem and tracking down the **root cause**. Bear in mind that this documentation is the first step in a process that will later lead to corrective action. When documenting the nonconformity, it is recommended that you record any characteristics of the medical device (or the service) at the time of the nonconformance. It will serve you later on when you evaluate the effects of the nonconforming product.

Rework

Corrections of nonconforming medical devices may be seen as reworking. It includes the **repair, reworks, reprocessing, or any other adjustments of the medical device**.

If a medical device needs to be reworked (one or more times), your company has to **document the rework process** in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. It has to be reviewed and approved in the same process as the original work instruction before being submitted for execution. Plus, each rework instruction will refer to a specific nonconformity.

Like everything else, parameters of the rework may affect the quality. Each person involved in the design and development of the device will evaluate and give their professional opinion regarding the effect of the rework.

What ISO 13485 considers under - Analysis of data?

Lesson 19

The ISO 13485 Standard requires collecting data from processes and activities and analyzing them to identify trends and patterns in your processes to verify the continuing suitability and control of the effectiveness of your QMS by maintaining improvement.

It's advisable to ask a lot of "how" based questions when analyzing your quality management system.

The data analysis includes an **examination of the effectiveness, information, and data gathered from various resources, generated from customer feedback, etc.**

Data analysis aims to see or check on your **QMS effectiveness**. It's most practicable to achieve it by setting goals and measure their fulfillment or improvement. Popular improvement operations can be CAPA, changes as a result of customer complaints, and advisory notices.

Once an improvement has been initiated and implemented, the analysis of data is a tool that can be used to evaluate **whether improvement activities have been successful and have achieved their goals.**

Strategy for identifying the data for analysis

The data analysis should relate to the issues relevant to the performance of your QMS. These issues will be **inputs for the data analysis**.
The requirements for data resources are the controls that were suggested throughout the standard. For example:

- **Human resources**
- **Work environment**

- **Substructures**
- **Product quality planning**
- **Control of product and processes**
- **Design and development plans**
- **Risk control performances**
- **Validation and verification, etc**

From these issues, you need to identify which processes trigger data that can be analyzed. The evaluation of each data will give you an answer to the requirements above. The analysis of the data will allow you to detect trends and patterns occurring on your processes that require attention.

You need to determine which kind of data will work out for you the best and then decide how it can be gathered. Keep in mind that your data do not to be statistical. Some processes can be shown in numbers and some cannot.

Determine the method and technique for analyzing the data. The purpose of the technique is to objectively demonstrate through data that processes meet their specifications.

Records

The recording is a must as usual as per ISO 13485. Remember, every medical device company has to document almost everything. The **records** will prove that the data was **gathered and analyzed according to your defined method**.

qmsWrapper provides Search and Report tool that allows you to extract data collected during processes, so the analysis, if the quality management system is suitable, adequate, and effective, is very easy. Search results can be exported, so you can get the report on a click!

Improvement through corrective and preventive action

Lesson 20

The ISO 13485 standard in this lesson wants to suggest you a few explanatory perspectives that may serve as inputs for improvement. It also expects you to define which inputs, and sources of information may indicate the need for improvement.

From your medical device company is required to initiate the link between quality activities such as **quality policy, quality objectives, audit results, CAPAs, etc**. and the systematical improvement. By this is meant to identify the relevant parties, processes, records, and outputs of these activities, collect the crucial data, evaluate the need for change, and decide whether the improvement is necessary or not.

Corrective action

One of the foundation elements of quality and also essential management for sustaining improvement is **corrective action**.

Corrective action promotes a systematic analysis of quality problems that have already occurred and the elimination of any root causes of nonconformities through the implementation of controlled measures.

The initiation of corrective action involves all levels of the medical device company – management, design, and development, purchase, production, collection, quality, service, and logistics. It's done methodically through the documented procedure.

In practice, the planning of the corrective action is to be documented and will serve as a quality record. The record may appear as a work plan, a project plan, or refer to such dossiers. Plus, it's required to review and verify the **effectiveness of the corrective action**.

Preventive action

What is the difference between corrective and preventive action? **Corrective action addresses existential nonconformities – that is**, the nonconformity occurred and was detected. A **preventive action** Is a quality tool for protecting medical devices from nonconformities - that is **evaluating risks and potential events** that may affect the quality of the medical device.

Think this way - the nonconformity has not yet occurred, but you know that it may—this is the time to capture and submit it to a controlled process.

By using traditional methods of identifying problems early, you will implement systematic quality tools that may ensure the liability and dependability of processes and maintain the quality of the medical device.

The process of evaluation of a root cause of a potential nonconformity is identical to the evaluation of a root cause of an occurred nonconformity. And as it is with corrective action, it's the same with the preventive action it must be documented. The main goals of these records are **monitoring and control**.

There is a lot of different solution for documenting and controlling corrective and preventive actions – from the simple traditional forms to sophisticated designated software, such as qmsWrapper.

As a medical device company, you need to find an appropriate solution for your organization and the nature of your process.

qmsWrapper provides a process for CAPA, that make sure non-step will be missed when it comes to this quality event. It will ensure the nonconforming event will be recorded, the action to eliminate such event will be defined, as well the action to prevent its re-occurrence and at the end, that it will be verified the actions don't adversely affect the ability the regulatory requirements will be met or the safety and performance of the device would be affected.

HOW TO ESTABLISH an ISO 13485: 2016 QUALITY MANAGEMENT SYSTEM

1. Plan your Quality Management System (QMS)

DEFINE YOUR QMS

1. QUALITY MANAGEMENT SYSTEM

- Document Quality Manual
- Establish Medical Device File
- Establish controls for documents and records

2. MANAGEMENT RESPONSIBILITY

- Management commitment to QMS
- Define Quality Policy and set Objectives
- Define responsibilities and authorities
- Appoint Management representative
- Plan periodic Management reviews

3. RESOURCE MANAGEMENT

- Provide resources
- Personnel
- Infrastructure
- Work environment

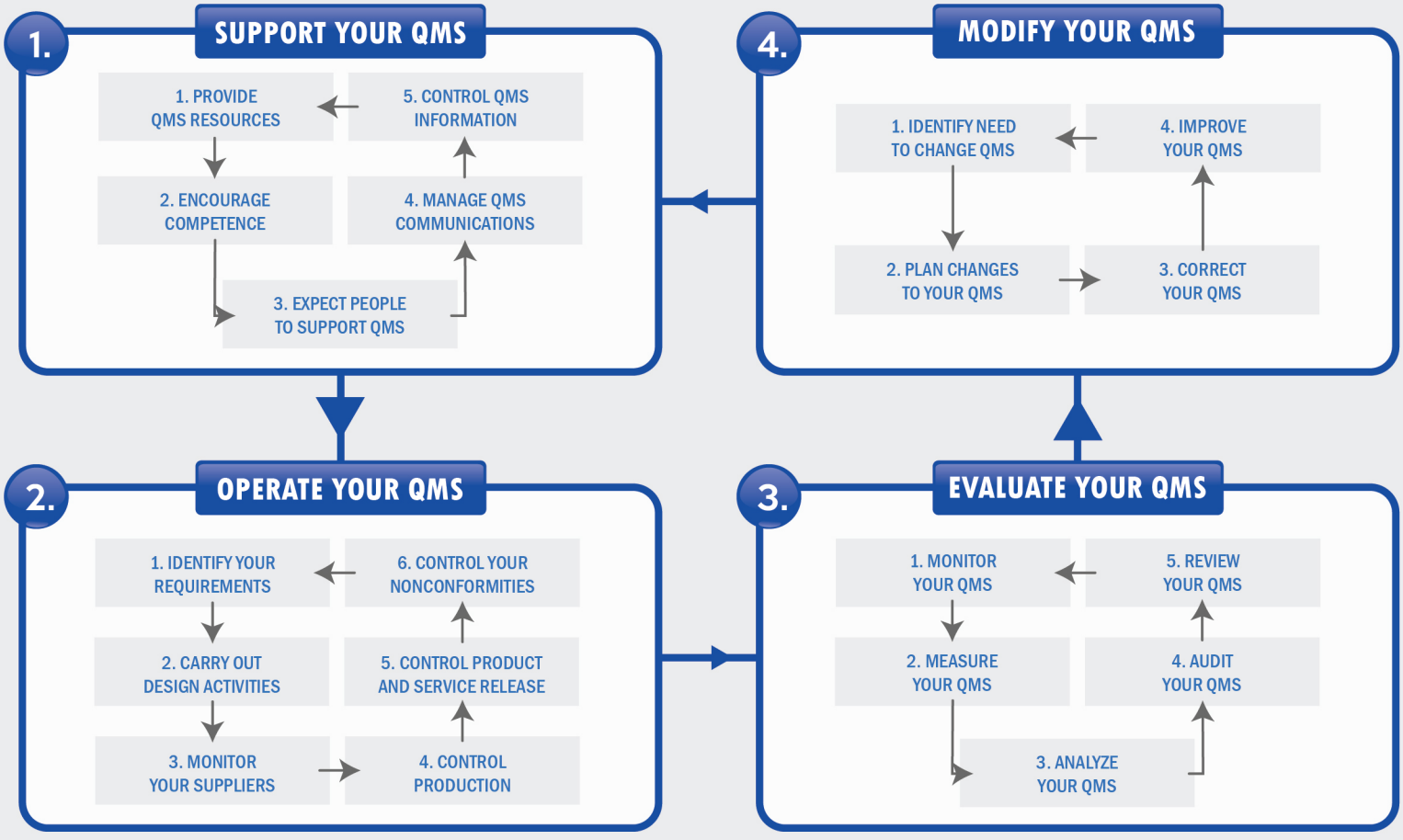
4. PRODUCT REALIZATION

- Plan product realization
- Define product requirements
- Establish Design and development procedure
- Establish Purchasing controls
- Establish controls for production and service provision
- Establish controls of monitoring and measuring equipment

5. MEASUREMENT, ANALYSIS, AND IMPROVEMENT

- Define monitoring and measurement requirements
- Establish controls over nonconforming product
- Define requirements for analysis of data
- Establish ways of controlling change and improvements

2. Implement your Quality Management System (QMS)



"Definitely we can organize better, trace efficiently
and manage all our documentation and more.
I am very satisfied with it and definitely I would recommend it
to my colleagues and people out there involved
with the medical device industry"
Louis W.
Medical device specialist

Find out more what others are saying.

It is not easy to fully understand the standards, which is why we, as a company that produces QMS software for medical devices companies, considered ourselves responsible to facilitate the path to implementation and interpret the ISO 13485 standard. For an even easier, faster, more reliable implementation, start using digital QMS:

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qmsWrapper provides the means for teams to work effectively together, integrating Quality Management, Documentation and Risk, Design Controls, and Team Communication. Startups, mature organizations, and quality-oriented teams will find qmsWrapper the right approach to achieving painless compliance.