Module 3: Measurement, Analysis and Improvement

After completing this module, you will be able to:

- Discuss all requirements stated in Clause 8 of ISO 13485:2016.
- Explain the requirements on Monitoring and Measurement.
- State controls so as to manage non-conforming product.
- Describe the complaint handling procedure in the case of medical devices.
- Specify the requirements on analysis of data.
- Outline the process of Improvement with its requirements.
- Differentiate correction, corrective action and preventive actions.
- Summarize the 7-Steps protocols for corrective and preventive actions.
- Explain why companies fail to effectively implement corrective and preventive actions.

Measurement, Analysis and Improvement (Clause - 8)

This is the last clause of the standard. It states the remaining requirements for a quality management system meant to be applied for medical devices suppliers and manufacturers. The Clause - 8 is divided into five sub-clauses:

- General (Clause - 8.1)
- Monitoring and Measurement (Clause - 8.2)
- Control of Non-Conforming Product (Clause - 8.3)
- Analysis of Data (Clause - 8.4)
- Improvement (Clause - 8.5)

General (Clause - 8.1)

This clause is about planning requirements about measurement analysis and improvement.

• Plan processes related to monitoring, measurement, and analysis.
• Plan how monitoring methods will be utilized to confirm conformity and effectiveness.
• Plan how measurement will be utilized to ascertain conformity and effectiveness.
• Plan how analytics will be utilized to make sure conformity and effectiveness.

Monitoring and measurement (Clause - 8.2)

Sub-Clause 8.2 is divided into six sub-sections:

• **Feedback** - Apply proper feedback methods and procedures (Clause - 8.2.1)
• **Complaint handling** - Develop and document complaint handling procedures (Clause - 8.2.2)
• **Reporting to regulatory authorities** - Develop and keep regulatory reporting procedures (Clause - 8.2.3)
• **Internal audit** - Plan and carry on internal audits at planned intervals (Clause - 8.2.4)
• **Monitoring and measurement of processes** - Find out whether processes achieve intended results (Clause - 8.2.5)
• **Monitoring and measurement of product** - Monitor and measure medical device product characteristics (Clause - 8.2.6)

Monitoring, Measurement and Analysis

Measurement involves the allocation of numbers to performance events or objects. For example in the case of a medical device industry; surgical scissors are tempered in a furnace, the temperature reading of the furnace is a measurement process.

Monitoring is done to verify compliance or non-compliance of a process or product. It can involve: testing results related to a medical device. In the case of furnace tempering the scissors, the furnace temperature should be in the desired acceptable range to be compliant. If the temperature is not kept in the desired range it is a non-compliance against the acceptable limit. Similarly as for the surgical scissors, the process impact on the scissors should yield the acceptable hardness value, tensile strength, yield strength etc. to be in the desired range for being compliant.

Analysis uses data to discover patterns, relationships and trends. It is related with measuring events. As in the case of surgical scissors being tempered in a furnace, the comprehension of the **furnace temperatures' trend** with respect to time, gaseous supplies, electricity consumption etc. will show the behavior of furnace. This analysis of furnace temperature will help the supervisor to better forecast the

behavior of furnace and to take preventive actions against malfunction (where possible).

Feedback (Clause - 8.2.1)

Implement proper feedback methods and procedures
• Develop feedback methods and procedures.
• Assess the information organization has gathered.
• Utilize feedback to measure QMS effectiveness.
• Utilize feedback to facilitate risk management.
• Utilize feedback to support improvement processes.
• Utilize feedback to enhance product realization.

Complaint handling (Clause - 8.2.2)

This clause is about development and documentation of complaint handling procedures

• Develop organization's complaint handling procedures.
• Document organization's complaint handling procedures.
• Implement organization's complaint handling procedures.
• Keep organization's complaint handling procedures.
• Maintain a record of implantable medical device testing and inspection.

Reporting to regulatory authorities (Clause - 8.2.3)

This clause is about establishing and maintaining regulatory reporting procedures. Requirements are:

• Develop reporting procedures when regulators expect your organization to report to them.
• Document reporting procedures when regulators expect your organization to report to them.
• Implement reporting procedures when regulators expect your organization to report to them.
• Keep reporting procedures when regulators expect your organization to report to them.

Internal audit (Clause - 8.2.4)

This clause is about planning and performing internal audits at planned intervals. Requirements are:

• Develop your organization's internal audit procedure.
• Plan organization-wide internal audit programs.

• Carry-out internal audits at planned intervals.
• Keep a record of audit plans and performance.
• Eliminate all reported non-conformities and their causes.
• Follow-up on measures implemented to resolve non-conformities.

To learn about audits join an interactive full course "**ISO Management System Audit Techniques and Best Practices**". You will be able to know about all above requirements. **Course Link:** https://alison.com/course/iso-management-system-audit-techniques-and-best-practices

Monitoring and measurement of processes (Clause - 8.2.5)

This clause is about finding out whether processes achieve intended results or not. Requirements are:

• Develop proper methods to monitor and measure each QMS process.
• Apply suitable methods to monitor and measure each QMS process.

Monitoring and measurement of product (Clause - 8.2.6)

This clause is about monitoring and measuring medical device product characteristics. Requirements are:

• Monitor and measure organization's product characteristics.
• Establish a record of product monitoring and measurement activities.
• Complete all planned arrangements before the product is released.

Complaint Handling and Reporting to Regulatory Authorities

What is complaint?

ISO 9001:2015 defines a complaint as an expression of dissatisfaction with a product or service, which is filed by a customer and received by an organization.

On the other hand, ISO 13485:2016 specifies the scope of a complaint by defining it as a "***written, electronic, or oral communication that alleges deficiencies***" in the following aspects of a medical device:
• Identity
• Quality
• Durability
• Reliability
• Usability
• Safety or Performance

ISO 13485 requirements on complaint

ISO 13485:2016 addresses complaint handling more clearly than ISO 9001:2015 – for example, involving complaints in risk management or identifying complaint-handling procedural requirements.

ISO 13485 considers complaints to be one of the mandatory inputs in management review (in the scope of clause 5.6.2 (b)), unlike ISO 9001:2015. Moreover, clause 8.2.2 of ISO 13485:2016 defines the procedural requirements of complaint handling for medical device suppliers.

Reporting to Regulatory Authority

The procedure of complaint handling must identify routing of serious complaints to regulatory authorities. Serious complaints about medical devices are those which have an adverse impact on a patients' health, surgical operation, etc., and have to be reported to regulatory authorities.
The authority can stop sales of this product for the period of investigation and corrective action.

In some cases, a particular device should have to be recalled from the market. The complaint has to be resolved and closed by the regulatory authority. All records of reporting to the regulatory authority have to be maintained by the company itself.

Recall of the Product

A recall is an important but reactive approach that is used by medical device manufacturers to remove a medical device from the market due to regulatory violation, serious risk of injury, damage, or deteriorating health of the patient.

A recall is an effective way to rescue a company from a lawsuit that could result in billions of dollars in claims.

Recall activities include return of a medical device to the supplier, rework on the recalled device by the supplier at the place where it is used or on the supplier's end, exchanging the device for a defect-free device and destruction of the recalled device, and increasing awareness about the handling of the recalled devices with the help of advisory notices.

Complaint Handling Procedure Elements

The organization is mandated, according to ISO 13485:2016, to

implement a complaint-handling procedure that addresses ten different elements. Five of these elements are discussed in the next slide, five are discussed here:

Applicable Regulatory Requirements

The complaint-handling procedure should be compliant with applicable regulatory requirements. For example, the Food and Drug Administration (FDA) governs regulatory requirements in the United States, and its 21 CFR section 820 is a designated regulation for medical device manufacturers and suppliers.

Receiving & Recording Information

A complaint is communicated by oral, written, or electronic means. The procedure should address how all received complaints are routed within the organization, recorded, and (all receiving information) saved in a complaint log or Complaint Management System (in the scope of an Enterprise Resource Planning (ERP) system).

Complaint Evaluation

After receipt of a complaint, the information is evaluated to determine whether it is valid or not. If the complaint is declared to be non-valid due to substantial reasoning (for example, the defect resulted from mishandling of the device, misinterpretation of a particular issue as a defect, etc.), the customer is notified and no further proceedings are made. Justification records are maintained for non-valid complaints.

Report to Regulatory Authorities

This element is already discussed in the previous slide.

Complaint Investigation

Under complaint investigation, root cause analysis is performed. This is the most important part of complaint management, as it helps to identify the root cause. It is only through the identification of the root cause that subsequent actions can be identified.

Handling of Complaint about Related Product

The complaint management procedure should also address the handling of customer-related products that are returned to the vendor or supplier organization. Are the returned instruments properly tagged and identified? Are returns reworked and shipped again? Or, are these returns discarded and replacements issued to the customer? The procedure of complaint handling should address all these queries so as to minimize the risk of returned product being mixed with inventory of production.

Correction and Corrective Action

After analyzing the root cause, the vendor must correct damages to the customer to resolve the complaint. A correction can be accomplished by rework, or sometimes it is done by offering a replacement. Corrective action includes actions to address the root cause. Records for corrections and corrective actions must be maintained.

Third-Party Involvement

Sometimes the complaint is a result of a third-party's services in the manufacturing or delivery of a medical device – for example, shipping services or external forging vendor of the medical device. The complaint-handling procedure should address the mode of communication with external providers. The investigation findings that highlight their contribution or any corrective action on their part must be shared with proper documented records.

Review of Servicing Records

Servicing records are details of activities taken under scheduled or breakdown maintenance. Servicing records must be assessed. If records identify any servicing issue as a complaint, then the whole complaint management process has to be initiated.

Complaints & Product Quality Risk Management

ISO 13485:2016 has a requirement to assess the risk of product failure and its inability to meet quality requirements. Complaints must also play a part in increasing the risk of failure. Complaints should be used as an input to the product's quality risk management cycle.

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1 ISO. 2016. ISO 13485:2016, Third Edition: Medical devices - Quality management systems - Requirements for regulatory purposes. 3rd ed. Washington, DC 20036: American National Standards Institute (ANSI) Publications.

Control of Non-Conforming Product (Clause - 8.3)

(Clause - 8.3.1)

This clause discusses prevention unintended delivery or use of nonconforming products

- Explain how you intend to prevent unintended product delivery or use.
- Avoid the unintended delivery or use of your nonconforming products.
- Keep a record of your organization's nonconforming product activities.

(Clause - 8.3.2)

This clause deals with pre-delivery non-conformities and mandates

suitable records. Requirements are:

• Deal with nonconforming products before delivery.
• Take action to eliminate detected non-conformities.
• Prevent the product's original intended use or application.
• Authorize nonconforming product use, release, or acceptance.

(Clause - 8.3.3)

This clause deals with management of nonconforming products detected after delivery. Requirements are:

• Recognize nonconforming products after delivery or after use.
• Act as appropriate to counter the effects that have been identified.
• Develop and keep a record of the actions that have been taken.
• Explain how company's advisory notices should be released and managed.
• Keep a record of actions taken when advisory notices are issued.

(Clause - 8.3.4)

This clause specifies how product rework should be carried out. Action items are:
• Explain how product rework should be performed.
• Clarify how product rework should be verified.
• Clarify how product rework should be reviewed.
• Clarify how product rework should be approved.
• Clarify how product rework should be recorded.

Detection of Non-Conforming Products after Use and After Delivery

The organization is required to detect nonconforming products after release or after use. It’s possible that a nonconforming product is released to the market because the sample-based inspection plan did not detect it during in-house processes.

For example, some lots, i.e., WIP (Work in Process) were identified with a particular defect because of an error in raw material. That specific batch of raw material was also used in some identified shipped lots that were not detected in sample-based in-process and final inspections. All those shipped lots are detected after the issue is traced out and analyzed. Therefore, in the non-conformance report, not only in-process lots are identified, but also the ones being shipped. Three possible

situations of such non-conformities can be:

Situation 1

Non-conformance does not pose a health hazard, but is unacceptable to regulatory authorities.

In Situation 1, where it is unacceptable to regulatory authorities, the organization must issue a return shipment for reversing nonconforming products back. The organization should analyze the root cause and take a corrective action. The organization is required to clearly tag, label, and quarantine all nonconforming material and, if needed, dispose of it. The effectiveness of the corrective action that is taken should be measured (e.g. nonconformance is checked in the next three shipments for measuring effectiveness of the corrective action).

Situation 2

Non-conformance does not pose a health hazard, and is acceptable to regulatory authorities.

In Situation 2, where it is acceptable to regulatory authorities and no health risk is assessed – the organization can communicate with the customer regarding monetary compensation, reworks, etc. If the customer agrees, then the organization takes the measure immediately. However, it is better for the organization to analyze the root cause and take a corrective action so as to avoid this non-conformity in the future.

Situation 3

Non-conformance poses a health hazard.

In Situation 3, where it poses a health risk, it means it is unacceptable for the customer as well as for regulatory authorities; the organization is required to issue a withdrawal from the market or a recall of the product. The organization must analyze the root cause and take corrective action. The effectiveness of the corrective action will be measured. Advisory notices, addressing the nonconformity and recall status of the devices, are issued to the relevant stakeholders, e.g.: customers, health care practitioners, regulatory authorities, etc. Non-conforming products are clearly tagged, identified, placed in a quarantine area, and disposed of if the issue cannot be corrected. When a product is recalled, a health hazard evaluation is conducted by regulatory bodies – for example, the Food and Drug Administration (FDA) in the U.S. The FDA also classifies the recall as Class 1, Class 2,

or Class 3 based on the health hazard posed by the non-conformity.

Advisory Notices

The organization needs to develop and document a procedure of advisory notices. An advisory notice is initiated to send information regarding what proceedings should be undertaken in the implementation, servicing, disposal, or return of a medical device. The procedure should require the committee who issues advisory notices to answer the following questions:

- What is the magnitude and kind of health hazard involved?
- If there is a recall notification, what should be the scope and magnitude of the recall?
- What is the medium of notices to consignees, e.g.: letter, email, fax, telephone, or multiple media?
- What is the content (recommendations) of the advisory notice to consignees?
- How is the effectiveness of advisory notices and recalls measured?
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Reading Activity: Brainlab AG Recalls Spine & Trauma 3D

The FDA has identified a recall, which is considered to be as the most serious type of recall. The Spine & Trauma 3D navigation software by Brainlab has been recalled because of its misleading display for navigating surgical instrument within the sensitive organs of the patient. The misinformation can lead to patient's injury that can require a subsequent surgical procedure or even it can lead to a life threatening situation.

The product recalled were having following specifications:

• Brainlab Spine & Trauma 3D Navigation 1.0
• Product code: HAW
• Manufacturing Dates: May 2018 to February 2019
• Distribution Dates: May 2018 to February 2019
• Devices Recalled in the U.S.: 60

Bibliography

1 ISO. 2016. ISO 13485:2016, Third Edition: Medical devices - Quality management systems - Requirements for regulatory purposes. 3rd ed. Washington, DC 20036: American National Standards Institute (ANSI) Publications.
1 FDA. 2019. Brainlab AG Recalls Spine & Trauma 3D Navigation Due to Inaccurate Display That May Result in User Misinterpretation. [ONLINE] Available at: https://www.fda.gov/medical-devices/medical-device-recalls/brainlab-ag-recalls-spine-trauma-3d-navigation-due-inaccurate-display-may-result-user. [Accessed 22 May 2019].

Analysis and Improvement

Analysis of data (Clause - 8.4)

Clause - 8.4 elaborates analytical requirements as:

• Plan how your organization is going to evaluate your QMS.
• Establish procedures to evaluate organization's QMS.
• Utilize analytical results to improve organization's QMS.

Improvement (Clause - 8.5) > General (Clause - 8.5.1)

Clause - 8.5.1 is the sub-clause of Clause - 8.5 i.e. Improvement. This sub-clause is about taking actions to change QMS and products:

• Recognize any changes that are necessary for improvement.
• Recognize changes that maintain QMS suitability, adequacy, and effectiveness.
• Figure-out changes needed to ensure medical device safety and performance.
• Initiate changes that must be made.

Improvement (Clause - 8.5) > Corrective action (Clause - 8.5.2)

Clause - 8.5.2 is the sub-clause of Clause - 8.5 i.e. Improvement. This sub-clause is about taking actions to correct actual non-conformities. Requirements are:

• Document a corrective action procedure.
• Explicate how actual problems will be investigated.
• Explain how corrective actions will be developed.
• Specify how corrective actions will be verified.
• State how corrective action will be taken.
• Explain how corrective action will be reviewed.
• Implement organization's corrective action procedure.

• Keep records of corrective actions that are made.

Improvement (Clause - 8.5) > Preventive action (Clause - 8.5.3)

Clause - 8.5.3 is the sub-clause of Clause - 8.5 i.e. Improvement. This sub-clause is about taking actions to prevent potential non-conformities. Requirements areL

• Document a preventive action procedure.
• Explain how potential problems will be investigated.
• Explicate how preventive actions will be developed.
• Specify how preventive actions will be verified.
• State how preventive action will be taken.
• Specify how preventive action will be reviewed.
• Implement organization's preventive action procedure.
• Keep records of preventive actions that are made into the QMS.

Correction, Corrective Action and Preventive Action

The first challenge is learning to differentiate between correction, corrective action and preventive action.

A **correction** occurs when you discover a problem, and implement an immediate fix to allow work to continue.

A **corrective action** discovers the root cause and correct it to prevent the problem from occurring again in the future.

A **preventive action** correct the root cause of a potential non-conformity. It means when a worker judges some problem in the process and corrects it before that process can create a non-conformity. That problem can be a root cause for various defects.

Example: Say you find a defect in a batch of medical devices. The immediate correction might be rework, so that those devices are still usable.

The corrective action would involve searching for the root cause, which might be incorrect calibration on a machine. So, you would fix that root cause by recalibrating a machine, and implement a quality check to make sure that the next batch is free of defects.

Preventive action in this case is only applicable when you first detect the root cause on its own prior to the product becoming defective. It

means you already found the incorrect calibration, you correct it and save the product from getting defected in the first place.

7-Steps Process for Managing Corrective Actions

1st Step: Define the problem

Quality professionals does not work on perceptions rather they define a problem with its specifications.

Utilize a “Should be ***required reality***/Is ***actual reality***” statement as a verification test, so that one can specify the problem along with the requirement that was needed to be fulfilled.

Example: Bone forcep handle should be chrome-plated/Bone forcep handle is missing chrome plating.

If you can’t specifically define the “should be,” then you may not have an actual problem on your hands.

2nd Step: Define the Scope

The second step of this process requires defining the impact or extent of the problem. The following questions may be helpful in defining the scope of the problem:

• Does this problem apply to only one individual part?
• Is it only found in today’s batch, or did the same problem happen yesterday, too?
• Is the defective part only found on one product, or are multiple products affected?

This step is important as it helps in the coming steps to develop appropriate corrective actions to help prevent the problem from recurring.

3rd Step: Immediate Action/Containment Actions/Corrections

The third step is containment of the problem, which can require immediate measures or temporary fixes or correction to halt the growth of the problem.

Then, one can study the root cause and know that if the problem can result again. After the growth of the problem has been halted, a root cause analysis can be undertaken to identify the cause of the issue and

whether it is likely to recur. In this instance, further corrective action can be taken to help prevent or reduce the risk of the same problem occurring again.

4th Step: Analyse the Root Cause

Root Cause Analysis (RCA) is a popular and often-used technique that helps people answer the question of why the problem occurred in the first place

There are complete comprehensive books and courses dedicated to this subject. Some common tools are:
• 5-Whys Analysis
• The Fish-bone Diagram

Root cause analysis ensures that one has identified the root issue, and not just the apparent problems. Also in this step, it is important to check the scope of the problem. If the scope has expanded, more containment actions will be needed so as to cope up with the expanded scope.

5th Step: Devise a Corrective Action Plan

A corrective action plan is a step-by-step plan of action plan, which is designed to eliminate the underlying root-cause of the subject problem. In essence, the corrective action plan should outline how to rectify the subject problem and may include changes to a task, process, product, and/or employee behavior when any of these factors produce errors or deviate from an intended plan.

It is also beneficial to conduct a cost/benefit analysis of each proposed corrective action to ensure these can be effectively implemented.

6th Step: Implement the Corrective Action

The next step is implementing the solution as per the step-by-step corrective action plan. It is important to confirm and verify that all of the required tasks described in the action plan are initiated, completed, and documented.

7th Step: Follow-up to Ensure the Plan is Effective

Once the corrective action plan has been successfully implemented, the following steps should be considered to ensure the plan is effective:

• Monitor the progress of the corrective action plan in resolving the subject problem. Offer assistance and feedback as needed.

• Provide and maintain evidence (e.g. documents, testing) that record your assessment of the corrective action plan's progress or lack of progress.
• Revise or discontinue the corrective action plan as needed. It is also important to document the successful resolution of problems and any revision or discontinuation of the corrective action plan.

There are various methods that can be used to track and monitor the progress of the corrective action plan depending on the type of company and industry. Examples of methods that can be used to track and monitor the effectiveness of the corrective action plan include:

• Automating the corrective action plan processes
• Using internal management information system and tools
• Developing periodic reports and analysis of the progress
• Following quality control and assurance procedures

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1 ISO. 2016. ISO 13485:2016, Third Edition: Medical devices - Quality management systems - Requirements for regulatory purposes. 3rd ed. Washington, DC 20036: American National Standards Institute (ANSI) Publications.

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3 CMS. Corrective Action Plan (CAP) Process. [ONLINE] Available at: https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/perm/downloads/2013correctiveactionpowerpoint.pdf. [Accessed 22 May 2019].

The key points from this module are:
Measurement, Analysis and Improvement (Clause - 8) outlines the QMS requirements for medical devices suppliers and manufacturers. Clause - 8 is divided into five sub-clauses, which are as follows:

Clause 8.1 - General

This clause is about planning requirements about measurement analysis and improvement.

Clause 8.4 - Analysis of Data

Clause - 8.4 elaborates analytical requirements as:

• **Plan** how your organization is going to evaluate your QMS.
• **Establish procedures** to evaluate organization's QMS.
• **Utilize analytical results** to improve organization's QMS.

Clause 8.2 - Monitoring and Measurement

Sub-Clause 8.2 is divided into six sub-sections:

• **Clause 8.2.1 - Feedback** - apply proper feedback methods and procedures.
• **Clause 8.2.2 - Complaint handling** - develop and document complaint handling procedures.
• **Clause 8.2.3 - Reporting to regulatory authorities** - develop and keep regulatory reporting procedures.
• **Clause 8.2.4** - **Internal audit** - plan and carry on internal audits at planned intervals.
• **Clause 8.2.5 - Monitoring and measurement of processes**
• **Clause 8.2.6 - Monitoring and measurement of product**

Clause 8.3 - Control of Non-Conforming Product

Sub-Clause 8.3 is divided into four sub-sections:

• **Clause 8.3.1 - General** - apply proper feedback methods and procedures.
• **Clause 8.3.2 - Actions in response to nonconforming product detected before delivery.**
• **Clause 8.3.3 - Actions in response to nonconforming product detected after delivery.**
• **Clause 8.3.4** - **Rework** - this sub-clause specifies how product rework should be carried out

Clause 8.4 - Analysis of Data

Clause - 8.4 elaborates analytical requirements as:

• **Plan** how your organization is going to evaluate your QMS.
• **Establish procedures** to evaluate organization's QMS.
• **Utilize analytical results** to improve organization's QMS.

Clause 8.5 - Improvement

Sub-Clause 8.5 is divided into three sub-sections:

• **Clause 8.5.1 - General** - take actions to change QMS and products.
• **Clause 8.5.2 - Corrective Action** - take actions to correct actual non-conformities.
• **Clause 8.5.3 - Preventative Action** - take actions to prevent potential non-conformities.

Key Definitions:

- A **correction** occurs when you discover a problem, and implement an immediate fix to allow work to continue.
- A **corrective action** discovers the root cause and corrects it to prevent the problem from occurring again in the future.
- A **preventive action** corrects the root cause of a potential non-conformity.
- **Root Cause Analysis** is used to identify the root cause of an issue, in order, to help eliminate the problem from recurring.

7-Steps Process for Managing Corrective Actions

1 Define the Problem
2 Define the Scope
3. Immediate Action/Containment Actions/Corrections
4. Study the Root Cause
5. Devise a Corrective Action Plan
6. Implement the Corrective Action
7. Follow-Up to Ensure the Plan is effective