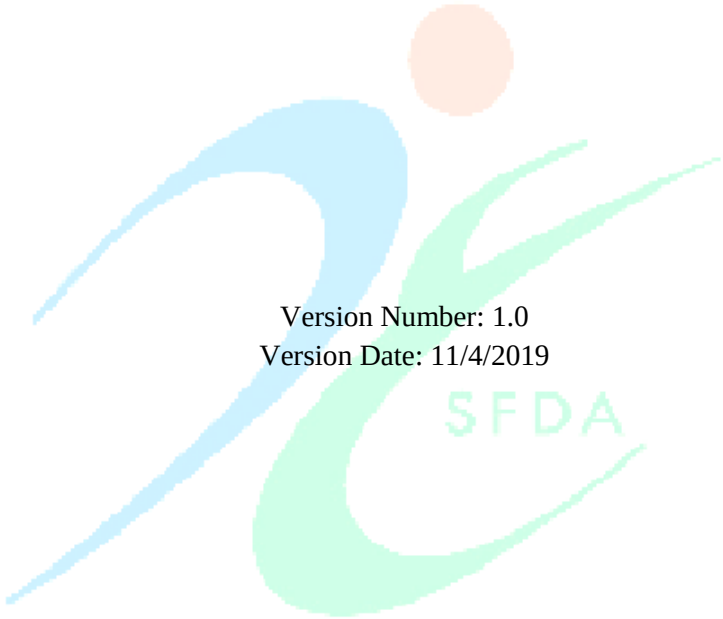
MDS-G35

Guidance to Implement a Medical Devices Standard "Quality Management System" Regulatory Requirement (ISO 13485:2016)



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Introduction

A quality management system (QMS) is the best way to guide establishment and control activities on away, which help establishment to achieve the intended results. Quality Management Systems contain organizational structure, implementation plans, statement of resources necessary and documentation of information used to ensure the achievement of quality goals. Therefore, establishment that implements quality management system shall have a deep understanding of the details of the requirements of this system and not there be a conflict between the system and the requirements of the product or service provided by the establishment whereas proper understanding and interpretation of the requirements in the standard helps application proper for these requirements.

Implementation of quality system management shall include the ability to achieve customer requirements and regulatory requirements applicable in Saudi Arabia and shall not resulting in bureaucracy or more paperwork or absence of flexibility. It also shall help to get rid of the non-useful financial obligations. It is worth mentioning that the adoption of SFDA to standard ISO 13485: 2016 will not add new requirements upon the establishment that has applied quality systems. The only need to establishment is updating these systems.

The adoption of a quality management system helps to improve establishment performance with continuous development and builds trust with the customer whereas the product or service provided cover customer needs and expectations. There are important matters taken into consideration, which included:

- Establishment's environment and expected changes.
- The needs of the establishment and its size.
- Establishment's objectives.
- Type of the product or service provided to the customer.
- The nature of the applicable procedures.
- Knowledge of legislative requirements and legislative applied in the market.

When it comes to discuss the risks in this standard, it is in the context of the safety and performance of the medical device and regulatory requirements and not to be confused between the financial risk or the performance. Nevertheless, emphasis on the risks in implementing and improving the quality management system. Also, reduce the undesirable effects of preventive procedures. This standard developed on the principle of procedure process within the Quality Management System. A series of activities implemented systematically in a logical sequence allows the establishment to achieve the desired goals. Procedures in a single system shall not be treated as separate and separate from each other. In addition, knowledge of intersections between the different procedures and clarify them in the system shall help to achieve product / service compliance with the customer needs and organizational needs. Whereas the procedure applied in the establishment, helps understand customer requirements and regulatory requirements as well as obtaining performance and efficiency results assist to improve activities within the establishment.

Purpose

The purpose of this document is to clarify implementation of the standard “Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)".

Scope

The scope of work includes all phases of device life cycle and highlights the responsibility of the establishment, regardless of do activities carried out within the establishment or through a third party and therefore it has to be good management of this relation. The guidance applies to the following parties:

- Local and overseas medical devices manufacturers
- Authorized representatives of medical devices manufacturers
- Importers and distributors of medical devices (including retails sellers).

As such scope of work shows that the establishment, regardless of its size or type of medical device which dealing with, shall apply the requirements of this standard. However, there is a possibility of excluding or not to implement certain activities, which are not included within the scope of the establishment‘s quality management system. It is important in the quality manual to identify, justify and record the reasons for not applying these requirements. For example, some design and development procedures can be excluded for products that do not have regulatory requirements related to design and development; this will be based on the level of risk of the device. Some requirements do not apply on certain establishments such as if the device is for single-use and does not require installation, and maintenance services operations and after sales requirements . Thus excluding the relevant requirements from the establishment quality system.

Basic Requirements

The establishment shall have knowledge of the basic instructions; understand the regulatory requirements and document all related to this aspect management system as the need for documentation, which is a normative process in this standard. Therefore, the relevant requirements shall be identified and the necessary decisions on procedures and activities should be taken to ensure that these requirements are fulfilled, documented, clarified, and defined. Along with identification of what to do, who will do so and what are the expected results and how to monitor them, so that all employees in the establishment can understand and apply them optimally.

When establishing and documenting a quality management system, the standard requires that the requirements established and documented in the establishment's policies and procedures and related work instructions to remain applicable regardless of internal and external changes and to train staff to assume responsibilities and improve the efficiency to perform their assigned activities. Examples of external changes include changes in regulatory requirements, customer complaints and the emergence of new technologies in the market. Examples of internal changes:

- The overall performance of the establishment
- Mergers, acquisitions and the launch of new products
- Resource availability,facilities and funds ... etc.)
- Human resources and the efficiency of people and changes in key personnel
- Operational factors such asthe ability for productionor delivery rules and procedures for decision-making or organizational structure.

The establishment may maintain the efficiency and effectiveness of the QMS by doing the following:

- Identify and promote processes leading to compliance with regulatory requirements.
- Continuous request for data and information.
- Identify and provide resources of all kinds.
- Making the necessary changes to the quality management system
- Responding and interacting with statements
- Initiation of corrective and preventive measures.
- Take advantage of external and independent assessments and responses.
- Use appropriate evaluation methods such as internal audit and periodic review.
- The establishment shall adopt risk-based approach in building quality management system.
- The establishment shall set installation and maintenance procedures according to the technical documents issued by the manufacturer.
- The establishment shall set medical device tracking procedures to ensure access in the event of recall or Field Safety Notices.

Working Procedures

- The procedures of the quality management system shall be documented and consistent with the establishment‘s quality policy. It is important to recognize that the structure and level of detail required in these procedures shall be compatible to the needs of your organization. The level of documentation in the QMS varies from one establishment to another as per:
  - Size of establishment
  - Type of activities
  - Level of complexity and overlaps in procedures
  - Skills and qualifications of employees working at the establishment
  - Risk level

- Procedures can be placed in text, graphic, audio or visual format. The documented procedures, including work instructions and flowcharts, should be stated simply, unequivocally and comprehensively, and shall indicate the methods of use and the criteria to be fulfilled. These procedures usually specify activities, their description, what to do, who to do, when, where and how, what materials, equipment and documents are used, how the procedure is monitored and measured, and what are the required records.

- Documents should be evaluated in relation to the effectiveness of the QMS against criteria, such as:
  - Relevance to purpose
  - Easiness of understanding, usage, and implementation.
  - Required resources
  - Policies and objectives
  - Easy communication with the establishment's customers and suppliers.

- The procedures can be defined and explained by how, by whom and how they interact with other processes. The level of control of procedures shall be based on the risk-based approach and on the risk level of the medical device. This approach should be used to ensure the safety of the device and its compliance with regulatory requirements, and not to the financial risks or business performance of the establishment.

- After defining the procedures for the quality management system and the risks associated with it, the establishment can provide a detailed explanation of each procedure. Some basic elements need to be clarified for each procedure. This can be determined by considering the following examples:
  1. How will the establishment ensure the effectiveness of the procedure?
  2. What should it do to ensure that the procedure works effectively?
  3. What controls are required to monitor the procedure?
  4. How will the establishment know that controls on the procedure are effective?
  5. What human and material resources are needed to operate and monitor the procedure?
  6. Who is responsible for the procedure and what are the competency requirements?

7. What information is needed to effectively implement and control the procedure?
8. Does the procedure control processes include all requirements specified in the planning?
9. How will the monitoring outputs be analyzed?

- Ensure that procedures in QMS are still effective in meeting customer requirements and regulatory requirements as well as achieving the objectives of the establishment.
- An important element in the management of the procedure is to make the changes necessary to develop and improve the quality management system, and it shall be evaluated before implementation to ensure that the effective operation of the QMS is not impeded or if there are any undesirable consequences.

Change, Development and Improvement of Quality Management System:

The establishment shall consider whether the change has an impact on the safety or performance of the medical device or on compliance with regulatory requirements. The standard contains a number of specific requirements for the elements of change, as follows:

- Identify the need for change
- Change in documents
- Make changes to records
- Changes in quality management system
- Statement of responsibility for top management of change management, including follow-up and review
- Variable / new regulatory requirements
- Change to customer requirements
- Design and development changes - if any-
- Approve changes

Outsourcing

- The establishment may employ another external party to carry out an activity on its behalf and such decisions are considered a strategic option of the top management of the establishment. The use of another external party for activities such as:
  - Funding
  - Human Recourses
  - Communication with customers such as call centers
  - Supply Chains
  - Manufacturing
  - Design and development
  - Calibration
  - Maintenance
  - Installation
  - Auditing
  - Consultancy services

- The external party shall be treated in accordance with the controls set out in the standard, and the determination of the level of controls based on the potential risks to the safety and performance of the medical device and its compliance with regulatory requirements.
- Dealing with an external provider does not exempt the responsibility from the establishment. The necessary supervision and monitoring shall be maintained to ensure that the service provided is in accordance with the agreed requirements. Therefore, it is important to have a written quality agreement specifying the responsibilities of each party.

Verification of Programs and Software Applications

Computer software can be used to help implement the quality management system and to carry out the required monitoring and analysis. Examples of some software applications that are used in:

- Design of products
- Testing
- Production control
- Labelling
- Distribution and tracking
- Inventory control
- Document and data management
- Complaints handling and follow-up
- Calibration of equipment and maintenance schedules
- Monitor the implementation of corrective or preventive actions.

Quality Manual

- Quality Manual is a specific quality management system document that provides an overview of the establishment, the quality management system and the procedures that constitute the quality management system.
- The scope of the QMS, as defined in the Quality Manual, may be affected by the role(s) of the establishment under the regulatory requirements to which it applies. It also indicates whether there are exceptions or non-compliance with the requirements of the standard; any exception or non- compliance should be documented in the quality manual with appropriate justification. The scope of the QMS determines the locations covered by the QMS as well as the procedures performed at each site, along with the various other locations of the establishment.

Document Control

- To control the internal and external documents, responsibilities shall be defined for the preparation, approval and issuance of documents, the immediate withdrawal of old copies, and the identification of a method to record the date of implementation of the document change
- Documents are reviewed as needed, for example:
  - Facilities, process, product, personnel or organizational changes,
  - Internal, external and third party audit activities,
  - Acquisitions,
  - New products, technologies or software,
  - Requirement of organization's quality management system for periodic review.

- Document control procedures should clearly indicate what document control information should be included in each document. For example:
  - title and scope,
  - document reference number,
  - date of issue/date effective,
  - revision status,
  - review date or review frequency, as required by the quality management system,
  - revision history,
  - originator or author,
  - person(s) approving it,
  - person(s) issuing it,
  - pagination.
- Previous documents shall also be kept as long as necessary to understand the content of records associated with the device, the establishment required to "apply an appropriate definition" to the obsolete documents such as stamp them manually or electronically. Obsolete documents should also be retained for as long as is necessary to understand the content of records which are related to the document.

Record Control

- Records can be in paper or electronic, and can be considered as one of the three categories
  - Related to design and manufacturing processes.
  - Related to the manufacture or distribution of the medical device.
  - Those that demonstrate the effective operation of QMS.

- Good recording practices can include the following procedures, as appropriate:
  - Data and observations entry as they occur;
  - Do not use another person's initial, signature or equivalent;
  - Complete all fields or check-offs when using a form;
  - Refer to raw data when transferring data, and have the transcription verified by a second person;
  - Number pages to ensure completeness.

Management Responsibilities

- Top management as defined as a person or a group who has the authority to delegate and provide resources within the establishment. It refers to individuals who supervise and control a unit or department of work (for example, a business unit quality manager). The purpose of this is to ensure the effectiveness of the quality management system as a result of commitment by management at the highest levels in the establishment. Top management makes decisions, authorizes procedures and sets priorities for the establishment and ultimately is responsible for product quality.

- Top management provides resources for the effective implementation of QMS by:
  - Commitment to quality management system
  - Strengthen the quality management system and transfer the values of the quality management system in the establishment through quality policy, quality objectives
  - Ensure that the quality management system works through periodic review
  - Provide staff training support in the quality management system, support the quality team and allocate the necessary resources to implement the quality management system requirements.
  - Ensuring sequence and interaction of actions to achieve planned results effectively
  - Ensure the validity of the inputs of the procedures and ensure their outputs and work effectively
  - Risk identification and management by conducting data analysis and necessary improvement of procedures.
  - Identify those responsible for implementing the procedures and give them the authority to do so.
  - The existence of written agreements with third parties - if any .
- The Top management shall ensure the source of input in the quality management system and understand these requirements and provide the necessary resources, and shall consider inputs such as:
  - Regulatory requirements
  - International or national standards
  - Customer requirements
  - Customer complaints
  - Reactions
  - Market trends, statistics and forecasting information

It depends on the following inputs:

- Design and development process
- Risk Management
- Periodic review reports
- Complaints
- Corrective or preventive actions

- Examples of outputs may be decisions such as:
  - Design and develop a new product
  - Redesign the current product
  - New or revised labeling
  - Risk management reports / files
  - Improve and develop
  - Re-planning quality, and policies, procedures or review.

- To ensure the provision of necessary resources, top management, for example, shall provide the following:
  - shall have a sufficient number of qualified persons to carry out the work, document the procedures that describe the processes that it uses to determine the competency

requirements of the staff assigned to the work assignments, and provide any training required.
  - Infrastructure includes buildings and workplaces and ensure appropriate temperatures and humidity, equipment and necessary operating programs and supporting establishment such as warehouses and others
  - Provide the necessary information from data, reports and others
  - Suppliers or partners
  - The financial resources necessary to achieve the objectives of the quality management system in the establishment
- The top management shall set quality policy of the establishment and ensure that it is consistent with the commercial procedures (such as marketing, sales and financing) of the establishment and carry out periodic review. The quality policy should reflect the commitment of the establishment to quality and its overall vision of what quality means to the business of the establishment and its customers. In order to demonstrate the commitment of the establishment to implement its quality policy, clear objectives shall be set for quality. The top management's commitment to the quality policy shall be visible, active and effective so that the employee can remember the basic elements of quality policy and explain the role of his/her work in supporting quality policy.
- In order to put quality policy into effect (implementation), top management shall defines quality objectives clearly, and the quality objectives shall be realistic and relate to measurable outcomes, such as:
  - Fulfill customer requirements and regulatory requirements
  - Reduce errors
  - Reduce processing time for customer complaints corrective or preventive actions resulted from periodic audit reports
  - Completion of plans according to the predetermined time.
  - Reduce processing time for customer complaints

- In order for the quality management system of the establishment to fulfills the requirements of the standard, the top management shall plan for the development and implementation of quality management, and when making significant changes in the quality management system. Typical inputs quality management system planning include:
  - Quality policy
  - Quality objectives
  - Regulatory requirements
  - Quality management system standards
  - Changes required as a result of management review, corrective or preventive actions.

- Outputs from quality management system planning include:
  - Quality manual and supporting documentation
  - Gap analysis
  - Impact assessment
  - Action plans

- Results of action plans

- Top management shall delegate the authority to fulfill these requirements of quality management system. This requirement usually achieved through the identification of responsibilities and authorities, and the development of organizational charts that describe, document and control the interrelationship between individuals. To do so, top management shall adopt the following:
  - The competency of individuals, the provision of human resources and ensuring consistency between assigned roles and responsibilities
  - Regulatory requirements to define specific roles and responsibilities
  - Qualifications required to ensure that any relevant requirements are fulfilled
  - Develop performance objectives and evaluation results to ensure that the right people are committed to meeting expected level of performance
  - Existence of Organizational structure

- Top management needs to develop procedures that encourage people within the establishment to communicate at all levels, and all employees should be able to ask questions or make suggestions on QMS and improve it. These communications processes should ensure that timely feedback is provided with sufficient clarity to demonstrate that the question / proposal obtained is properly reviewed. Examples of means of communication include:
  - Staff meetings
  - Focus groups
  - Staff surveys and their results
  - Suggestion boxes
  - Quality alerts
  - Websites and e-mail
  - Generalization of information via a hard copy.
- Top management reviews information, evaluates improvement opportunities and the need for changes to quality management system to ensure its effectiveness. The quality policy is reviewed to ensure that it is still appropriate and relevant to the purpose and objectives related to QMS and that it has been created at the relevant functions and levels within the establishment. Conduct management reviews at planned time intervals documented in QMS while maintaining audit records that shall identify and document the following:

  - Review Date
  - Persons participating in the management audit, including top management representatives or their delegates and any other participants.
  - Summary of the review of the information provided by the inputs about the QMS
  - Decisions taken and actions raised to improve the quality management system and its processes, and improve the product in view of customer requirements
  - Implement changes related to new regulatory requirements
  - Identify the resources needed to implement and maintain the quality management system
  - Effectiveness and fulfillment of regulatory and customer requirements
  - The persons responsible for the actions to be taken and the target dates for completing these procedures

- Approval of the management review record by participants.
- Record the distribution of the management review record and the date and time planned of the next management review.

Purchasing procedures and selection of suppliers

- Suppliers monitoring is through standard setting, evaluation, selection, continuous monitoring and reassessment. Implementation depends on the nature and risks associated with the product or service, including outsourcing. The process of establishing controls for products and services obtained from third parties consists of the following stages:
  - Planning
  - Selection of potential supplier(s)
  - Evaluate and accept suppliers
  - Setting controls
  - Delivery, submission and monitoring
  - Outcomes of customer communication and corrective and preventive actions
  - Re-evaluation
- The establishment create a form of monitoring and evaluation of the product provided by its suppliers, by means of a simple test that shows that what has been delivered is what has been requested, and can go to the supplier's headquarters to verify it through scheduled inspection.

Additional Requirements for Factories

- The use of risk-based approach to determine how the risk processing in the product and processes designed to ensure the safety performance of the medical device and improve the output and results statement unwanted, and this is reflected positively in improving the effectiveness of the quality management system and helps to maintain the system and achieve .the desired goals. for example SWOT Analysis ,Porter's 5 force Industrial analysis ,What if technique ,FMEA and FMECIA.

- When identifying risks, an establishment shall plan to address these risks and determine the complexity of the procedures as simple procedures require a simple explanation when complex procedures require sufficient explanation that enables employees to understand in order to perform their roles effectively

- There are several steps to enable the stablishment to identify risk
  - Responsibilities and authorities
  - Implementation of Audit and Control
  - Calibration of measurement and control devices
  - Implementation of the product according to the approved design
  - Do corrective actions
  - Documentation of results and work instructions Guidelines

- The manufacturer is required to document a process or series of risk management processes in relation to the safety and performance of the medical device from design and development to post-production activities and standards ISO14971 provides specific information regarding the management of medical device risk.
- The programs that operate the medical device and its applications are verified as part of the product or as a separate product by itself.

- The manufacturer should use the computer software to help implement the quality management system and carry out the required monitoring and analysis. Examples of some software applications that are used in:

- product design
- testing
- production
- labelling
- distribution inventory control
- document management
- data management
- complaint handling
- equipment calibration and maintenance
- corrective action or preventive action.

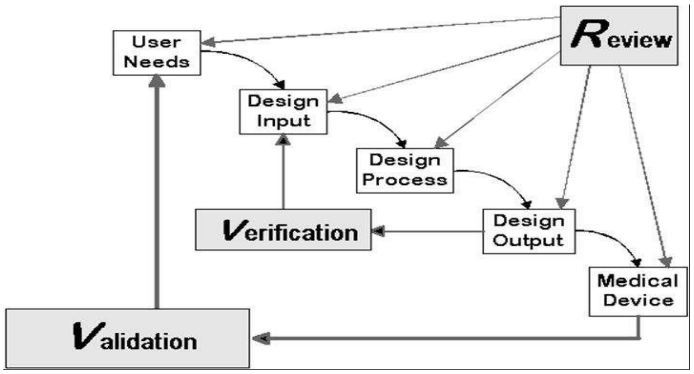
- Software verification process to demonstrate that the way the application is used is appropriate and that the result is effective.
- The requirements of the standard for validation of computer software used in the control of procedures, whether purchased, developed, maintained or modified for automated production or control of procedures, shall apply.
- The manufacturers of medical devices or their representatives to provide a file for each type or model of medical devices, may be called this file the name of the technical file or file design, this file can include, but not limited to:

  - General description of the medical device and, as appropriate, the device classification.
  - Product specifications including drawings, composition, formulation, component specifications and medical device software specifications
  - Production process procedures, including equipment specifications, production methods, any special processing and infrastructure requirements.
  - Quality assurance procedures and specifications including acceptance criteria and measuring equipment to be used.
  - Packaging specifications, including methods and processes.
  - Description of intended use/purpose.
  - Records of risk management including the results of risk analysis, risk mitigations, resulting residual risk and risk/benefits analysis.
  - Procedures or instructions related to the maintenance of product.
  - Clinical data material and component data used in the construction of the medical device together with the biological safety and biocompatibility.

- Storage and transport requirements.
- A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it.
- The standards applied or other methods employed to demonstrate conformance with the applicable general safety and performance requirements.
- The method(s) used to demonstrate conformity with each applicable general safety and performance requirement.
- Identification of incorporated medicinal substance and/or tissue of animal or human origin in the medical device and data on the tests conducted to show the safety, quality, and the usefulness of such substance
- Identification of any substance in the medical device that, if used alone, would be regulated as a medicinal product and data on the tests conducted to show the safety, quality, and the usefulness of such substance.

Requirements for quality and safety of the product

- The manufacturer shall develop the necessary plans in the quality management system procedures to ensure the safety of the medical devices produced and implemented as required. Plans shall be consistent with other QMS processes in the system and may include:
  - Identify required inputs
  - Determine the desired outcome for each procedure
  - Identify and document the sequence of actions, including target completion dates required to obtain the desired result
  - Appropriate resource allocation in terms of staff and clearly defined responsibilities
  - Identification of variables and monitoring of standards
  - Create a risk management file and the details will be based on the severity of the product
- The manufacturer shall determine the requirements of the product, design, development, manufacturing, packaging, supply, storage, installation and maintenance operations, and ensure that the customer complies with the technical specifications of the product.
  These requirements include:
  - Supply, storage and delivery requirements
  - Customer requirements (e.g. delivery schedules, payment terms, delivery activities)
  - Regulatory requirements.
- The manufacturer determines who is responsible for communicating with customers about product information, inquiries, contracts, advisory notices, customer complaints or comments.
- The manufacturer should describe design and development controls as a coherent set of practices and procedures involved in the process.
- Emphasis should be placed on ensuring design inputs, based on user needs, are met during design outputs. To ensure that this is true, systematic reviews are conducted during this process to provide checks and balances. As a result, deficiencies in the requirements for design inputs and inconsistencies between designs and proposed requirements are clearly demonstrated earlier in the development process. As shown in the figure below.



- This approach will provide managers and designers with improved visibility of the design process. With improved visibility, managers are empowered for more effectively direct the design process that is, to recognize problems earlier, make corrections. Designers benefit both by enhanced understanding of the degree of conformance of a design to user and patient needs.
- The manufacturer is required to verify that the results at the end of the design and development process meet the requirements specified in the design and development process (Verification).
- Make sure that the final product and service provided meet the customer requirements and regulatory requirements (Validation)
- The manufacturer prepares the design and development file for each medical device describing the date of the design of the final device

- The manufacturer sets the controls of the label to avoid errors, especially during packaging, by segregation of packaging and labelling operations from other manufacturing or other packaging and labelling operations, avoidance of packaging and labelling product of similar appearance in close proximity, line identification, application of line clearance procedures, destruction of unused batch-coded materials on completion of packaging and labelling, use of roll-feed labels, use of a known number of labels and reconciliation of usage.
- The manufacturer determines the requirements for cleaning the product, including removing process agents. These factors have a negative impact on the quality of the product. The manufacturer shall develop documented procedures, work instructions, reference materials and reference measurement procedures when necessary.
- Installation is a procedure for placing the medical device in the location where it will be used, taking into consideration the needs of the infrastructure such as electricity supply, plumbing and waste disposal.
- The final test is performed for medical devices to be used to ensure the proper functioning of the medical device.
- If the medical device needs maintenance services for proper use, and if the manufacturer provides some or all of the product services through the warranty or contract, the manufacturer quality management system shall include the procedures necessary to provide maintenance services. for example:

- clarification of servicing responsibilities among your organization, distributors and users;
- planning of service activities, whether carried out by your organization or by a separate agent;
- validation of design and function of special-purpose tools or equipment for handling and servicing products after installation;
- control of measuring and test equipment used in field servicing and tests;
- instructions for use in availability
- spare parts and consumables availability
- provision for adequate back-up, to include technical advice and support, customer training, and spares or parts supply;
- training of servicing personnel;
- provision of competent servicing personnel;
- take action regarding client complaints and comments

- Sterilization and retention procedures are established and relevant international standards are applied for routine validation and control of the sterilization process.
- It is important to verify the validity of the sterilization process and not rely on the implementation of the procedure alone without verification because this does not ensure continuity sterilization of the medical device. The microbiological state of incoming raw materials should be monitored and stored, and the environment in which the medical device is manufactured, assembled and packaged, and controls established in documented procedures.
- The manufacturer should clearly place the identifying information on the product, raw materials and components of medical devices for the following reasons:
  - Control the movement of materials at all stages of manufacturing.
  - Know product source, safety requirements
  - Easy tracking
  - Speed detection errors

- Traceability from the source of the product or service to the delivery should be documented using the product identification through the order code, the serial number or any electronic means of tracking.
- Monitoring is the supervision, verification or monitoring over a period of time. Measurement is the determination of quantity, volume, size or dimension using measuring devices. It includes monitoring, calibration and measurement devices, including computer programs. Documented procedures Details of equipment type, location, frequency of tests, verification method, and standards.

Requires the factory to fulfill the following requirements:

• Planning includes identification and identification of internal and external data sources to ensure product performance or product quality, adequate resources and responsibilities and authorities. Resources may include technical experts, laboratories for medical devices, data management, analysis, infrastructure, training, acceptance criteria, escalation procedures and nonconformity reports.

• Measurement and analysis, including regulatory requirements, technical documents of the agency, review of previous reports, suppliers' performance information, complaint handling procedures, incident reports, internal and external audits of quality management systems, product recall, spare

parts, after-sales service, handling of recovered equipment and market survey. And the development of risk management procedures

• The work of improvement and development includes the adoption of acceptance criteria for procedures and devices and review the specifications specified during the design and development activities, including quality management system, delivery operations and after-sales services, installation and distribution activities.

• Provide top management with the necessary data to ensure their participation in the audit and to take approval of actions taken in response to nonconformity.

- Develop complaint procedures to ensure that complaints are processed in a timely manner in accordance with applicable regulatory requirements, including receipt and recording of information, investigation and indication of the need to inform the SFDA, how to deal with the complaint product and determine corrective action if necessary; that.

- Conduct internal quality audit activities, review all procedures to ensure compliance with customer requirements and regulatory requirements, and determine whether actions are effectively implemented to ensure the implementation of quality policy and fulfill quality objectives.

The appropriate monitoring and measurement of each of its operations in relation to their impact on conformity to the requirements of the product and the adequacy, adequacy and effectiveness of the quality management system.

To monitor and measure the equipment to ensure that it conforms to the approved specifications and includes the testing and testing activities of the device.

The establishment shall identify and control the non-conforming product to prevent pollution or use. A general procedure for defining controls, responsibilities and authorities is documented in order to identify, document and isolate a non-conforming product and to carry out evaluation procedures and, if necessary, dispose of it.

Non-conformity is defined as failure to fulfill the design, regulatory or documented requirements of the QMS.

- The establishment shall empower employees with the authority and responsibility to report nonconformities at any stage of the process.

-Non-conformity procedures should be established for the following purposes:

• To identify the product that is not identical and in any period of production, this situation occurred, what is the production line and the number of products that are not identical to isolate and distinguish the product not identical to the corresponding product

• Document the non-conformity and make the necessary reports to notify those who may be affected by the lack of conformity including the client if necessary.

• Evaluate the nature and nature of the nonconformity

• Provide alternatives and dispose of non-conforming product

- In the case of re-operation of non-conforming products, the establishment shall document the re-work procedure to ensure that the final product is free from any defects and to ensure that there is no possibility of any risks before and after use
- The establishment shall perform documented procedures for the purpose of analyzing the data according to the criteria established during the planning stage to identify potential nonconformities or non-conformances or to identify potential stages of non-conformance cases for further investigation to demonstrate the adequacy, efficiency and effectiveness of QMS procedures and ensure that the product fulfills customer requirements Regulatory requirements,

analytical programs, experts in the field, or independent reviewers can be utilized, and the results of the analysis shall be recorded.

- Data analysis helps the establishment to continuously improve the quality and final product procedures by conducting a comprehensive investigation, identifying the root cause of the nonconformity, determining the procedures needed to address it and following up on its implementation, and ensuring the effectiveness of the action taken.
- The establishment shall perform without delay appropriate corrective measures to address the cause of non-conformity and ensure that this is not repeated.
- Preventive action should be taken for potential nonconformities as a result of analysis of data from records and other relevant sources of information, such as risk management file, data analysis results, potential risks and constraints with suppliers.