MDS – G024

Guidance for ISO 13485 Requirements and Corresponding SFDA-MDS Requirements

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Introduction

Purpose

The purpose of this document is to guide medical devices manufacturers, authorized representatives, importers and distributors that comply with requirements of ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes1 (ISO 13485) in light of regulatory documents issued by the SFDA medical devices sector (SFDA-MDS).

Scope

This guidance applies to various establishments, including but not limited to, manufacturers, authorized representatives, importers and distributors of medical devices. It can be used as a basis for certification for Quality Management System (QMS).

Background

SFDA has issued this guidance document in accordance to the following:

Medical Devices Law issued by the Royal Decree No. (M/54) dated 06/07/1442 H, through Article 22 stipulated that "Establishments wishing to trade in medical devices in Kingdome of Saudi Arabia (KSA) shall adhere to the implementation of a Quality Management System (QMS).

Requirements for Inspection and QMS Auditing for Medical Devices Manufacturers and Establishments (MDS – REQ10) states that:

- Medical devices manufacturers, importers and distributors of categories (A) and (B) shall obtain a certificate of compliance with the requirements of medical devices quality management system (QMS) in accordance to the Saudi standards (SFDA.MD/GSO ISO 13485) or equivalent.
- Medical devices authorized representatives, importers and distributors of categories (C) and (D) shall submit a documented proofs or get inspection report issued by the SFDA about their adherence to compliance with the requirements of medical devices quality management system (QMS) in accordance to the Saudi standards (SFDA.MD/GSO ISO 13485:2017) or equivalent.

This guidance document is intended to help the reader understand key concepts in ISO 13485 to create a compliant medical device QMS and illustrate how these requirements are expected in the Kingdom of Saudi Arabia (KSA) "Medical Devices Law" and its implementing regulation. Additionally for manufacturers, importers, distributors, service providers or certification bodies that want more details on the development, implementation and maintenance of their quality management system in accordance with ISO 13485, a supporting document is available and was created by the technical experts of ISO/TC 210 "ISO 13485:2016 – Medical device - A practical guide"[2].

ISO Terms and Definitions, and Corresponding SFDA-MDS Regulatory Terms and Definitions

ISO 13485 section 3 contains specific definitions used in the medical devices sector beyond those of the standard International Standards Organization (ISO) definitions. Users should study and understand how these sector specific definitions apply to their organization or establishment, and any regulatory requirements in the markets where their medical devices are intended to be sold.

These definitions are often based on already harmonized definitions established by the "International Medical Device Regulators Forum" (IMDRF) (Previously known as the "Global Harmonization Task Force" (GHTF))[3], Global Harmonization Working Party (GHWP) (Previously known as the "Asian Harmonization Working Party" (AHWP)) or are unique to the medical devices sector and have now become standard in many jurisdictions. However, national regulations may not always be aligned with the definitions in ISO or other documents. Any definitions in regulations will always take legal precedence over the definitions of other documents.

Users of the standard will see that many of the definitions provide notes for guidance to help with understanding. These NOTES are intended to provide additional information and are not considered requirements of the standard.

ISO 9000 standardized definition	SFDA-MDS Use
3.2.1 organization person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.7.1) Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, *association* (3.2.8), charity or institution, or part or combination thereof, whether incorporated or not, public or private. Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 1 to entry.	Establishment is the party that practice activities which are subject to the provisions of the "Medical Devices Law" (Article 2) and its Implementing Regulation" (Article 2.1, "First"). It includes manufacturer, authorized representative, importer, distributor, warehouse, Contract Research Organization (CRO), technical consultation provider, testing laboratory, and maintenance services provider.

3.7.6 product *output* (3.7.5) of an *organization* (3.2.1) that can be produced without any transaction taking place between the organization and the *customer* (3.2.4) Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between *provider* (3.2.5) and customer, but can often involve this *service* (3.7.7) element upon its delivery to the customer. Note 2 to entry: The dominant element of a product is that it is generally tangible. Note 3 to entry: Hardware is tangible and its amount is a countable *characteristic* (3.10.1) (e.g. tyres). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of *information* (3.8.2) regardless of delivery medium (e.g. computer programme, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license).	Medical devices, Medical Supplies, Medical Device Accessories, Procedure Packs or Medical Imaging Materials as defined in the "Medical Devices Law" (Article 1) and it's Implementing Regulation (Article 1.1).
3.7.7 service *output* (3.7.5) of an *organization* (3.2.1) with at least one activity necessarily performed between the organization and the *customer* (3.2.4) Note 1 to entry: The dominant elements of a service are generally intangible. Note 2 to entry: Service often involves activities at the interface with the customer to establish customer *requirements* (3.6.4) as well as upon delivery of the service and can involve a continuing relationship such as banks, accountancies or public organizations, e.g. schools or hospitals. Note 3 to entry: Provision of a service can involve, for example, the following: — an activity performed on a customer-supplied tangible *product* (3.7.6) (e.g. a car to be repaired); — an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return); — the delivery of an intangible product (e.g. the delivery of *information* (3.8.2) in the context of knowledge transmission); — the creation of ambience for the customer (e.g. in hotels and restaurants); Note 4 to entry: A service is generally experienced by the customer.	Third-party services such as contract sterilization, contract packaging, testing services, maintenance services or consulting services

ISO 13485 standardized definition	SFDA-MDS definition
SFDA Medical Devices Law has defined the term "**Quality Management System**" as: ***A system adopted by the SFDA to verify the quality, effectiveness, and safety of the medical device at all stages in its life cycle in accordance with the latest version of the technical standard (ISO 13485), or its equivalent, as set out in the Regulation.***	
3.1 advisory notice notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information or to advise on action to be taken in the: — use of a medical device, — modification of a medical device, — return of the medical device to the organization that supplied it, or — destruction of a medical device Note 1 to entry: Issuance of an advisory notice can be required to comply with applicable regulatory requirements.	**Medical Devices Law - Article (1)** ***Safety Alert:*** A notification issued by SFDA NCMDR indicating the risk associated with a medical device and the corrective action to be taken to mitigate the associated risk.
3.2 authorized representative natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation	**Medical Devices Law - Article (1)** ***Authorized Representative:*** A legal person based in the KSA who is authorized, in writing, by a Manufacturer located outside the KSA to represent it within the KSA with regard to the implementation of the "Medical Devices Law and its Regulation".
3.3 clinical evaluation assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer	**Medical Devices Law - Article (1)** ***Clinical Trial/Investigation:*** Applied research in which a medical device is used on one or more persons to assess its safety and sufficiency when used.
3.4 complaint written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been released from the organization's control or related to a service that affects the performance of such medical devices	**Implementing Regulation of the Medical Devices Law - Article (1.1)** ***Complaint*:** Any form of written or oral communication regarding deficiencies related to the medical device. These include, but are not limited to: • quality; • efficacy; • efficiency; • usability; • safety or performance; and/or • deficiencies related to maintenance that affect the performance of the medical device.
3.5 distributor natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user	**Implementing Regulation of the Medical Devices Law - Article (1.1)** ***Distributor:*** An establishment in the supply chain which provides a medical device to another distributor or its end user.

3.6 implantable medical device medical device which can only be removed by medical or surgical intervention, and which is intended to: — be totally or partially introduced into the human body or a natural orifice, or — replace an epithelial surface or the surface of the eye, and — remain after the procedure for at least 30 days	**Implementing Regulation of the Medical Devices Law - Article (1.1)** ***Implantable Medical Device:*** A medical device surgically introduced into the human body or to replace a superficial / epithelial surface, or the surface of the eye and intended to remain in place after the surgical procedure. This includes devices intended to: - be partially or wholly absorbed. - remain in the body for thirty (30) days or more.
3.7 **importer** natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed	**Implementing Regulation of the Medical Devices Law - Article (1.1)** ***Importer:*** An establishment in the supply chain that imports a medical device to the KSA.
3.8 **labelling** label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents	**Medical Devices Law - Article (1)** ***Identifying Information:*** Any statement or information drawn or illustrated / written or printed on the medical device, including: • Name of the device; • Code / lot or serial number; • technical description; • method of use; and / or • manner of storage and transportation.
3.9 life-cycle all phases in the life of a medical device, from the initial conception to final decommissioning and disposal	**No Conflict**
3.11 **medical device** instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: — diagnosis, prevention, monitoring, treatment or alleviation of disease; — diagnosis, monitoring, treatment, alleviation of or compensation for an injury; — investigation, replacement, modification, or support of the anatomy or of a physiological process; — supporting or sustaining life; — control of conception; — disinfection of medical devices; — providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means	**Medical Devices Law - Article (1)** ***Medical Device:*** Any instrument, apparatus, applied devices, implant devices, in vitro diagnostic reagent or calibrator, software, or material used for operating medical devices, any other similar or related article, intended to be used alone or in combination with other devices for diagnosis, prevention, monitoring, controlling, treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or a physiological process; supporting or sustaining life; controlling or assisting conception; sterilization of medical devices; providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in return it may be assisted in its intended function by such means.

3.12 **medical device family** group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use and function	**Requirements for Medical Devices Marketing Authorization (MDS-REQ1)** Annex (15): Bundling Criteria 1. Medical Devices: 1.1. Medical Devices Family A maximum of 5 TFs of Medical devices may be bundled/grouped within one application only if they have: ▪ same legal manufacturer, ▪ same intended use/purpose, ▪ same risk class, ▪ same GMDN code (optional), and ▪ has a common physical design, construction material and manufacturing process. Note: TOTAL NUMBER of medical device that are grouped/bundled within a single application shall NOT EXCEED 50 items.
3.13 **performance evaluation** assessment and analysis of data to establish or verify the ability of an *in vitro* diagnostic medical device to achieve its intended use	**Medical Devices Law - Article (1)** ***Clinical Trial/Investigation:*** Applied research in which a medical device is used on one or more persons to assess its safety and sufficiency when used.
3.14 **post-market surveillance** systematic process to collect and analyse experience gained from medical devices that have been placed on the market	**Implementing Regulation of the Medical Devices Law - Article (1.1)** ***Surveillance:*** A set of procedures to control the safety, efficacy, quality, and effectiveness of medical devices during their circulation within the KSA.
3.15 **product** result of a process	**No Conflict**
3.16 **purchased product** product provided by a party outside the organization's quality management system	**No Conflict**
3.17 **risk** combination of the probability of occurrence of harm and the severity of that harm	**No Conflict**

ISO 13485 Requirements, and Corresponding SFDA-MDS Regulatory Requirements

4 Quality management system

4.1 General requirements

ISO 13485 clause 4.1 sets the foundation and requirements to create and maintain an effective QMS. For the organization to succeed the following foundational understandings are critical:

- The requirements of the QMS standard,
- Knowledge of the regulations where the medical devices are manufactured and sold
- Identified legal role the organization and suppliers must fulfill, and
- A plan to design, implement, and maintain the QMS.

This is emphasized in 4.1 - General Requirements where an organization needs to identify the role(s) undertaken by the regulations (e.g. manufacturer, authorized representative, importer, contract sterilizer, distributor, etc...), identify criteria for monitoring the QMS, apply a risk-based approach, and assure the appropriate resources are available to support a healthy and effective QMS.

4.2. Documentation requirements

ISO 13485 clause 4.2 provides expectations around documentation which is critical in meeting regulatory obligations in the medical device industry. Documents provide objective evidence to assure a product was made correctly and that an organization’s establishment’s processes were applied correctly to meet regulatory purposes. This subclause defines the need for QMS documentation and product/service records, as well as a process for control of documentation and records in the organization.

ISO 13485 Clause/Subclause	SFDA-MDS Requirement(s)	Evidence(s) of Compliance
4.1 Quality management system - General requirements and particular requirements related to documentation	**Medical Devices Law - Article (6) - All MD Establishments** An establishment may not engage in any of the activities subject to this Law unless registered and a license is obtained; as for manufacturers, an industrial license must be obtained from the competent agency. **Implementing Regulation of the Medical Devices Law - Article (10.16) - Manufacturers** Obtain the necessary licenses from the Competent Authorities. **Medical Devices Law - Article (27) - All MD Establishments** Both the establishment and Authorized Representative shall provide the SFDA with any document or information required by the SFDA to practice its competencies set forth in the Medical Devices Law and its regulation. **Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) - Manufacturers** Medical device manufacture shall establish, document and maintain an effective quality management system (QMS) according to the international ISO standard (ISO 13485:2016) or any identical adopted standard for the same issue/version. **Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) - Manufacturers and Authorized Representatives** Agreement between the manufacturer and the authorized representative shall be documented, approved and subject to the regulations in KSA. **Implementing Regulation of the Medical Devices Law - Article (15.1) - Authorized Representatives** The Authorized Representative shall document the implementation of the necessary operations to perform the tasks entrusted to them and preserve for inspection by the SFDA the records generated by those tasks. **Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) - Authorized Representatives** Documentation of the necessary processes for performing the tasks assigned to him with attachment of relevant documents.	1. License(s) 2. ISO 13485 Compliance Certificate 3. Quality Manual 4. Standard Operating Procedures (SOPs) 5. QMS Documented Procedures 6. Documented Agreement between the manufacturer and the authorized representative 7. Accreditations and Certificates 8. Reports, Records and Logs related to Tracking, Transport, Storage, After-Sale Services, Communication and others 9. Reports, Records and Logs generated from the inventory management system - if applicable -

	The agreement with the manufacturer shall specify the activities in which the authorized representative acts on behalf of the manufacturer in its dealings with the SFDA. The agreement with the manufacturer shall specify the type or group of medical devices subject to the Medical Devices Law and Executive Regulation to be marketed in KSA. **Implementing Regulation of the Medical Devices Law - Article (10.11) - Importers and Distributors** Provide and pledge to implement a documented and effective tracking procedures of documenting information related to: a) medical device (MD); b) communicating with MD manufacturers; c) supply, distribution and use of MD; d) quantities of supplied MD; e) transportation and storage of MD; and f) communicating with MD users. **Implementing Regulation of the Medical Devices Law - Article (10.11) - Importers and Distributors** Importers and distributors of medical devices shall submit a documented procedure for: o Tracking the medical device during the importing or distribution phase and submitting an undertaking to implement and adhere to the procedure. o Storage and transportation of the medical device in accordance with the instructions provided by the Manufacturer. Submit an undertaking to implement and adhere to the procedure. **Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) - All MD Establishments** Documented and effective procedures for storage and transportation shall be available and applied in accordance to Requirements for Transporting and Storage of Medical Devices (MDS – REQ 12). **Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) - Importers, Distributors & Optical Establishments, and Authorized Representatives** Existence of documented procedure for storing and transporting medical devices in accordance with manufacturers' requirements, and submitting a pledge to implement and comply with the procedure.	

	Requirements for Inspection and QMS Auditing for Medical Devices Manufacturers and Establishments (MDS – REQ10) - All MD Establishment Providing and implementing effective and appropriate tracking procedures for documenting information related to distribution and use of medical devices, which help in tracking the medical device in accordance to Requirements for Unique Device Identification (UDI) for Medical Devices (MDS-REQ7). **Requirements for Inspection and QMS Auditing for Medical Devices Manufacturers and Establishments (MDS – REQ10) - Manufacturers** Before the visit, the manufacturer shall send the following data and documents within the specified period: Quality Manual and Standard Operating Procedures according to the latest version of the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent. **Requirements for Inspection and QMS Auditing for Medical Devices Manufacturers and Establishments (MDS – REQ10) - Importers, Distributors and Authorized Representatives** Before QMS auditing visit, the establishment shall Send the following data and documents: Quality Manual and Standard Operating Procedures according to the latest version of the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent. **Requirements for Inspection and QMS Auditing for Medical Devices Manufacturers and Establishments (MDS – REQ10) - Authorized Representatives** An authorized representative shall provide and implement effective operating procedures to follow up on reports of medical devices and field safety corrective actions proposed by the manufacturer and approved by the SFDA.	

4.1.5 Quality management system - Purchasing	**Guidance on Manufacturing Paths of Medical Devices (MDS-G011) - Manufacturers** ○ Annex (1): Manufacturing paths and their associated Marketing Authorization and QMS requirements ▪ 2nd Path - Legal main manufacturer located inside the KSA delegates manufacturing to a branch manufacturer located outside the KSA ▪ 3rd Path - Legal manufacturer located inside the KSA contracts a manufacturer located outside the KSA for partial manufacturing or contracts a critical supplier	1. ISO 13485 Compliance Certificate(s) 2. Quality assurance agreement between the legal manufacturer and the contracted manufacturers/critical supplier 3. Reports, Records and Logs
4.2.2 Documentation requirements - Quality manual	**SFDA Checklist for Quality Manual Form - All MD Establishments**	Quality Manual
4.2.3 Documentation requirements - Medical device file	**Implementing Regulation of the Medical Devices Law - Article (15.1) - Manufacturers or Authorized Representatives** The following technical requirements shall be submitted to obtain a Marketing Authorization Certificate for medical devices: 2. Technical Documents for the medical device including: a) Description of the medical device and its characteristics, including variations and accessories; b) Design and manufacturing information; c) Risk management file; d) Verification and validation of the product including clinical trials; e) Post Market Surveillance Plan; and f) Periodic Safety Update Reports and Post-Market Surveillance reports. 3. Information on measures related to environmental conditions and/or usage in the Kingdom.	1. Technical Files submitted through GHAD portal as a Medical Devices Marketing Authorization (MDMA) Application 2. Reports, Records and Logs
4.2.4 Documentation requirements - Control of documents 3rd paragraph **4.2.5 Documentation requirements - Control of records** 1st paragraph and 5th paragraph	**Requirements for Licensing of Medical Devices Establishments (MDS-REQ9) - All MD Establishments** The establishment shall Provide a database to archive all relevant data and documents in order to be easily accessed and retrieved for a period of no less than (5) years. **Requirements for Transporting and Storage of Medical Devices (MDS-REQ12) - All MD Establishments** All documents related to storage and transportation shall be kept for a period of at least (3 years).	Records and Reports related to Tracking, Transport, Storage, Communication and others.

5 Management responsibility

ISO 13485 clause 5 highlights the role leadership, referred to as Top Management, in the organization has to maintain and support an effective QMS. It emphasizes the accountability of this leadership in maintaining the QMS and understanding the regulations. The expectation is that although leadership can delegate activity and tasks, they are ultimately accountable for compliance with the QMS and applicable regulations.

ISO 13485 clause 5.6 – Management Review is a key process that Top Management owns to assure the QMS is effective, and that the regulations are being met in markets where the organization operates. This process identifies specific areas that are required to be monitored and reported to leadership and should be conducted on a pre-determined cycle. The input, discussion, and outcomes of this process are to be recorded for regulatory purposes and may be audited.

6 Resource management

ISO 13485 clause 6 requires that the organization's QMS addresses specific areas that could affect the quality and safety of a medical device.

Clause structure and titles

6.1 Provision of resource

6.2 Human resources

6.3 Infrastructure

6.4 Work environment

ISO 13485 clauses 6.1 and 6.2 address the need for identification and planning of adequate resources to meet the QMS requirements. Resources are anything from human resources to suppliers/partners and facilities. They need to be identified from a QMS effectiveness and regulatory requirements view. Clause 6.2 then specifically discusses requirements for human resource planning including requirements for training, competency, and skills of human resource needs in the organization.

ISO 13485 Clause/Subclause	SFDA-MDS Requirement(s)	Evidence(s) of Compliance
5 Management responsibility	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishments** Manufacturers, authorized representatives, importers and Distributors shall appoint an authorized person to communicate with the SFDA. **Requirements for Inspection and QMS Auditing for Medical Devices Manufacturers and Establishments (MDS – REQ10) - Manufacturers**	1. Documented job description for: ○ Quality Manager ○ Technical Manager 2. Reports, Records and Logs related to SFDA Regulatory and Safety Communications

	A two full-time biomedical engineer, biomedical technician or a qualified person in other specialties related to medical devices shall be appointed as a quality manager and a technical manager for the manufacturing facilities. One of them shall be appointed as authorized person for handling SFDA regulatory related affairs. Each of them shall held the following responsibilities and duties: ○ **Quality Manager:** ▪ Supervise and manage all aspects related to quality in the manufacturing facilities, including processes and procedures necessary for design assurance, manufacturing quality control and inspection compliance. ▪ Develop, implement and monitor quality management system (QMS) in the manufacturing facilities, including documentation and continuous improvement of processes, procedures and indicators. ▪ Ensure compliance with applicable regulatory requirements, including: • Medical Devices Law; • Implementing Regulation of the Medical Devices Law; • Requirements for Medical Devices Marketing Authorization (MDS-REQ1); • Requirements on Importation and Shipments Clearance of Medical Devices (MDS-REQ5); • Requirements for Unique Device Identification (UDI) (MDS-REQ7); • Requirements for Approval of Medical Devices Advertising and Campaigns for Charity or Awareness Involving Use or Display Medical Devices (MDS-REQ8); • Requirements for Licensing of Medical Devices Establishments (MDS-REQ9); • Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11);	

	• Requirements for Transporting and Storage of Medical Devices (MDS-REQ12); and • Medical devices QMS Requirements for regulatory purposes in accordance to the Saudi Standard (SFDA.MD/GSO ISO 13485:2017) or similar. ▪ Manage all aspects related to QMS, including quality manual and procedures/processes associated with QMS that include: control of data, planning of quality, training, acceptance and monitoring of suppliers, maintenance and calibration of manufacturing equipment, handling and directing of complaint, handling of recalls and safety alerts and field safety corrective actions (FSCA), preventive and corrective actions, control of nonconforming materials, and initial and final check of materials and equipment in the manufacturing facilities. ▪ Ensure communication with/responding to the SFDA National Center for Medical Devices Reporting (NCMDR) for all matters related to incidents, FSCA, recalls and complaint. ▪ Ensure creation, development and continuous update of technical documents of medical devices by the technical manager. ▪ Verify compliance with technical regulations and standards for medical devices being manufactured. ▪ Supervise all risk management processes, including risk identification, risk analysis, risk evaluation, risk assessment and risk control. ▪ Supervise sterility assurance testing and biocompatibility testing for medical devices and accessories - if applicable -. ▪ Manage cleanrooms used for processing of medical devices and accessories - if applicable -. ▪ Conduct internal audits, manage processes related to external audits and ensure their compliance with audit criteria. ▪ Represent the QMS in the manufacturing facilities (Top Management Representative), and represent the	

	manufacturer in dealing with external parties. ▪ Report QMS progress to the top management. ○ **Technical Manager:** ▪ Supervise innovation and development of medical devices, including feasibility studies, prototypes design and manufacturing processes, and tests associated with these processes. ▪ Manage design and development processes, including "Design Inputs", "Design Verification" and "Design Validation". ▪ Develop and update technical specifications related to safety and performance of medical devices, including Standard Operating Procedures (SOPs) and test methods. ▪ Ensure compliance with technical regulations and standards for medical devices being manufactured. ▪ Plan, implement, develop and improve production, including collection and evaluation of data throughout manufacturing stages, validation of manufacturing processes, qualification and maintenance and calibration of manufacturing equipment, and provide necessary support to personnel working in production and quality control. ▪ Supervise product testing, including "Product Verification" and "Product Validation". ▪ Supervise preparation and submission of medical device technical file for obtaining SFDA Medical Devices Marketing Authorization (MDMA). ▪ Ensure updating of technical documents of medical devices, and submission of the updated documents to the SFDA in case of any changes to the manufacturer or the product. ▪ Ensure keeping up with new technologies in manufacturing, conduct necessary development to level up safety, efficacy, quality and effectiveness of medical devices being manufactured.	
6 Resource management	**Establishing, implementing, maintaining and recording as per requirements set in 6.1 through 6.4.**	

7 Product realization

ISO 13485 clause 7 is the largest clause of the standard and is where the requirements of the product are identified and controlled. This clause has numerous subclauses listed below that cover product and organizational needs from conception to market delivery.

Clause structure and titles

7.1 Planning for product realization

7.2 Customer related processes

7.3 Design and development

7.4 Purchasing

7.5 Product and service provision

7.6 Control of monitoring and measuring equipment

7.1 Planning for product realization

ISO 13485 clause 7.1 starts by following the Plan-Do-Check-Act (PDCA) process approach. Planning includes identification of the product requirements, quality objectives, and documentation to support the design and development ensuring the product meets the need of the user/patient. This clause is important to ensure the organization understands and succeeds in product realization and compliance.

7.2 Customer-related processes

ISO 13485 clause 7.2 instructs the organization to determine and gather customer requirements to assure the product realization outcome meets the intended needs of the user. ISO 13485 also includes requirements to determine any regulatory requirements and training needs for product use. Clause 7.2.3 provides specific requirements for communication methods to suppliers, customers, and regulatory agencies. Organizations need to identify and create processes to communicate with regulatory authorities according to applicable regulations.

7.3 Design and development

ISO 13485 clause 7.3 is often referred to as design control and sets out the requirements to establish a design control process that often follows the following diagram.

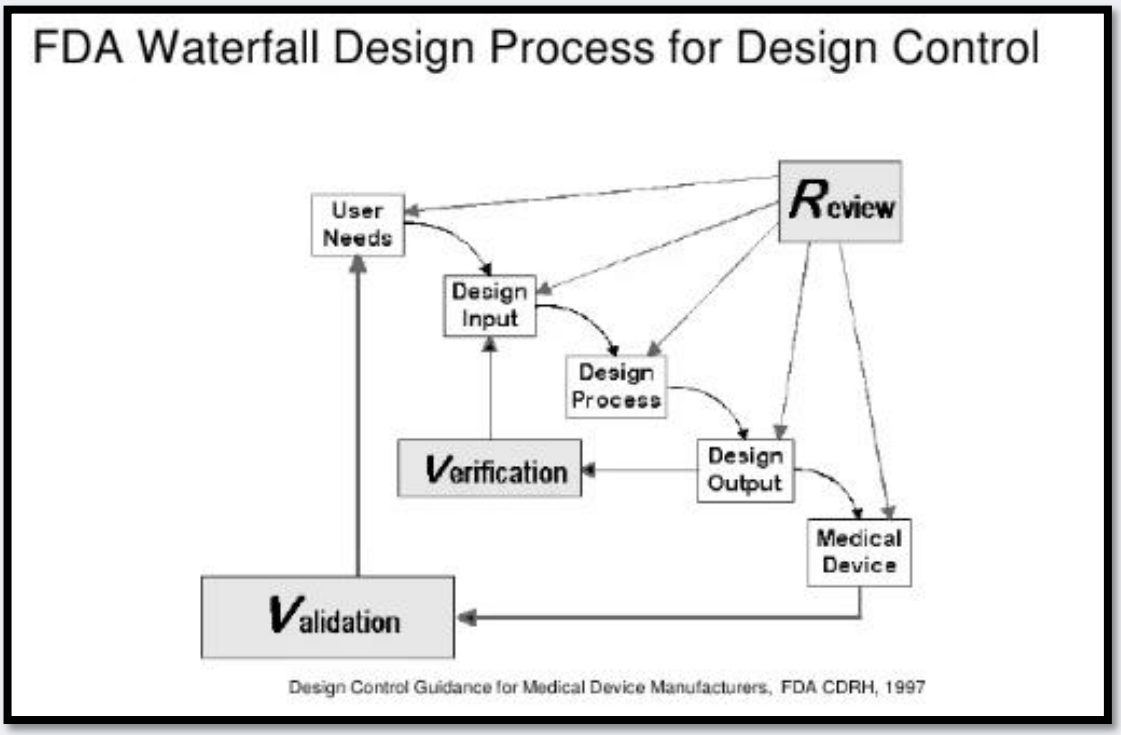

Figure 1: Design Control Process

[Source: FDA CDRH *Design Control Guidance For Medical Medical Device Manufacturers*, FDA-2020-D-0957, 1997]

Design control process starts with design and development inputs (7.3.3) and verifies that the design and development outputs (7.3.4) meet those inputs through verification and validation checks (7.3.6 and 7.3.7).

Design inputs (7.3.3) are specifications or requests provided by the user, or applicable regulatory requirements and standards that the product must meet to address clinical safety and performance needs. Each design and development input should have a mechanism to either verify or validate that it has been considered in the design control process and documented in a design and development outputs.

As part of the design and development process, a critical step is the design and development review (7.3.5) process. This process is a review by the organization that the processes of design and development inputs (7.3.3) and design and development outputs (7.3.4) have been followed, and design and development inputs have been addressed by appropriate design and development outputs. The outcome of this review can lead to acceptance of the design or actions to change design. If action to change the design are warranted, the design and development process starts again. If the design is accepted the process requirements for a design and development transfer (7.3.8) are initiated.

ISO 13485 clause 7.3.9 control of design and development changes addresses requirements for product changes. Product changes should be reviewed and approved to assure they are not impacting safety and effectiveness or regulatory requirements. This includes the changes be verified (or validated -see 7.5.6) against the final design and development input requirements.

If changes impact the design and development inputs or outputs, regulatory actions may be required. Additionally, changes should be evaluated against the product's risk management file

to evaluate if any new risks could be raised, or if existing risk levels could be affected. Changes and design history are to be documented in the organization's design and development files (7.3.10).

7.4 Purchasing

ISO 13485 clause 7.4 sets the requirements for an organization to have a purchasing process that covers products and services. The process should include a method to define requirements, evaluate, and select suppliers of products and services. This includes 3rd party contracted manufacturers (e.g. sterilizer, packagers, and assemblers) including critical suppliers of products (e.g. components, labeling, materials) and services (e.g. assembler, contract sterilizers). This includes the monitoring and re-evaluation of suppliers proportionate to the risk their product or service could have on the medical device's safety and effectiveness.

As part of the purchasing process, purchasing information (7.4.2) is to be documented including written agreements on how to manage changes in products or services, and mechanisms to verify that the purchased products or services has been provided appropriately (7.4.3). In the case of a third party provided services or products, the ultimate responsibility to meet the requirements belong to the organization that is considered the "medical device legal manufacturer" per applicable regulations and cannot be delegated to the third-party provider.

7.5 Product and service provision

ISO 13485 clause 7.5 outlines the requirements for the medical device supply chain processes and requires that they be planned, executed, and monitored to assure the medical device is correctly produced and placed in the market. 7.5.1 Provides the basic production controls that need to be addressed and encompasses controls through post-delivery activities that may be required for a device. These should include the following areas, but this list is not limited:

- Infrastructure compatibility and use;
- Use and parameters needed for monitoring and measuring equipment;
- Labeling and packaging operations;
- Product release, delivery and field activities; and
- Customer supplied property (7.5.10).

Documentation and record keeping are expected to be maintained to provide traceability of the production or service.

ISO 13485 subclause 7.5.2 – cleanliness of product has specific requirements around assuring the product is manufactured in a hygienic manner according to its requirements, and where environmental controls concerns are addressed. This clause should be applied in alignment with the requirements of 7.5.5 and 7.5.7 if the medical device is sterile, and all products need to address the requirements to preserve the conformity of the product as per 7.5.11 including packaging. Installation activities in clause 7.5.3 describe the requirements for any medical device installation regardless of who conducts the installation (e.g. manufacturer, supplier or external party), and 7.5.4 addresses the servicing of medical devices that require post-delivery support.

Where outputs in the production or service provision cannot be verified, validation is expected and should be conducted to a level appropriate of the risk a non-conformance could have to the safety and effectiveness of the medical device. Sub clause 7.5.6 Validation provides the

framework and requirements of validation including the need to validate software used in production or service provision. Users should see 13485:2016 standard – ISO 13485:2016 – Medical device – A practical guide1 for additional guidance, or GHTF/SG3/N17:2008 *Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers*[4].

ISO 13485 subclause 7.5.8 – Identification sets out the requirements to be able to clearly identify the product and its status throughout production and delivery. This clause is where the requirements for use dates, lot numbers and specific labeling based on regulatory requirements are considered including unique device identifiers (if applicable). 7.5.9 – Traceability requires the organization/establishment to document procedures to trace the product through the supply chain based on applicable regulatory requirements.

7.6 Control of monitoring and measuring equipment

ISO 13485 clause 7.6 is often referred to as the calibration clause and starts with requirements to identify what monitoring and measuring equipment is necessary to assure product and process(es) conform as expected. Then it requires the organization to maintain and monitor that equipment for proper use. Monitoring and measuring equipment often include software and this subclause addresses the validation requirements of such software in the QMS.

ISO 13485 Clause/Subclause	SFDA-MDS Requirement(s)	Evidence(s) of Compliance
7 Product realization **7.1 Planning of product realization** **7.2 Customer-related processes** **7.2.1 Determination of requirements related to product** **7.2.2 Review of requirements related to product**	○ SFDA Recognized Standards (Supporting Medical Device Premarket Submissions) (MDS-G020) - Manufacturers or Authorized Representatives ○ Guidance for Requirements of Surgical and Medical Examination Gloves - Recognized Standards (MDS – G004) - Manufacturers or Authorized Representatives ○ Guidance for Requirements of sterile single-use hypodermic syringes - Recognized Standards (MDS – G005) - Manufacturers or Authorized Representatives ○ Guidance for Requirements of blood glucose metering devices and strips for home use - Recognized Standards (MDS – G006) - Manufacturers or Authorized Representatives ○ Guidance for Surgical Sutures (MDS-G021) - Manufacturers or Authorized Representatives	1. Certificate(s) of Compliance with SFDA Applicable Recognized Standards 2. Certificate(s) of Compliance with International and Saudi and Other Applicable Standards 3. Reports and Records of Compliance with Manufacturer's Own Specifications and SOPs. 4. Test Reports
7.2.3 Communication	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishments** ○ 1) Reporting and investigation of adverse events and complaints of medical devices ○ 3) Safety alerts and field safety corrective action (FSCA) for medical devices	1. Forms and Records related to reporting and investigation of adverse events and complaints 2. Forms and Records related to Safety alerts and field safety

		corrective action (FSCA) 3. Reports, Records and Logs related to SFDA Regulatory and Safety Communications
7.3 Design and development	**Requirements for Medical Devices Marketing Authorization (MDS-REQ1) - Manufacturers or Authorized Representatives** o Annex (1) Essential Principles of Safety and Performance for Medical Devices other than In-Vitro Medical Device ▪ Requirements Regarding Design and Manufacture o Annex (2) Essential Principles of Safety and Performance for In-Vitro Medical Device ▪ Requirements Regarding Performance, Design and Manufacture **Guidance on MDMA – Significant and Non-Significant Changes (MDS-G012) - Manufacturers or Authorized Representatives** Reporting or notifying the SFDA of significant and non-significant changes to marketing authorized medical devices (medical devices (including IVDs) that has obtained SFDA Medical Devices Marketing Authorization (MDMA).	1. Technical File(s) related to performance, design and manufacture submitted through GHAD portal as a part of MDMA Application 2. Documented Procedures for reporting or notifying the SFDA of significant and non-significant changes to marketing authorized medical devices 3. Reports, Records and Logs
7.4 Purchasing	**Guidance on Manufacturing Paths of Medical Devices (MDS-G011) - Manufacturers** o Annex (1): Manufacturing Paths and Marketing Authorization ▪ 2nd Path - Manufacturer within the KSA performs contract/partial manufacturing and releases the product for use under its own name ▪ 3rd Path - Manufacturer within the KSA performs contract/partial manufacturing and releases the product for use under the name of another manufacturer	1. Quality assurance agreement between the legal manufacturer and the contracted manufacturers 2. Reports, Records and Logs

7.5 Production and service provision **7.5.1 Control of production and service provision**	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishments** Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related to medical devices imported and distributed within KSA, and provide the SFDA NCMDR with the information upon request according to the following: o Contact information of medical devices manufacturers; o Information of supply, distribution and points of sale; o Quantity supplied and information of their transfer and storage; o Lists of users' names and contact information; and o Information of the circulated medical device, including its name, brand name, identification number, serial numbers, batches supplied, and other information necessary to identify and track it.	1. Reports, Records and Logs related to Tracking, Transport, Storage, After-Sale Services, Communication and others 2. Reports, Records and Logs generated from the inventory management system - if applicable -
7.5.2 Cleanliness of product	**Requirements for Medical Devices Marketing Authorization (MDS-REQ1) -Manufacturers or Authorized Representatives** o Annex (1) Essential Principles of Safety and Performance for Medical Devices other than In-Vitro Medical Device ▪ Requirements Regarding Design and Manufacture 11. Infection and microbial contamination o Annex (2) Essential Principles of Safety and Performance for In-Vitro Medical Device ▪ Requirements Regarding Performance, Design and Manufacture 11. Infection and microbial contamination	1. Technical File(s) related to infection and microbial contamination submitted through GHAD portal as a part of MDMA Application 2. Certificate of Compliance with one of the following recognized standards: o ISO 17664-1:2021 o ISO 17664-2:2021 3. Reports, Records and Logs
7.5.3 Installation activities **7.5.4 Servicing activities**	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) Manufacturers or Authorized Representatives** o 7) After-sale and maintenance services for medical devices	Reports, Records and Logs related to After-Sale Services, specifically generated from the maintenance management system and the inventory management system - if applicable -

7.5.5 Particular requirements for sterile medical devices **7.5.6 Validation of processes for production and service provision** **7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems**	**Requirements for Medical Devices Marketing Authorization (MDS-REQ1) - Manufacturers or Authorized Representatives** o Annex (1) Essential Principles of Safety and Performance for Medical Devices other than In-Vitro Medical Devices ▪ Requirements Regarding Design and Manufacture 11. Infection and microbial contamination o Annex (2) Essential Principles of Safety and Performance for In-Vitro Medical Device ▪ Requirements Regarding Performance, Design and Manufacture 11. Infection and microbial contamination	1. Technical File(s) related to performance, design and manufacture submitted through GHAD portal as a part of MDMA Application 2. Technical File(s) related to infection and microbial contamination submitted through GHAD portal as a part of MDMA Application 3. Reports, Records and Logs
7.5.8 Identification	**Requirements for Medical Devices Marketing Authorization (MDS-REQ1) -Manufacturers or Authorized Representatives** o Annex (1) Essential Principles of Safety and Performance for Medical Devices other than In-Vitro Medical Devices ▪ Requirements Regarding Information Supplied with the Device 23.1. General requirements regarding the information supplied by the manufacturer. o Annex (2) Essential Principles of Safety and Performance for In-Vitro Medical Devices ▪ Requirements Regarding Information Supplied with the Device 20.1. General requirements regarding the information supplied by the manufacturer. **Requirements for Unique Device Identification (UDI) (MDS-REQ7) - All MD Establishments** **Requirements for Transporting and Storage of Medical Devices (MDS-REQ12) - MD Warehouses** o Traceability in the Storage Area Annex (4): Written Procedure on storage and transportation of medical devices	1. Technical File(s) related to information supplied with the device submitted through GHAD portal as a part of MDMA Application 2. Written Procedure on storage and transportation of medical devices 3. Reports, Records and Logs
7.5.9 Traceability	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishments** Manufacturers, authorized representatives, importers and distributors shall establish a tracking system to record all information related	1. Reports, Records and Logs generated from the inventory management system - if applicable

	to medical devices imported and distributed within KSA, and provide the SFDA NCMDR with the information upon request according to the following: o Contact information of medical devices manufacturers; o Information of supply, distribution and points of sale; o Quantity supplied and information of their transfer and storage; o Lists of users' names and contact information; and o Information of the circulated medical device, including its name, brand name, identification number, serial numbers, batches supplied, and other information necessary to identify and track it.	2. Reports, Records and Logs
7.5.10 Customer property	**Establishing, implementing, maintaining and recording as per requirements set in 7.5.10**	
7.5.11 Preservation of product	**Requirements for Transporting and Storage of Medical Devices (MDS-REQ12) - MD Warehouses** o Adherence with Instructions Provided by the Manufacturer o Documented Procedures	1. Documented Procedures 2. Reports, Records and Logs
7.6 Control of monitoring and measuring equipment	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - Manufacturers or Authorized Representatives** 7) After-sale and maintenance services for medical devices	1. Reports, Records and Logs generated from the maintenance management system 2. Reports, Records and Logs

8 Measurement, analysis, and improvement

ISO 13485 clause 8.1 provides the requirements for what and how an organization will monitor the product and the QMS effectiveness. The below diagram provides a picture of this concept and is included in GHTF/SG3/N18:2010, *Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes*[5].

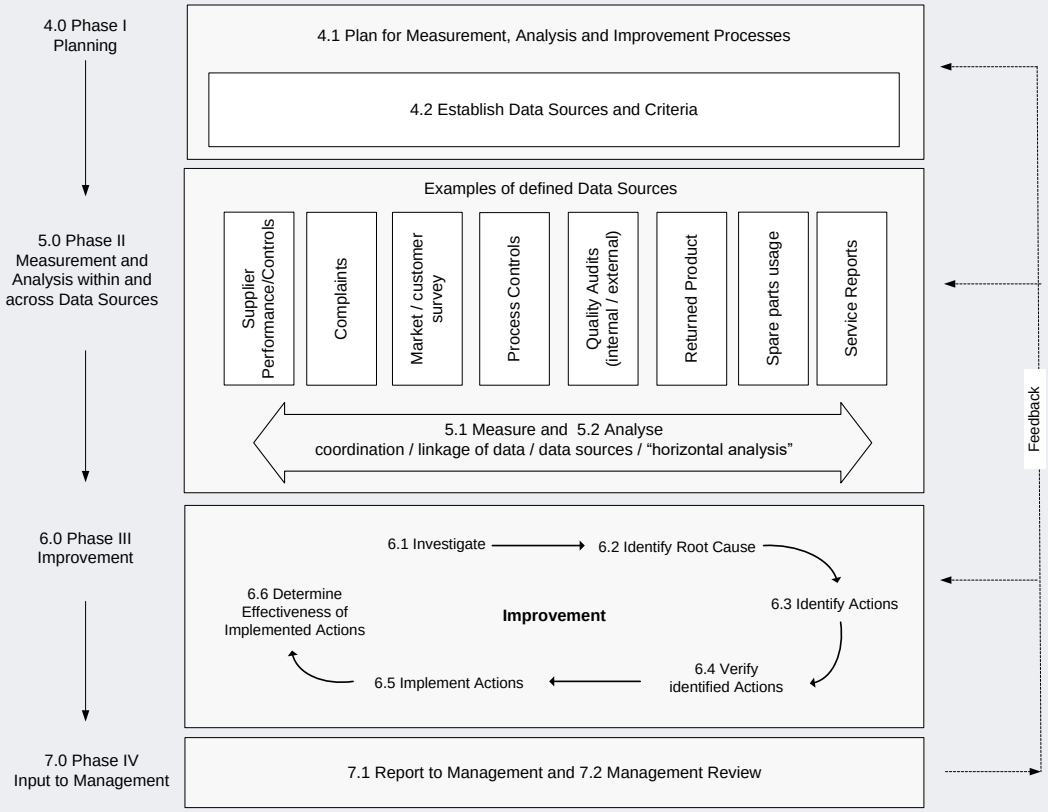

Figure 2: Processes for measurement, analysis and improvement

[Source: GHTF *Quality management system-Medical Devices-Guidance on corrective action and preventive action and related QMS processes,* GHTF/SG3/N18:2010]

This requires a planning phase to identify data sources that are important and should be monitored to gather feedback, including investigation thresholds or alerts for each data source.

8.2 Monitoring and measurement

ISO 13485 clause 8.2 requires that the organization monitors identified data sources of 8.1 and other sources of feedback to make sure things are behaving as expected. 8.2.1 - Feedback brings in the concept of complaints and other postproduction activities as data sources, and 8.2.2 – Complaint handling provides the requirements for a complaint specific handling procedure that needs to be compliant with any regulatory requirements including the need to report to regulatory authorities (8.2.3) where applicable. If data sources indicate room for improvement or non-conformance, they may be used as an input to initiate 8.5 the improvement process.
The next three subclauses provide specific areas that planned data sources should cover as areas of feedback:

8.2.4 Internal audits,
8.2.5 Monitoring and measuring of processes, and
8.2.6 Monitoring and measuring of product.

8.3 Control of nonconforming product

ISO 13485 clause 8.3 sets out the requirements for a process to handle nonconforming product when it does not meet the requirements as expected. Actions vary and can be different based on whether the nonconforming product is in the organization's control (8.3.2) or if it has been delivered (8.3.3). If the organization decides to rework the product 8.3.4 – Rework requires that the processes are documented and meet regulatory requirements.

8.4 Analysis of data

ISO 13485 clause 8.4 broadens the concept of clause 8's product data sources to data that supports the suitability of the QMS to meet its objectives. This clause requires the organization to identify and determine methods to monitor the QMS's effectiveness. If analysis of the data determines room for improvement or non-conformance, the data should be used as an input to initiate improvement (8.5).

8.5 Improvement

ISO clause 8.5 requires the organization to establish a process for improvement. This clause provides the requirements for a Corrective and Preventive Action (CAPA) process with 8.5.2 – Corrective Action (CA) addressing nonconformities and 8.5.3 – Preventive Action (PA) addressing potential nonconformities. Both processes require documentation and root cause analysis to assure actions taken address the non-conformance or potential non-conformance. As part of the CA or PA process a review of effectiveness is also required to assure the action addressed the root cause and did not create any new risks. CA and PA are two separate actions, and a CA does not require or contain a PA as a non-conformance has already occurred unless the action is replicated in a different QMS or non-related product.

Where the non-conformance can be addressed with a Correction and does not warrant escalation to the improvement phase, a root cause analysis and effectiveness checks are not required. However, Corrections should be monitored for any unexpected impact to the QMS or product requirements, as this may require an escalation to improvement.

ISO 13485 Clause/Subclause	SFDA-MDS Requirement(s)	Evidence(s) of Compliance
8 Measurement, analysis and improvement **8.1 General**	**Establishing, implementing, maintaining and recording as per requirements set in 8.1**	
8.2 Monitoring and measurement **8.2.1 Feedback** **8.2.2 Complaint handling** **8.2.3 Reporting to regulatory authorities**	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishments** ○ 1) Reporting and investigation of adverse events and complaints of medical devices	1. Records related to reporting and investigation of adverse events and complaints 2. Forms and Records related to Safety alerts and field safety corrective action (FSCA)

	○ 3) Safety alerts and field safety corrective action (FSCA) for medical devices	3. Reports, Records and Logs related to SFDA Regulatory and Safety Communications
8.2.4 Internal audit	**Establishing, implementing, maintaining and recording as per requirements set in 8.2.4**	
8.2.5 Monitoring and measurement of processes	**Establishing, implementing, maintaining and recording as per requirements set in 8.2.5**	
8.2.6 Monitoring and measurement of product	**Establishing, implementing, maintaining and recording as per requirements set in 8.2.6**	
8.3 Control of nonconforming product **8.3.1 General** **8.3.2 Actions in response to nonconforming product detected before delivery**	**Requirements for Medical Devices Marketing Authorization (MDS-REQ1) - Manufacturers or Authorized Representatives** ○ Annex (3) Medical Device Technical Documentation 3) Design and Manufacturing Information iv) Final inspection and acceptance criteria 6) Product Verification and Validation ○ Annex (4) IVD Technical Documentation 3) Design and Manufacturing Information iv) Final inspection and acceptance criteria 6) Product Verification and Validation	
8.3.3 Actions in response to nonconforming product detected after delivery	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishment** ○ 1) Reporting and investigation of adverse events and complaints of medical devices ○ 2) Reporting violating medical devices ○ 3) Safety alerts and field safety corrective action (FSCA) for medical devices	○ Records related to reporting and investigation of adverse events and complaints ○ Forms and Records related to Safety alerts and field safety corrective action (FSCA)
8.3.4 Rework	**Implementing Regulation of the Medical Devices Law - Articles (20.3) and (20.4)**	
8.4 Analysis of data	**Establishing, implementing, maintaining and recording as per requirements set in 8.4**	
8.5 Improvement	**Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11) - All MD Establishments** ○ 1) Reporting and investigation of adverse events and complaints of medical devices ○ 3) Safety alerts and field safety corrective action (FSCA) for medical devices	○ Records related to reporting and investigation of adverse events and complaints ○ Forms and Records related to Safety alerts and field safety corrective action (FSCA)

Bibliography

1. 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*[1] (available from the International Standards Organization or selected National Standards Body organizations) – available at https://www.iso.org/standard/59752.html

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3. GHTF/SC/N4:2012 (Edition 2) - Date posted: 9 November 2012 *Glossary and Definition of Terms Used in GHTF Documents* – available at - GHTF Steering Committee | International Medical Device Regulators Forum

4. GHTF/SG3/N17:2008 *Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers* – available at GHTF Study Group 3 - Quality Systems | International Medical Device Regulators Forum (imdrf.org)

5. GHTF/SG3/N18:2010 *Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes* - available at GHTF Study Group 3 - Quality Systems | International Medical Device Regulators Forum (imdrf.org)