MDS – REQ 10

Requirements for Inspections and Audit of Quality Management System (QMS) on Medical Devices Manufacturers and Establishments

Version Number: 2
Version Date: 27/01/2025

MDS-REQ-010-V2/250127
"Translated Copy"

Table of Contents

Introduction

Purpose

The purpose of this document is to specify and clarify the requirements related to the inspection and audit of Quality Management System (QMS) conducted by the SFDA on medical device manufacturers and establishments, as well as to specify and clarify the inspector's powers, rights and duties.

Scope

- The Requirements outlined in the "General Requirements" section apply to all establishments and activities subject to the "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 06/07/1442 AH and its implementing regulation issued by the SFDA Board of Directors decision No. (3-29-1443) dated 19/2/1443 AH in accordance to Article 2 of the Law and Article (2/1), part "First" of the Regulation.

- QMS inspection and audit requirements specified in the sections "Inspection and Audit of Quality Management System (QMS) for Manufacturers" and "Inspection and Audit of Quality Management System (QMS) for Establishments" apply to the following establishments:
    - Manufacturers;
    - Authorized representatives;
    - Importers; and
    - Distributors.

These requirements apply to the following types of inspection visits -if applicable-:

- **Initial Visit:** This visit aims to gather preliminary information about the manufacturer, production processes and medical devices being manufactured.
- **Licensing Visit:** This visit is conducted to perform an initial assessment of the manufacturer/establishment applying for a license.
- **Routine/Periodic Visit:** This visit aims to:
    - Evaluate the manufacturer's/establishment's compliance with SFDA's requirements.
    - Audit the manufacturer's/establishment's conformity to requirements of QMS for medical devices, in accordance to the Saudi standard (SFDA.MD/GSO ISO 13485:2017) or its equivalent.

- **Follow-up Visit:** This visit aims to verify that the manufacturer/establishment has implemented corrections, corrective and preventive actions to address non-conformities detected during previous inspection visits.
- **Reactive Visit:** This visit is conducted to investigate with the establishment about incidents or complaints related to medical devices.
- **Medical Devices Verification Visit:** This visit aims to verify that medical devices being manufactured, circulated or handled by the establishment comply with the requirements of the Law and Regulation.
- **Surprise Visit**: Inspection visit conducted by the SFDA without prior notice to the manufacturer/establishment, intended to verify compliance with any of the SFDA's requirements.

Background

SFDA has issued this document in reference to:

- "Medical Devices Law" issued by the Royal Decree No. (M/54) dated 6/7/1442 AH through:
    - Article (22) that states "Establishments seeking to circulate medical devices and supplies in the Kingdom shall adhere to the Quality Management System."
    - Article (27) that states "An establishment or an authorized representative shall provide the SFDA with the documents or information required thereby in accordance to this Law and its Regulations."
    - Article (33) that states "The SFDA shall be in charge of inspecting establishments and medical devices and supplies to ensure application of the Law, the Regulations, and the technical regulations. Inspection shall be carried out by inspectors who are appointed pursuant to a decision by the chairman of the Board."
    - Article (35) that states "The inspector shall present their job card when performing inspection and seizure works. The establishment shall enable the inspector to perform their work and not hinder them."
    - Article (39) that states "The SFDA may take the necessary precautionary measures if it suspects any harm, misleading claim, or compromise to the safety and efficacy of medical devices and supplies, as determined by the Regulations."

- "Implementing Regulation of Medical Devices Law" issued by the Saudi Food and Drug Authority Board of Directors decision No. (3-29-1443) dated 19/2/1443 AH through:
    - Article (33/1) that states “The SFDA shall inspect the Manufacturer's Quality Management System at the pre-marketing stage. The inspection report, issued by SFDA or by a recognized conformity assessment body of medical devices and Quality Management System, shall be deemed one of the documents required to obtain a Marketing Authorization Certificate.”
    - Article (33/2) that states “The SFDA may conduct inspection visits to Manufacturers at the post-marketing stage. The SFDA has the right to appoint conformity verification and auditing establishments to take this role on its behalf.”
    - Article (33/3) that states “The SFDA shall issue inspection requirements and the Quality Management System for medical devices, which contains the inspector's powers, duties and rights.”
    - Article (33/4) that states “Establishments shall be inspected in accordance to the Requirements for Inspections and Quality Management System for Medical Devices.”
    - Article (39/1) part (1) and (4) that states “The SFDA may take preventive and precautionary measures in case of harm, misleading claims or an impact on the safety and efficacy of medical devices, as follows: 1. Seizing the medical device until its safety and efficacy is verified. 4. Taking a sample to be examined in a laboratory and conducting the necessary tests, at the expense of the establishment.”
    - Article (39/2) part (2) that states “If the SFDA finds that the medical device is in violation of the Medical Devices Law, its Regulation, or technical regulations, it may take one or more of the following actions: Continuing to hold the medical device, if it was previously seized, until the corrective action is completed, if it is correctable.”
    - Article (39/3) that states “The Manufacturer, Authorized Representative and establishment shall implement the SFDA's decisions related to precautionary measures until the safety and efficacy of the medical devices affected by the decision are ascertained.”

General Requirement

License Validity	**1**	– A valid license issued by the SFDA shall be obtained according to the relevant activity (examples include, but are not limited to: manufacturer license, authorized representative license, importer/distributer license, warehouse/third-party storage license). Note: This requirement does not apply if the inspection visit is for licensing purpose. – An SFDA-licensed authorized representative shall be appointed for each category or general group of medical devices manufactured by a manufacturer located outside KSA. – Manufacturer's/establishment's information provided to the SFDA shall be continuously updated. – Any other branches or warehouses of the manufacturer/establishment shall be disclosed through SFDA's official communication channels. – The manufacturer/establishment shall comply with all requirements and obligations stipulated in the "Requirements for Licensing of Medical Devices Establishments (MDS-REQ9)".
Regulatory Compliance and Validity of Medical Devices	**2**	– All medical devices shall hold a valid Marketing Authorization certificate and/or a valid import permit issued by the SFDA. – Medical devices that have been released with a "Pledge Not to Dispose", or those for which the Marketing Authorization certificates have been suspended, or those seized by the SFDA, or subject to recall, shall not be disposed of until the SFDA issues a decision permitting such action. – Expiry dates of medical devices shall be monitored, and expired or damaged devices shall be promptly segregated, destroyed, and disposed of in accordance to the "Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11)". – Non-compliant medical devices that violate the provisions of the Law or the Regulations shall not be circulated, and the SFDA shall be immediately informed of such devices in accordance to the

		"Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11)".
Evidence of compliance with Quality Management System requirements	**3**	– Manufacturers, importers, and distributors of medical devices in Categories (A) and (B) shall obtain a Certificate of Conformity to the requirements of QMS for medical devices, in accordance to the Saudi standard (SFDA.MD/GSO ISO 13485:2017) or its equivalent, issued by an SFDA-designated Conformity Assessment Bodies (CAB) for Medical Devices and QMS. – Authorized representatives, importers, and distributors of medical devices in Categories (C) and (D) shall either submit documented evidence of conformity or obtain an SFDA-issued inspection report demonstrating conformity to QMS requirements for medical devices, in accordance to the Saudi standard (SFDA.MD/GSO ISO 13485:2017) or its equivalent. Note: SFDA-designated Conformity Assessment Bodies (CAB) refer to establishments located within the KSA that hold a license issued by the SFDA, or establishments located outside the KSA that hold an accreditation certificate issued by an accreditation body that is a member of the International Accreditation Forum (IAF). Note 2: The " Checklist for Quality Manual Form" may be used as a reference.
Documentation	**4**	– The required documentation for licensing shall be provided, including the Quality Manual, as well as the educational and professional qualifications of personnel. – The following documents shall be maintained in English, and additionally in Arabic in case that the end user is a layperson: o Identifying Information. o Instructions for handling, transportation, storage, installation, maintenance and disposal of medical devices. o Promotional and advertising materials. – For manufacturers, the following technical documentation shall be maintained in English: o Description and features of the medical device, including variations and accessories.

		○ Design and manufacturing information. ○ Risk management file. ○ Product verification and validation, including clinical trials. ○ Post-market surveillance plan. ○ Post-market surveillance report and Periodic Safety Update Report (PSUR). – All technical documentation and procedures shall be written in either Arabic or English, or translated into one of these two languages. – Documented and effective procedures for transportation and storage shall be established and implemented in accordance with the manufacturer's instructions and the "Requirements for Transporting and Storage of Medical Devices" (MDS – REQ 12). – Effective and appropriate tracking procedures shall be established and implemented to document supply, distribution and usage information for medical devices, and consequensly enable full traceability of each device. – A unique device identification, including a machine-readable code, shall be provided in accordance to the "Requirements for Unique Device Identification (UDI) for Medical Devices" (MDS – REQ 7). – Written working procedures shall be documented and implemented for reporting and followup medical device incidents and field safety corrective actions with the National Center for Medical Devices Reporting. – Procedures and records for resale, loaning or donation of used medical devices shall be documented and provided to the SFDA upon request. – Procedures and records for the destruction of used medical devices shall be documented and retained for at least three (3) years. – A database shall be established to archive all establishment and medical devices related information and documents, and consequently ensure easy access and retrieval for a minimum retention period of five (5) years.

		– Records of actions taken to address all observations of previous inspection reports shall be maintained. – All requested documents and information shall be submitted to the SFDA within the timeframe specified by the SFDA, not exceeding ten (10 working days) from the date of request.
Personnel	**5**	– The manufacturer/establishment shall provide a sufficient and appropriate number of personnel and resources including buildings, facilities and equipment, according to the responsibilities assigned to it. – The establishment shall appoint a designated representative to communicate with the SFDA, providing that he/she holds an appropriate qualification in a relevant speciality. – The manufacturer shall appoint a full-time Quality Manager and a full-time Technical Manager, both of whom shall be biomedical engineers, medical device technicians, or hold qualifications in a relevant speciality. One of them shall be designated as a representative to communicate with the SFDA. Each of them shall have the following duties and powers: ○ **Quality Manager:** ▪ Supervise and manage all quality-related activities for the manufacturer, including necessary processes and procedures for design verification, manufacturing quality control and audit compliance. ▪ Develop, implement, and monitor the manufacturer's Quality Management System (QMS), including documentation and continuous improvement of processes, procedures and performance indicators. ▪ Ensure compliance with all applicable regulatory requirements, including the Law and the Regulations, as well as Requirements for Medical Devices Marketing Authorization (MDS-REQ 1), Requirements on Importation and Shipments Clearance of Medical Devices (MDS-REQ 5), Requirements for Unique Device Identification (UDI) for Medical Devices (MDS – REQ 7),

		Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical devices (MDS-REQ 8), Requirements for Licensing of Medical Devices Establishments (MDS-REQ 9), Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11), and regulatory requirements for QMS for medical devices in accordance to the Saudi standard (SFDA.MD/GSO ISO 13485:2017) or its equivalent. ▪ Manage all QMS-related aspects, including the Quality Manual and procedures/processes related to QMS such as information control, quality planning, training, suppliers admission and monitoring, maintenance and calibration of manufacturing equipment, complaints handling and directing, handling of recalls safety alerts, and corrective and preventive actions (CAPA), , control of non-conforming materials, and initial/final inspection of materials and equipment at manufacturing sites. ▪ Ensure timely communication and response to the National Center for Medical Devices Reporting (NCMDR) regarding incidents, field safety corrective actions, recalls and complaints. ▪ Ensure that medical device technical documentation is established, developed and continuously updated by the Technical Manager. ▪ Verify conformity with applicable technical regulations and standards for manufactured medical devices. ▪ Supervise all risk management activities, including risk identification, assessments, analysis, evaluation and mitigation. ▪ Supervise sterilization and biocompatibility validation tests of medical devices and accessories, -if applicable-. ▪ Manage the environment of clean rooms used in the processing of medical devices and accessories, -if applicable-. ▪ Conduct internal audits and manage external audit processes, and ensuring responding to the audit findings.

		▪ Act as the QMS representative within the manufacturer (i.e., maufacturers's top management representative) as well as in dealing with external parties. ▪ Prepare and submit QMS performance reports to maufacturers's top management. ○ **Technical Manager:** ▪ Supervise the innovation and development of medical devices, including feasibility studies, design and prototyping processes and related testing activities. ▪ Manage design and development processes, including design inputs, design verification and design validation. ▪ Develop and update technical requirements for the safety and performance of medical devices, including Standard Operating Procedures (SOPs) and test methods. ▪ Ensure compliance with applicable technical regulations and standards for manufactured medical devices. ▪ Plan, develop, implement and enhance production processes, including data collection and evaluation throughout manufacturing process stages, validate manufacturing process, qualify, maintain and calibrate manufacturing equipment, as well as providing necessary support to production and quality control personnel. ▪ Supervise product testing, including product verification and product validation activities. ▪ Supervise the preparation and submission of the technical file for each medical device to obtain Marketing Authorization (MDMA) from the SFDA. ▪ Ensure that technical documentation is kept up to date and that updated documents are submitted to the SFDA whenever changes occur related to the manufacturer or the product. ▪ Ensure alignment with modern industrial technologies, and implement necessary improvements and enhansements to raise quality, safety, performance and effectiveness levels of manufactured medical devices.

		– Personnel involved in the marketing and sale of medical devices shall have sufficient product knowledge to ensure accurate information is provided during marketing and sales activities. – Authorized representatives shall appoint a designated person responsible for regulatory affairs and post-market surveillance activities in accordance with the Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11).
Advertising	**6**	All promotional and advertising materials intended for publication shall obtain prior approval from the SFDA in accordance with the Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical devices (MDS-REQ8)
Post-Market Surveillance	**7**	– Compliance with the Requirements for Post-Market Surveillance of Medical Devices (MDS – REQ11. Key requirements are those related to: o Maintenance for medical devices. o Resale, loaning or donation used medical devices. o Destruction of used medical devices. – Not to dispense any high-risk medical device for use outside healthcare facilities without a medical prescription, in accordance to the "List of Medical Devices Requiring a Prescription" records of such prescriptions shall be retained for a minimum of five (5) years. – If a manufacturer/establishment intends to provide maintenance services for medical devices not originally supplied by them, they shall obtain a medical device service provider license in accordance with the "Requirements for Licensing of Medical Devices Establishments" (MDS-REQ9).
Confidentiality of Information	**8**	Confidentiality of information, procedures and operations accessed before, during, or after inspection visits shall be maintained.

Inspection and Audit of Quality Management System (QMS) for Manufacturers

Inspection Visit Preparation and Planning	**1**	– The inspection fee for medical devices manufacturers shall be paid within the timeframe specified by the SFDA upon receipt of a payment request. – The manufacturer located within the KSA or the authorized representative of a manufacturer located outside the KSA shall respond to the SFDA's inspection visit scheduling request, and submit the following information and documents within the specified timeframe: o Manufacturing site address, including GPS coordinates of all production, sterilization, packing, packaging and storage locations. o Scope of manufacturing and related activities. o Quality Manual and Standard Operating Procedures (SOPs). o Note: The "Checklist for Quality Manual Form" published on the SFDA website may be used as a reference. o Previous inspection/audit reports, -if available-. o ISO 13485 conformity certificate -if applicable-. o List of medical devices with their risk classification, and copies of their conformity certificates. o Any manufacuring sites specific instructions, such as entry/exit instructions, and security, health and safety rules. o Notice for acceptance the attendance of SFDA observers or trainees within the inspection team, -if requested by the SFDA-. o Logistical and practical informationsuch as nearby airports and accommodation options. o Any additional documents requested by the SFDA. – The SFDA will develop an inspection plan, including the determination of the inspection visit type and duration, and the inspection team members. Such determination will be based on factors including: (QMS scope, number of production lines, nature

		and risk classification of the medical devices, and the manufacturer's compliance records). – The manufacturer shall review the inspection plan and prepare relevant documents and sites to be audited accordingly. – A copy of updated Quality Manual, SOPs, and related records in either Arabic or English shall be available on-site during the visit. – The following equipment shall be provided: o Dedicated office or meeting room. o Printer. o Wireless networking technology (Wi-Fi). o Interpreter, if communication between the inspection team and manufacturer personnel in Arabic or English is not possible.
Conducting the Inspection Visit	**2**	– The duration of the inspection visit shall be adhered to as specified in the inspection plan prepared by the SFDA. However, the manufacturer may propose modifications to the plan, if needed, upon coordination with the Inspection Team Leader. – The following requirements shall be met during the opening meeting: o Attendance of top management representatives in addition to the inspection visit relevant personnel. o Signing the attendance sheet. o Providing a brief overview about the manufacturer, its activities, and the medical devices being manufactured. o Discussing findings of previous inspection visits - if applicable -. o Confirming the inspection plan and other related arrangementssuc as date and time of the closing meeting and any meetings between the inspection team and manufacturer personnel. o Confirming the language to be used during the inspection. o Confirming confidentiality and information security controls. o Confirming health, safety, emergency and security measures.

		○ Confirming the availability of neccessary resources and facilitations to conduct all inspection activities. ○ Confirming that inspectors will be enabled to review documents during the inspection, and that any requested documents will be made available immediately. ○ Confirming that inspectors will be enabled to collect and verify evidence and information, including access to requested sites and conducting interviews with relevant personnel. – The following requirements shall be met during the inspection: ○ Granting inspectors full access to all manufacturing facilities, including but not limited to,: ▪ Receiving and storage zones for initial products (raw materials). ▪ Production areas, including cleanrooms and sterilization zones. ▪ Quality control laboratories. ▪ Finished product storage zones. ▪ Water purification and treatment stations. ▪ Maintenance zones. ▪ Loading/unloading docks and means of transportation. ▪ Any other facilities related to manufacturing activities. ○ Providing personal protective equipment (PPE) for the inspectors, -as needed-. ○ Notifying inspectors of any potential hazards upon entry to any facility and inform them on applicable health, safety, emergency and security measures. ○ Providing all requested documents in either Arabic or English. – The following requirements shall be met during the closing meeting: ○ Attendance of top management representatives in addition to the inspection visit relevant personnel. ○ Signing the attendance sheet. ○ Review observations and non-conformities detected during the inspection -if applicable-.

		○ Confirmation of procedures and controls related to the inspection report and implementation of corrective actions, -if applicable-. ○ Confirmation the possibility of objection toward observations or non-conformities mentioned in the inspection report in accordance to the applicable legal procedures.
Inspection Report and Corrective Actions	**3**	– The SFDA shall issue the inspection report, including any detected non-conformities, within (15 working days) following the conclusion of the inspection visit and deliver it to the manufacturer located within the KSA or the authorized representative of a manufacturer located outside the KSA via email or the SFDA's administrative communication system. – The manufacturer (or its authorized representative) shall acknowledge receipt of/or sign the inspection report. – A thorough root cause analysis investigation shall be conducted to determine root cause of non-conformities mentioned in the inspection report -if applicable-. – The manufacturer shall respond to the non-conformities using the form attached to the inspection report, and submit a corrective action plan within the timeframe specified by the SFDA. – The corrective action plan shall include the following: ○ Determination of the root causes of the detected non-conformities. ○ Immediate correction of the detected non-conformities. ○ Corrective actions to address the causes of non-conformities and prevent recurrence. ○ Preventive actions to address potential causes of non-conformities and other potential undesirable situations. ○ Requested timeframe for implementation of corrective action plan , providing that it is proportionate to the nature and number of detected non-conformities. – The SFDA will evaluate the submitted response and the corrective action plan and communicate one of the following decisions: ○ Acceptance.

		○ Rejection, with returning of the form and/or corrective action plan to the manufacturer for modification within a specified timeframe. – If the corrective action plan is rejected, the SFDA will grant the manufacturer a maximum of (3 opportunities) to revise and resubmit the plan. – If the manufacturer fails to revise the plan within the specified timeframe or exhausts all allowed revision opportunities, the case will be escalated for appropriate further action. – The approved corrective action plan shall be fully implemented within the timeframe set by the SFDA. – The manufacturer shall notify the SFDA upon the full implementation of the corrective action plan. – SFDA confirmation of the full implementation of the corrective action plan shall be obtained. – If any medical devices have been seized, the seizure shall remain in effect until the SFDA confirms that corrective actions have been completedfor the medical devices that are capable of being corrected. – If the Marketing Authorization certificate for any medical device has been suspended, the device shall not be disposed of until the suspension is cleared by the SFDA. – The SFDA will schedule a follow-up visit to verify the implementation of corrections, corrective and preventive actions -if needed-. – The follow-up visit report will be sent to the manufacturer located within the KSA or to the authorized representative of a manufacturer located outside the KSA via email or the SFDA's administrative communication system.

Inspection Visit Preparation and Planning	**1**	○ The establishment shall respond to the SFDA's inspection visit scheduling request, and submit the following information and documents within the specified timeframe : ○ Establishment site address, including GPS coordinates of the main premises and any branches or warehouses under its operation. ○ Scope of activities: authorized representation, import, and/or distribution. ○ Quality Manual and Standard Operating Procedures (SOPs). Note: The " Checklist for Quality Manual Form" published on the SFDA website may be used as a reference. ○ Previous inspection/audit reports, -if available-. ○ ISO 13485 conformity certificate -if applicable-. ○ List of medical devices with their risk classification, and copies of their conformity certificates. ○ Any manufacuring sites specific instructions, such as entry/exit instructions, and security, health and safety rules. ○ Notice for acceptance the attendance of SFDA observers or trainees within the inspection team, -if requested by the SFDA-. ○ Any additional documents requested by the SFDA. ○ The SFDA will develop an inspection plan, including the determination of the inspection visit type and duration, and the inspection team members. Such determination will be based on factors including: (QMS scope, number of production lines, nature and risk classification of the medical devices, and the establishments's compliance records). ○ The establishment shall review the inspection plan and prepare relevant documents and sites to be audited accordingly. ○ A copy of updated Quality Manual, SOPs, and related records in either Arabic or English shall be available on-site during the visit. – The following equipment shall be provided: ○ Dedicated office or meeting room.

		○ Printer. ○ Wireless networking technology (Wi-Fi). Interpreter, if communication between the inspection team and establishment personnel in Arabic or English is not possible.
Conducting the Inspection Visit	**2**	– The duration of the inspection visit shall be adhered to as specified in the inspection plan prepared by the SFDA. However, the establishment may propose modifications to the plan, if needed, upon coordination with the Inspection Team Leader. – The following requirements shall be met during the opening meeting: ○ Attendance of top management representatives in addition to the inspection visit relevant personnel. ○ Signing the attendance sheet. ○ Providing a brief overview about the establishment, its activities, and the medical devices being manufactured. ○ Discussing findings of previous inspection visits - if applicable -. ○ Confirming the inspection plan and other related arrangementssuc as date and time of the closing meeting and any meetings between the inspection team and and establishment personnel. ○ Confirming the language to be used during the inspection. ○ Confirming confidentiality and information security controls. ○ Confirming health, safety, emergency and security measures. ○ Confirming the availability of neccessary resources and facilitations to conduct all inspection activities. ○ Confirming that inspectors will be enabled to review documents during the inspection, and that any requested documents will be made available immediately. ○ Confirming that inspectors will be enabled to collect and verify evidence and information, including access to requested sites and conducting interviews with relevant personnel. – The following requirements shall be met during the inspection: ○ Granting inspectors full access to all establishment facilities, including but not limited to:

		▪ Receiving and storage zones. ▪ Maintenance zones. ▪ Loading/unloading docks and transport vehicles. ▪ Loading/unloading docks and means of transportation. ▪ Any other facilities related to manufacturing activities. o Providing personal protective equipment (PPE) for the inspectors, -as needed-. o Notifying inspectors of any potential hazards upon entry to any facility and inform them on applicable health, safety, emergency and security measures. o Providing all requested documents in either Arabic or English. – The following requirements shall be met during the closing meeting: o Attendance of top management representatives in addition to the inspection visit relevant personnel. o Signing the attendance sheet. o Review observations and non-conformities detected during the inspection -if applicable-. o Confirmation of procedures and controls related to the inspection report and implementation of corrective actions, -if applicable-. Confirmation the possibility of objection toward observations or non-conformities mentioned in the inspection report in accordance to the applicable legal procedures.
Inspection Report and Corrective Actions	**3**	– The SFDA shall issue the inspection report, including any detected non-conformities, within (10 working days) following the conclusion of the inspection visit and deliver it to the establishment via email or the SFDA's administrative communication system. – The establishment (or its authorized representative) shall acknowledge receipt of/or sign the inspection report. – A thorough root cause analysis investigation shall be conducted to determine root cause of non-conformities mentioned in the inspection report -if applicable-.

		– The establishment shall respond to the non-conformities using the form attached to the inspection report, and submit a corrective action plan within the timeframe specified by the SFDA. – The corrective action plan shall include the following: o Determination of the root causes of the detected non-conformities. o Immediate correction of the detected non-conformities. o Corrective actions to address the causes of non-conformities and prevent recurrence. o Preventive actions to address potential causes of non-conformities and other potential undesirable situations. o Requested timeframe for implementation of corrective action plan, providing that it is proportionate to the nature and number of detected non-conformities. – The SFDA will evaluate the submitted response and the corrective action plan and communicate one of the following decisions: o Acceptance. o Rejection, with returning of the form and/or corrective action plan to the manufacturer for modification within a specified timeframe. – The corrective action plan is rejected, the SFDA will grant the manufacturer a maximum of (3 opportunities) to revise and resubmit the plan. – If the establishment fails to revise the plan within the specified timeframe or exhausts all allowed revision opportunities, the case will be escalated for appropriate further action. – The approved corrective action plan shall be fully implemented within the timeframe set by the SFDA. – The establishment shall notify the SFDA upon the full implementation of the corrective action plan. – SFDA confirmation of the full implementation of the corrective action plan shall be obtained. – If any medical devices have been seized, the seizure shall remain in effect until the SFDA confirms that corrective actions have been

		completedfor the medical devices that are capable of being corrected. – If the Marketing Authorization certificate for any medical device has been suspended, the device shall not be disposed of until the suspension is cleared by the SFDA. – The SFDA will schedule a follow-up visit to verify the implementation of corrections, corrective and preventive actions -if needed-. – The follow-up visit report will be sent to the establishment located within the KSA or to the authorized representative via email or the SFDA's administrative communication system.

Inspector's Powers, Rights and Duties

Inspector's Powers	**1**	– Review all documents related to the manufacturing scope and activities , or to the establishments activities. – Review electronic systems and software related to the manufacturer's/ establishment 's activities. – Access all manufacturer's/establishment's facilities, including receiving, production, maintenance, storage, unloading, loading and transportation zones. – Review documents and records of the manufacturer's/establishment's customers. – Review manufacturing equipment within the manufacturer's facilities and record their information. – Access documents and records of all product-related studies (e.g., clinical trials). – Interview and ask any personnel inside the manufacturer's/establishment's facilities. – Photocopy or request copies of any document, or paper or electronic record. – Accompanying additional personnel beyond those listed in the inspection visit plan to join the inspection team when deemed necessary. – Bring any devices or tools required to carry out inspection activities. – Photograph or documenting manufacturer's/establishment's facilities related to the scope of manufacturing or establishment activities if violations is suspected. – Collect samples of any medical device, and conduct necessary tests at the establishment's expense to verify compliance with applicable standards, in accordance with the "Guidance on Medical Devices Samples Collection (MDS-G013)". – Re-inspect any facility whenever deemed necessary. – Seize or detain any in violation or suspected medical device .

		– Call security forces or other relevant authorities when deemed necessary. – Suspend the inspection visit in any of the following circumstances: o The manufacturer/establishment prevents the inspector from carrying out inspection and enforcement duties. o The manufacturer/establishment not respond to the inspector requests during the inspection and enforcement process. o The inspector is subjected to threats, verbal or physical abuse, or any form of harassment. o There is a potential risk related to health, safety, emergency or security.
Inspector's Rights	**2**	– The inspector shall be enabled to perform inspection and seizure works without any hindering. – The inspector's official job card shall not be detented or pawned as a condition for entry into the establishment's facilities. – The inspector's official job card shall not be photographed or copied after authentication. – The inspector shall not be requested to sign any undertaking or commitment during the inspection duties. – Inspection activities and inspectors shall not be recorded or photographed. – The inspector has the right to get certain logistical and practical information from the manufacturer located outside the KSA or its authorized representative, including requirements for travel, entry visa, transportation and others related to the country where the manufacturing site is located. – The inspector has the right to coordinate with the manufacturer located outside the KSA or its authorized representative to facilitate the issuance of the entry visa to the country where the manufacturing site is located; however, visa fees shall be paid by the inspector.

		– The inspector has the right to askthe manufacturer about the recommended accommodation; however, accommodation costs shall be paid by the inspector. – The manufacturer located outside the KSA is responsible for arranging and providing the inspector's transportation between the port of entry/exit and the accommodation, as well as between the accommodation and the manufacturing sites, throughout the duration of the inspection visit.
Inspector's Duties	**3**	– Present the official job card during the inspection visit. – Wear the distinct SFDA inspectors uniform during inspection visits within the KSA, except in special circumstances as needed. – Comply with requirements of general safety, radiation safety and chemical safety, as well as any other health, safety, emergency and security procedures during inspection activities. – Refrain from accepting any invitations to banquets or meals treat from the manufacturer/establishment; however, light refreshments offered by the manufacturer/establishment may be accepted. – Refrain from accepting invitations to trips or visits outside the scope of the inspection. – Refrain from accepting any gifts, gratuities. – Maintain confidentiality of information.

Final Provisions

- Whoever commits any violation of these requirements shall be penalized according to the "Table of the Classifications of Violations and Penalties According to the Medical Devices Law and its Implementing Regulation".
- Manufacturers/establishments have the right to object toward observations or non-conformities mentioned in the inspection report, and submit supporting justifications in accordance to the applicable legal procedures.
- Establishments may file a complaint regarding inspection activities or inspectors in accordance to the applicable legal procedures.

- The SFDA shall issue dedicated guidance documents outlining the requirements, procedures and required documents to conform with the Saudi standard (SFDA.MD/GSO ISO 13485:2017) for both manufacturers and establishments.

Annexes

Annex (1): Definition & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Medical Devices Law
Regulation	Executive Regulations of the Medical Devices Law
QMS	Quality Management System
National Center	National Center for Medical Devices Reporting
Medical Devices	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.
Medical Supply	Medical materials and products used in diagnosis, treatment, replacement, modification, disability cases or other medical uses for humans, including medical gases.
User	A professional, lay person, or a patient who uses a medical device.
Manufacturer	Any national or foreign establishment whose purposes include designing or manufacturing medical devices to offer them for use in its own name, whether inside or outside the Kingdom. Manufacturing includes: • refurbishing; • assembling; • packaging; • wrapping; and • labelling.

Authorized Representative (AR)	A legal person based in the Kingdom who has written authorization from a manufacturer located outside the Kingdom to represent it in the Kingdom with regard to the implementation of this Law and its Regulation.
Importer	An establishment in the supply chain that imports a medical device to the Kingdom.
Distributor	An establishment in the supply chain which provides a medical device to another distributor or its end user.
License	A document issued by the SFDA to practice any of the activities subject to the Law.
Marketing Authorization	A document issued by the SFDA for any medical device it allows to be traded in the markets.
Safety Alert	A notification issued by NCMDR indicating the risk associated with a medical device and the corrective action to be taken to mitigate the associated risk.
Filed Safety Corrective Action	An action taken by the Manufacturer to eliminate or reduce the risks affecting the safety of a medical device.
Medical Device Adverse event	Any defect, malfunction or change in the characteristics or performance of a medical device that may directly or indirectly cause or contribute to the death or serious injury of a user.
Advertising	Any written, audible, or visible or other media displays intended to promote a medical device or its technology, or to facilitate a direct or indirect sale.
Corrective Action	An action taken to address nonconformity reasons for the establishment, manufacturer, or medical device.
Unique Device Identification (UDI)	A series of numbers and letters created according to a globally accepted device identification and coding with the aim of identifying the medical device specifically and clearly during all stages of trading.
Inspection	A systematic and documented procedure carried out by the SFDA to verify the establishment and / or the Manufacturer's obligations with regard to the particular conditions and requirements for facilities and medical devices set forth in the Law and its Regulation.

Audit	A systematic and documented evaluation of the manufacturer's/facilities Quality Management System to assess conformity with the regulatory requirements for Quality Management Systems.
Quality Manual	A defined Quality Management System document that provides a comprehensive overview of the establishment's activities, scope of the Quality Management System, quality policy and objectives, and procedures and records that constitute the Quality Management System.

Annex (1): List of Changes on the Previous Version

Number & Date of the Previous Version	Changes Description
1.0 **22/06/2022**	• Modify the document **title** to: "Requirements of Inspections and Audit for Quality Management System (QMS) on Medical Devices Manufacturers and Establishments (MDS-REQ10)." • Editorial changes to the "**Purpose**" section. • Changes to the "**Scope**" section. • Changes to the "**Background**" section. • Changes to the "**General Requirements**" section. • Changes to the "**Specific Requirements**" section, which has been replaced with two sections: "**Inspection and Audit of Quality Management System (QMS) for Manufacturers**" and "**Inspection and Audit of the Quality Management System (QMS) for Establishments**." • Addition of duties and powers for the **Quality Manager** and **Technical Manager** of the manufacturer. • Changes to the '**Inspector's Powers, Rights and Duties**" section • Changes to the "**Final Provisions**" section. • Changes to **Annex (1): Definitions and Abbreviations**.