الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

MDS – REQ 10

Requirements for Inspections and Quality Management System for Medical Devices

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Introduction

Purpose

The purpose of this document is to specify and clarify the requirements for inspection and Quality Management System for establishments and medical devices, which subject to the medical devices law and its executive regulation. In accordance to Article (33/3) of the regulations, stipulated that, “The SFDA shall–issue requirements for inspection and Quality Management System for medical devices, which includes duties, authorities, obligations, and rights of the inspector”.

Scope

This document applies to establishments and medical devices which referred to in (Article Two) of the “Medical Devices Law” and Article (2/1) of its Regulation.

For verifying compliance with the requirements stated in this document, the SFDA shall apply the following –if applicable-:

- Primary visit/visit for the purpose of licensing: with the aim of an initial assesment of the establishment requesting the license or to assess the condition of the manufacturer, in which preliminary information about the manufacturer, production processes and products are collected.
- Routine/periodic visit: for the following purposes:
    - Assessing the establishment's fulfillment of the SFDA's requirements.
    - Assessing the establishment's fulfillment of the requirements of the Quality Management System according to the latest version of the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.
- Follow-up visit: for the purpose of assessing the establishment's application of corrective procedures for non-conformities that were detected during previous visits.
- Interactive visit: for the purpose of investigating the establishment as a result of a complaint, a report or a problem.
- Products verification visit: in order to ensure compliance of medical devices that were manufactured, circulated, or handled with the requirements of the Law and the regulation.

Background

SFDA has issued this document in accordance to "Medical Devices Law" published by the Royal Decree No. (M/54) dated 6/7/1442H in reference to the following:

- Article (22), which stipulates that "Establishments seeking to circulate medical devices in the Kingdom shall adhere to the Quality Management System".
- Article (33), which stipulates that "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), which stipulates that "An inspector shall show his credentials upon performing his inspection duties, and the establishment shall cooperate with him".

In addition to the regulation of the "Medical Devices Law" issued by Saudi Food and Drug Authority Board of Directors decree No. (3-29-1443) dated 19/2/1443 AH through:

- Article (33/3), which stipulated, "The SFDA shall issue requirements for inspection and Quality Management System for medical devices, which includes duties, authorities, obligations, and rights of the inspector."

Requirements

Establishments wishing to engage in any activities subject to the “Medical Devices Law” shall comply with the law and its regulation, including the requirements for inspection and Quality Management System specified in this document.

A. General Requirements

All establishments shall adhere to with the following:

1. Obtaining a valid license from the SFDA.
2. Continuous updating of the establishment information registered at the SFDA.
3. Adhere to the requirements and obligations contained in the requirements for establishments licensing for medical devices and guidance published on the SFDA's website.
4. Validity of information and provision of documents submitted for obtaining a license, including employee’s data, and their scientific and practical qualifications.
5. The technical documents and procedures shall be in Arabic or English or translated into one of the two languages.
6. Maintaining confidentiality of the information, procedures, and processes viewed before, during or after the inspection visits.
7. All medical devices manufacturers, importers and distributors of categories (A) and (B) shall obtain a Quality Management System certificate from SFDA’s accredited Conformity Assessment Bodies (CAB) for medical devices and for quality management system, in accordance to the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.

Note: The SFDA accredited conformity assessments bodies are those who carry out their activities inside the Kingdom and have a license from the SFDA, or those located outside the Kingdom that are accredited by the International Accreditation Forum (IAF).

8. Authorizes representatives, importers and distributors of categories (C) and (D) for medical devices shall submit evidence of the application of the Quality Management System or an inspection report from the SFDA, that confirms their

compliance with the requirements of the Quality Management System in accordance with the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.

9. Providing a sufficient and appropriate human resources and other resources shall be provided according to the activity of the establishment and the tasks assigned to it to fulfill all the requirements of the Law and its regulation.
10. All medical devices circulated by the establishment shall have a marketing authorization certificate and/or an import permit issued by the SFDA.
11. Providing and implementing effective and appropriate tracking procedures for documenting, distribution and use of medical devices, which help in tracking the medical device according to the Requirements for Unique Device Identification (UDI) for Medical Devices.
12. Providing and implementing effective and appropriate procedures for storage and transportation according to the requirements of the manufacturer and the requirements for transportation and storage of medical devices published on the SFDA's website.
13. Follow up on the expiry date of medical devices.
14. Compliance with the conditions and requirements of destruction, reprocessing, refurbishing, reselling or donating in accordance with the requirements for post-marketing surveillance for medical devices published on the SFDA's website.
15. Maintaining records of medical devices disposal in accordance with the requirements for post-marketing surveillance for medical devices published on the SFDA's website.
16. In the event that a product was seized in violation of the Law, the seizure of the medical device will continue until the completion of corrective action if the product is capable of being corrected.
17. Process all observations contained in previous inspection reports.
18. All advertising and promotional materials prepared for publication shall obtain the approval from the SFDA in accordance with the requirements for approval of advertising and organizing awareness or charitable campaigns for medical devices.
19. 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.
20. Disclose about any other unlicensed branches or warehouses of the establishment.

21. Adhere to the requirements for post-marketing surveillance for medical devices published on the SFDA's website.
22. Do not circulate medical devices in violation of the Law.
23. Adhere to the following after the inspection:
    a. Signing/acknowledgement of receipt the inspection report.
    b. Conducting a comprehensive investigation if requested by the SFDA in the events of non-conformity mentioned in the inspection report.
    c. Submit a corrective plan, if requested by the SFDA, to address cases of non-conformity - if any - within the period specified in the request.
    d. Implementation of the corrective plan after its acceptance by the SFDA within the specified period.
    e. Notify SFDA of the completion of the implementation of the corrective plan.

B. Particular Requirements

In addition to what is mentioned in the general requirements, each establishment shall comply with the particular requirements mentioned below according to the type of each establishment.

First: Medical Devices Manufacturers

1. Adhere to the following requirements:

1.1. The design of the manufacturer's facility compatible with the nature of the medical device to be manufactured.

1.2. The presence of a full-time technical manager and a full-time quality manager who are medical devices engineers/technicians, or qualified in one of the related specialties.

1.3. A pledge that the manufacturer bears full responsibility for the quality of all manufactured batches

1.4. Unique Device Identification (UDI) requirements for medical devices

1.5. Maintain and provide the following documents upon request:

1.5.1. The identifying information (labeling) in English, as well as in Arabic if the user is a lay person.

1.5.2. Instructions related to the handling, transportation, storage, installation, maintenance and disposal of medical devices in English, as well as in Arabic if the user is a lay person.

1.5.3. Advertising, promotional and marketing information in English, as well as in Arabic if the user is a lay person.

1.5.4. Description of the medical device and its specifications, including differences and accessories.

1.5.5. Design and manufacturing information.

1.5.6. Risk management file.

1.5.7. Verification and validation of the product including clinical trials (studies).

1.5.8. Post-marketing surveillance plan.

1.5.9. Post-marketing surveillance report and periodic safety update report.

1.5.10. Written procedures to take the necessary field safety corrective actions mentioned in the safety notice.

1.6. Report to the National Center for Medical Devices Reporting (NCMDR) about incidents of its medical devices.

1.7. Provide after-sales services in accordance with Articles (16/1) and (16/2) of the Regulation.

1.8. The implanted medical device card shall contain the following information:

1.8.1. Information that allow identification of the device, including device name, serial number, batch number, UDI data, device model, name, address and website of the manufacturer.

1.8.2. Any warnings, precautions, or measures to be taken by the patient or healthcare provider regarding mutual interference with foreseeable external influences, medical examinations or anticipated environmental conditions.

1.8.3. Any information about the expected lifetime of the device and any necessary follow-up of the device's performance.

1.8.4. Any other information to ensure the safe use of the device.

2. Before the visit, the manufacturer shall:

2.1. Pay the fees for the visit within the specified period, according to what is published on the SFDA's website.

2.2. Reply to the visit time confirmation request sent to the local manufacturer/authorized representative of the foreign manufacturer within the specified period.

2.3. Send the following data and documents within the specified period

2.3.1. Manufacturer address (coordinates of the site and any other locations related to manufacturing and storage processes).

2.3.2. The scope of manufacturing and related activities.

2.3.3. Quality Manual and Standard Operating Procedures according to the latest version of the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.

2.3.4. Previous audit reports.

2.3.5. A list of manufactured medical devices with its risk -based classification and quality certificates.

2.3.6. Any instructions specific to the manufacturing site, such as entry and exit instructions, security, health and safety, etc.

2.3.7. Notification for approval of the attendance of observers and trainees (if any).

2.3.8. Any other documents requested by the SFDA.

3. The SFDA shall create a visit plan where the type of visit, number of days and inspection team members are determined based on several factors, which include: (the scope of the quality management system, number of production lines, the type and risk class of products, compliance records for the manufacturer), and the manufacturer shall:

3.1. View the visit plan and prepare the documents and sites that will be audited according to the plan.

3.2. Provide a copy of the latest version of the Quality Manual, Standard Operating Procedures (SOPs) and records to be ready on site during the visit.

4. During the visit, the manufacturers shall:

4.1. Commit to the audit period according to the plan.

4.2. Provide an office or a meeting room with a printer.

4.3. Provide an interpreter if the inspection is approved in a language other than English.

4.4. Commit to the following during the opening meeting:

4.4.1. The presence of representatives of the top management in addition to the related employees.

4.4.2. Sign the attendance sheet.

4.4.3. Confirm the inspection plan and other related arrangements, such as the date and time of the closing meeting and any meetings between the inspection team and the manufacturer.

4.4.4. Confirm the language to be used during the inspection.

4.4.5. Confirmation of matters related to confidentiality and information security.

4.4.6. Confirmation of health, safety, emergency and security procedures.

4.4.7. Confirm the availability of the resources and facilities required to perform all inspection activities.

4.4.8. Emphasize on permitting inspectors to review documents during inspection and providing those documents immediately upon request.

4.4.9. Emphasize on permitting inspectors to collect and verify information, including opening the sites they request and interviewing people when necessary.

4.4.10. Provide a brief explanation about the manufacture, its activity and its products.

4.4.11. Discuss the results of previous inspection - if any -.

4.5. Commit to the following during the visit:

4.5.1. Permit the inspectors to view all the facilities of the manufacturer, which include - but not limited to -:

4.5.1.1. Areas for receiving and storing primary products (raw materials).

4.5.1.2. Production areas (including clean rooms and sterilization areas).

4.5.1.3. Quality laboratories.

4.5.1.4. Finished product storage areas.

4.5.1.5. Water desalination and treatment plants.

4.5.1.6. Maintenance areas.

4.5.1.7. Transportation.

4.5.1.8. Any other facilities associated with the manufacturing activity.

4.5.2. Provide protective clothing in case it is necessary to wear certain clothing to enter some facilities for the purpose of product and people safety.

4.5.3. Providing documents/records in Arabic or English.

4.5.4. Notify the inspection team upon entering any facility of potential risks regarding health, safety, emergency and security.

4.6. Commit to the following during the closing meeting:

4.6.1. The presence of top management in addition to the relevant employees.

4.6.2. Signing the attendance sheet.

5. The SFDA shall issue the inspection report within (15) days from the end of the visit and deliver it to the local manufacture or the authorized representative of the foreign manufacturer through e-mail, SFDA administrative communications or any other means.

6. After the visit, the manufacturer shall comply with the following, in addition to what was mentioned in Paragraph No. (23) of the “General Requirements” section:

6.1. Respond to cases of non-conformity and submit the corrective plan using the form sent with the inspection report, within the specified period, provided that the plan shall include the following:

6.1.1. Respond to all cases of non-conformity detected in the inspection report.

6.1.2. Clarify the root cause of the non-conformities.

6.1.3. Procedures for immediate correction of non-conformities.

6.1.4. Corrective actions for non-conformities.

6.1.5. Preventive procedures for non-conformities.

6.1.6. Date of implementation of the corrective plan.

6.2. The date of implementation of the corrective plan shall be proportional to the nature of non-conformities.

6.3. The SFDA shall evaluates the corrective plan submitted by the manufacturer, and respond to the manufacture with the evaluation result, either acceptance or not, with returning the form to the manufacture to amend the corrective plan.

6.4. Submit the amended corrective plan within the period specified in the request.

7. The SFDA shall grants the manufacture a maximum of three opportunities to amend the corrective plan.

8. The SFDA shall schedule a follow-up visit to ensure the implementation of corrective and preventive procedures - when needed -.

9. The SFDA shall send the inspection report to the manufacturer.

10. In the event that the manufacture fails to provide an acceptable corrective plan within the specified period, or when the given opportunities for amending are exceeded, the case will be escalated to take the appropriate action.

Second: Distributors, Importers and Authorized Representatives

1. Distributors and importers shall adhere to the following requirements:

1.1. The presence of an authorized representative licensed by the SFDA for each overseas manufacturer that the establishment deals with.

1.2. Appointing an authorized representative for the establishment to deal with the SFDA, provided that he holds an appropriate qualification in one of the relevant specialties.

1.3. Acquiring a warehouse license or a third-party storage license issued by the SFDA in accordance with the requirements for licensing medical devices establishments. As for retailers, a storage area inside the establishment can be sufficient with adherence to the requirements of transportation and storage for medical devices.

1.4. If the establishment wishes to provide maintenance services for its medical devices, it must adhere to the manufacturer's instructions and the requirements for maintenance services of medical devices contained in the requirements for post-marketing surveillance for medical devices published on the SFDA's website. In the event that the establishment wishes to provide maintenance services for medical devices that are not affiliated with it, license for providing maintenance services for medical devices shall be obtained in accordance with the requirements for licensing medical devices establishments.

1.5. Individuals who are concerned with marketing and selling medical devices shall have sufficient information about the devices in order to provide the correct information related to its marketing and sale.

1.6. Medical devices categorized as high risk may not be dispensed for use outside the facility of the healthcare provider without prescription, in accordance with the list of high-risk medical devices published on the SFDA's website, while keeping its records for a period of no less than (5) years.

2. An authorized representative shall comply with the following requirements:

2.1. The presence of an official to deal with tasks related to regulatory affairs and post-marketing surveillance for medical devices in accordance with the requirements of post-marketing surveillance of medical devices published on the SFDA's website.

2.2. A valid authorized representative license shall be obtained from the SFDA for each manufacturer that the establishment represents.

2.3. Report to the National Center for Medical Devices Reporting (NCMDR) about accidents of its medical devices.

2.4. Providing and implementing effective operating procedures to follow up on reports of medical devices and corrective actions approved by the SFDA and the manufacturer contained in safety notices.

3 Before the Quality Management System verification visit, the establishment shall:

3.1. Send the following data and documents:

3.1.1. Address and coordinates of the establishment.

3.1.2. Specify the activities and operations practiced by the establishment: storage, distribution, installation and maintenance, etc.

3.1.3. Quality manual and the Standard Operating Procedures (SOPs) according to the latest version of the Saudi Standard (SFDA.MD/GSO ISO 13485) or its equivalent.

3.1.4. Previous audit reports issued by conformity assesment bodies - if any -.

3.1.5. List of medical devices.

3.1.6. Any instructions specific to the site, such as instructions for entry, exit, security, health and safety, etc.

3.1.7. Any other documents requested by the SFDA.

3.2. During the visit, the establishment shall:

3.2.1. Commit to the agreed inspection period.

3.2.2. Provide an office or a meeting room with a printer.

3.2.3. Provide an interpreter if the inspection is approved in a language other than English.

3.2.4. The presence of top management representatives to the opening session.

3.2.5. Permit the inspectors to review the relevant documents during the inspection and provide them immediately upon request.

3.2.6. Permit the inspectors to collect and verify information, including opening the sites they request and interviewing people when necessary.

3.2.7. Provide copies of relevant documents.

3.2.8. Attend the closing session.

3.2.9. Signing the attendance sheet.

3.3. The SFDA shall issue the inspection report within (10) days from the end of the visit through e-mail, SFDA administrative communications or any other means.

3.4. After the visit, the establishment shall comply with what was mention in paragraph No. (23) of the "General Requirements".

Inspection authorizations, responsibilities, obligations and rights

1. **The inspector shall have the following authorities and rights:**

1.1. Interview and question any employee within the establishment's facilities.

1.2. View all records and documents related to the establishment's activity.

1.3. Photocopy/request a copy of any document or record.

1.4. View all equipment and devices in the manufacturer’s facilities and record their data.

1.5. Access to electronic systems and programs related to the establishment's activity.

1.6. View documents and records of all studies conducted on the product (as an example: clinical trials (studies)).

1.7. View all records and documents of the establishment's clients.

1.8. Accompany any other member not mentioned in the visit plan to join the inspection team whenever needed.

1.9. Bring any equipment or tools to be used for inspection purposes.

1.10. Photographing or documenting the manufacturer’s facilities related to manufacturing activities in case of suspected violations.

1.11. Withdraw samples from any product for the purpose of ensuring that it conforms to the specifications in accordance with the Guidance for the Medical Devices Samples for Laboratory published on the SFDA’s website.

1.12. Take notes during the visit or review records and documents.

1.13. Re-preview any facility when needed.

1.14. Seizing any violating or suspicious product.

1.15. Call the security authorities or the competent authorities when needed.

1.16. End the visit when health, safety, emergency and security risks may arise.

1.17. It is not allowed to take the work ID badge as a condition for entering the facility.

1.18. Coordinating with the manufacturer to suggest the appropriate hotel, provided that the costs of accommodation are paid by the inspection team members.

1.19. Obtaining some logistic information from the manufacturer/authorized representative that does not conflict with the inspection tasks.

1.20. Coordination with the manufacturer/authorized representative to facilitate the issuance of visas to the inspection team members by the competent authorities, provided that the visa costs are paid by the inspection team members.

1.21. The overseas manufacturer is responsible for insuring transportation for the inspection team members from the airport to their residence, as well as from the residence to the manufacturing facility during the inspection period.

1.22. Not to photocopy or copy the inspector's work ID badge after viewing it.

1.23. Not to request the inspector's signature on any pledge or commitment while performing the inspection tasks.

1.24. Not to record or photograph the inspectors while they are carrying out inspection activities.

2. The inspector shall adhere to the following duties and obligations:

2.1. Show the work ID badge card during carrying out inspection tasks.

2.2. Wear the inspection uniform for local visits, except for some special cases as needed.

2.3. Adherence to the procedures included in the Guidance for the Medical Devices Samples for Laboratory Testing published on the SFDA’s website.

2.4. Adhere to general safety, radiological and chemical safety requirements during inspections and any other procedures related to health, safety, emergency and security.

2.5. Not accepting any meals, banquets and parties invitations from establishments, however the establishment may provide a light lunch.

2.6. Not accepting any invitations for trips or visits outside the scope of the inspection.

2.7. Not accepting gifts or gratuities.

2.8. Maintain confidentiality of information.

Final Provisions

1. Whoever commits any violation of the provisions of these requirements shall be penalized according to the SFDA's schedule of violations and penalties published on its website.

2. Establishments have the right to object to the observations or non- conformities contained in the inspection report and provide justifications for that. The objection shall be in accordance with the applicable legal procedures.

3. The establishment has the right to file a complaint regarding inspection and audit procedures and/or the inspectors in accordance with the applicable legal procedures.

4. The SFDA shall clarify in a specific annex within the Saudi Standard (SFDA.MD/GSO ISO 13485), the extent of application of the standard's clauses according to each establishment.

Annexes

Annex (1): Definitions & Abbreviations

KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
Law	Medical Devices Law
Executive Regulations	Executive Regulations of the Law
NCMDR	The National Center for Medical Devices Reporting
Medical Device	Any instrument, apparatus or implement or implant or in vitro reagent or calibrator or software, or material used for operating medical devices, or any other similar or related article, intended to be used alone or in combination with other devices for diagnosis or prevention or monitoring or controlling or treatment, or alleviation of disease or injury, or for compensation for an injury; investigation, replacement, modification, or support of the anatomy or of 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, but which may be assisted in its intended function by such means.
Medical Supply	A medical material or product used in diagnosis, treatment, replacement, or correction/ straightening; or in disability cases or other medical uses for humans, including medical gases.
Establishment	A legal entity engaged in an activity related to medical devices and supplies.
User	A person, whether a professional, non-professional, or patient, who uses a medical device or supply.
Manufacturer	Any national or foreign establishment the purposes of which include designing or manufacturing medical devices or supplies for use under its name within the Kingdom or abroad. Manufacturing shall include refurbishing, assembling, packaging, and labelling.
Health Care Provider	Any government or private establishment that provides health care services.
Authorized Representative	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

	Regulations.
License	A document issued by the SFDA to authorize engaging in any of the activities subject to this Law.
Marketing Authorization	A document issued by the SFDA permitting the handle/ exchange of a medical device or supply in the market.
Quality Management System	A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device or supply in accordance with the latest version of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations.
Quality Assurance	A set of technical tests, measurements, and calibrations approved by the SFDA to verify the safety, accuracy, and quality of medical imaging devices, in order to ensure the efficacy of diagnosis and treatment.
Technical Regulations	Mandatory documents issued by the SFDA for medical devices and supplies which specify the principles of safety, performance, and manufacturing and provide relevant instructions, including terms and symbols as well as packaging and labelling requirements.
Safety Alert	A notice issued by the National Centre for Medical Devices Reporting indicating the risk associated with a medical device or supply and the corrective action required to avoid such risk.
Corrective Action	An action taken to solve nonconformity reasons for the establishment, manufacture or medical device.
Accidents of Medical Devices	Any defect or change in the characteristics or performance of a medical device or supply 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 matters intended to promote medical device or supplies or technology, or to direct or indirect sale.
Field Safety Corrective Action	An action taken by the manufacturer to limit or reduce the risks compromising the safety of a medical device or supply.
Implantable Medical Device	a medical device intended to be totally surgically introduced into the human body or to replace superficial/epithelial surface or the surface of the eye. Including those partially or wholly absorbed and remain in place after the medical surgical intervention and include those devices that partially surgically introduced for a purpose of 30 days or more of usage.

UDI	Unique Device Identification for Medical Devices
Inspection	a systematic and documented process through field visits to ensure the establishment's compliance with requirements.
Auditing	a systematic and documented evaluation of the efficiency of the quality management systems of an establishment to determine their compliance with requirements.
Quality Manual	A specific quality management system document that provides an overview of the establishment, the quality management system, and the procedures that make up the quality management system.
Direct correction	a procedure to remove the cause of the non-conformity and prevent its recurrence.

Annex (2): Changing to Previous Documents

Number and date of previous version	Descriptions
MDS-G35 1.0 11/04/2019 MDS-G45 1.0 01/02/2020 01/10/2018	• Update and merge the following documents: – Guidance to Implement a Medical Devices Standard "Quality Management System" Regulatory Requirement (ISO 13485:2016) (MDS-G35). – The Saudi Quality Management System Requirements for distributors, importers and authorized representatives. – The Saudi Quality Management System Requirements for Medical Devices.