Guidance on General Requirements for Medical Device Manufacturing

Saudi Food and Drug Authority

Medical Devices Sector

Version Number: 1.0
Version Date: 15/04/2020

Table of Content

Introduction

To be sure medical device manufactures fulfil safety, performance and quality requirements; this guidance has been published in order to clarify regulatory and technical requirements to be taken into consideration during the design and manufacture stages of Medical Devices and its products. In addition, clarifying lists of relevant standards and guidelines, as well as important contact information and links.

Scope

This Guidance applies to medical devices manufacturers.

Requirements

General requirements for the device	1	- Data of the device to be manufactured - Manufacturing and design information - Conformance to Quality Management System (ISO 13485:2016) - Meet the essential principles of safety and performance - Risk/benefit analysis and risk management - Conformity with relevant standards/ national requirements - Product verification (including clinical assessment and biocompatibility) - Post-market clinical follow-up plan (PMCF)
Requirements for the manufacturer	2	- Obtain establishment licensing from SFDA (MDEL) and meet requirements in: - Guidance for local manufacturers: https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G2).pdf - Local medical device manufacture licensing guide https://www.sfda.gov.sa/ar/oper/Documents/Investor's-MD-LocalFactoryLicenseGuide.pdf

Required tests for manufacturing Medical Devices

- Medical device manufacturers shall conduct the necessary technical tests to prove their products' compliance with the regulatory requirements for safety, performance and quality including: electrical, mechanical, biological, usability and stability tests, in addition to other tests according to the nature of the medical product.
- Technical and reference tests shall be conducted according to standards issued by local, regional and international organizations in accredited laboratories, and submit all reports and certificates to SFDA.

Relevant Standards and Guidelines

The Saudi Quality Management System Requirements for Medical Devices according to (ISO 13485:2016)	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/RequirementsQualityManagementSysMD-en.pdf
Implementing Rule on Marketing Authorization	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS%E2%80%93IR6)en.pdf
Guidance on Requirements for Medical Device Listing and Marketing Authorization	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MDS-G5.pdf
Guidance on SFDA Recognized Standards	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/MDS%E2%80%93G44.pdf
Guidance of Requirements for Preliminary Products Importation for the Purpose of Local Manufacturing of Medical Devices	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G26)en.pdf
Guidance for Manufacturers of Home Use Medical Devices	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G13)en.pdf
Guidance for Local Manufacturers	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G2).pdf
Guidance on Requirements for Clinical Investigations of Medical Devices	https://www.sfda.gov.sa/ar/medicaldevices/regulations/DocLib/(MDS-G20)en.pdf

Contact us

For more information regarding standards, requirements and guidelines:

- Regulation and standards section: md.standards@sfda.gov.sa
- Products registration support section: md.rs@sfda.gov.sa

Important Links

SFDA Standards Web Store	https://mwasfah.sfda.gov.sa/
SFDA Requirements and Guidelines	https://www.sfda.gov.sa/en/medicaldevices/regulations/pages/requirementsandconditions.aspx
GCC Standardization Organization (GSO)	https://www.gso.org.sa/en/
International Organization for Standardization (ISO)	iso.org/home.html
International Electrotechnical Commission (IEC)	https://www.iec.ch/