MDS – G 016

Guidance on Biotechnology-based Medical Devices

Version Number: 1.0
Version Date: 20/11/2023

Table of Content

Introduction

To assure that 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 manufacturing stages of biotechnology-based 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 biotechnology-based medical devices manufacturers.

Background

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

- Article 8: Medical devices cannot be marketed/used unless obtaining a registration and Marketing Authorization, and The SFDA may exempt some medical devices from the requirement to obtain a Marketing Authorization, after ensuring their safety, and not using them for commercial purposes, in accordance with rules approved by the Board".
- Article 26: The SFDA shall monitor the compliance of healthcare providers with technical regulations within healthcare facilities in order to ensure the safety and efficacy of medical devices and supplies in diagnosis and treatment".

Requirements

Requirements for the manufacturer	1	Manufacturers shall obtain an establishment license from SFDA and meet requirements in: - Local manufacturer shall obtain Establishment license and overseas manufacturer shall assign a licensed authorized representative as mentioned in Requirements for Medical Devices Establishments Licensing (see MDS-REQ 9)
General requirements for the MD	2	- For the purpose of obtaining a Medical Devices Marketing Authorization (MDMA) manufacturers shall comply with the requirements mentioned in " requirements for Medical Devices Marketing Authorization" (see MDS-REQ1)

		- For Manufacturing medical devices at Points of Care (POC) refer to Guidance for Points of Care (POC) Medical Devices Manufacturing (see MDS-G009)
Additional requirements for the MD	3	For biotechnology-based medical devices, the following additional requirements shall be addressed and provide more prescriptive details to the manufacturer on what is required: - **review of technical documentation** manufacturer shall consider the full medical device lifecycle e.g: design & development process, safety, design Verification and Validation, Post market activities… etc) for further details (see MDS-REQ1) • Annex (3) Medical Device Technical Documentation • Annex (4) IVD Technical Documentation • Annex (6) Clinical Evaluation and Post-Market Clinical Follow-Up • Annex (7) Performance Evaluation, Performance Studies and Post-Market Performance Follow-Up - **Performance evaluation /clinical trials** • Sponsors of a medical device clinical investigation or an IVD clinical performance study must apply to the SFDA for approval • must have obtained approval by a local research ethics committee (EC) prior to SFDA application for further details (see MDS-REQ2) • The intended purpose and characteristics of your medical device • The analyte or marker you're using • Intended use, user, and indications for use • Essential Principles of Safety and Performance • The methods you're using to examine the analytical and clinical performance of the device • Technical/clinical specifications for high risk IVD-based medical devices • An outline of your development phases, including the methods for determining the scientific validity and the analytical and clinical performance.

		• A description of the current State of the Art • Benefit-risk considerations • Post-market Performance Follow-up (PMPF) plan
Risk Classification		For the purpose of biotechnology-based medical devices classification, please refer to the requirements mentioned in Annex (5) of the " requirements for Medical Devices Marketing Authorization" (see MDS-REQ1)
Artificial Intelligence		Artificial intelligence (AI) is constantly bringing improvements to the field of medical devices, with AI technology being embedded in software used as a medical device or being a medical device by itself. AI algorithms as tools to analyse patient data are by no means a replacement for diagnosis by a healthcare professional, but they are invaluable assets when it comes to analysing data sets with increasingly astute accuracy. With the ability to analyse vast amounts of data, identify patterns, and make predictions, AI-powered medical devices are enhancing diagnostics and patient care. considerations during design and development (D&D) phases to the validation and verification (V&V) activities shall be focused on: • Transparency and explicability • Controllability and instability • Risk management • Safety and liability
Quality Management		Manufacturers shall establish a structured system that documents the procedures and processes throughout the lifecycle of a medical device in accordance with (SFDA.MD/GSO ISO 13485) or its equivalent mentioned in the Requirements for Inspections and Quality Management System for Medical Devices. For further details (see MDS-REQ-10)

Relevant documents: Requirements, Guidelines and Standards and (examples)

requirements for Medical Devices Marketing Authorization (MDS-REQ1)	https://www.sfda.gov.sa/en/regulations/68759
Requirements for Clinical Trials of Medical Devices (MDS-REQ 2)	https://sfda.gov.sa/en/regulations/66129
Requirements on Importation and Shipments Clearance of Medical Devices and Supplies (MDS-REQ5)	https://sfda.gov.sa/sites/default/files/2023-07/MDS-REQ5E.pdf
Requirements for Medical Devices Establishments Licensing (MDS-REQ 9)	https://www.sfda.gov.sa/sites/default/files/2023-03/RequirementsLicensingMDEstablishments_0.pdf
Requirements for Inspections and Quality Management System for Medical Devices (MDS – REQ10)	https://sfda.gov.sa/en/regulations/87120
Requirements for Post-Market Surveillance of Medical Devices (MDS-REQ11)	https://sfda.gov.sa/en/regulations/87494
Requirements for Transporting and Storage of Medical Devices (MDS – REQ 12)	https://www.sfda.gov.sa/sites/default/files/2023-10/MDS-REQ12E.pdf
Guidance for Points of Care (POC) Medical Devices Manufacturing (MDS-G009)	https://sfda.gov.sa/en/regulations/87669
Guidance on Medical Devices Classification	https://www.sfda.gov.sa/sites/default/files/2022-12/MDS%E2%80%93G008.pdf

Contact us

For more information regarding standards, requirements and guidelines, kindly contact 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://sfda.gov.sa/en/regulations?tags=3
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/

Annex

Definitions

SFDA	Saudi Food and Drug Authority
MDS	Medical Devices Sector
MDMA	Medical Devices Marketing Authorization
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.
Quality Management System	A system approved by the SFDA to verify the quality, effectiveness, and safety of a medical device in accordance with the latest edition of the Technical Standard (ISO 13485) or its equivalent, as provided in the Regulations.
Clinical Performance	The ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer
Intended Use	The purpose specified by the manufacturer for the use of a medical device.
POC Manufacturing	Manufacturing a medical device inside a healthcare facility which may include: - Putting together of a medical device from raw materials or component parts; - The complete rebuilding of an existing medical device; or - Medical device software development (including AI)
Medical Device Marketing Authorization	A document issued by the SFDA permitting the circulation of a medical device or supply in the market.
Biotechnology-based medical devices	are those that use biological materials, living organisms or biological systems for device manufacture and/or operation.
Software as a Medical Device (SaMD)	A software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device