ClinChoice

REVIEW

Questions And Answers On Custom-made Devices & Considerations On Adaptable Medical Devices And Patient-matched Medical Devices

Contents

1 INTRODUCTION

Rapid technological advancements, such as 3-D printing, have made it possible for manufacturers to produce personalized medical devices[1] much faster and on a commercial scale. The European Medical Device Coordination Group (MDCG) recently issued a Q&A document[2] to help address some of the key regulatory questions and clarify ambiguities regarding custom-made devices (CMDs) defined in the new EU's MDR[3], and adaptable medical devices and patient-matched medical devices described by the International Medical Device Regulators Forum (IMDRF)[4].

2 PERSONALIZED MEDICAL DEVICES: DEFINITIONS AND CATEGORY OVERVIEW

MDR Article 2(3) defines a CMD as any device specifically made per a written prescription of any person authorized by national law by virtue of that person's professional qualifications, which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their conditions and needs.[5] MDCG notes that an authorized person does not have to be a healthcare professional, but any individual qualified and authorized according to the Member State's national law. It further clarifies that the specific design characteristic in the written prescription contains particular information regarding the design and measured data such as models, dental impressions, material selection unique to the individual patient's anatomic-physiological features, and pathological condition.

According to MDR Article 2(3), any mass-produced devices adapted to meet the specific requirements of any professional user and mass-produced devices utilizing industrial manufacturing processes per the written prescriptions of any authorized person are not considered CMDs. Since the MDR only provides a definition of CMDs and does not define any other personalized medical devices that could be, for example, mass-produced, the IMDRF identified and defined two additional categories of personalized devices: adaptable medical devices and patient-matching medical devices, respectively. Unlike CMDs, these devices are typically mass-produced or produced in batches and do not require a written prescription. The Q&A document notes that the personalized medical devices that do not meet the definition of a CMD must comply with all relevant sections of the MDR, including conformity assessment, before placing on the market.

Adaptable medical devices are intended to be adapted, adjusted, shaped, or assembled per validated manufacturer's instructions at the point of care (POC) to meet a patient's anatomo-physiologic features before use, such as orthotic braces and hearing aids (otoplastic and amplifier)[6]. Per MDR Article 16(1), the individual, usually a healthcare professional, performing these activities is not considered a manufacturer as long as these modifications do not change the device's intended purpose or affect its compliance with applicable requirements.

Patient-matched medical devices are intended to be matched to a patient's anatomy within a specified design envelope using techniques such as the scaling of the device based on anatomic references or using the full anatomic features from patient imaging[7]. For example, 3D printed implants from a template model, and DICOM files or contact lenses are made to order and produced in batches.

CONSIDERATIONS AND APPLICATION OF MDR TO CUSTOM MEDICAL DEVICES

As described in the Q&A document, in addition to MDR Annex XIII, CMD manufacturers should ascertain and apply appropriate requirements of Annex I, implement a Quality Management System (QMS) commensurate to the risk class of the device, and ensure compliance with all aspects of Article 10(9). For implantable Class III CMDs, a QMS conformity assessment by a notified body must be performed following either Annex IX Chapter I or Annex XI Part A. Additionally, as per Annex XIII Section 2, the CMD manufacturers must establish procedures and document post-market surveillance reports for Class I devices per Article 85 and Periodic Safety Update Reports (PSURs) for Class IIa, IIb, and III devices per Article 86. However, CMDs are exempt from UDI requirements, Summary of Safety and Clinical Performance (SSCP) requirements, and registration of an appointed person responsible for regulatory compliance (PRRC) in EUDAMED. Furthermore, the Q&A document clarifies when other devices, parts, components, or materials specifically intended for the manufacture or use with CMDs may be CE marked and what regulatory considerations for such "intermediate products" need to be considered if placed on the market on their own.

MDCG encourages the application of CMD-related MDR requirements, such as risk management, post-market surveillance, and clinical evaluation life cycle processes, to CMDs grouped according to the same intended purpose, materials, and processes, same principal design among other criteria rather than per each CMD. The International Medical Device Regulators Forum (IMDRF) Personalized Medical Device – Regulatory Pathways[8] document provides recommendations regarding regulatory pathways and considerations for applying regulatory requirements for CMDs, adaptable medical devices, and patient-matched medical devices.

4 CONCLUSION

Even though the Q&A answers some of the key regulatory questions related to personalized medical devices, the manufacturers should be prepared to address the inherent complexities of device customizations and take into consideration all relevant regulatory requirements (e.g., intended purpose, risk class, manufacturing or design changes, manufacturing and use of personalized medical devices with other CE and non-CE product, among other parameters) to correctly categorize and classify their device, determine appropriate regulatory pathways, and maintain regulatory compliance.

In summary, implementing the new MDR regulations and further clarification, including MCDG documents for the manufacturers of personalized medical devices, may require additional resources and personnel to ensure compliance with the new regulations and post-market surveillance. Some of these may include:

1. Experienced regulatory intelligence consultants to interpret and apply the MDR, other MDCG/IMDRF documents, and national laws
2. Liaisons to engage with Health Authorities or other regulatory agencies on behalf of clients in the EU and other countries to assist clients in meeting regulatory, compliance, and manufacturing/post-market laws
3. Robust medical device call center with experienced personnel capable of engaging with relevant external stakeholders (including patients) to collect, document, and analyze feedback regarding the devices' quality, performance, and safety in the field
4. Compliant infrastructure for incident reporting and experienced authors of required reports such as Periodic Safety Update Report (PSUR)
5. Appointment of a person responsible for regulatory compliance as defined in the new MDR

REFERENCES

[1,4,6,7] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181018-pmd-definitions-n49.pdf
[2] https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-3_en.pdf
[3,5] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L_.2017.117.01.0001.01.ENG
[8] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-pmd-rp-n58.pdf

ALMA RELJA
RAC,CQIA

ABOUT THE AUTHOR

Alma brings expertise in regulatory affairs and quality assurance, with over fifteen years of experience related to medical devices regulations. She specializes in developing and managing regulatory and quality strategies, leading regulatory projects, and establishing new processes for management of clinical trials, CSV and design controls.

ABOUT US

ClinChoice is a global clinical stage Contract Research Organization (CRO), with over 2000 clinical research professionals in seven different countries across North America, Asia, and Europe. ClinChoice has been a leading provider of contract research services offering high-quality solutions to pharmaceutical, biotechnology, medical device and consumer products customers for the past 26 years, working across a wide array of service functions and therapeutic areas. Under its new brand, ClinChoice continues to offer high-quality, full-service clinical development and commercial solutions to pharmaceutical, biotechnology, medical device, and consumer product companies globally. For our partners, it means a reliable partner and quality results.