RA news round-up
CW22 of 2021

Europe

Genetic variants on SARS-COV-2 in vitro diagnostic medical devices

The MDCG published the document 2021-07 “Notice to manufacturers and authorized representatives on the impact of genetic variants on SARS-COV-2 in vitro diagnostic medical devices". In this new notice the MDCG clearly states that the existing COVID-19 tests have to be re-evaluated regarding their performance characteristics to detect the present and upcoming genetic variants like e.g. B.117 or B.1617. Any limitation to the performance should be clearly stated in the IFU and technical documentation. In case that changes of the performance may result in direct or indirect harm, a Field Safety Corrective Action needs to be performed by the manufacturer.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-7_en.pdf

Clinical investigation application/notification templates

The latest MDCG document 2021-08 on "Clinical investigation application/notification documents" provides templates for the application and notification of clinical investigations including all the necessary information to be subjected by study sponsors. The documents are to be used until the corresponding functionality of EUDAMED has been released. At least the later design of the online tool has already been used.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-8_en.pdf

Implementation of UDI requirements for ophthalmic products

The MDCG released a third document: "MDCG 2021-9: MDCG Position Paper on the Implementation of UDI requirements for contact lenses, spectacle frames, spectacle lenses & ready readers".

Article 27 of Regulation (EU) 2017/745 on Medical Devices introduces a Unique Device Identification system, which aims to improve the identification of devices and enhance the effectiveness of post-market safety-related activities for medical devices. This Position Paper is focusing on UDI assignment

solution of specific ophthalmic products and should be read in conjunction with the relevant provisions of Regulations (EU) 2017/745 (notably Chapter III and Annex VI) and related UDI guidance documents.

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_2021-9_en.pdf

Notified Bodies / IVDs

Team NB, the association of Notified Bodies in Europe, has published a position paper in which recommendations are given for the certification of in vitro diagnostics of the risk class D. The recommendations are based on a number of recommendations from the MDCG. Since neither expert panels nor the reference laboratories required by the IVDR are currently available, the procedure described in MDCG Guidance 2021-4 is to be applied.

For manufacturers of class D IVDs, this means: no need to hurry. If Common Specifications are already available for a particular IVD, the assessment process can start as soon as a expert panel is available. For the remaining medical devices, there is no specific procedure. The document can be accessed via the following link:

https://www.team-nb.org/wp-content/uploads/2021/05/Team-NB-PositionPaper-ClassD-20210519-V4.4.pdf

International News

IMDR

The IMDRF document on Post-Market Clinical Follow-Up Studies has finally been published - certainly a topic of interest to some manufacturers. First, the question is answered in which cases such a study is required. Then, the study design and implementation aspects are discussed. Three informative appendices also address practical implementation issues. The Guidance can be found on the IMDRF homepage:

http://www.imdrf.org/documents/documents.asp

Taiwan

Opening of the Smart Medical Equipment Project Office

The Taiwan Food and Drug Administration has opened its Smart Medical Equipment Project Office. Only in May of this year, the new Medical Device Management Act came into effect, which will ensure the safety, efficiency and quality of medical devices from now on. A large focus from now on will also be on software as a medical device such as machine learning or cloud solutions.

The newly created Smart Medical Equipment Project Office will inform, advise and audit manufacturers, operators and users. There is also an information platform. Unfortunately, the information on the Smart Medical Equipment Project Office is only available in Chinese language:

https://www.fda.gov.tw/TC/siteListContent.aspx?sid=310&id=36842

Cybersecurity in medical devices

A guidance with the exciting topic "Management of Cybersecurity in Medical Devices" is also available in English. Here, the FDA describes the general principles of the security of medical IT systems and presents possibilities for verification and validation.

The point "post-market monitoring" (i.e. post-market surveillance) would certainly have deserved its own guidance. Here it remains with two paragraphs. In addition, it deals with the handling of hazards and incidents.

https://www.fda.gov.tw/ENG/lawContent.aspx?cid=5063&id=3331

Australia

Consultation on legislation of human cell and tissue products

Until July 11, interested parties have the opportunity to participate in a consultation process of the Australian TGA on the remaking of the legislation of human cell and tissue products. The broad-based process bundles six documents that are up for discussion.

Participation is possible via the newly established Consultation Hub-Tool:

https://consultations.health.gov.au/tga/consultations-health-gov-au-tga-remake-tgos-hct-bl/

Declaration of conformity of class I devices

The Australian TGA retains templates for the declaration of conformity of Class I products. A new guidance document explains in detail how to complete them in order to declare conformity. In particular, the document is aimed at manufacturers of Class I non-sterile non-measuring, Class 1 in vitro diagnostic (IVD) medical devices, Class I Medical Device (Export Only) and Class 1 IVD Medical Device (Export Only).

https://www.tga.gov.au/resource/guidance-declaration-conformity

Reclassification

Australia is reforming its regulatory system. Due to safety concerns with individual product classes, changes to the classification system are also imminent. In addition, the reclassification will take into account the latest changes to the European classification system (the MDR sends its regards) and thus ensures international harmonization.

Currently, guidance documents are available for three product classes. In the documents for the reclassification of

- active medical devices for therapy with a diagnostic function,
- active implantable medical devices and
- medical devices that administer medicines or biologicals

examples are given and the transition period is explained. European manufacturers who make their products available on the Australian market should therefore check whether their products comply with the future regulations. The documents and all information on the transition of the Australian regulations can be found here:

https://www.tga.gov.au/medical-devices-reforms-reclassification-certain-medical-devices

Singapore

A few days ago, a consultation procedure was opened by the Medical Device Branch in Singapore. The subject of the procedure is a guidance which is to explain a future UDI system of Singapore. Currently there is no such system in place. The established standards of the IMDRF are to be taken into account in the implementation. The document, which is still open for comments until the end of june, summarizes the planned system in its entirety and describes, among other things, the structure of the UDI, the labeling requirements and the subsequent

registration. European manufacturers can only dream of such guidance!

https://www.hsa.gov.sg/announcements/regulatory-updates/consultation-for-guidance-on-the-medical-device-unique-device-identification-(udi)-system