RA news round-up
CW 31 of 2022

Europe

Legacy Devices under the IVDR

Based on the publications of the MDCG with reference to the IVDR, it is clear that the date of application is no longer too far in the future.

After the guidance on transitional provisions of the IVDR, a document on legacy devices has now appeared. It explains the various requirements that apply to MDD-certified devices using the transitional provisions of the IVDR. Of course, manufacturers of legacy devices should not lose sight of MDCG 2022-6, which deals with significant changes.

The document, which explains, among other things, the requirements for post-market surveillance and vigilance, can be downloaded from the European Commission's site:

https://health.ec.europa.eu/system/files/2022-05/mdcg_2022-8_en.pdf

IVDR and Eudamed

Also, a technical solutions document was released, which will apply until Eudamed is fully functional. When a similar guidance focusing on the MDR was released in May 2021, no one probably thought that a similar document would be needed for the IVDR a good year later.

According to a timeline published by the European Commission in July (https://health.ec.europa.eu/system/files/2022-07/md_eudamed_timeline_en.pdf) Eudamed is expected to be fully functional in the second quarter of 2024.

Of course, the registration requirements for devices and economic operators already apply. However, the new MDCG 2022-12 guidance explains how to provide information about performance studies or incidents.:

https://health.ec.europa.eu/system/files/2022-07/md_mdcg_2022-12_guidance-admpractice_techsol_eudamed_en_0.pdf

Q&A on interfaces between Regulation (EU) 536/2014 and the IVDR

MDCG Guidance 2022-10 describes the interfaces between Regulation (EU) 2017/746 - i.e. the IVDR - and Regulation (EU) 536/2014 on clinical trials on medicinal products for human use. 16 questions have been formulated, which are answered quite extensively.

The document is particularly exciting for research institutions that have so far paid little attention to the requirements of the IVDR. Especially when using in-house IVDs or novel assays, attention should be paid to their compliance.

The document is linked here:

https://health.ec.europa.eu/system/files/2022-05/mdcg_2022-10_en.pdf

International News

USA

Final Document on Post-Market Surveillance

With GUDID, the FDA maintains a database containing the device identifiers of all products that have a UDI. The submission requirements for certain Class I devices have now been relaxed and the corresponding guidance has been adapted.

The requirements for inclusion in the database were not introduced until 2020. However, manufacturers of Class I devices now get 75 more days and do not have to comply with 21 CFR 830.300 until December 08, 2022. For other risk classes, the requirements will apply as previously stated.

The document can be found on the FDA website:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices?utm_medium=email&utm_source=govdelivery