RA news round-up
CW 45 of 2022

Europe

Legacy Devices under IVDR

The In Vitro Diagnostics Regulation has entered into force since May 2022. Not only pays attention our current qtec spotlight to this fact but the MDCG Guidance 2022-15 also deals with the requirements of the IVDR.

In detail, it deals with surveillance activities by the Notified Body for devices made available on the market using the transitional provisions of the IVDR. The final deadline is on May 26th, 2025 (for risk class D devices).

During the transition period, surveillance must of course continue even if a Notified Body certified under the IVDR has not yet been involved by the manufacturer. Guidance 2022-15 describes options for how surveillance activities can be designed by the existing Notified Body (which may not even be seeking IVDR certification).

The Guidance can be found at the following link:

https://health.ec.europa.eu/system/files/2022-09/mdcg_2022-15_en.pdf

Definition „first certification“

The next MDCG Guidance also deals with the IVDR. Article 48(6) requires the involvement of a panel of experts if certain criteria are met. One of the criteria is "the first certification for that type of device". What exactly this means is described in the Guidance 2021-22.

In the first revision, which has been published recently, a paragraph has been corrected and a number of examples have been added. The document can be downloaded here:

https://health.ec.europa.eu/system/files/2022-09/mdcg_2021-22_en.pdf

Information on Authorised Representatives

MDCG Guidance 2022-16 on Authorised Representatives is particularly exciting: the guidance applies equally to MDR and IVDR.

The document summarizes the requirements for Authorised Representatives, references the relevant paragraphs of both regulations and clarifies ambiguous sections.

If you are still looking for an Authorised Representative, please take a look at the website of our qtec EuRep! In the meanwhile, you can find the document of the MDCG here:

https://health.ec.europa.eu/system/files/2022-10/mdcg_202216_en.pdf

International News

USA

Countdown to FDA electronic submission

As announced, 510(k) submissions can soon only be made electronically. The targeted date for all submissions is currently October 1st, 2023. As part of the rollout plan, a new guidance has now been released which describes the exact timeline and technical details.

The electronic submission is supported by the eSTAR template, which guides through and hopefully facilitates the process. This template can already be used voluntarily. There are no exceptions (other than exempt devices) in the new guidance as of October 2023.

The Guidance can be found here:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions?utm_medium=email&utm_source=govdelivery

Further information on the voluntary use of the eSTAR template can be found here:

https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program?utm_medium=email&utm_source=govdelivery

Devices incorporating Machine Learning

The number of medical devices that use machine learning (a form of artificial intelligence) is growing continuously. Moreover, this technology has aroused the general interest of medical devices manufacturers. The FDA has now established a list that includes all devices approved in the USA. Expectedly, the majority of the products listed are currently assigned to the field of radiology. It remains exciting to observe in which areas machine learning will still establish itself. The list is publicly accessible and updated regularly.

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices?utm_medium=email&utm_source=govdelivery