RA news round-up
CW 15 of 2022

Europe

UDI User guide

No, this is not a guidance, but a user guide of the European Commission - beware of confusion. This document explains the registration process in EUDAMED and actually contains more helpful information than some of the official MDCG guidance.

Many questions that have been circulating in online forums or social networks are finally answered and the fear of registering devices in EUDAMED is taken away from economic actors.

https://ec.europa.eu/health/system/files/2022-04/md_eudamed_udi-devices-user-guide_en.pdf

Update on IVDR

Once again, there is an update to the Joint Implementation and Preparedness Plan of the Regulation (EU) 2017/746. However, there is not much new to announce. Currently, six Notified Bodies are available - further accreditations will follow.

Otherwise, legacy devices are discussed (it is complicated) and the status of EUDAMED is explained (still not working). The plan can be found on the page of the European Commission:

https://ec.europa.eu/health/latest-updates/update-joint-implementation-and-preparedness-plan-regulation-eu-2017746-vitro-diagnostic-medical-2022-04-01_en

International News

USA

Draft Guidance on Cybersecurity

There are now regular warnings of new security vulnerabilities that affect virtually every electronic device - from printers to smart toasters to servers that store sensitive data. Unfortunately, vulnerable software can also be found in medical devices.

The FDA has unveiled a new guidance on cybersecurity. This replaces the 2018 Guidance, but as of today, it is only available in draft form. So actually, the new guidance then replaces the only final version from 2014. Of course, a lot has happened in that time.

For example, the final guidance from 2014 is a measly nine pages long. The statements range from trivial to outrageous. The draft

guidance published in 2018 has 24 pages, but still rarely goes beyond the superficial. Practical but not very detailed tips are given and interfaces to the QM system according to 21 CFR 820 are elaborated.

The just published draft has 49 pages and already the table of contents shows that for the creation somewhat more time was taken (one rumors scarcely two years).

In fact, it is now possible to find some really practical information that is in line with the state of the art. For example, the SPDF approach has been newly included. The Secure Product Development Framework covers the complete lifecycle of a medical product and includes a number of different processes aimed at ensuring the safety of software.

The document is currently in draft status and is open for comments until August 07. The document can be found on the following website:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cybersecurity-medical-devices-quality-system-considerations-and-content-premarket-submissions?utm_medium=email&utm_source=govdelivery

Changes on QS Regulation

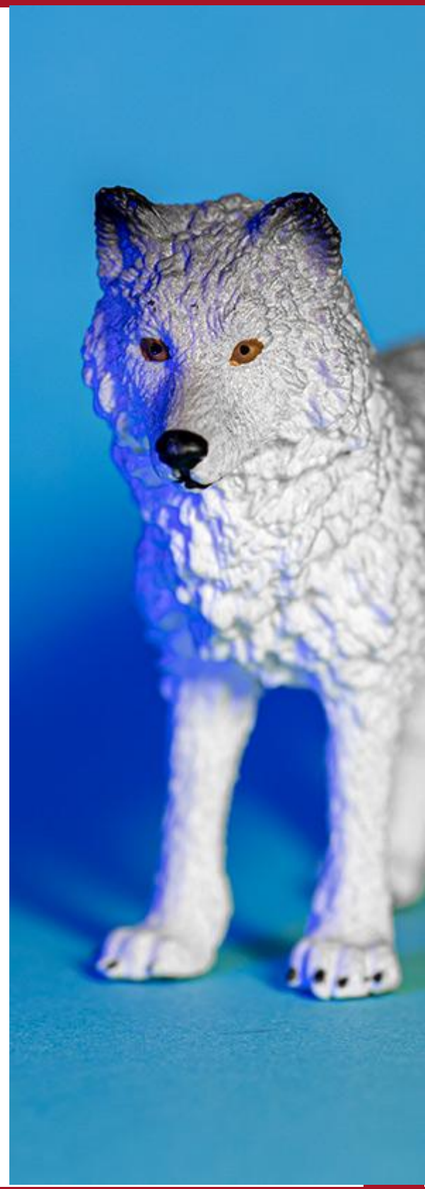
The FDA is finally putting a long-announced plan into action: the 21 CFR 820 will be adapted to international quality standards. In concrete terms, this means that the requirements of ISO 13485:2016 are to be adapted. The result will be called Quality Management System Regulation (QMSR).

The FDA has determined that the requirements of ISO 13485 are quite similar to those of 21 CFR 820. Basically, the standard is to be adopted with a few additional requirements from the currently valid QS Regulation. The change is intended to make it easier for manufacturers to meet both US and international quality requirements in the future and to reduce expenses. In addition, the FDA expects enormous cost savings.

The Proposed Rule is currently in draft status. The document is open for comments until the end of May. The rule can be accessed here:

https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments#print

There is also already a short FAQ about the planned adjustment



https://www.fda.gov/medical-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices/proposed-rule-quality-system-regulation-amendments-frequently-asked-questions

510(k) Submission: Safety and Performance Based Pathway

Two additional Final Guidances on the Safety and Performance Based Pathway of a 510(k) submission have been published. This approach, which is part of the abbreviated 510(k) submission, allows manufacturers to achieve 510(k) clearance by applying predetermined performance criteria.

The two new Guidances now present performance criteria for surgical sutures and orthopedic fracture fixation plates. A total of 7 such documents are available on different product groups, which are all considered "well-understood".

The complete list of all groups with link to the respective performance criteria can be found on the FDA site:

https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway