RA news round-up
CW 51 of 2022

Europe

Common Specifications for medical devices without an intended medical purpose

There are not yet many Common Specifications (CS). Frankly speaking, there are three CS for MDR and IVDR together. The third one has just been published and contains requirements for medical devices without medical use.

Common specifications are rules that describe the implementation of MDR (or IVDR) requirements, and are needed when no harmonized standard exists or one is insufficient to meet the essential safety and performance requirements.

Much of the focus of the new CS for non-medical use devices is on the application of appropriate risk management and the provision of safety-related information. In part, the application areas by which the annexes are divided seem a bit whimsical, but liposuction is also covered by this document:

https://health.ec.europa.eu/latest-updates/commission-implementing-regulation-eu-20222346-1-december-2022-laying-down-common-specifications-2022-12-06_en

Infopack on IVDR Reference Laboratories

The European Commission has published a so-called Infopack on the subject of European Union Reference Laboratories (EURLs). This Infopack, which is more or less a simple PDF, describes the requirements of the IVDR, but also those of the Implementing Regulation (EU) 2022/944 and (EU) 2022/945.

The document is of course only a summary and does not contain any new, binding requirements. Nevertheless, it is useful. It summarizes all information in a comprehensible way, contains further links and is therefore suitable for all stakeholders.

The document or the Infopack can be found here:

https://health.ec.europa.eu/system/files/2022-12/md_candidate-laboratories_infopack_en.pdf

International News

USA

Draft Guidance on Human Factors Information

The FDA has published a draft guidance describing the human factors information that should be included in the marketing submission.

The information is provided to verify that all potential risks posed by the user interface have been identified by the manufacturer and either eliminated or minimized to the greatest extent possible.

Comments on the document can be submitted to the FDA until early March 2023:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions

Cybersecurity Preparedness and Response Playbook

Mitre Corporation is a non-profit organization that works exclusively for the U.S. government. The company maintains a handful of research centers that report directly to various federal agencies and provides information on diverse, technological issues.

In 2018, the Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook was commissioned by the FDA to provide the healthcare sector with a guide to potential cybersecurity attacks. This playbook has now been revised.

From our point of view, this playbook is extremely helpful for healthcare institutions and also manufacturers of medical devices can find helpful input here, for example for the formulation of stakeholder requirements.

https://www.mitre.org/news-insights/publication/medical-device-cybersecurity-regional-incident-preparedness-and-response?utm_medium=email&utm_source=govdelivery

Switzerland

Switzerland to import medical devices with FDA approval

It will probably soon be possible to import products with FDA approval into Switzerland. At least, the Swiss Federal Council was commissioned with a corresponding motion at the end of October. However, the parliament must now first give its approval.

A date for the implementation of the Motion Müller Damian was not given, however. Implementation is probably not to be expected until 2024. With this decision, Switzerland wants to prepare for future disasters and associated shortages.

The motion appeared in the official bulletin of the Swiss parliament:

https://www.parlament.ch/de/ratsbetrieb/amtliches-bulletin/amtliches-bulletin-die-verhandlungen?SubjectId=58905