RA news round-up
CW30

Medical Device Regulation:

The 15th notified body under the MDR was officially designated:

GMED (NB 0459) was approved to perform medical device certification under the MDR 2017/745. The French conformity assessment body offers a range of certification for example for

- Active implantable devices, e.g. for delivering drugs or for stimulation/inhibition/monitoring
- Active non-implantable devices, e.g. for imaging, monitoring and/or diagnosis or for therapeutic purposes
- Non-active implants, e.g. non-active dental implants and dental materials, as well as for
- Non-active non-implantable devices.

https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.html&ntf_id=307572&version_no=10

MDCG updates

New guidance document (MDCG 2020-13) *'Clinical evaluation assessment report template'* was released by the Medical Devices Coordination Group. This guidance is addressed to notified bodies to help them to clearly document the conclusions of its assessment of the clinical evidence presented by the manufacturer in the clinical evaluation report (CER). But it can also help manufacturers to better understand what the notified body requires and how they assess this highly complex deliverable. A must read for all clinical affairs professionals!

https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_clinical_evaluationtemplate_en.pdf

Corona related news (excerpt):

The European Commission updated the Q&A guidance document *'Conformity assessment procedures for protective equipment'*. It gives manufacturers of protective equipment an overview of regulatory frameworks and requirements.

https://ec.europa.eu/docsroom/documents/42311/attachments/1/translations/en/renditions/native

International news:

USA

According to the new guidance *'Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking'*, the FDA extends the deadlines for applying the UDI on low-risk medical devices until September 24th, 2022. Reasons for this extension are the COVID-19 pandemic and the challenges of the implementation of the UDI for class II and III devices.

https://www.fda.gov/media/110564/download

Australia

The TGA published a document on the *'Actual and potential harm caused by medical software'*. The purpose of this *rapid literature review of safety and performance issues* is to help to verify the safety, accuracy or effectiveness of medical software in times of digital health, smartphone apps and more frequent remote consultations and diagnosis.

https://www.tga.gov.au/resource/actual-and-potential-harm-caused-medical-software

Malaysia

The Malaysian Medical Device Authority (MDA) released a new guidance documents relating to post-market surveillance. There are now documents about:

- Medical Device Recall (MDA/GD/0015)
- Mandatory Problem Reporting (MDA/GD/0014)
- Field Corrective Action (MDA/GD/0013)
- Complaint Handling (MDA/GD/0011)

https://portal.mda.gov.my/doc-list/guidance-document.html

Taiwan

New guidance on in vitro companion diagnostic devices was issued *'Technical Standards of Companion In Vitro Diagnostic Medical Devices':*

https://www.fda.gov.tw/TC/siteListContent.aspx?sid=310&id=33957