RA news round-up
CW 35 of 2021

Europe

First certification of class D IVDs

In the latest Guidance 2021-22, the MDCG discusses the meaning of "first certification" of class D IVDs. The term originates from Article 48(6) of the IVDR. There, it is required that in the absence of Common Specifications and at the same time first certification of a Class D IVD, the Notified Body consults a panel of experts.

The new Guidance now explains exactly what is meant by the article and how a Notified Body has to proceed in such a case. The first certification of a medical device is, of course, largely related to its intended purpose. A new intended purpose also means a new product.

The document can be found at the following link:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-22_en.pdf

International News

USA

New Fiscal year

In the USA, a new fiscal year begins for the FDA on October 01. For manufacturers, this also means increased expenses for approval in the US market. As every year, the fee catalog is also adjusted. The price for a 510(k) premarket notification, for example, has risen from USD 11,594 to USD 12,432.

https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa

Australia

Webinar on global UDI system

In mid-August, the TGA released the third part of a webinar series. Together with Dennis Black (Becton Dickinson), Michelle Van Wijk talks about the possibility of a global UDI system and its advantages.

With the MDR, a unique product identifier was also introduced in Europe. Of course, it would be desirable to be able to use this identifier worldwide. Whether this can be implemented in the foreseeable future remains to be seen.

The presentation can be downloaded as a PDF or viewed directly on YouTube.

https://www.tga.gov.au/webinar-presentation-challenges-and-considerations-journey-global-udi-system-17-august-2021-0

Personalized medical devices

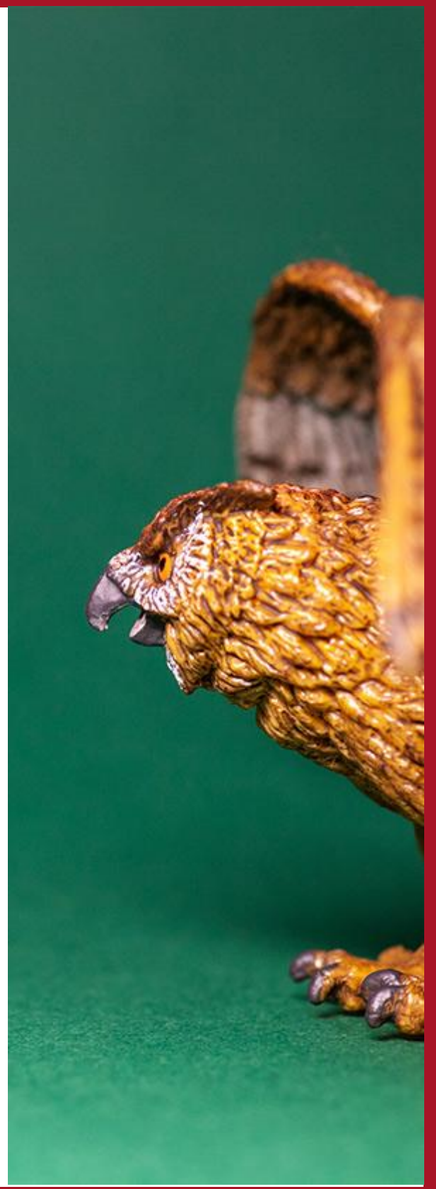
Of course, there are further changes to the regulatory framework in Australia as part of the medical device reforms. This time in the scope: personalized medical devices. The changes are not new, but now there is also a guidance for this product class. It summarizes the latest changes and lists some examples for the different categories.

The document can be found via another link on the following page:

https://www.tga.gov.au/medical-devices-reforms-personalised-medical-devices

Guidance on Qualification of Software

Is my medical device even a medical device as defined by the applicable regulations? Manufacturers know this question. Especially in the case of software products, the question is often not quite so easy to answer. The TGA has therefore prepared a guidance document containing examples of regulated and unregulated software.



For software manufacturers seeking registration in Australia, this guidance is worth its weight in gold. For all others, it is at least worth taking a look to discover possible stumbling blocks in the declaration of conformity in the home market.

https://www.tga.gov.au/resource/examples-regulated-and-unregulated-software-excluded-software-based-medical-devices

India

Device classification

A lot has happened in India since the last issue of the RA news round-up: 13 more lists for classifying individual product groups have been put online. As already described, an explicit Intended Use is provided for each device, against which comparisons can be made. Practical: the lists are no longer merely scanned, but even searchable. They can be found on the homepage of the Central Drugs Standard Control Organization under Public Notes.

https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/

Taiwan

Artificial Intelligence/Machine Learning based Software as a Medical Device

It's time to open Google Translate again: the Taiwan Food and Drug Administration has issued a new guideline for the "Inspection and Registration of Artificial Intelligence/Machine Learning based Software as a Medical Device". The document makes use of recent publications from other authorities and Guidances from IMDRF. The eight pages from Taiwan certainly do not do justice to such a complex topic.

https://www.fda.gov.tw/TC/siteListContent.aspx?sid=310&id=37447