RA news round-up
CW42

Europe

The 5th **Device Specific Vigilance Guidance** was published which provides guidance for manufacturers of **Insulin Infusion Pumps and Integrated meter systems**. It contains specific scenarios that should be considered when determining if an incident is reportable. The scenarios are divided in the categories:

- Report as individual incidents
- Can be included in periodic summary reports (PSR)
- Report at the time the adverse trend is identified

https://ec.europa.eu/health/sites/health/files/md_sector/docs/dsvg_05_en.pdf

International news

Australia:

The TGA announced changes to the **ARTG inclusion process for non-measuring, non-sterile Class I** medical devices. The changes include new deliverable for the application and a non-mandatory audits of Class I applications where there are concerns that the device does comply with the legal requirements for Class I medical devices.

https://www.tga.gov.au/changes-artg-inclusion-process-non-measuring-non-sterile-class-i-medical-devices-0

China:

In 2019 the Chinese National Medical Products Administration (NMPA) published requirements for the **implementation of the Unique Device Identification (UDI)** for medical devices. At the moment there is still a pilot project running which delayed the implementation time to January 1st, 2021. From 2021, the first batch of high-risk Class 3 medical devices will need to carry an UDI and the manufacturer has to carry out product coding, data upload and maintenance in accordance with the "Medical Device Unique Identification System Rules".

https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200930165228171.html

Russia:

The Russian government passed a resolution which updated the criteria for medical devices that are **exempted from registration** in Russia. The criteria were harmonized with the Eurasian legislation and includes e.g. custom-made medical devices.

http://publication.pravo.gov.ru/Document/View/0001202009030024

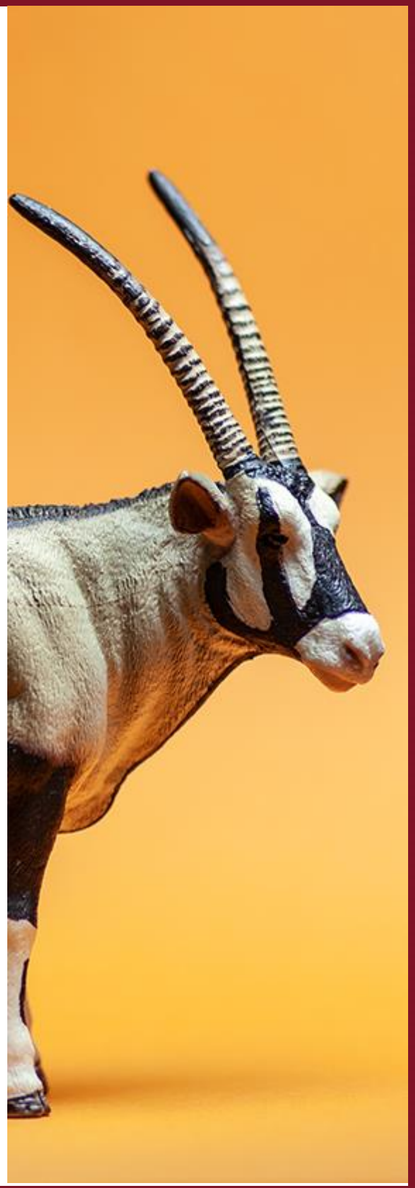
Russian **registration certificates** for medical devices that were **issued before 2013** and have unlimited validity need to be updated until the end of this year. Those certificates were issued under the old medical device regulation system and need an update in accordance a specific administrative replacement procedure.

https://roszdravnadzor.gov.ru/news/23399

South Korea:

South Korea's Ministry of Food and Drug Safety published several new and updated guidance documents:

- Medical Respiratory Protective Equipment Licensing and Review Guidelines (Handbook-1048-01)
- Guidelines for Major Modifications in Innovative Medical Device Software (Handbook-1047-01)
- Guidelines for the Step-by-Step Screening of Innovative Medical Devices (Handbook-1046-01)
- Guidelines for the Approval/Examination of Digital Treatment Devices (Handbook-1045-01)
- Guidelines for reporting abnormal cases of medical devices (Complainant's Guide) (Handbook-0858-02)
- Medical Device Re-evaluation Guidelines (Handbook-0100-002) (updated)
- Complainant's Guide to Report Minor Changes to Medical Devices (Link)



USA:

The FDA published a proposed rule regarding the **intended use** of medical devices. It contains the amendment of the respective regulations that everyone can comment on until October 23th. The regulations

- describe the types of evidence that help determining whether a product is intended for use as a device
- contain FDA's implementing regulations, whether an approved or cleared medical product is intended for a new use.

Previous efforts trying to amend the existing rules from 2015 to 2017 never became effective due to concerns from the industry and other stakeholders regarding the off-label use. Therefore, we recommend everyone to analyze the impact of the amendment to your products and comment on the rule if any concerns appear. Especially pay attention to any off-label use that could be considered by the FDA to be part of the intended use of the product.