RA news round-up
CW32

Europe:

The Compliance and Enforcement Group (COEN) published a guidance for the *"Instructions For Use for reusable and re-sterilisable Medical Devices"* containing a checklist for the IFU base on the EN ISO 17664 and checklist for the assessment of the validation of reprocessing procedures based on the EN ISO 14937.

https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_checklists-iso-17664-14937_en.pdf

The Scientific Committee on Health, Environmental and Emerging Risks SCHEER released guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties.

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_015.pdf

United Kingdom:

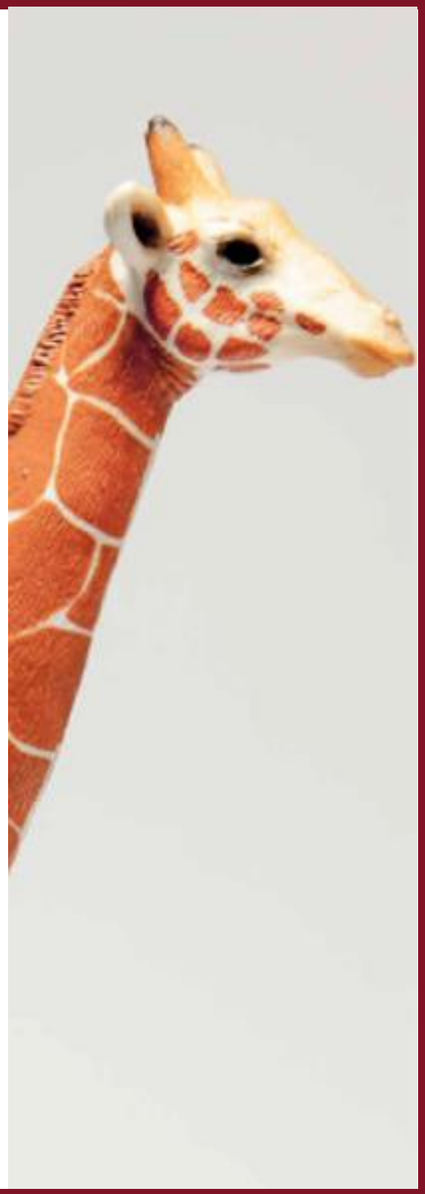
The British MHRA gives a statement on certificates being issued by certification bodies headed "certificates of compliance" or "Attestation of Compliance". They are aware that these certificates are not evidence that the manufacturer has met the regulatory requirements and should not be taken as proof of such.

https://www.gov.uk/government/news/medical-device-certificates-of-compliance-attestation-of-conformity-have-no-legal-standing-under-mdr?utm_source=c2f30400-cdfe-4a71-b529-d9195ea45ddc&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

Switzerland:

The Swiss Federal Council approved the new Medical Device Ordinance (MedDO) and the new Ordinance on Clinical Trials for Medical Devices (ClinO-MD). The new version of the MedDO integrates the MDR into the national law and thereby it keeps Switzerland in the EU market for medical devices.

https://www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html



Corona related news (excerpt):

The European Commission released an analysis of the *"Availability and capacity of notified bodies to carry out conformity assessments for COVID-19 related medical devices and in vitro diagnostic medical devices"*. This document is based on a survey conducted with notified bodies in charge of the certification of COVID-19-related medical devices and in vitro diagnostic medical devices.

https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_survey-conformity-assess-covid-19.pdf

International news:

USA:

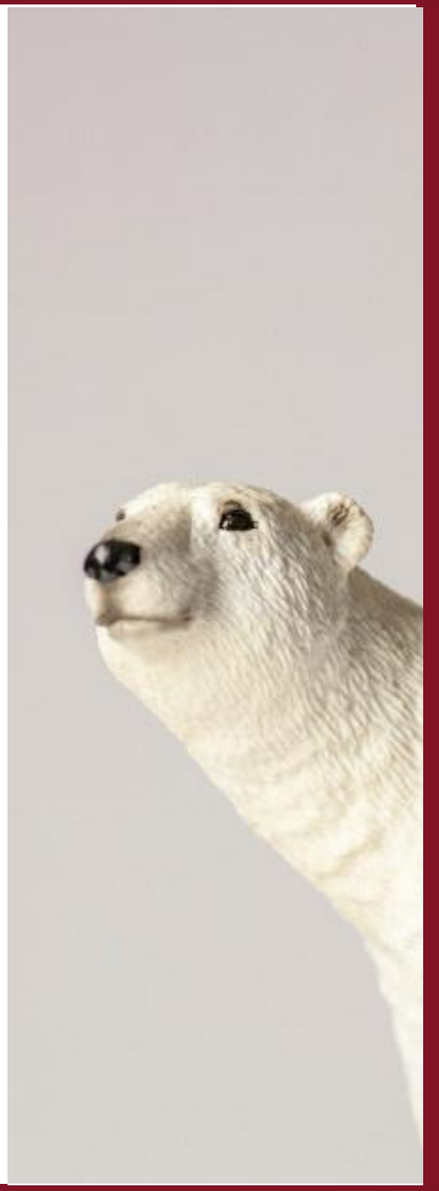
The FDA published a new guidance document on *"Multiple Function Device Products: Policy and Considerations"*. Products with at least one device function and at least one "other function" are referred to in this guidance as "multiple function device products." The purpose of this guidance is to identify the principles, premarket review practices, and policies for FDA's regulatory assessment of such products and to provide examples of the application of these policies.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations

The FDA added new standards to their database of Recognized Consensus Standards, e.g. in the following fields:

- Biocompatibility (e.g. ISO 10993-9 Third edition 2019-11; ISO 10993-18 Second edition 2020-01)
- General I (QS/RM) (e.g. IEC 62366-1:2015 and IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION)
- Sterility (e.g. ISO 17664: 17664 Second edition 2017-10)

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/results.cfm?start_search=1&sortcolumn=pdd&productcode=&category=&title=&organization=&referencenumber=&regulationnumber=&recognitionnumber=&effectivedatefrom=&effectivedateto=&PAGENUM=500



The FDA also added more categories of Class II medical devices that are exempt from 510(k) premarket notification. Some of the categories have limitations to the exemption though. The categories are:

- Accessory, Assisted Reproduction
- Media, Reproductive
- Instruments Designed for Press-Fit Osteochondral implants
- Interactive Rehabilitation Exercise Devices
- Massager, Therapeutic, to Internally Massage Trigger Points in the Pelvic Floor Musculature

https://www.govinfo.gov/content/pkg/FR-2020-07-22/pdf/2020-15256.pdf

Last but not least the FDA announced a their new user fees payable starting from October 1st. Medical device companies pay fees e.g. for the registration of their establishments or for listing of their devices when they submit an application or a notification to market a new medical device in the USA.

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

Australia:

The Australian TGA provides information about 3-D printing (additive manufacturing) of medical devices to assist manufacturers with addressing the relevant risks and meeting the Australian regulatory requirements for medical devices.

https://www.tga.gov.au/3-d-printing-additive-manufacturing-medical-devices

Some delays to the commencement of certain medical device regulatory changes were announced by the TGA, e.g. for the reclassification of certain devices, for medical device software, personalised medical devices (including 3D printed devices) and systems or procedure packs.

https://www.tga.gov.au/delays-commencement-certain-medical-device-regulatory-changes