RA news round-up
CW48

Europe

One less Notified Body for the IVDD

The Turkish Notified Body TSE is no longer designated for the In-Vitro Diagnostic Device Directive 98/79/EC since mid of October. Until now, neither the European Commission nor TSE provided reasons for the suspension of the designation.

MDCG - long awaited IVDR classification guidance

The Medical Device Coordination group recently published the *"Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746"*.

In this guidance the underlaying definitions and principles of the classification scheme are explained, and each classification rule is analyzed and rationalized. A must read for all manufacturers of IVDs.

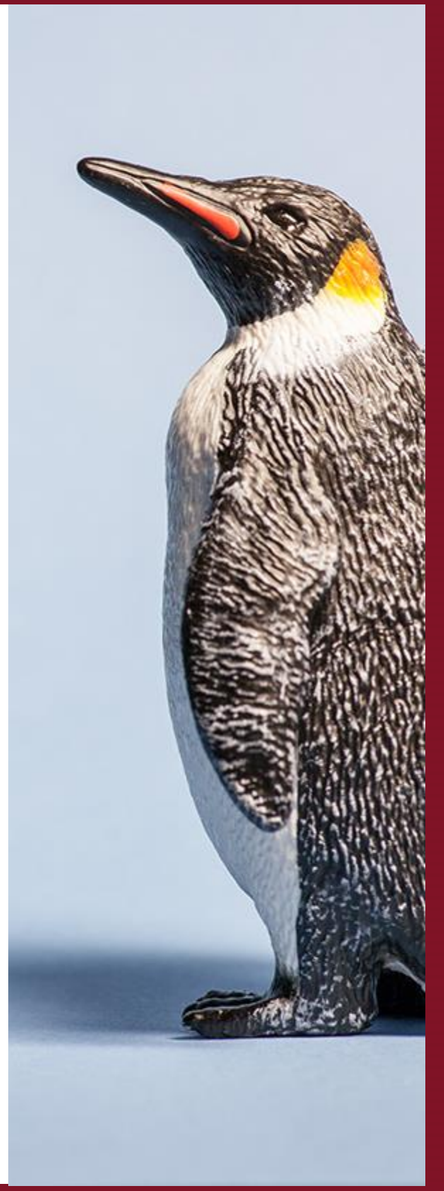
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_guidance_classification_ivd-md_en.pdf

U.S. FDA - Electromagnetic Compatibility

The FDA published a draft guidance on the electromagnetic compatibility of medical devices. The guidance addresses the contents that are required for premarket submissions. Although the IEC 60601-1-2 was a recognized consensus standard before, the new draft guidance provides more details towards other emitting devices and their possible ranges of disturbance and thus might alter the testing scope relate to EMC testing.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices?utm_medium=email&utm_source=govdelivery

Microneedling devices

Among other new guidance's, a new guidance for *"Regulatory Considerations for Microneedling Products"* was published. It helps to understand when devices using needles are considered medical device and would hence be required to be marketed as such.
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-microneedling-products?utm_medium=email&utm_source=govdelivery



International news

Hong Kong

The department of health- Medical Device Division has issued two FAQ brochures on Medical devices and In-Vitro Diagnostic devices. The two FAQ documents briefly describe which products are considered medical devices and the classification of devices.

https://www.mdd.gov.hk/english/emp/emp_gp/files/what_is_medical_device.pdf

https://www.mdd.gov.hk/english/emp/emp_gp/files/md_infographics.pdf

Australia

The Therapeutic Goods Administration (TGA) has changed the name of the Clinical Trial Exemption (CTX) scheme to the Clinical Trial Approval (CTA) scheme.

The name change from CTX to CTA more accurately reflects the nature of the scheme under the Therapeutic Goods Act 1989, which involves sponsors applying for the TGA's approval to supply unapproved therapeutic goods in Australia via a clinical trial despite the therapeutic goods are not being entered in the Australian Register of Therapeutic Goods (ARTG). The scheme's previous name of CTX underscored the exemption given by the TGA to a sponsor from entering their therapeutic good in the ARTG before conducting a clinical trial.

https://www.tga.gov.au/clinical-trial-exemption-ctx-scheme-renamed-clinical-trial-approval-cta-scheme