RA news round-up
CW28

MDR:

The European Commission published a declaration of interest (DOI) form which is the Annex II of the *call for expression of interest for expert panels on medical devices and in vitro diagnostic medical devices (2019/C 323/05)*. Applicants for the expert panels must submit a DOI form indicating any interest that may compromise their independence.

https://ec.europa.eu/docsroom/documents/42201?locale=de

Corona related news (excerpt):

USA:

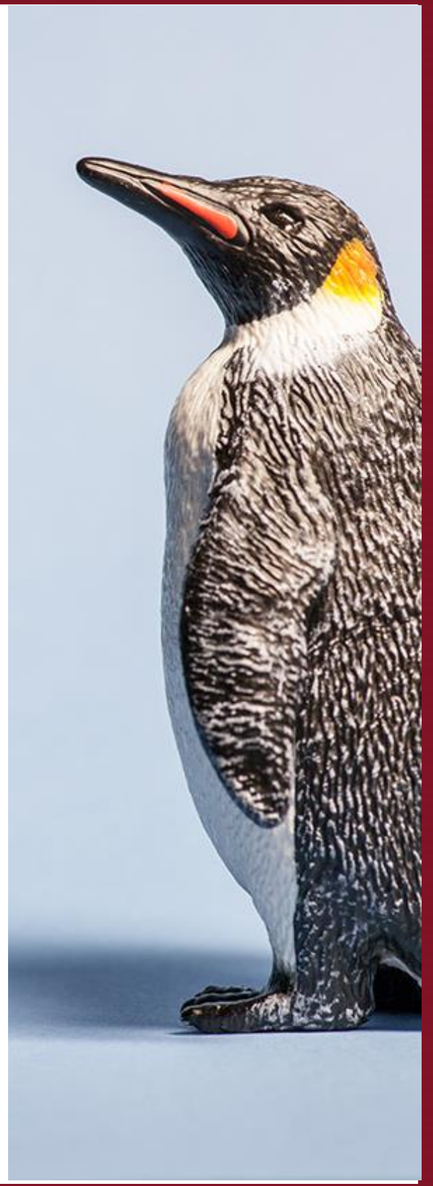
The FDA published the guidance document *"Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers"*. This guidance is issued to provide answers to frequently asked questions from the industry related to device development for the duration of the COVID-19 public health emergency.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/effects-covid-19-public-health-emergency-formal-meetings-and-user-fee-applications-medical-devices

Singapore:

New guidance on medical devices for decontamination of single use respirators during the COVID-19 situation was released by the HSA. Due to the increasing demand for respirators and the global supply constraints, HSA facilitates the access for medical devices intended for decontaminating used respirators via the provisional authorization pathway. This guidance contains the key regulatory requirements for the provisional authorization.

https://www.hsa.gov.sg/announcements/regulatory-updates/guidance-on-medical-devices-for-decontamination-of-single-use-respirators-during-the-covid-19-(coronavirus-disease-2019)-situation



International news:

USA:

The new guidance document *"Review and Update of Device Establishment Inspection Processes and Standards"* was released by the FDA. This guidance describes how FDA will implement uniform inspection processes and standards. The guidance also describes standardized methods of communication during the inspection process.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/review-and-update-device-establishment-inspection-processes-and-standards

Russia:

1. The Russian Federal Service for Surveillance in Healthcare *Roszdravnadzor* updated the guidelines on the registration of software as a medical device. The document contains amongst other things criteria on how to identify software considered as a medical device, a classification algorithm, requirements on technical documentation, as well as an algorithm for technical testing and clinical trials.

https://roszdravnadzor.ru/i/upload/images/2020/6/10/1591779046.41107-1-10512.pdf

2. The Russian President Vladimir Putin gave the order to draft a new law for batch notification for medical device importers in Russia. Manufacturers and importers will have to notify Roszdravnadzor of every series and batch of medical devices imported and circulated in Russia.

http://kremlin.ru/acts/assignments/orders/63565?fbclid=IwAR19DWpXWOfprAE_20wmYhCapsQ-ZxBSn7ekFQ4HXBYiegwblerDZ7bZsmg

Malaysia:

The MDA offers a webinar on the new *medical device regulations under act 737: Advertisement and post market requirements* in august this year. The primary goal of the webinar is to enhance the understanding of the new regulation. There is a fee for the webinar and participants are limited.

https://www.mda.gov.my/announcement/561-medical-device-webinar-2020-new-medical-device-regulations-under-act-737-advertisement-and-post-market-requirements-august-17,-2020.html