NEWSLETTER September 2019

Brussels, 18.06.2019

Phthalates in medical devices – do your Benefit-Risk Assessment properly

"These Guidelines describe the methodology on how to perform a Benefit-Risk Assessment (BRA) for the justification of the presence of CMR 1A or 1B and/or ED phthalates (CMR/ED phthalates) in medical devices at percentages above 0.1% by weight (w/w). They also describe the evaluation of possible alternatives for these phthalates used in medical devices, including alternative materials, designs or medical treatments."

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

Brussels, 26.06.2019

Request to CEN and Cenelec to revise the existing harmonised standards and to draft new standards in support of Regulation (EU) 2017/745 for medical devices

"Draft standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (IVDR)."

Read more:
https://ec.europa.eu/docsroom/documents/36104/attachments/1/translations/en/renditions/pdf

Brussels, 29.06.2019

Prepare for the of legal repercussions of Brexit

"Withdrawal of the United Kingdom and EU rules in the field of good laboratory practice (GLP)."

Read more:
https://ec.europa.eu/info/sites/info/files/good-laboratory-practice_en.pdf

Brussels, 01.07.2019

Blueprint of an implant card (IC) - what you need to know

"This document provides guidance for Member States, concerned industry and other stakeholders on a blueprint of an implant card (IC) required by the MDR. It describes the intended use, content and information to be provided by the manufacturer."

Read more:
https://ec.europa.eu/docsroom/documents/36167/attachments/1/translations/en/renditions/pdf

Brussels, 01.07.2019

The PRRC needed in you company and how to select them

"*Guidance on Article 15 of the MDR and IVDR regarding a 'person responsible for regulatory compliance' (PRRC)."*

Read more:
https://ec.europa.eu/docsroom/documents/36166/attachments/1/translations/en/renditions/native

Brussels, 10.07.2019

Guidance for the Medical Device Vigilance System – check out the EU commission website rather the Annexes of the MEDDEV 2.12-1 rev. 8, 2013.

"This document provides additional guidance in relation to the Medical Device Vigilance System that is currently in operation under the Medical Devices Directives. The guidance should complement and be used in conjunction with MEDDEV 2.12-1 rev. 8, 2013."

Read more:
https://ec.europa.eu/docsroom/documents/36292/attachments/1/translations/en/renditions/native

21.06.2019

ISO 10993-18:2019 under development and expectet in autumn

"The Formal Vote of the Final Draft of ISO 10993-18 (ISO/FDIS 10993-18:2019, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process) has been positively concluded."

11.09.2019

Rules for the designation of expert panels in the field of medical devices have been established

"*The Commission has identified areas in which the provision of consistent scientific, technical and/or clinical advice is needed. Expert panels should be designated in those areas and the principles of their organisation and operation should be defined, including the procedures for the selection and appointment of their members, as to ensure that they work according to the highest scientific competence, impartiality, independence and transparency.*"

Read more: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1396&from=EN

Agosto 2019

IMQ is the 4th notified body designated under the European Union Medical Device Regulation

IMQ (Istituto italiano del marchio di qualità) is the 4th notified body under the MDR. IMQ joints Germany's Dekra and TÜV SÜD, as well as the United Kingdom's BSI.

03.09.2019

BSI certifies 1st medical device under MDR

Notified body BSI has issued a conformity certificate to a Novartis inhaler under the MDR, the first of its kind!

Berlin 19.09.2019

BIOTRONIK obtains 1st MDR Certification for a Class III Medical Device

BIOTRONIK announced that it is the world's first manufacturer to receive MDR certification for a Class III medical device.

03.09.2019

Further guidance on the regulation of medical devices if there's no Brexit deal

"In a no deal scenario, the UK's current participation in the European regulatory network for medical devices would end, and the MHRA would take on the responsibilities for the UK market currently undertaken through the EU system."

Read more: https://www.gov.uk/guidance/regulating-medical-devices-in-the-event-of-a-no-deal-scenario

We will be there, come and find us!

26 september 2019
Dublin (Ireland)
Partner/attendance, Oral presentation by A. Conto "Microplastics: a new challenge for environmental protection"

11 october 2019, h 9.00 - 13.00
Milan (Italy)
Two persons, workshop "Regolamento biocidi EU 528/212: dall'approvazione del principio attivo all'autorizzazione del prodotto biocida. Come affrontare le criticità tecniche e finanziarie per le PMI"

28-29 october 2019
Bruxelles (Belgium)
Attendance, two persons

12-13 november 2019
Frankfurt Am Main (Germany)
Oral presentation by A. Conto, "Environmental impact of active pharmaceutical ingredients (API) and their ED properties

20-22 january 2020
Sao Paulo (Brazil)
Exhibition booth with three persons