REGULATORY NEWSLETTER

WWW.APOTECHCONSULTING.COM

Apotech consulting

April 2024

Top News

FDA Publish Cybersecurity Draft Guidance

EC Publish Notified Bodies Survey

EU Publish Clinical Investigations Guidance

Whats New?

MDCG Publish Clinical Investigation Plan Guidance

The MDCG has published "MDCG 2024-3 Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices" This guidance document has been written to support sponsors developing their Clinical Investigation Plan (CIP) by describing in greater detail what type of information is expected in the respective CIP sections, to pre-empt questions from the competent authorities during the assessment of the clinical investigation application. Moreover, a CIP with the appropriate content will be instrumental in the conduct of the clinical investigation.

https://health.ec.europa.eu/document/download/690de85a-ac17-45ea-bb32-7839540c25c4_en?filename=mdcg_2024-3_en_0.pdf

FDA Publish Cybersecurity Draft Guidance

FDA has developed this draft guidance to propose select updates to the FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions." The new section identifies the cybersecurity information FDA considers to generally be necessary to support obligations under section 524B of the FD&C Act. FDA provides recommendations regarding premarket submissions for changes to cyber devices that had been previously authorized by FDA through 510(k), De Novo, HDE, PDP, and PMA submission pathways, and that require premarket submission.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-premarket-cybersecurity-guidance-section-524b-fdc-act

EC Publish Notified Bodies Survey

The European Commission has published the "Notified Bodies Survey on certifications and applications (MDR/IVDR) survey results of the 6th NB survey with data status 31 October 2023" with some figures adjusted from the previous release.

The aim of the study is to support monitoring and analysing the availability of medical devices on the EU market in the context of the implementation of medical devices and in vitro diagnostic devices regulations from the perspectives of key stakeholders. See the full results below:

https://health.ec.europa.eu/latest-updates/updated-document-notified-bodies-survey-certifications-and-applications-mdrivdr-survey-results-data-2023-07-25_en

FDA Publish Draft Guidance on Thermal Effects of Medical Devices

The FDA has published the Draft guidance "Evaluation of Thermal Effects of Medical Devices that Produce Tissue Heating and/or Cooling" provides the FDA's recommendations on testing to assess thermal effects of medical devices and relevant information that should be provided in a premarket submission (i.e., premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, premarket notification (510(k)) submissions, investigational device exemption (IDE) applications and De Novo requests).

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/evaluation-thermal-effects-medical-devices-produce-tissue-heating-andor-cooling

EU MDR/IVDR Harmonised Standards

The European Commission has published two Implementing Decisions regarding medical device harmonised standards.

"Implementing Decision (EU) 2024/815 of 6 March 2024 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for medical gloves for single use, biological evaluation of medical devices, sterilization of health care products, packaging for terminally sterilized medical devices and processing of health care products."

"Implementing Decision (EU) 2024/817 of 6 March 2024 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products and packaging for terminally sterilised medical devices."

Link Decision (EU) 2024/815: https://lnkd.in/eiARD-a2
Link Decision (EU) 2024/817: https://lnkd.in/eGe2piuU

Update to MDR/IVDR Language Requirements

The EC has released the first update to the MDR Language Requirements. The first revision highlights the decision by France to allow English for documents for conformity assessment (for certain parts). See the revision below:

https://health.ec.europa.eu/document/download/aa9760e3-c864-4173-8b16-d790dac66d74_en?filename=md_sector_lang-req-table-mdr.pdf%20o%20IVDR:%20https://health.ec.europa.eu/document/download/1e312d8f-8b34-45da-a5fa-1918ba618aca_en?filename=md_sector_lang-req-table-ivdr.pdf

EC Holds Public Consultation on Phthalates

The EC launched a public consultation on the first update of SCHEER guidelines on the benefit-risk assessment of phthalates, in medical devices specified in the mandate, which have one or more of the following properties: carcinogenic, mutagenic, toxic to reproduction (CMR) or endocrine-disrupting (ED). These are an update of the SCHEER Guidelines from 2019. The consultation deadline is 28 April 2024- please find the link below:

https://health.ec.europa.eu/consultations/scheer-public-consultation-preliminary-update-scheer-guidelines-benefit-risk-assessment-presence_en

Team Notified Body

Team NB has scheduled another MDR training session for Monday, 29 April 2024, to review the MDR requirements related to Technical Documentation and share notified bodies insights.

https://www.team-nb.org/fifth-session-mdr-technical-documentation-training-for-manufacturers/

Global Regulatory Updates

Sweden announces RISE Medical as a designated Notified Body under MDR.

Türkiye provides strong reminder on MDR transition period to different parties.

FDA renews proposed ban on electrical stimulation devices.

Australia releases document for sponsors who undertake recall and non-recall.

Saudi Arabia releases document to comply with the SFDA.

Brazil extends the validity of the MDSAP GMP Certificate to four years.

India announces new Online System for PSURs submissions.

Malaysia announces approval of applications in 14-21 working days.

China organises and formulates four registration review guidelines.

MHRA Advice on Electrical Aspects for Clinical Investigations

The MHRA has released 'Electrical guidance for clinical investigations', a document which aims to provide basic supporting explanatory advice for devices that are electrically powered. See the document below:

https://assets.publishing.service.gov.uk/media/65fb0d66aa9b76001dfbdc28/MHRA_Electrical_Guidance_for_Clinical_Investigations_Modified_12_Feb.pdf

Upcoming Conferences

Med-Tech Innovation Expo
5 June - 6 June 2024 Birmingham, UK

Med-Tech Conference
15 October - 17 October 2024 Toronto, Canada

American Medical Device (AMD) Summit
30 September - 1st October 2024 Chicago, USA

Medica 2024
11 November - 14 November 2024 Düsseldorf, Germany

MedTech Forum
22 May - 24 May 2024 Vienna, Austria

RAPS Euro Convergence
6 May- 8 May 2024 Berlin, Germany

MedTechLIVE
18 June - 20 June 2024 Stuttgart, Germany

Please reach out to us at contact@apotechconsulting.com to learn more about the impact of these updates!