REGULATORY NEWSLETTER

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Top News

Team AB Announced

EU AI Act Final Draft Available to Browse

MHRA Reveal Selected IDAP Pilot Technologies

EC Endorses New Measures to Help Prevent Medical Device Shortages

Whats New?

Formation of Team Approved Body in the UK

The UK Association for Medical Device Approved Bodies (Team-AB) has launched with backing from 11 medical device certification bodies ranging from BSI Assurance to TUV Rheinland and TÜV SÜD. The new industry body aims to represents the UK Approved Bodies for medical devices and IVDs in their dealings with associated stakeholders. Key stakeholders include the MHRA, other UK Government departments, the European Commission, industry associations, or the media. The Team-AB forum permits the sharing of experience, co-ordination of practice and discussion on aspects of the medical device regulation and conformity assessment between member certification bodies. See their statement on LinkedIn!

European Union's long-awaited Artificial Intelligence Act (AI Act)

On 21 February 2024 the European Artificial Intelligence Office was launched within the Commission, falling under the Directorate-General for Communication Networks, Content and Technology to support the implementing of the AI Act, especially for general-purpose AI. The EU's 27 member states have unanimously endorsed the AI Act, affirming the political agreement reached in December. With the publication of the agreed text (final draft) of the AI Act now available to browse below:

https://artificialintelligenceact.eu/the-act/

MHRA Reveals Eight Technologies Selected by IDAP Partners Selected to Receive Tailored Regulatory and Access Support.

The Innovative Devices Access Pathway (IDAP) pilot is an initiative to bring new medical technologies to the National Health Service (NHS) to help with medical needs that are currently unmet. The MHRA have recently released the eight selected technologies. The pilot phase of the development of a new pathway supporting innovative technologies to address unmet clinical needs in the UK has entered the next phase. See the full applicant details at

https://www.gov.uk/government/publications/the-innovative-devices-access-pathway-idap/the-innovative-devices-access-pathway-idap-pilot-phase#the-eight-selected-innovative-medical-devices

FDA Reminds Medical Device Manufacturers to Scrutinize Third-Party-Generated Data

The U.S. Food and Drug Administration (FDA) has released a letter to industry to remind sponsors of device studies and manufacturers of devices ("device firms") to carefully evaluate the third parties they engage to conduct performance testing and to independently verify all testing results before submitting to the FDA. It is the responsibility of device firms to qualify third parties that generate data and to ensure that all information submitted to the FDA is truthful and accurate. To protect patients and healthcare providers and ensure that U.S. patients have access to safe, effective, and high-quality medical devices, the FDA is pursuing various actions to identify and confront data integrity violations including the Bioresearch Monitoring Program, a unified research compliance hub for the FDA:

https://www.fda.gov/medical-devices/industry-medical-devices/fraudulent-and-unreliable-laboratory-testing-data-premarket-submissions-fda-reminds-medical-device?utm_medium=email&utm_source=govdelivery

MDCG has published "Procedures for the updates of the European Medical Device Nomenclature"

The Medical Device Coordination Group (MDCG) has published "MDCG 2024-2 Procedures for the updates of the European Medical Device Nomenclature". This document lays out the procedures for the annual revision as well as the procedure for ad-hoc requests of EMDN codes requiring an expedited review. See the guidance below:

https://health.ec.europa.eu/document/download/de470384-e8be-45e7-a334-226757f8816d_en?filename=mdcg_2024-2_en.pdf

Swissmedic Announce Swissdamed Database Delay

Swissdamed – the Swiss Database on Medical Devices – is a Swissmedic IT system that makes it possible to apply the Swiss regulations on medical devices and in vitro diagnostic medical devices. Development of the first ACT module has been completed in functional terms. Work on the UDI module is underway. Development of this new IT infrastructure, together with the associated transfer of swissdamed, has resulted in the "going-live" date being deferred to the 2nd half of 2024.

https://www.swissmedic.ch/swissmedic/en/home/medical-devices/medizinprodukte-datenbank/swissdamed-ueberblick.html

TGA and Health Canada agreement on GMP Inspections

The Therapeutic Goods Administration (TGA) and Health Canada have signed a Memorandum of Understanding (MoU) to further increase collaboration and reliance on Good Manufacturing Practice (GMP) inspections conducted in countries outside each other's borders (referred to as extra-jurisdictional inspections). This agreement builds on the existing Mutual Recognition Agreement that entered into force on 1 January 2006 for GMP inspections performed within each other's jurisdictions. From 1 March 2024, sponsors providing GMP evidence from Health Canada inspections in third countries as part of certain GMP Clearance applications will, require less documentary evidence, not be charged compliance verification fees, undergo abbreviated GMP Clearance assessments. Due to differences between the respective regulatory frameworks, these benefits will only apply to Active Pharmaceutical Ingredient (API) manufacturers, contract testing laboratories and contract sterilisers.

https://www.tga.gov.au/news/notices/health-canada-agreement-gmp-inspections

Health Canada update draft guidance on how to interpret 'significant change' of a medical device:

In the regulations, section 34 describes 6 instances when a manufacturer must apply for an amended medical device licence. Similarly, section 68.13 describes the instances when a manufacturer must apply for an amended authorization. Under these sections, the manufacturer must submit an amendment application when a "significant change" is proposed to a Class III or IV device. This guidance document aims to help you identify these "significant changes". It outlines the crucial elements of what constitutes a significant change. Specific types of changes (such as a change in design or manufacturing processes) are addressed and related examples are provided to help you understand the difference between a significant and non-significant change.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/interpret-significant-change-medical-device.html

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/

Other Regulatory Updates

Malaysia publishes Harmonized Guidance on Post-Market Surveillance Information Exchange for ASEAN Member States.

Brazil ANVISA announces priorities for the 2024-2025 year.

Mexico presents agenda to strengthen the medical device industry.

Qatar create policy to define how to use telemedicine.

Australia issues multiple case guidance's about the transition to EU MDR.

2024 ISO 9001 Updates

There have been recent updates to the ISO 9001 standard including the following;
4.1 The organisation shall determine whether climate change is a relevant issue.
4.2 Relevant interested parties can have requirements related to climate change.
Apotech will have to keep this in mind for our current 9001 QMS build!

Sous le haut patronage de Monsieur Emmanuel MACRON Président de la République
MEDINTECHS

Come find us at MedInTechs!

This year, our CEO and Founder **Fabien Pezous** will be attending MedInTechs in Paris from March 11-12. MedIntechs is an annual trade fair which allows you to present, understand and experience the power and potential of innovation in health in Europe. Please feel free to reach out to us directly to schedule a meeting or simply meet us for a coffee to discuss international regulatory support.
See you there!

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!