REGULATORY NEWSLETTER

APOTECHCONSULTING.COM

apotech

October 2024

Global Complexity, Simplified Locally

What's New?

MHRA AI Airlock pilot call for applications!

The MHRA has officially opened applications for manufacturers and developers of innovative AI-powered medical devices to join the AI Airlock regulatory sandbox pilot.

This is a fantastic opportunity to collaborate with industry and regulatory experts, benefit from a bespoke testing plan, and gain deeper insights into the regulatory framework and data standards required for AI medical technologies.

Key criteria for eligibility:
The device must have the potential to deliver benefits to patients and the NHS
It should be novel or innovative
Must present a regulatory challenge that's ready to be tested

Applications are open for two weeks—until Monday, 7th October. Quick! Apply now at:

https://www.gov.uk/government/publications/ai-airlock-pilot-call-for-applications

MHRA Strategy for Improving Safety Communications

The aim is to transform safety communications to be more coordinated, targeted, and impactful for healthcare professionals and patients through:

- **Consultation Feedback:** Insights highlighted the need for better targeting, clearer information, and improved digital systems.
- **Strategic Changes:** Plans include redesigning communications, optimizing channels, increasing transparency, and enhancing website usability.
- **Engagement:** Strengthening relationships with healthcare professionals, patient safety organizations, and the public to improve safety communications and patient safety.

https://lnkd.in/dPvGyqyb

Top News

The FDA has published 3 draft guidance's on the 'Accreditation Scheme for Conformity Assessment (ASCA)

The following guidance's have been released:

- The Accreditation Scheme for Conformity Assessment (ASCA) Program: **https://lnkd.in/enJVaAhC**
- Biocompatibility Testing of Medical Devices - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: **https://lnkd.in/ecxNaSrq**
- Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program: **https://lnkd.in/exwGjFif**

These guidance's include updates to the ASCA program based on feedback from public meetings, webinars, stakeholder meetings, and lessons learned internally during the pilot phase.

The draft guidance's are available for comments until 22 November 2024.

Team NB Code of Conduct for NB v5

In this version 5 of the Code of Conduct, the changes and new inputs include:

- Removal of references to Directives and general update of references and terminology
- Compliance with Medical Device Coordination Group (MDCG) Guidance, Team-NB and NBCG-Med Papers
- Estimation of time needed for Technical Documentation review included
- Clarified requirements for unannounced audit
- Detailed explanation of re-certification requirements
- Estimation of time needed for Corrective and Preventive Action (CAPA)
- Included examples for Structured Dialogue
- Enforcement changed to complaint / appeal process

https://www.team-nb.org/wp-content/uploads/2024/09/Code-of-Conduct-Team-NB-V5-0-20240916.pdf

Swissmedic Issued a Letter to ARs and Importers

Swissmedic has issued a letter to inform Swiss Authorized Representatives and Importers of the expectations regarding follow-up on the transitional provisions and obligations related to legacy medical devices that comply with the Directives taking into account the September 26, 2024 deadline.

- Transitional provisions apply to devices compliant with the Directives and seeking certification under the MDR. The eligible devices may be placed into the market until 2027 or 2028, provided regulatory requirements are met.
- Authorized representatives and importers must verify and document the conformity of devices. A self-declaration by the manufacturer and a confirmation letter from the designated/notified body is required.
- Devices that do not meet the transitional provisions cannot be placed on the market.
- Importers and authorized representatives must ensure conformity before placing into the market. Feedback to Swissmedic is not required.
- Swissmedic can inspect devices on the market at any time.

EMA Language Models

The EMA published the first version of the "Guiding principles on the use of large language models in regulatory science and for medicines regulatory activities".

The guiding principles cover various aspects of using LLMs, from ensuring safe input of data, to applying critical thinking and cross-checking outputs, to knowing whom to consult when concerns arise. Responsible use of LLMs requires familiarity with the tools. The importance of continuous learning is emphasised to keep pace with the fast-changing field.

MHRA UK-wide licensing for medicines comes into effect on 1 January 2025: Are you ready?

The new arrangements for medicines under the Windsor Framework come into effect on 1 January 2025. This should make the supply of medicines to the UK market simpler by ensuring they are available across the UK in the same packaging at the same time and on the same basis.

From 1 January 2025, in order to enable medicines to use the same packaging and labelling across the UK, packaging for all UK medicinal products (Prescription Only Medicine and Pharmacy and General Sales List) must carry a clearly legible **'UK Only'** label to be placed on the UK market.

The MHRA have now published updates to the following control testing guidance to reflect the requirements of the Windsor Framework:

1. Guidance for manufacturers: Independent control testing (batch release) for the United Kingdom ➡ **https://bit.ly/4dwBeR1**

2. Apply to release a vaccine or a blood product to market ➡ **https://bit.ly/3ZP0puS**

Check out Apotech's most recent article on how to navigate the QMSR!

Visit our website to read more on how medical device manufacturers can prepare for the QMSR:

https://apotechconsulting.com/navigating-the-qmsr-what-medical-device-manufacturers-need-to-know/

Global Regulatory Updates

China proposes medical device legislative changes.

Switzerland publishes an update on accepting US FDA devices.

Slovakia releases an update on MDR/IVDR to address the significant increase in applications and extended processing times.

Hong Kong release overview of the Medical Device Administrative Control System.

MHRA release plans for Med Tech regulatory change

Read the latest on the MHRA's regulatory changes for medical devices.

Laura Squire OBE, Med Tech Regulatory Reform Lead, shared an update on the programme of regulatory changes for medical devices.

The blog contains all you need to know about our intentions for the Post Market Surveillance regulation, a future Pre-Market regulation, international reliance, MHRA team changes and more: **https://bit.ly/3zxqCTO**

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