REGULATORY NEWSLETTER

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Global Complexity, Simplified Locally

What's New?

The FDA has released final guidance on 'Electronic Submission Template for Medical Device De Novo Requests

This final guidance outlines the technical standards for preparing the electronic submission template used for De Novo classification requests, allowing the submission to be made entirely in electronic format. The template provides the information and guided prompts that the FDA considers most effective for organizing and compiling the necessary components of a 'complete' submission. See the full guidance below:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-de-novo-requests

The MHRA has added the awaited public webinar for the AI Airlock, the regulatory sandbox for AIaMD

Last month, the MHRA set out its strategic approach to AI in response to a white paper published in 2023. They introduced the pilot project which aims to help the Agency identify and address the challenges for regulating standalone AI medical devices (AIaMD), initially seeking out and supporting 4-6 virtual or real-world projects through simulation. The MHRA AI Airlock project is now underway and they will launch a call for product applications shortly. **Please reach out to us to learn more about the criteria's to apply to this program.** See the webinar below:

https://www.youtube.com/watch?v=1uSANxB9CeQ

Top News

MDSAP has published a new version of MDSAP Audit Approach

The Medical Device Single Audit Program MDSAP has released an updated audit model (**MDSAP AU P0002.009**). The revision primarily focuses on Australian requirements with practically minimal changes for other participating countries. This document contains specific instructions for performing audits under the MDSAP program. It incorporates an audit sequence, instructions for auditing each specific process and identifies links that highlight the interactions between the processes. This includes new guidance on TGA requirements across multiple areas, including: Management (T 5 & 8), Device Marketing Authorisation and Facility Registration (T 1,2,3), Measurement, Analysis and Improvement (T 7&12), Medical Device Adverse Events and Advisory Notices Reporting (T1&2) and Purchasing (T5).

https://www.fda.gov/media/166672/download

Switzerland Extends IVD Regulatory Transition to Align with EU-IVDR

The Federal Department of Home Affairs informed the Federal Council of the decision to adjust and extend the transition periods for the new IVD requirements in Swiss law, aligning them with Regulation (EU) 2024/1860, which amends the EU-IVDR. The amendment of the MedDO and IvDO is scheduled for autumn 2024. For IVD devices with certificates issued under Directive 98/79 EC ("IVDD") that expired before July 9, 2024, or will expire after this date, Swissmedic will tolerate the conditions for extending the certificate's validity in line with the EU-IVDR amendment as part of therapeutic products legislation enforcement. Additionally, the simplified labelling requirements for certain IVDs will continue indefinitely. The requirement to register medical devices and in-vitro diagnostics in a central database is expected to take effect in 2026.

FDA Release Predetermined Change Control Plan

The FDA issued this draft guidance to propose a policy for Predetermined Change Control Plans (PCCPs) and recommendations on the information to include in a PCCP in a marketing submission for a device. The recommendations in this draft guidance apply to devices, including device-led combination products, reviewed through the 510(k), De Novo, and PMA pathways. Submit either electronic or written comments on the draft guidance by 20 November 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

www.fda.gov/media/180978/download

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https://academie.dm-experts.fr/product/article-fda-pccp/?lang=en

European Commission Publishes Fees on Notified Bodies

The EC has recently shared a document listing hyperlinks to published fee's on notified bodies websites for MDR and IVDR related services. We recommend that you reach out to multiple NBs due to limited scopes, bandwidth and current demand. See the full document on the Euroopean Commission website.

MHRA Release Guidance on Pharmacovigilance following agreement of the Windsor Framework

This guidance is designed to provide information on the implementation of changes to pharmacovigilance for medicines authorised in the UK following the agreement of the Windsor Framework. These changes will be implemented from 1 January 2025. From 1 January 2025, all medicines approved in the UK will be licensed by the MHRA and authorised under the Human Medicines Regulation 2012.
Products that fall within the mandatory or optional scope of the EU's Centralised Procedure that were eligible for authorisation by the EC in NI (as a Centrally Authorised Product (CAP)) will no longer be authorised in this manner. Instead, these products will be authorised UK-wide under UK requirements by the MHRA. These products will be known as Category 1 products under UK law and will be legally required to follow Part 11 of the HMRs for pharmacovigilance with further pharmacovigilance requirements outlined in Schedule 12A of the HMRs.

https://www.gov.uk/government/publications/pharmacovigilance-following-agreement-of-the-windsor-framework/pharmacovigilance-following-agreement-of-the-windsor-framework

BSI Share Updated UKCA Brochure

This guide will take you through the BSI certification process starting from your application, to UKCA Certificate issuing to your company. See the brochure at:

www.bsigroup.com/siteassets/pdf/en/insights-and-media/insights/brochures/bsi-md-ukca-certification-process-en-gb.pdf

Global Regulatory Updates

UK proposes increased MHRA fees.

Thailand has released a list of regulators and agencies it will accept for certification and inspection.

Hong Kong has delayed released timelines for multiple new features of the Medical Device Information System (MDIS) to September 2024.

Mexico releases changes to GMP regulations.

Upcoming LDT Webinar!

On September 24, 2024, the U.S. Food and Drug Administration (FDA) will host a webinar to provide information on how to comply with labelling requirements for IVDs, including LDTs. See the registration details below:

https://www.fda.gov/medical-devices/medical-devices-news-and-events/webinar-labeling-requirements-in-vitro-diagnostic-products-ivd-including-ldts-under-21-cfr-80910b

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