REGULATORY NEWSLETTER

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Global Complexity, Simplified Locally

What's New?

FDA update on Laboratory Developed Tests LDTs!

The U.S. Food and Drug Administration (FDA) has published the final guidance "Laboratory Developed Tests: Small Entity Compliance Guide".

FDA has prepared this Small Entity Compliance Guide to assist small entities in complying with the requirements established in FDA regulations as they apply to in vitro diagnostic products (IVDs), including LDTs. The LDT Final Rule amends FDA regulations to make explicit that IVDs are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laboratory-developed-tests-small-entity-compliance-guide

MDCG released updated guidance on Standardisation for medical devices

The Medical Device Coordination Group (MDCG) released this morning (Tuesday 02 July 2024) updated guidance document MDCG 2021-5 Rev. 1.

The document aims to provide guidance on different aspects related to standards in the medical devices sector in support of the requirements laid down in the applicable EU legislation, taking into account its specificities. See the full document at:

https://health.ec.europa.eu/document/download/59ac4cb0-f187-4ca2-814d-82c42cde5408_en?filename=md_mdcg_2021_5_en.pdf

Top News

US FDA/UK MHRA/Health Canada Update on ML Enabled Medical Devices

The FDA, Health Canada, and the MHRA have jointly released 'Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles'.

IFDA, Health Canada, and MHRA jointly identified guiding principles for transparency for machine learning-enabled medical devices. These principles build upon the guiding principles for Good Machine Learning Practice which were published in 2021.

These guiding principles are intended as considerations when adopting and advancing good transparency practices.

https://www.gov.uk/government/publications/machine-learning-medical-devices-transparency-principles/transparency-for-machine-learning-enabled-medical-devices-guiding-principles

ICH Release Harmonised Guideline on Good Clinical Practice (GCP)

The objective of this ICH GCP Guideline is to provide a unified standard to facilitate the mutual acceptance of clinical trial data for ICH member countries and regions by applicable regulatory authorities.

This guideline builds on key concepts outlined in ICH E8(R1) General Considerations for Clinical Studies. This includes fostering a quality culture and proactively designing quality into clinical trials and drug development planning, identifying factors critical to trial quality, and engaging stakeholders, as appropriate, using a proportionate risk-based approach. See the full guidance at:

https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

MHRA update performance metrics for clinical trials and established medicines assessment.

The MHRA has updated the transparency data for clinical trials and established medicines assessment. The MHRA have added Performance Metrics-Assessment of Clinical Trial Authorisation Applications and performance Metrics: Assessment of New Marketing Authorisation Applications and Variations and updated HTML to reflect updates. Here they provide the MHRA performance data including timelines for applications for clinical trials and marketing authorisations for established medicines and variations to existing approvals. Our aim is to help applicants with decision-making, based on our performance.

https://www.gov.uk/government/publications/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines/mhra-performance-data-for-assessment-of-clinical-trials-and-established-medicines--2

EU MDR News!! (Orphan Medical Devices)

The MDCG has published "MDCG 2024-10 Clinical evaluation of orphan medical devices"

This document provides guidance to manufacturers and notified bodies on the clinical evaluation pursuant to the MDR of medical devices and accessories for medical devices that qualify as 'orphan devices' (OD) and medical devices and accessories for medical devices that have an orphan indication.

https://health.ec.europa.eu/document/download/daa1fc59-9d2c-4e82-878e-d6fdf12ecd1a_en?filename=mdcg_2024-10_en.pdf

Looking for more information on ISO 42001 AI Management System?

The need for a robust AI governance framework has led the international standards community to produce ISO 42001, which provides a certifiable AI management system framework within which AI products can be developed as part of an AI assurance ecosystem. Check out BSI's brochure to learn more about ISO 42001 and the certification process.

https://www.bsigroup.com/siteassets/pdf/en/insights-and-media/insights/brochures/iso_42001_brochure_2024.pdf

GMDN Agency News

The GMDN agency are asking organisations to share experiences of using the GMDN. If you would like to share, please email Paul Wadsworth at

communications@gmdnagency.org

List of National competent authorities (human medicines)

The national competent authorities are primarily responsible for the authorisation of medicines available in the EU that do not pass through the centralised procedure. Access to the full list and contact details can be found at:

https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human#list-of-national-competent-authorities-in-the-eea-section

Global Regulatory Updates

Switzerland announce that the Swiss Actor Registration Module will become mandatory starting 6 August 2024.

Mexico release Supplement of Medical Devices of the Mexican Pharmacopoeia which inserted regulatory requirements for SaMD.

Australia update Medical Device Regulation Changes.

New Zealand announces the intent to repeal the Therapeutic Products Act 2023.

Upcoming Conferences

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

Medica 2024
11 November - 14 November 2024
Düsseldorf, Germany

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

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