# REGULATORY NEWSLETTER

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May 2024

## Top News

FDA Release Final Rule on Laboratory Developed Tests (LDTs)

European Parliament Approves the Amending Regulation for MDR & IVDR

MHRA Publish the Impact of AI on the Regulation of Medical Products

## Whats New?

### FDA has released its final rule on Laboratory Developed Tests (LDTs)

The FDA has released its final rule on Laboratory Developed Tests (LDTs). ThIs ruling follows years of industry back and forth and sees the government body choosing to exercise its right to impose regulations on the market. The document is aimed at giving the body greater oversight into how LDTs are designed and validated for use. The FDA has now issued a policy confirming that over the course of the next four years, it will phase out its current discretionary approach towards LDTs. The final rule is expected to be published in the Federal Register on May 6, 2024. See the full report at https://lnkd.in/e8E8YSPf.

### The European Parliament approves the amending regulation for MDR & IVDR

The European Parliament approved the amending regulation for the MDR/IVDR. The amending regulation not only gives notified bodies and manufacturers of legacy IVDs a longer transition period, but also sets new requirements related to the reporting of supply interruptions and a gradual roll-out of EUDAMED for both medical and in-vitro diagnostic device manufacturers, as well as require manufacturers to report potential disruption to supply of critical products (including discontinuation). You can see the full press release here https://ec.europa.eu/commission/presscorner/detail/en/IP_24_2291

### MHRA Publish 'Impact of AI on the Regulation of Medical Products'

The MHRA has set out its strategic approach to artificial intelligence (AI) and is the MHRA response to both the Pro/innovation approach to the regulation of AI publication and Secretary of State letter of 1 February 2024. This publication provides on update on the MHRA's use of AI as a regulator of AI products, as a public service organisation delivering time-critical decisions and as an organisation making evidence-based decisions that impact public safety. See the full publication at

https://www.gov.uk/government/publications/impact-of-ai-on-the-regulation-of-medical-products?utm_medium=email&utm_campaign=govuk-notifications-topic&utm_source=64feb8ba-5a41-4747-8da7 b274cde1eec6&utm_content=immediately

## MHRA Annouce RegulatoryConnect

The Medicines and Healthcare Regulatory Agency have launched RegulatoryConnect, a service that provides the capability to track applications and view live authorisation details.

The RegulatoryConnect portal will provide greater transparency and visibility for regulatory assessments to industry. The functionality will let industry users log in using existing MHRA submission credentials and access RegulatoryConnect, where they will be able to:

- Use the Applications page to track the status of an application and see which stage it is at.
- Use the Current Granted View page to view live authorisation details, including status, key data and documents held against existing licences.

## Brazil ANVISA IVD Regulation RDC 830/2023 Nears

Brazil's medical device regulator, ANVISA has released three guidance documents on RDC 830/2023, which becomes effective June 1, 2024, which will require manufacturers to assess gaps between RDC 36/2015 and RDC 830/2023, and review the classification of their IVDs. The 3 documents include:

- Q&A on RDC 830/2023 including responses to questions posed about RDC 830/2023
- IVDs with risk classifications that have changed
- IVDs with more than one risk classification.

## FDA QMSR Reminder!!

On February 02, 2024, the FDA announced the Quality Management System Regulation (QMSR), amending 21 CFR Part 820 by incorporating ISO 13485:2016 standards to streamline regulation and lessen the burden on device manufacturers. The QMSR has an effective date set for February 02, 2026. We recommend manufacturers being to review the final QMSR ruling immediately and consider drafting a plan for the transition.

## MHRA Release Windsor Framework Document Collection

The Windsor Framework sets out the long-term arrangements for the supply of medicines into Northern Ireland. It will ensure that medicines can be approved and licensed on a UK-wide basis by the Medicines and Healthcare products Regulatory Agency (MHRA) , with medicines using the same packaging and labelling across the UK, and provides for the disapplication of European Union (EU) Falsified Medicines Directive (FMD) requirements for medicines marketed and supplied in Northern Ireland.These documents include:

- Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework
- UK Parallel Import Licences Following Agreement of the Windsor Framework

See the full collection of documents below:

https://www.gov.uk/government/collections/mhra-windsor-framework?utm_medium=email&utm_campaign=govuk-notifications-topic&utm_source=b2191f88-9d28-4963-a58e-af4199e779c3&utm_content=immediately

## Team Notified Body

**Team NB** has scheduled a 4th IVDR training session for Wednesday, July 3, 2024. The details are available at

https://www.team-nb.org/fourth-session-ivdr-technical-documentation-training-for-manufacturers/

## Global Regulatory Updates

**Hong Kong** announces additional leveraged country authorisations and a digital platform.

**Mexico** COFEPRIS announces revised draft labelling standard.

**EU** release new guidance on Clinical investigation Investigator's Brochures.

**South Korea** release the English translated version of the "Regulations on Unique Device Identification Management.

**EU** release updates to IVDR Summary of Safety and Performance Template.

**MHRA** update borderlines with medical devices and other products in Great Britain.

## DEADLINE REMINDER!

May 26th 2024 is the deadline to lodge an application for MDR conformity assessment and to have an MDR QMS in place.

## 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*



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