REGULATORY NEWSLETTER

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Top News

FDA Announce Final Rule Amending 21 CFR

MHRA Publishes Roadmap Towards the Future Regulatory Framework for Medical Devices

EC Publishes New Proposals for EUDAMED and IVDR Extension

Whats New?

EC Announce MDR/IVDR - Language Requirements for Manufacturers

The European Commission has published tables which aim to help manufacturers of medical devices and in vitro diagnostic medical devices, particularly small and medium-sized ones, understand the language requirements for the information and instructions that accompany a device in a specific country. The tables provide an overview of the language requirements for each Member State.

MHRA Publishes Roadmap Towards the Future Regulatory Framework for Medical Devices

The MHRA have published a roadmap which outlines the intended timelines for delivering the future regulatory framework for medical devices. The new regulations will put patient safety first and help to ensure that patients continue to have access without delay to the devices they need, whilst enhancing the UK's position as a world-leading environment for medical technology innovators. It is intended that priority measures to enhance post-market surveillance will be put in place first in 2024, with core elements of the new framework expected to be in place in 2025. *https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices*

EC Publishes New Proposals for EUDAMED and IVDR Extension

This proposal aims to further extend the transitional period for certain IVDs (depending on the type of device) to mitigate the risk of shortages of these products, especially of high-risk IVDs. Secondly, the proposal aims to enable a gradual roll-out of the electronic systems integrated into the European database on medical devices ('EUDAMED') that are finalised from the end of 2025, instead of deferring the mandatory use of EUDAMED until the last of the six modules is completed. In addition, the proposal aims to impose a requirement on manufacturers to give prior notice before interrupting the supply of certain critical medical devices and IVDs.

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2024%3A43%3AFIN

FDA Announce Final Rule Amending 21 CFR

The FDA issued a final rule amending the current good manufacturing practice (CGMP) requirements of the Quality System Regulation (QSR) under 21 CFR 820 to align more closely with the international consensus standard for Quality Management Systems for medical devices used by many other regulatory authorities around the world, in preparation for the implementation of the QMSR in 2026.

This rule amends 21 CFR 820 by incorporating the quality management system requirements of the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016.

FDA publishes updated Final Guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labelled as Sterile"

This guidance document updates and clarifies the information regarding sterilization processes that we recommend sponsors include in 510(k)s for devices labelled as sterile. This guidance document also provides details about the pyrogenicity information that we recommend sponsors include in a 510(k) submission.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled

MDCG Publishes 5 Documents Regarding Device Specific Vigilance Guidance

MDCG has published 5 new documents regarding Device Specific Vigilance Guidance (DSVG). The Initial Document "MDCG 2024-1 Guidance on the vigilance system for CE-marked devices DSVG 00 Device Specific Vigilance Guidance (DSVG) Template" outlines the structure of the DSVGs.

The aim of the Device Specific Vigilance Guidance (DSVG) is to harmonize vigilance reporting and provide guidance for manufacturers of specific devices.

The documents released alongside the template are:

- MDCG 2024-1-1 DSVG 01 on Cardiac ablation: https://lnkd.in/giNbr-j4
- MDCG 2024-1-2 DSVG 02 on Coronary stents: https://lnkd.in/gNJ5WNDi
- MDCG 2024-1-3 DSVG 03 on Cardiac implantable electronic devices (CIEDs): https://lnkd.in/gdYQJHKz
- MDCG 2024-1-4 DSVG 04 on Breast implants: https://lnkd.in/gT_XNiYE

MDCG publishes "Joint implementation and preparedness plan for Regulation (EU) 2017/746) on IVDR."

To meet the challenges related to implementation of the IVDR, it is essential that all actors involved further step up their efforts and work closely together. This paper reassesses the implementation priorities and sets out a joint plan of the Member States and the Commission services, including concrete priority actions in order to have an operational system in place before the date of application and provide key supporting elements as soon as possible.

https://health.ec.europa.eu/document/download/558ede8b-ff9a-4a8f-bb9d-d61e4a515b6a_en?filename=md_joint-impl-plan_en.pdf

MHRA announces two new UK Approved Bodies to Certify Medical Devices

The Medicines and Healthcare products Regulatory Agency (MHRA) has designated two new UK Approved Bodies, delivering increased capacity for the certification of the performance and safety of medical devices, for healthcare professionals and the public. LNE-GMED UK and Scarlet NB UK join the seven current UK Approved Bodies, increasing capacity for the certification of medical devices in the UK.

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/

IMDRF SaMD Working Group publishes draft guidance document on 'Medical Device Software: Considerations for Device and Risk Characterisation'.

The objective of this document is to promote and inform clear and accurate characterizations of medical device software and introduce a general strategy for characterizing software-specific risks that leverages the key features of a comprehensive medical device software characterisation.

www.imdrf.org/sites/default/files/2024-02/IMDRFSaMD%20WGN81%20DRAFT%202024%2C%20Medical%20Device%20Software%20Considerations%20for%20Device%20and%20Risk%20Characterization%20-%20final%20draft.pdf

Other Regulatory Updates

Thailand has implemented 5 new expedited routes for MD and IVD registration to speed up the approval process and streamline market access.

Israel has implemented revised registration requirements for some Class I medical devices and IVDs.

USA FDA has transitioned to electronic export documents.

Israel have revised registration and approval requirements for some low-risk medical devices and in vitro diagnostic (IVD) products.

Upcoming Conferences

RAPS Global Regulatory Strategy Conference
5 March- 7 March 2024 Baltimore, USA

RAPS Euro Convergence
6 May- 8 May 2024 Berlin, Germany

Med-Tech Innovation Expo
5 June - 6 June 2024 Birmingham, UK

MedTech Forum
22 May - 24 May 2024 Vienna, Austria

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

Medica 2024
11 November - 14 November 2024 Düsseldorf, Germany

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

MedTechLIVE
18 June - 20 June 2024 Stuttgart, Germany