# ABHI Regulatory Round-up - December 2024

## Contents



ABHI

3rd January 2025

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ABHI

3rd January 2025

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## Introduction

In this regulatory round-up, you will find updates from UK, EU, US and internationally as well as some upcoming dates for your diary.

We have included a list of current BSI standards projects, new and updated MHRA notices, some training events from TOPRA and RAPS, plus international updates from industry and regulators across the world. There are also a few member opportunities. If you have any updates that you want us to consider for a future edition, please get in touch.

*Regulatory Updates are provided in collaboration with MedBoard, the data intelligence platform monitoring regulatory news from 225+ Countries in 15+ Regulatory Areas, in real time. Visit www.MedBoard.com to learn more about the cloud platform and its regulatory, clinical, and market solutions to stay on top and manage information and data within the MedTech industry.*

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## ABHI

Key updates from ABHI (please make sure you are registered and logged in to 'My ABHI')

Webinar recording: Regulatory & Export Support for **Northern Ireland**

Upcoming regulatory group meetings

IVD Regulatory

- 27th February 2025 2-4pm
- 29th May 2025 2-4pm
- 4th September 2025 2-4pm
- 27th November 2025 2-4pm

MD Regulatory

ABHI

3rd January 2025

- 2025 dates tbc

## Member Offers

**TOPRA** Training Courses - 10% discount

**MedBoard**: Unified Data Platform –5-20% discount

**RegMetrics** – 15% discount

**Psephos** Biomedica Regulatory Consulting – free 30 minute consultation

**OMC Medical** Regulatory Consulting – free 30 minute consultation

If you would like to extend an offer to our wider membership, get in touch with communications@abhi.org.uk

Sign up for our other ABHI newsletters *Primed* and *Monthly Bytes*

You can find past ABHI regulatory resources by clicking 'regulation' in the ABHI resource hub.

# MHRA

**New**

| Subject | Relevance |
|---|---|
| Post market surveillance requirements | New legislation on requirements for **post-market surveillance** was signed off on 16th December 2024 and comes fully into force on 16th June 2025. We are working on an engagement plan that includes working with MHRA on guidance documents and with members to make sure everyone is aware of the new requirements. |
| MedRegs blog: Festive reflections on Med Tech | Review of activity and updated roadmap |
| Guidance: **AI Airlock** pilot cohort | The five selected sandbox candidates |
| MHRA newsletter Dec 24 | Updates on AI airlock, regulatory consultation, MedRegs blog. |
| Medicines and medical devices: Six tips for staying healthy and safe this festive season | Includes a tip for mental health apps |

# ABHI Regulatory Round-up - December 2024

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|---|---|
| New MHRA Chair Anthony Harnden outlines priorities as he starts role | Priorities for the first 100 days |

**Updates**

| Subject | Update | Relevance |
|---|---|---|
| **Clinical investigations** guidance | Updates to section 'Northern Ireland'. Includes attachments for 'flow chart' and 'accompanying guidance' and revised wording underneath SAE reporting. | If you run clinical investigations in Northern Ireland, this update will help you decide if you need to apply to MHRA |
| **Roadmap** towards the future regulatory framework for medical devices V2 | New regulatory roadmap that updates v1 | Includes planned 2025 activities on post market and premarket regs, policy development and software regulations |
| Guidance: Make a **payment** to MHRA | Amended to update Ledger Split and Extension numbers | Be aware |
| Guidance: In-house manufacture of medical devices in Great Britain | Amended to add note that guidance is currently under review | Be aware |
| AI Airlock: the regulatory sandbox for AIaMD | Press Release added 'MHRA trials five innovative AI technologies as part of pilot scheme to change regulatory approach'. | Be aware |

## Other UK Government updates

UKHSA: **Diagnostic Accelerator** launched to speed up pandemic preparedness

Open consultation **Copyright and Artificial Intelligence** closes on 25 February 2025

UK Standards for Microbiology Investigations *open consultation on testing for **Clostridioides difficile***

## Team AB

LinkedIn post: **annual meeting**

LinkedIn post: **post market surveillance**

## BSI standards update

ABHI have been working with BSI standards to ensure that membership of the individual UK-based standards committees is appropriate.

In the past, ABHI have 'sponsored' membership of BSI working groups, depending on the expertise of interested individuals from within appropriate ABHI Working Groups, although this practice has relaxed in recent years. Whilst membership of standards working groups is voluntary, the personal rewards with regards to personal development and networking are significant. Indeed, National standards involvement can lead to international and/or global exposure, as BSI recommend standards experts at the European and Global level.

If any member of ABHI would like to be considered for standards work, please contact Phil, Steve and Lindsey Ferrari at BSI.

# ABHI Regulatory Round-up - December 2024

## Upcoming events from TOPRA & RAPS

**TOPRA events** **Remember to use the 10% off TOPRA courses for ABHI members*

- CRED Successful and Skilful **Communication** London 21 January 2025
- Sponsored Webinar-Augmenting **Regulatory Intelligence with AI** 28 Feb online
- CRED Regulatory **Document Writing** and Management 18-19 March in person and online
- Regulatory **Careers** Live 2025 – 28th March Dublin
- Essentials of **European Medical Device Regulatory** Affairs London/online 21 May 2025
- **US Regulation** of Medical Devices London 3-5 June 2025
- Regulatory **Careers** Live 2025 – 13 June Brussels
- Regulatory **Careers** Live 2025 – 9 September, London
- Medical Devices/IVDs **Symposium** 2025 Berlin 30 September - 1 October 2025

**RAPS events**

- Webcast: 2024 **NMPA (CFDA) Key Updates** and Look Ahead on 2025 online 23rd January
- 2025 **Combination Products** Summit presented by DIA and RAPS, 27 - 29 January 2025, Brussels
- Workshop: Software as a Medical Device (**SAMD**)Online 10th February
- RAPS Webcast: Get Certified in Regulatory Affairs: Get Your **RAC** 12 Feb online
- RAPS Webcast: Get Your Regulatory Compliance Certification (**RCC**) 13 Feb online
- Sponsored Webcast: Planning Your Enterprise's **UDI Strategy** for EUDAMED and Beyond18 Feb online
- RAPS Workshop: **Digital Health:** Fundamentals of FDA Regulation 26 Feb online
- RAPS Workshop: Survivor: The **FDA 510(k)** Program Edition 4 March online
- RAPS Webcast: Get Your **FRA** Now 15 April online
- Workshop: **Cybersecurity** Unauthorized Online 25th March
- RAPS Workshop: **Conflict Resolution and Negotiation**: Effective Tools and Techniques 24 April online
- RAPS Workshop: **Strategies in Meetings**: Achieving Your Objectives 8 May online
- RAPS **Euro Convergence 2025** Brussels 13-16 May
- RAPS Workshop: **Dangerous Documents**: Avoiding Land Mines in your Records and Emails 22 May online
- RAPS Workshop: The **Role of the PRRC** Under the MDR and IVDR 29 May online

# ABHI Regulatory Round-up - December 2024

## EU news - MedTech Europe

MedTech Europe's post-EPSCO statement on the necessary **reforms of MDR/IVDR**
MedTech Europe **Priorities for the Polish Presidency** of the Council of the European Union
Position paper: **Smooth transition to the mandatory use of EUDAMED**

## EU news – European Commission

Study Supporting the **Monitoring of the Availability of Medical Devices** on the Eu Market: 2nd Survey for Md and Ivd Manufacturers, Authorised Representatives, Importers and Distributors
Factsheet for **Healthcare Professionals and Health Institutions**
Factsheet for **Authorities in Non-eu/eea States** on Medical Devices and in Vitro Diagnostic Medical Devices
Factsheet for **Procurement Ecosystem** of Medical Devices and in Vitro Diagnostic Medical Devices
**COMBINE** Programme Strategy
Call for Evidence: EU Rules on Medical Devices and in Vitro Diagnostics – **Targeted Evaluation**
Q&A on practical aspects related to the implementation of the obligations to inform about **interruption or discontinuation of supply** of certain devices laid down in Article 10a MDR and IVDR as introduced by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual **roll-out of Eudamed**, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices Rev.1
National Rules on **Reprocessing of Single-use Devices**
Report From the Commission to the European Parliament and the Council on the operation of Article 17 of Regulation (EU) 2017/745 of the European Parliament and of the Council on **single-use devices and their reprocessing**
Study on implementation of **Article 17 to the MDR** - Dashboard
Commission designates three more **EU reference laboratories** for public health

ABHI

3rd January 2025

# ABHI Regulatory Round-up - December 2024

## EU news – European Commission (MDCG)

MDCG 2022-3 Rev. 1 **Verification of Manufactured Class D IVDs** by Notified Bodies
MDCG 2019-13 Rev.1 Guidance on Sampling of Devices for the **Assessment of the Technical Documentation**
MDCG 2024-16: Manufacturer Information Form on **Interruption or Discontinuation of Supply** of Certain Medical Devices and IVDs
MDCG 2024-15: Guidance on Publication of **Clinical Investigation Reports** in Absence of EUDAMED

## EU news – European Commission (EMA)

EMA/144066/2021: Questions & Answers on the consultation procedure to the European Medicines Agency by notified bodies on an **ancillary medicinal substance or an ancillary human blood derivative** incorporated in a medical device Rev.3
EMA/CHMP/578661/2010: European Medicines Agency recommendation on the procedural aspects and dossier requirements for the consultation of the European Medicines Agency by notified body on an **ancillary medicinal substance or an ancillary human blood derivative** incorporated in a medical device or active implantable medical device Rev.2
EMA/198592/2022: Guidance on the procedural aspects for the consultation to the European Medicines Agency by a notified body on companion diagnostics Rev.1

## EU news – European Council

Joint paper of Croatia, Finland, France, Germany, Ireland, Luxembourg, Romania, Malta and Slovenia on **necessary reforms in MDR and IVDR**: priorities / main points

## EU news - Team NB

**MDR Certification Process** (including Pre-application, Application, and Post-application Phases) – Consensus Document
Team-NB 2024, in a few **facts and figures**
Press Release: Important update on the Implementation of **Class D oversight by EURLs**: endorsement of Multi Services Agreement template
Team-NB High level position on the **regulatory framework for the medical devices sector**

ABHI

3rd January 2025

# ABHI Regulatory Round-up - December 2024

## US news – AdvaMed

Medical Device Submissions Workshops – **510(k) and De Novo** February 3-4 online
Medical Device Submissions Workshops – **Investigational Device Exemption** (IDE) February 5 online
Medical Device Submissions Workshops – **Premarket Approval** (PMA) February 6-7 online

## US news – FDA

CDRH Unveils **Home as a Health Care Hub**'s Idea Lab to Help Reimagine How New and Existing Medical Technologies Can Be Incorporated Into the Home
Frequently Asked Questions for the **Home as a Health Care Hub**
Protocol Deviations for **Clinical Investigations** of Drugs, Biological Products, and Devices
**Biocompatibility and Toxicology** Program: Research on Medical Devices, Biocompatibility, and Toxicology
**Clinical Decision Support Software** Frequently Asked Questions (FAQs)
How **Total Product Life Cycle Advisory Program** (TAP) Facilitates Engagement with Non-FDA Parties
Prepare for **GUDID**
Global Unique Device Identification Database (**GUDID**): Guidance for Industry and Food and Drug Administration Staff
**GUDID** Data Trends: November 2024
Report on Risks and Benefits to Health of **Non-Device Software Functions**
Marketing Submission Recommendations for a **Predetermined Change Control Plan for Artificial Intelligence-Enabled Device** Software Functions: Guidance for Industry and Food and Drug Administration Staff

ABHI

3rd January 2025

# ABHI Regulatory Round-up - December 2024

## International news – IMDRF

27th IMDRF Management Committee Meeting will be held in Tokyo, Japan from March 10-14, 2025 (**registration now open**)

## International news – GHWP

GHWP/WG7/F001:2024: White Paper QMS Requirements in GHWP member county or region against ISO 13485:2016
GHWP/WG3/F001:2024: White Paper Software as a Medical Device (SaMD) PreMarket Submission Requirement

## International news – GMDN

The 2024 GMDN Annual Stakeholder Survey
GMDN FOCUS - December 2024

## International news – national regulators

| | |
|---|---|
| Portugal (Infarmed) | Communication of **Unavailability of Medical Devices** - Implementation of Regulation (EU) 2024/1860 of 13 June 2024 |
| Netherlands (IGJ) | Amendment of the Medical Devices Act in connection with the obligation to inform in the event of interruption or cessation of supply |
| Australia (TGA) | Complying with the **Unique Device Identification** regulations for medical devices |
| Germany (BfArM) | Guidance for the application procedure (**clinical investigations/performance studies**) |
| Singapore (HSA) | GN-37-R1: Guidance on **Change Management Program (CMP) for SaMD**, including machine-learning enabled SaMD |

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3rd January 2025