ABHI Regulatory Round-up – April 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 new and updated MHRA notices, some training events from TOPRA and RAPS, Standards updates, 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.

MedBoard

ABHI

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

🌼**5th June** This session will be held at **IQVIA's London** headquarters and is designed to provide you with critical insights into **post-market surveillance (PMS)** and the practical implementation of the new MHRA requirements. **Register to gain insights on MHRA's new guidelines, post-market surveillance, and compliance strategies from industry and regulatory experts.** 🌼

Friday, 3 October **ABHI Member Briefing** This seminar is aimed at introducing potential members, new members, and new employees of member companies, to the work of ABHI. It is also a great opportunity to understand the broader work we do outside of your immediate sphere of interest/expertise. The event will provide attendees with detailed information on the current critical issues relevant to the health technology industry, as well as ABHI's workstreams.

Understanding The **FDA's 510(K) Process: Lessons For UK Regulatory Reform** Created in collaboration with leading experts in US regulation, it aims to dispel common myths surrounding the 510(k) pathway, highlighting its structured review process and robust post-market requirements. It also offers valuable insights to inform UK regulatory reform, supporting risk-based oversight, international alignment, and future pathways for global cooperation.

Advance notice: ABHI HealthTech Conference 2025

"An unmissable opportunity to connect with peers, gain practical knowledge, and identify the growth opportunities shaping the future of HealthTech."

11 - 12 November 2025 (Day 1: UK Market, Day 2: Regulation) Early Bird discount now available

Upcoming regulatory group member meetings

IVD Regulatory

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

MD Regulatory

- 3rd June 10.30-12.30

Member Offers

8foldgovernance - Free Post Market Surveillance Review

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

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

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

RegMetrics – 15% **discount**

TOPRA Training Courses - 10% **discount**

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ABHI Professional Associate Members with an expertise in Post-Market Surveillance work, who have expressed an interest in assisting ABHI manufacturers include:

2Harris Consulting; Kathleen Harris, Managing Director, Kathleen@2Harris.com
8Fold Governance; Daniel Mannion, Director of Professional Services, daniel@8foldgovernance.com
AKRA Team; Dr. Andrew Gibson, Managing Consultant, andrew.gibson@akrateam.com
Brabners; Claire Burrows, Partner, claire.burrows@brabners.com
IMed Consultancy; Jonathan Ripley, Managing Director, jonathan@imedconsultancy.com
LFH Regulatory; Helen George, Business Manager, info@lfhregulatory.co.uk

ABHI Member Travelers paper: The Growth & Future of the MedTech Industry

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 in the ABHI resource hub.

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MHRA

New

Subject	Relevance
MHRA RegulatoryConnect Webinar - 22nd May 2025 15.30 to 17.00 BST	Update on RegulatoryConnect including plans for future functionality.
MHRA Safety Roundup: April 2025	Summary of the latest safety advice for medicines and medical device users (now includes link to published FSNs)
MEDREGS blog: **MedTech regulatory reform and the importance of partnerships**	MHRA's Rob Reid emphasizes **partnerships** in shaping UK medical device regulation, aiming to balance safety, innovation, and global competitiveness. Under CEO Lawrence Tallon, MHRA commits to collaborative, risk-based reforms, with **industry involvement** central. MHRA prioritizes **international cooperation.**

Updates

Subject	Update	Relevance
Guidance on **Clinical investigations for medical devices**	Updated guidance document: Clinical investigations of medical devices – guidance for manufacturers (now version 10 April 25) Clarification of terms (UK MDR and EU MDR definitions of medical device are now both included, 'participants' is now preferred to 'subjects')	If you are planning on running a clinical investigation in the UK, review the guidance update to understand the impact for your application.
MHRA Governance	The list of people on MHRA's 'Executive Committee' has now been expanded to include additional senior staff at MHRA	To be aware of MHRA governance update
List of UK approved bodies	Eurofins E&E CML Limited added to the list of UK approved bodies.	ABHI Member Eurofins is now a UK Approved Body
MHRA performance data	MHRA continue to assess **clinical investigation** applications within the statutory deadline	This is the only devices KPI published by MHRA

List of MHRA webinars relevant to medical devices and IVDs

Subscribe to MHRAgovuk on youtube for past events and MHRA conferences page for future events.

MHRA Board meetings held in public	(from 2020)
EU Exit and post-transition guidance, Regulation of Medical Devices Webinar	October 2020
Medical devices consultation webinar – Industry	October 2021
Medical Devices Regulations Webinar	January 2023
Regulatory Management System webinar	March 2023
MHRA MedTech Regulatory Reform Webinar	March 2024
MHRA RegulatoryConnect portal launch webinar	March 2024
AI Airlock Webinar	July 2024
MHRA Digital Mental Health Technologies	July 2024
MHRA Chair Anthony Harnden starts role	January 2025

There is also a suite of video tutorials on registering your devices with MHRA

Other UK updates

Breakthrough in **bowel cancer research** will speed up diagnosis

CADDA Launch events (Centre for Advanced Diagnostic Development and Application)

London Launch Event – 6th May

Manchester Launch Event – 8th May

BSI updates

In June 2025, BSI will be running Healthcare Week consisting of five webinars:

09 June 2025 12:00 - 13:00 **Digital & AI in Healthcare**

10 June 2025 12:00 - 13:00 **PFAS phase out and its impact on medical devices**

11 June 2025 12:00 - 13:00 **Regulatory update - what's happening in the world of medical devices in the EU and UK**

12 June 2025 12:00 - 13:00 **Circularity in Healthcare**

13 June 2025 12:00 - 13:00 **The Power of In Silico Trials: AI, Innovation, and Its Impact on Healthcare**

Status	Closing date	Description	Committee
Published standard		BS ISO 8536-6:2025 Infusion equipment for medical use. Freeze drying closures for infusion bottles	CH/212 - IVDs
Published standard		BS EN ISO 8871-5:2025 Elastomeric parts for parenterals and for devices for pharmaceutical use. Functional requirements and testing	CH/212 - IVDs
Published standard		BS EN ISO 5840-1:2021+A1:2025 Cardiovascular implants. Cardiac valve prostheses. General requirements	CH/150/2 - Cardiovascular implants
Published standard		BS EN ISO 5840-2:2021+A1:2025 Cardiovascular implants. Cardiac valve prostheses. Surgically implanted heart valve substitutes	CH/150/2 - Cardiovascular implants

Published standard		BS EN ISO 13402:2025 Surgical and dental hand instruments. Determination of resistance against autoclaving, corrosion and thermal exposure	W/- - Miscellaneous Standards
Published standard		BS EN ISO 5840-3:2021+A1:2025 Cardiovascular implants. Cardiac valve prostheses. Heart valve substitutes implanted by transcatheter techniques	CH/150/2 - Cardiovascular implants
Published standard		BS ISO 19223-2:2025 Lung ventilators and related equipment. Vocabulary and semantics. High frequency and jet ventilation	CH/121 - Anaesthetic and respiratory equipment
Published standard		BS EN IEC 60601-2-68:2025 Medical electrical equipment. Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	CH/62/3 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry
Draft for public comment	03/05/2025	BS EN ISO 10477 Dentistry. Polymer-based crown and veneering materials	CH/106/2 - Prosthodontic materials
Draft for public comment	03/05/2025	BS EN ISO 10524-3 Pressure regulators for use with medical gases. Part 3: Pressure regulators integrated with cylinder valves (VIPRs)	CH/121/6 - Medical gas supply systems
Draft for public comment	06/05/2025	BS EN ISO 10873 Dentistry — Denture adhesives	CH/106/7 - Oral hygiene products
Draft for public comment	20/05/2025	BS EN ISO 10322 Ophthalmic optics. Semi-finished blanks	CH/172/3 - Spectacles
Draft for public comment	21/05/2025	BS EN ISO 23402-1 Dentistry. Portable dental equipment for use in non-permanent healthcare environment. Part 1: General requirements	CH/106 - Dentistry
Draft for public comment	21/05/2025	BS EN ISO 10993-11 Biological evaluation of medical devices. Part 11: Tests for systemic toxicity	CH/194 - Biological evaluation of medical devices

Draft for public comment	22/05/2025	BS EN IEC 80601-2-60/AMD1 ED.2 Medical electrical equipment. Part 2-60: Particular requirements for the basic safety	CH/62/4 - Particular medical equipment, software, and systems
Draft for public comment	28/05/2025	BS EN ISO 10993-3 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	CH/194 - Biological evaluation of medical devices
Draft for public comment	02/06/2025	BS EN ISO 18739 Dentistry. Vocabulary of process chain for CAD/CAM systems	CH/106 - Dentistry
Draft for public comment	03/06/2025	BS EN ISO 22367 Medical laboratories. Application of risk management to medical laboratories	CH/212 - IVDs
Draft for public comment	04/06/2025	BS EN IEC 62570 Ed.2.0 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	CH/62/2 - Medical imaging equipment, software, and systems
Draft for public comment	10/06/2025	BS ISO 25557 Care quality for older persons at home and in care facilities	CH/314 - Ageing Societies
Draft for public comment	11/06/2025	BS EN ISO 3630-8 Dentistry. Endodontic instruments. Part 8: Accuracy of electronic apex locator	CH/106 - Dentistry
Draft for public comment	11/06/2025	BS EN ISO 8325:2023/Amd 1 Dentistry. Test methods for rotary instruments. Amendment 1	CH/106 - Dentistry
Draft for public comment	11/06/2025	BS EN ISO 8980-3:2022/Amd 1 Ophthalmic optics. Uncut finished spectacle lenses. Part 3: Transmittance specifications and test methods. Amendment 1	CH/172/3 - Spectacles
Draft for public comment	11/06/2025	BS ISO 20364 Healthcare organization management. Guidance for healthcare organizations' response to the surging diagnostic demands in a pandemic	CH/304 - Healthcare Organization Management
Draft for public comment	11/06/2025	BS EN ISO 19211 Anaesthetic and respiratory equipment. Fire-activated oxygen shut-off devices for use during oxygen therapy	CH/121 - Anaesthetic and respiratory equipment

Draft for public comment	11/06/2025	BS EN ISO 8980-4 Ophthalmic optics — Uncut finished spectacle lenses —. Part 4: Specifications and test methods for the properties of anti-reflective coatings and hydrophobic coatings	CH/172/3 - Spectacles
Draft for public comment	14/06/2025	BS EN ISO 3964-1 ISO 3964-1 Dentistry. Coupling dimensions for handpiece connectors. Part 1: Mechanical properties	CH/106 - Dentistry
Draft for public comment	17/06/2025	BS EN 1422 Sterilizers for medical purposes. Ethylene oxide sterilizers. Requirements and test methods	CH/198 - Sterilization and Associated Equipment and Processes
Draft for public comment	18/06/2025	BS EN ISO 7396-1 Medical gas pipeline systems. Part 1: Pipeline systems for compressed medical gases and vacuum	CH/121/6 - Medical gas supply systems
Draft for public comment	18/07/2025	BS EN 18167 Quality along the patient pathway in medical imaging in Radiology services	CH/304/-/2 - Patient Pathways

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Upcoming events from TOPRA & RAPS

The TOPRA **Employer Partner** programme is designed for organisations that want to formally demonstrate their outstanding commitment to the professional development and wellbeing of regulatory affairs professionals.

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

- **Innovative Medical Devices**: How to Navigate the Regulated MedTech Landscape to Place These on the Market Online 6th May
- Essentials of **European Medical Device Regulatory** Affairs London/online 21 May 2025
- Regulatory **Careers** Live 2025 – 13 June Brussels
- The **Medical Device Introductory Course** 16 - 18 June, London
- Essentials of **In-Vitro Diagnostics Regulatory** Affairs 11 July, London/online
- **US Regulation** of Medical Devices London/online 23-25 July 2025
- Regulatory **Careers** Live 2025 – 9 September, London
- Design Development and Certification of Medical Devices 8-10 September London/Online
- Medical Devices/IVDs **Symposium** 2025 Berlin 30 September - 1 October 2025
- Regulation of **In-Vitro Diagnostics Medical Devices** London/online 20-22 October
- **Leadership and Strategic Management** in Regulatory Affairs London/Online 10-12 November
- Essentials of **European Medical Device Regulatory Affairs** London/online 26 November
- Regulation of **Electrical, Electronic and Software Devices** London/online 2-4 December

RAPS events

- 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
- RAPS Workshop: Unlocking the Power of Generative **AI in Regulatory Intelligence** 04 June online
- RAPS Workshop: **Global Expedited Pathways** (US/Global) – Medical Devices 09 September online

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EU news - MedTech Europe

The **MedTech Forum** 2025, Lisbon 13-15 May

MedTech Europe responds to the **European Commission's targeted evaluation**

MedTech Europe and industry partners call for stronger **future governance of medical technologies**

EU news – European Commission

Commission Implementing Decision (EU) 2025/681 of 8 April 2025 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for **medical gloves** for single use, **sterilization** of medical devices and patient handling equipment used in **ambulances**
Commission Implementing Decision (EU) 2025/679 of 8 April 2025 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for **sterilization** of medical devices

EU news – European Commission (EUDAMED)

EUDAMED User Guide: **UDI Devices - Playground** v3.11.0
EUDAMED User guide: **Legacy Devices registration - Playground** v3.11.0
EUDAMED User guide: **Registration of Old/custommade devices in the Vigilance module - Playground** v3.11.0
EUDAMED User guide: **Vigilance for EOs - Playground** v3.11.0
EUDAMED User guide: **Market Surveillance - Playground** v3.11.0

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EU news – European Commission (EMA)

EMA roundtable with stakeholders on the 20th anniversary of the **SME Regulation**
EMA/619893/2022 Rev.2: Questions & Answers - Practical arrangements on the **companion diagnostics** consultation procedure to the European Medicines Agency by notified bodies

EU News - Team NB

Fifth Session : **IVDR Technical Documentation Training** for Manufacturers
New session : **MDR Clinical Training** for Manufacturers
IVDR Certification Process (including Pre-application, Application and Post Application phases) – Consensus document
TEAM NB Position Paper on **European Artificial Intelligence Regulation** V2
TEAM NB Position Paper on Best Practice Guidance for the **Submission of Technical Documentation** under Annex II and III of Medical Device Regulation (EU) 2017/745 v3

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US news – AdvaMed

Advamed's **MedTech Conference**. 5-8th October, San Diego

AdvaMed Releases "AI Policy Roadmap"

US news – FDA

Blogpost: Make the FDA Great Again!

FDA: Electronic Submissions Gateway

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International news – IMDRF

Consultation document (closes 30th May): Playbook for Medical Device **Regulatory Reliance** Programs

IMDRF/MC/N1FINAL:2025 (Edition 8): IMDRF **Terms of Reference**

IMDRF/MC/N2FINAL:2025 (Edition 13): IMDRF **Standard Operating Procedures**

IMDRF/NCAR WG/N14 (Version 5) - Medical Devices: **Post-Market Surveillance**: National Competent Authority Report Exchange Criteria and Report Form

Swissmedic becomes a member of the IMDRF Management Committee

International news – GHWP

29th GHWP Annual Meeting will be held in Bangkok 1-4 Dec 2025

International news – GMDN

GMDN FOCUS - April 2025

International news – WHO

WHO prequalifies 2 additional HIV RDTs, including the first **HIV-1 self-test by urine**

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International news – Other Global Trade Associations

Canada's MedTech **Conference 8 May** Canada's Regulatory & Quality Medtech **Conference 10-12 June**

Swiss MedTech welcomes the Federal Council's decision for devices from non-European regulatory systems to be placed on the Swiss market. **"Swiss patients will be able to benefit from FDA-approved products"**

International news – national regulators

TGA	**Consultation: Proposed changes to the IVD medical device classifications and definitions** (closes 8th May 2025)