

UK regulator brings new AI and MedTech agenda to AdvaMed

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UK's Medicines and Healthcare products Regulatory Agency (MHRA) sets out its next phase of MedTech and AI regulation to US industry leaders at AdvaMed 2026.

Speaking at the conference on Tuesday 20 October, Jessica Paulsen, MHRA Deputy Director for AI and Software, will outline the UK regulator's developing approach to software and AI-enabled medical devices, including more flexible lifecycle regulation, regulatory sandboxes and closer international collaboration.

She is speaking on following the publication of the MHRA 2030 Strategy, which sets out plans to modernise regulation for an era of AI and personalised medicine. For MedTech, this includes creating a modern, adaptive framework for AI as a medical device, establishing a new MHRA Centre for AI and Digital Health, improving device data and traceability, and expanding reliance and recognition routes with trusted international regulators, including the FDA.

The MHRA 2030 strategy sets an ambition for the MHRA to deliver a global standard for safe and agile regulation of MedTech and AI by 2030, supporting faster access to innovative technologies while strengthening patient safety. This month, the UK Government accepted all 44 recommendations of the NHS doctor-led independent National Commission into the Regulation of AI in Healthcare, supporting a more proportionate, lifecycle-based approach to AI regulation.

The MHRA is already testing this approach through its AI Airlock, its regulatory sandbox for AI-enabled medical devices. It is complemented by a series of new regional partnerships including with NHS London and Manchester University NHS Foundation Trust, leveraging the UK's unique healthcare system and academic excellence to test innovative technologies in real health settings and generate evidence to inform future regulatory approaches.

Together, this work will help the MHRA develop regulation that can respond to AI-enabled devices that evolve throughout their lifecycle, while giving developers greater clarity on regulatory requirements.

Jessica Paulsen, MHRA Deputy Director for AI and Software, said:

"AI is changing medical technology, and regulation must keep pace. In the UK we are moving from policy into practice, using initiatives like AI Airlock to build a more proportionate, lifecycle-based approach.

"These are global technologies, so close collaboration with the FDA and other regulators will be critical to giving innovators greater clarity while maintaining strong protections for patients."

The MHRA is simultaneously putting new infrastructure behind its relationship with the FDA. The

MHRA-FDA Pioneer Programme, announced in June, establishes dedicated reciprocal liaison roles within the two regulators. The programme is designed to deepen day-to-day collaboration, scientific exchange and coordination on emerging regulatory challenges, including medical devices and AI. Both agencies will continue to make independent regulatory decisions.

The initiative builds on existing UK-US work on medical technology and AI. At AdvaMed in 2025, the MHRA set out ambitions to strengthen regulatory alignment and reciprocity with the FDA, reduce transatlantic barriers to market access and explore greater use of international reliance routes, including for devices already approved by the FDA.

The MHRA is now recruiting a Regional Deputy Director of US Partnerships, based in Washington, D.C., who will serve as the MHRA's dedicated Liaison Officer to the FDA under the Pioneer Programme. The senior role is intended to deepen the relationship with the FDA, strengthen scientific and regulatory collaboration, and build connections between the UK and US life sciences ecosystems.

The appointment forms part of a wider MHRA ambition not simply to maintain a US presence, but to build relationships that deliver for patients, innovation and the UK's position in global life sciences.

Alongside AI and international collaboration, the MHRA is progressing wider medical device reform, including improved post-market surveillance and proposed legislative changes to support a more responsive future regulatory framework.

The overall direction is set out in the [MHRA 2030 Strategy announcement](#), alongside recent action on the [National Commission into the Regulation of AI in Healthcare](#), details on the London and [Manchester health innovation sandbox](#) and [wider regulatory reform](#) announcements made recently by the UK regulator.

Notes to Editors

- The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. The MHRA is an executive agency of the Department of Health and Social Care.
- For media enquiries, please contact newscentre@mhra.gov.uk or call 020 3080 7651.

<https://www.gov.uk/government/news/uk-regulator-brings-new-ai-and-medtech-agenda-to-advamed>