

# Medical Device & AI Regulations

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**Anita Sands, Agnes Kijo, Agnès Leotsakos**

How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

**Stephen Gilbert**

Improving the Regulation of Medical Devices and Artificial Intelligence

**Gabriella M. Racca**

Digital Transformation in Healthcare Procurement

**Penny Pinnock**

Growing Pressures Driving the Shift to Healthcare Digitalisation

**Elena Demosthenous**

Standards in Support of the EU Medical Devices Regulations

**Susana Álvarez Gómez**

Effective Management in Times of Health Crisis



# Editorial



STEPHEN  
LIEBER

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## Medical Device and AI Regulations

The quickly evolving major presence of Artificial Intelligence in healthcare means the current regulatory landscape is changing. AI-based medical devices are rapidly revolutionising the industry across the globe, but along with the many positive developments made in healthcare delivery, calls for more regulatory oversight are growing. Many countries are rethinking and re-tooling their regulatory protocols to account for AI-based medical technologies to achieve effectiveness and ensure patient safety.

In this issue, our contributors discuss **Medical Device and AI Regulations**, particularly the measures needed for improved regulation of devices and AI tools, some ongoing regulatory reforms, and what can be expected in the future.

Elena Demosthenous discusses the use of harmonised standards as a proven and trusted way of ensuring medical devices comply with regulations and safety standards for patients, healthcare professionals and others. Stephen Gilbert shares his insights and thoughts regarding the need for improved and balanced regulation of medical devices and artificial intelligence.

Agnès Leotsakos, Agnes Kilo and Anita Sands highlight that effective regulatory systems are a vital component of health system strengthening, particularly in the age of AI/ML-enabled medical devices.

Gabriella Racca explores the potential of AI coupled with digital innovation for future healthcare procurement.

Medical digital algorithms have the potential to transform healthcare and improve patient outcomes. Taner Ozcan delves deeper to uncover what medical digital algorithms are, how they work, and the benefits

they offer in healthcare.

Generative AI is one of the powerful tools in radiology and has the potential to revolutionise the field. Josep Munuera and Arnau Valls discuss its role and contributions across the field, yet cautioning us that the multiple uses of generative AI imaging also carry limitations that need to be solved before this being ready for wide adoption.

Penny Pinnock highlights the need for healthcare organisations to refresh their existing technology and accelerate the adoption of digital and AI-driven technologies to improve patient outcomes, reduce costs and improve care delivery.

Emily Zampella and Michele Klain discuss radionuclide therapy and how it represents a valid, highly specific therapy option in paediatric patients. Valeria Guadieri and Alberto Cuocolo talk about peptide receptor imaging and PRRT as a new frontier in personalised medicine, allowing for tailored treatment plans.

Susana Álvarez Gómez shares the strategies and experiences of the public procurement department of Madrid Health in facing the recently ended pandemic, as well as the innovative actions taken to respond to this worldwide health crisis.

We hope you enjoy reading this issue and welcome any feedback.

Happy reading!

A handwritten signature in black ink that reads "Steve Lieber". The signature is written in a cursive, flowing style.



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