IMed Consultancy explores regulatory challenges for AI and ML in medical devices and digital health products

OXFORD, OXFORD, UNITED KINGDOM, June 12, 2024 /EINPresswire.com/ -- Med Consultancy, a rising international regulatory compliance consultancy with proven experience supporting digital and AI-based medical device manufacturers launch and maintain their products on global markets, shares free paper assessing the regulatory state of play for Artificial Intelligence (AI) and Machine Learning (ML)-powered medical devices in the UK, US an EU.

“Digital Dilemmas: Regulatory challenges for Artificial Intelligence and Machine Learning in medical devices and digital health products”, can be downloaded free of charge here https://imedconsultancy.com.

From wearable sensors that monitor vital signs to AI-powered diagnostic tools, the range of innovations is vast and promises to revolutionize healthcare delivery. AI-powered algorithms can analyse vast troves of health data to identify disease biomarkers, predict disease trajectories, and tailor interventions to individual patients. Regulators are thus striving to keep pace with technological advancements, while addressing concerns regarding data security, potential bias and safety impacts possible from poorly performing clinical software tools, that underscore the need for robust regulatory frameworks such as the EU AI Act which regulates AI across a range of sectors, including healthcare.

Navigating the evolving regulatory landscape poses challenges for manufacturers implementing AI and ML, especially as digital health solutions can blur the lines between medical devices and non-medical tools. In fact, regulatory scrutiny varies across regions, with new regulations like the EU AI Act introducing additional complexities. Current and forthcoming initiatives like the FDA’s pre-determined change control plan and the UK's regulatory sandbox for software medical devices incorporating AI, aim to provide developers with a clearer and more predicable runway to achieve regulatory compliance in this rapidly evolving space.

Right from the initial steps of device development, when market demand is assessed and tools are initially developed, it is critical to have a clear understanding of the objectives, risks and potential of the tool across different markets. Understanding the expectations of regulators and assessing the strategic considerations necessary for incorporating AI into a device may also prove key to ensuring a smoother launch into the market.

“When launching innovative AI or ML-based devices it is important to harness the expertise of professionals with in-depth knowledge of regional regulations and emerging trends to help avoid pitfalls and expedite market entry. As standards and requirements evolve, navigating nebulous definitions and requirements correctly can be the make-or-break for new devices that pave the way for transformative digital health solutions.” comments Leeanne Baker, Managing Director and Senior QA/RA Consultant at IMed Consultancy.

About IMed Consultancy

Founded in 2012, IMed Consultancy offers a wide range of regulatory and compliance services to the medical technology industry supporting medical device and in vitro medical device manufacturers through all stages of the product lifecycle from: concept and design consultancy through to providing resources and strategic counsel regarding clinical studies and post market surveillance activities. IMed Consultancy’s team of highly skilled and experienced medical regulatory professionals offer an outstanding yet accessible global regulatory service. With over 50 years of combined hands-on problem-solving expertise, our remit is truly global, ensuring that client devices are successfully launched and maintained in total compliance in the UK, EU and internationally.

For more information visit www.imedconsultancy.com

Josephine Ornago
OutspokenPR
+39 366 225 0305
email us here
Visit us on social media:
LinkedIn