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Global Harmonization Working Party re-elects Taiwan FDA to Chair medical devices regulation

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For shaping the future of medical technology governance



The Taiwan Food and Drug Administration (TFDA) has been re-elected as Chair of the Global Harmonization Working Party (GHWP) Working Group 3 (WG3) on Pre-market: Software as a Medical Device (SaMD).

This renewed mandate underscores Taiwan's leadership in advancing international regulatory convergence, particularly in the rapidly evolving field of artificial intelligence (AI)-enabled SaMD.

GHWP WG3 plays a pivotal role in shaping global regulatory frameworks for SaMD, including AI/ML-based technologies that are transforming healthcare delivery.
Under TFDA's chairmanship, the group has successfully developed guidance documents and white papers that support regulators, industry, and healthcare providers in ensuring patient safety while fostering innovation.

Looking ahead, TFDA will focus on three strategic priorities:
Advancing Cutting-Edge Technology SaMD Regulatory Frameworks: Building consensus on innovative new algorithms, transparency, and cybersecurity pre-market requirements to ensure safe and effective deployment of cutting-edge technology SaMD.
Strengthening International Collaboration: Enhancing dialogue among regulators, industry stakeholders, and academic experts to accelerate harmonisation and minimise regulatory fragmentation.
Capacity Building and Education: Supporting GHWP members with training programs, workshops, or technical resources to improve regulatory readiness and foster trust in emerging technologies.