

Activities

[1] During February 2026, Asia University formalized a Memorandum of Understanding with a company recognized for its strength in professional services.

[2] We successfully had a proposal accepted for the Fujitsu Quantum Simulator Challenge 2025–26 event.

[3] We recently succeeded in having five proposals accepted by the Ministry of Education. Click [here](#) for more information.

Regulatory Impacts on Quantum Artificial Intelligence in *In Vitro* Diagnostic Medical Devices

Executive Summary

The convergence of Quantum Artificial Intelligence (QAI) and In Vitro Diagnostic (IVD) medical devices offers unprecedented capabilities in genomic sequencing, early-stage biomarker discovery, and highly accurate liquid biopsies. However, the non-deterministic nature and immense computational dimensionality of quantum mechanics fundamentally challenge current global regulatory frameworks designed for classical, deterministic software.

The European Union: Dual Compliance and Bottlenecks

In the EU, Quantum AI IVDs face a stringent dual-compliance mandate under the **In Vitro Diagnostic Medical Devices Regulation (IVDR)** and the newly enacted **Artificial Intelligence Act (AIA)**.

- **The "Significant Change" Dilemma:** The AIA mandates strict oversight for high-risk diagnostic systems. Because Quantum Machine Learning (QML) models often undergo continuous active learning, defining what constitutes a "significant design change" that triggers a new conformity assessment remains a critical regulatory hurdle.
- **Notified Body Capacity Crisis:** Auditing hybrid quantum-classical software pipelines requires multidisciplinary expertise (quantum physics, data science, bioinformatics) that current third-party Notified Bodies severely lack, threatening to bottleneck the market entry of novel devices.

The US FDA Paradigm: Q-Submissions and Agility

The United States Food and Drug Administration (FDA) has adopted a more adaptive approach, primarily leveraging the **510(k)** and **De Novo** pathways.

- **Early Engagement:** The FDA heavily encourages utilizing the **Q-Submission program** early in the development cycle. Quantum technologies are inherently multimodal—analyzing genomic, transcriptomic, and proteomic data simultaneously—which challenges traditional FDA frameworks that typically review each diagnostic function in isolation.
- **Performance Monitoring:** The FDA requires robust Predetermined Change Control Plans (PCCPs) to manage the performance drift inherent to QML algorithms when exposed to diverse, real-world patient populations.

The Epistemic Opacity Problem

Quantum algorithms operate in fluid states of superposition and entanglement, creating profound "epistemic opacity" (an extreme version of the AI black-box problem). Regulators strictly mandate algorithmic transparency: explainability, interpretability, and accountability. To achieve clinical validation, developers must utilize **Quantum Explainable AI (QXAI)** frameworks (such as QSHAP or LIME) to mathematically interpret diagnostic outputs. Furthermore, developers must enforce "proportionality-by-design" to ensure patient privacy is not compromised by quantum-powered data de-anonymization.

The Cybersecurity Imperative: Surviving "Q-Day"

The most immediate regulatory mandate for Quantum AI in healthcare pertains to data security. Cryptographically relevant quantum computers will soon be capable of breaking current global encryption standards (an event known as "Q-Day").

- **US Mandates:** Section 524B of the FD&C Act and CNSA 2.0 guidelines require immediate cybersecurity resilience and a phased transition of medical networks to **Post-Quantum Cryptography (PQC)** by 2035.
- **EU Mandates:** Agencies like ENISA and Germany's BSI explicitly mandate "cryptographic agility"—the architectural ability to update device encryption protocols over-the-air using hybrid classical/PQC algorithms without requiring hardware recalls.

Anticipatory Governance

Because technological velocity vastly outpaces traditional legislative cycles, regulators are shifting to anticipatory governance models:

- **AI Regulatory Sandboxes:** Article 57 of the EU AI Act mandates operational national sandboxes by August 2026, allowing developers to test quantum diagnostics in legally controlled, safe-harbor environments alongside regulatory authorities.
- **The EU Quantum Act:** Anticipated for mid-2026, this dedicated legislation is expected to specifically address hybrid computing systems, supply chain security, and quantum liability, adding another layer to the global regulatory matrix.

Edited by
Ka-Lok Ng ^{2,3}
Distinguish Professor & Deputy Director

¹ [Sysmex Europe](#), Hamburg, Germany

² [Department of Bioinformatics and Medical Engineering](#), Asia University

³ [AI and Quantum Research Center \(AIQRC\)](#), Asia University, Taiwan

AI and Quantum Research Center (AIQRC)

Room A110, Asia University, No. 500, LiuFeng Rd., WuFeng Dist., Taichung City
41354 Taiwan.

Email: qphys.qcomp@gmail.com Office: 04-23323456 ext. 6631

Web: <https://quantum.asia.edu.tw/>