CLEIO Renews Its ISO 13485 Certification for Medical Device Development

Certification renewed for 3 years after a successful recertification audit, reinforcing quality, traceability, and compliance for MedTech product development.

CLEIO renews its ISO 13485 certification

MONTREAL, QUEBEC, CANADA, April 23, 2026 /EINPresswire.com/ -- CLEIO, a North American product development firm specialized in medical device development announced that its ISO 13485 certification has been renewed for another 3 years. CLEIO has maintained ISO 13485 certification since 2020, reflecting the strength of its Quality Management System (QMS) and its commitment to quality, traceability, and regulatory compliance.

External audits are conducted annually to maintain certification. After a successful surveillance audit last year with 0 nonconformities, CLEIO's QMS was fully reassessed during its triennial recertification audit. The result confirmed a robust, well-documented system that supports consistent processes across design and development, risk and change management, purchasing, equipment control, and training.

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>
> *Caroline Lau*

ISO 13485 is a globally recognized standard for quality management systems in the MedTech industry. It provides a structured framework for developing safe, effective, and compliant medical devices. For companies building regulated products, ISO 13485 supports stronger risk management, process consistency, and readiness for international markets.

At CLEIO, quality is embedded into day-to-day work, not limited to audit preparation. Over time,

a strong quality culture has been reinforced through internal training initiatives that help teams understand quality requirements and apply them consistently across projects.

“The QMS has matured significantly in recent years. Through continuous improvements, we’ve introduced new elements to strengthen our processes and refine our methods,” said Caroline Lau, Quality Assurance Coordinator at CLEIO.

Recent improvements have strengthened several areas of operations, including design and development, cybersecurity, prototyping, and client collaboration. Documentation and traceability remain central to these efforts, supporting successful regulatory submissions and helping clients bring compliant medical devices to market with confidence.

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