eLeaP QMS Delivers Purpose-Built Support for ISO 13485:2016 Medical Device Manufacturers

eLeaP QMS gives medical device manufacturers the document control, design control, CAPA, and traceability tools needed to meet ISO 13485 requirements.

LOUISVILLE, KY, UNITED STATES, September 8, 2026 /EINPresswire.com/ -- eLeaP, a quality management software provider serving regulated industries for more than 20 years, today announced expanded support within its eLeaP QMS platform for organizations pursuing or maintaining ISO 13485 certification. The announcement formalizes capabilities medical device manufacturers already rely on inside eLeaP's integrated Quality Management System (QMS) and Enterprise Learning Management System (LMS).

ISO 13485 sets the international standard for quality management systems specific to the design, development, production, and servicing of medical devices. For device makers, staying audit-ready under the standard typically means managing design controls, document revisions, supplier qualifications, and personnel training across multiple disconnected systems - a gap regulators and auditors frequently flag.

Adoption of the standard continues to grow: the most recent ISO Survey recorded 31,215 valid ISO 13485:2016 certificates worldwide, held across 43,957 sites. The standard also underpins the Medical Device Single Audit Program (MDSAP), which lets manufacturers satisfy quality-system requirements in the United States, Canada, Brazil, Japan, and Australia through a single audit instead of five separate ones.

The standard's role in the U.S. changed further this year. When the FDA's Quality Management System Regulation (QMSR) took effect on February 2, 2026, it amended 21 CFR Part 820 to incorporate ISO 13485:2016 by reference, meaning U.S. medical device manufacturers must now demonstrate compliance with the international standard directly rather than a separately written domestic equivalent. The FDA has noted substantial overlap between the prior Quality System Regulation and ISO 13485, easing the transition for manufacturers already certified — but for the standard's clauses, that overlap now carries the weight of federal regulation.

eLeaP QMS addresses that gap by connecting every quality process to training verification in a single platform. Its Design & Development module manages devices from concept through commercialization with full traceability across requirements, specifications, verification, and validation, while automatically cascading training requirements to affected engineers and

technicians whenever specifications change. Document Control provides version control, approval workflows, and effective dating, with approved documents automatically triggering required retraining. Supplier Management extends the same rigor to vendor qualification, audits, and certificate tracking.

Mapped to the standard's clause structure, these modules address the areas auditors weigh most heavily: Design & Development covers Clause 7.3, Document Control covers Clauses 4.2.4 and 4.2.5, Supplier Management covers Clause 7.4, and CAPA covers Clauses 8.5.2 and 8.5.3 — corrective and preventive action, respectively. ISO 13485:2016 requires a documented procedure at each of these clauses, not simply a described process, which makes them recurring targets for nonconformity findings during certification audits.

"Medical device manufacturers fail audits when their quality records and their training records live in separate systems that don't talk to each other," said Don Weobong, President at eLeaP. "We built eLeaP QMS so that a design change, a document revision, or a supplier update automatically produces the training record an auditor is going to ask for. Compliance stops being a scramble before the audit and becomes a byproduct of how the team already works."

eLeaP QMS supports the full set of standards medical device organizations typically must demonstrate alongside ISO 13485, including QMSR (21 CFR Part 820), 21 CFR Part 11 electronic signatures, and EU MDR, giving device makers a single system of record across U.S. and international regulatory frameworks.

The platform is available today to medical device, digital health, and Software as a Medical Device (SaMD) organizations as part of eLeaP's broader eQMS suite, which also includes modules for Risk Management, Change Control, CAPA, Event Management, and Training Management.

Availability

eLeaP QMS for medical device manufacturers is available now. Organizations can request a free demo.

About eLeaP

eLeaP is a comprehensive quality management system with enterprise learning management built into one unified platform, purpose-built for regulated industries including medical devices, pharmaceuticals, biotechnology, aerospace, automotive, and food & beverage. Unlike standalone QMS solutions, eLeaP automatically connects quality processes - documents, design & development, risk, change, events, and suppliers — to training verification, closing the compliance gap that exists when QMS and training records live apart. With 20 years of experience serving more than 1,200 regulated companies, eLeaP helps organizations achieve faster regulatory submissions and maintain continuous audit readiness. Learn more at https://quality.eleapsoftware.com

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