MERIT Announces Successful FDA Inspection

MADISON, WI, UNITED STATES, March 30, 2026 /EINPresswire.com/ -- MERIT CRO, Inc., a global leader in clinical trial endpoint services and technology, today announced the successful completion of its recent U.S. Food and Drug Administration (FDA) inspection, with the FDA Establishment Inspection Report noting no FDA-483 observations.

MERIT, Your Clinical Endpoint Expert

EXCELSIOR Software by MERIT

A key focus of the inspection was MERIT's EXCELSIOR cloud based software platform, which is classified as Software as a Medical Device (SaMD). Because EXCELSIOR performs detection, measurement, and quantitative analysis of medical image findings used in clinical trials, it requires and holds FDA 510(k) clearance. The platform is cleared as a Class II medical device (K#220929)—a regulatory designation specifically tied to software that directly performs measurement functions influencing clinical decision making.

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> *Yijun Huang, CEO of MERIT*

With this clearance, EXCELSIOR is subject to the same design controls, verification and validation standards, production practices, and post market requirements that govern traditional medical device manufacturers. This regulatory rigor ensures that any measurement or quantitative output generated by the software meets FDA expectations for accuracy, consistency, and auditability.

Because EXCELSIOR is an FDA cleared measurement device, clinical trial sponsors benefit from a technology environment built within a fully regulated, 21 CFR 820 compliant framework. This foundation strengthens confidence in the traceability of measurement data, the integrity of image based endpoints, and the system's readiness for global regulatory submissions—critical factors in

ophthalmology, radiology, and other measurement driven therapeutic areas.

MERIT's no 483 inspection outcome underscores the strength of its Quality Management System (QMS), affirming that the company's processes are robust, comprehensive, and fully aligned with FDA expectations for organizations developing and maintaining regulated measurement software. Achieving a clean inspection is a significant milestone for any medical device entity and reflects MERIT's commitment to quality, compliance, and continuous improvement.

"We are very proud of this result," said Yijun Huang, CEO at MERIT. "A no 483 outcome is a testament to the discipline, expertise, and dedication of our entire team. Every function contributed to demonstrating the integrity of our systems and the high standards we uphold in serving our global partners and advancing patient outcomes."

The FDA inspection outcome further reinforces MERIT's position as a trusted partner in delivering FDA-cleared technology and high quality imaging endpoint services for clinical trials worldwide.

ABOUT MERIT
MERIT is an innovative, global clinical and preclinical trial endpoint and technology services provider working in a variety of therapeutic areas, including ophthalmology, respiratory, oncology, and cardiology. We partner with pharmaceutical and biotech sponsors as well as CROs to deliver reliable endpoint services in multi-regional trials. Together, our work advances and accelerates the improvement of therapeutic options for patients worldwide. MERIT has offices in Madison, WI, Shanghai, China, Toronto, Canada, and Sydney, Australia. https://meritcro.com/

Stacy Sanderson
MERIT
+1 608-284-8810
email us here
Visit us on social media:
LinkedIn
YouTube
X