MERIT Receives ISO 13485:2016 Certification

MADISON, WI, UNITED STATES, July 13, 2022 /EINPresswire.com/ -- MERIT CRO, Inc., a global endpoint service provider focusing on the ophthalmic, respiratory, and oncology therapeutic areas, announced today the company received ISO 13485:2016 certification.

The certification confirms that MERIT's Quality Management System (QMS) has been designed to meet international standards as a medical device company and to provide the structure and controls required for clinical endpoint assessment and adjudication. The QMS supports procedures for ensuring optimal product performance and customer service standards to promote continuous improvement per 21 CFR Part 820 Quality systems regulations and ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes. MERIT's QMS supports clinical study execution and ensures that our processes meet industry standards. Its technical and procedural controls reflect not only ISO 13485 and 21 CFR Part 820 Quality System Regulation, but also 21 CFR Part 11, GDPR, HIPAA, ICH E6 (R2), and GxP industry standards.

> MERIT strives to attain the highest standards in everything we do. This certification strongly demonstrates our commitment to quality and meeting customer and regulatory expectations"
>
> *Yijun Huang, Co-Founder and CEO of MERIT*

"MERIT strives to attain the highest standards in everything we do. This certification strongly demonstrates our commitment to quality and meeting customer and regulatory expectations," said Yijun Huang, Co-Founder and CEO of MERIT.

"I am very proud of the hard work of our Quality Assurance team," stated Kym Larson, Director of Regulatory Compliance at MERIT. "We appreciate the support of the entire company in achieving this important milestone."

For more information, visit https://meritcro.com/iso-13485-certified-quality-management-system/

ABOUT MERIT

MERIT is a global endpoint service provider specializing in the ophthalmology, respiratory, and oncology therapeutic areas. We partner with CROs and pharmaceutical and biotech companies to deliver reliable endpoint services in multi-regional clinical trials. Together our work advances and accelerates the improvement of therapeutic options for patients worldwide.

MERIT's EXCELSIOR™ technology platform increases accuracy and efficiency by providing a suite of advanced endpoint analysis tools designed based on our extensive collaboration with biopharma companies.

MERIT's offices are located in Madison, WI, North Liberty, IA, and in Shanghai, China. We conduct studies across the globe with experience managing clinical sites in 58 countries. Visit our website to learn more: https://meritcro.com/

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