Quality Assurance

MERIT's deep knowledge of the regulatory requirements for our specialized therapeutic areas forms the cornerstone for our successful management of clinical trial data.

HIGHLIGHTS

- MERIT's Quality Management System (QMS) is ISO 13485 certified
- MERIT's Information Security Management System (ISMS) is ISO 27001 certified
- We prioritize data privacy; MERIT is GDPR compliant in both our processes and with our proprietary EXCELSIOR™ software
- EXCELSIOR is a 510(k) cleared medical device for ophthalmic and radiological indications that is HIPAA compliant and meets all 21 CFR Part 11 requirements for electronic records and signatures

Our Quality Assurance team has extensive experience with GxP, ISO, ICH, software validation, auditing, medical devices, pharmaceuticals, quality management systems, process improvement, risk assessment, and CAPA.

ISO 13485 CERTIFICATION

MERIT is ISO 13485 certified to provide imaging services to global pharmaceutical, biotechnology, medical device, and CROs that are conducting clinical trials. Our ISO 13485 certified Quality Management System (QMS) has been designed to:

- Meet international standards as a medical device company
- Provide the structure and controls required for clinical endpoint assessment and adjudication
- Support clinical study execution
- Ensure that our processes meet industry standards


Certificate of Registration

This certifies that the Quality Management System of

MERIT CRO Inc

6527 Normandy Lane
Madison, Wisconsin, 53719, United States

has been assessed by NSF-ISR and found to be in conformance to the following standard(s):

ISO 13485: 2016

Scope of Registration:
MERIT CRO provides image management and review services to global pharmaceutical, biotechnology, medical device and clinical research organizations that are conducting clinical trials.

Certificate Number: C0605631-MDI
Certificate Issue Date: 03-JUN-2022
Registration Date: 03-JUN-2022
Expiration Date *: 02-JUN-2025

Jennifer Morecraft,
Senior Managing Director

NSF International Strategic Registrations
789 North Dixboro Road, Ann Arbor, Michigan 48105 | (888) NSF-9000 | www.nsf-isr.org

Our QMS includes technical and procedural controls that reflect not only ISO 13485, but also 21 CFR Part 820 Quality System Regulation, ICH E6 (R2), and GxP industry standards. Our ISO 13485 certification validates our ability to provide imaging services that consistently meet customer and regulatory requirements applicable specifically to medical devices. MERIT's certification has been assessed by NSF-International Strategic Registrations (NSF-ISR) and found to be in conformance with ISO 13485.

ISO 27001 CERTIFICATION

MERIT is ISO 27001 certified, confirming that our ISMS has been assessed by NSF-ISR, an independent third-party auditor accredited by the ANSI-ASQ National Accreditation Board (ANAB). MERIT's ISMS conforms with ISO 27001 for MERIT's expert image management and review services provided to global pharmaceutical, biotechnology, medical device, and clinical research organizations that are conducting clinical trials.


Certificate of Registration

This certifies that the Information Security Management System of

MERIT CRO Inc

6527 Normandy Lane
Madison, Wisconsin, 53719, United States

has been assessed by NSF-ISR and found to be in conformance to the following standard(s):

ISO 27001:2013

Scope of Certification:
MERIT CRO provides expert image management and review services to global pharmaceutical, biotechnology, medical device and clinical research organizations that are conducting clinical trials.

Statement of Applicability (SOA): SB/2023 Version 1.1

Certificate Number: C0605631-ISM1
Certificate Decision Date: 02-JUN-2023
Certificate Issue Date: 02-JUN-2023
Cycle Effective Date: 02-JUN-2023
Certificate Expiration Date*: 30-OCT-2025

Sameer Vachani
Senior Director, NSF-ISR

ISO 27001 is the best-known international standard for ISMS and their requirements, including best practice in data protection and cyber resilience as well as managing security of assets such as financial information, intellectual property, employee data and information entrusted by third parties. The ISO standard provides companies with guidance for creating, executing, and continually improving an ISMS.

This certification assures customers that MERIT's documented processes for managing company information, HR processes, and IT systems meet rigorous ISO standards. Conformity with ISO 27001 demonstrates MERIT has an ISMS in place that manages risk related to the security of data owned or handled by the company.

QUALITY POLICY

MERIT strives to provide safe, reliable, efficient, high quality data analysis and management for clinical trials to the pharmaceutical and biotech industries. We are committed to consistently meeting all applicable regulatory requirements through maintaining and improving an effective and efficient quality management system and associated quality objectives.

EXCELSIOR IS A 510(K) CLEARED MEDICAL DEVICE

EXCELSIOR is a cloud-based software platform cleared with the FDA as a Class II medical device (K#220929), with specific indication for managing ophthalmic and radiological clinical trial data. Consequently, MERIT is organized as a medical device manufacturer, following cGMP.

21 CFR PART 11 ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

MERIT's flagship software, EXCELSIOR, is a fully integrated platform that meets all regulatory requirements for 21 CFR Part 11 Electronic Records. There is a full audit trail that is provided in a human readable format to track each action taken in the data management process, including user access, upload of images, review of images in the quality control step, and each grading step. EXCELSIOR users are required to sign off on each step in the workflow for a two-point authentication per the regulatory requirements defined in 21 CFR Part 11.

GDPR

MERIT has taken the appropriate steps to become a GDPR compliant organization. The use of EXCELSIOR ensures that the data hosting and analysis at a reading center remains GDPR compliant. This means that MERIT verifies that the EXCELSIOR platform and MERIT internal framework ensures EU individual rights. Additionally, MERIT has the organizational measures in place to maintain GDPR compliance.

Individual Consent and Rights

- Stricter conditions for consent
- Right to rectification
- Right to erasure, right to be forgotten
- Right to data portability
- Right to object and automated individual decision making

Organizational Measures

- Data Protection Impact Assessment (DPIA)
- Inventory of all personal data
- Data protection by design and default
- Framework for GDPR Compliance

PRIVACY SHIELD

MERIT complies with the EU-U.S. Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the European Union and the United Kingdom to the United States in reliance on Privacy Shield. MERIT has certified to the Department of Commerce that it adheres to the Privacy Shield Principles with respect to such information.

REGULATORY COMPLIANCE

MERIT meets the regulatory requirements of a medical device company. In addition, the Quality Management System is structured to support ongoing clinical and preclinical study activities, including:

- Electronic records
- Internal audits
- Archival of data
- Validation of computerized systems
- Software development life cycle procedures
- Business continuity and disaster recovery
- Vendor and contractor assessments and qualifications

To ensure ongoing regulatory compliance, MERIT supports a full suite of Standard Operating Procedures, Standard Evaluation Procedures, and Policies.

QUALITY MANAGEMENT SYSTEM

MERIT's QMS is ISO 13485 certified. It has been designed to provide the structure and controls required for EXCELSIOR as a medical device, and to support clinical study execution and ensure that our processes meet industry standards. Our QMS includes technical and procedural controls that reflect 21 CFR Part 820 Quality System Regulation, ICH E6 (R2), and GxP industry standards.

INTERNAL AND SPONSOR AUDITS

We regularly perform internal audits to ensure study data quality and compliance to MERIT's Quality Systems requirements and industry regulations. In addition, MERIT routinely hosts sponsor audit activities and supports inspections conducted by regulatory agencies. Our Quality Assurance and Regulatory Affairs (QA/RA) team works with clients and partners to support meeting regulatory requests and/or on-site inspection requirements, including sponsor-run mock inspections.

MERIT
Your Clinical Endpoint Expert

Connect with us to learn more about how our expertise and approach can support bringing your product to market on-time and on-budget. Your success is our priority.

START A CONVERSATION

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