OpenClinica
Compliance Support Service

The OpenClinica Compliance Support Service (f/k/a OpenClinica Regulatory Support) makes it easy for our customers to achieve, maintain, and demonstrate compliance with:

- regulations (e.g. from FDA, EMA, including 21 CFR Part 11, HIPAA, GDPR, ICH-GCP),
- data practices and security standards (ISO, SOC), and
- institutional policies (e.g. your SOPs, security assessments, etc.).

The service provides you with continuously maintained documentary evidence, access to OpenClinica's internal Quality System, and ongoing support and guidance for compliance-related issues.

Access to the OpenClinica Quality System

OpenClinica's Quality System is regularly audited by leading organizations performing clinical trials regulated by the FDA and other authorities. Our compliance support service provides you with access to:

- **Our Quality Manual and Standard Operating Procedures (SOPs)**, mandating practices that ensure the highest quality of information security, software engineering, support, and human resources
- **Software Requirements Specifications**, detailing product requirements and acceptance criteria
- **Traceability Matrix** that ties test cases, results, and artifacts to relevant requirements, including 21CFR Part 11 requirements
- **Release Plans** that define the processes, methods, and systems used to prepare each software release.
- **A Summary Report** for each release, which lists the status of the release, defines the tagging and packaging of the release, and lists any deviations that occurred throughout the development process.
- **Access to human resources records**, including CVs, job descriptions, and training records
- **OpenClinica Cloud security and validation artifacts**

Validation of Installation and Upgrades

OpenClinica fully validates installations and upgrades, providing you with key documentary evidence:

- **Installation Qualification (IQ) Test Reports**, which show the system is installed correctly
- **Operational Qualification (OQ) Test Reports**, which demonstrate that your system has been appropriately configured and is operating as designed
- **Upgrade Qualification on (UQ) Test Report**, demonstrating operational qualification of each upgrade
- **Performance Qualification (PQ) materials**, including detailed requirements, tests and traceability matrices

Access to OpenClinica's Compliance Team

Maintaining compliance is an ongoing effort, and OpenClinica's compliance department is dedicated to working with you to help ensure you are able to demonstrate compliance at any time. Whether it's best-practice guidance for UAT, presenting SOP artifacts, conducting security reviews, fielding miscellaneous regulatory questions, or hosting a full-fledged audit, we're here to help you succeed.

617-621-8585
sales@openclinica.com
openclinica.com

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