Meeting today's
FDA COMPLIANCE

Meeting FDA 21 CFR Part 11

FDA 21 CFR Part 11 defines the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records. Qualtrax is designed with the Technical C ontrols necessary for 21 CFR Part 11 compliance.The closed system provides robust electronic document and record control, revision tracking, electronic signatures, and audit trails. No software vendor can offer a certified FDA compliant solution, since it is the responsibility of the user to implement the Procedural and Administrative Controls to ensure overall Part 11 compliance. However, Qualtrax does offer services and tools to help with this process.

Technical Controls

Qualtrax meets FDA 21 CFR Part 11 technical requirements with the following features:

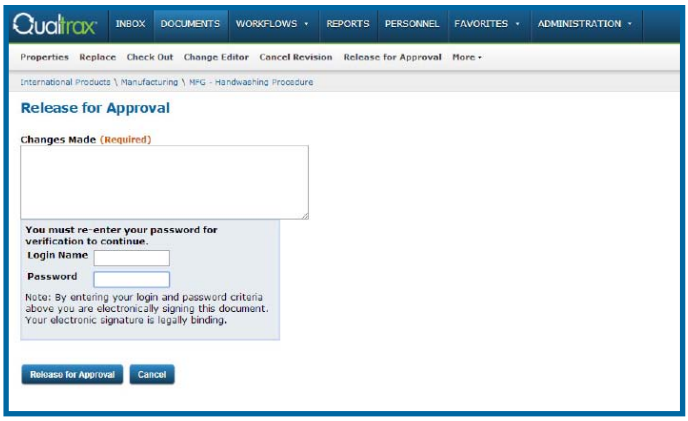
Electronic Records
Qualtrax provides complete management of electronic records, including revision and approval tracking with time and date stamps. Records are never removed from the Qualtrax system; rather they are retired and can be accessed with the appropriate permissions for audit purposes.

Audit Trail
Qualtrax records an audit trail of all the actions taken on documents, tests, workflows, users, and groups.

Electronic Signatures
Qualtrax forces users to reenter their login name and complex password for any documents that require a legally binding electronic signature.

Procedural and Administrative Controls

Qualtrax provides tools and services to help implement the necessary procedural and administrative controls for FDA compliance. The FDA Compliance functionality includes:



Site Acceptance Test
Prior to the validation process, the Site Acceptance Test is conducted by Qualtrax to determine if the software installation is operating according to specifications.

Validation Protocol Workbook
This workbook reduces the time and cost associated with validation of the system. The workbook serves as a template for compliance officers to use as a means of testing usage of Qualtrax for the control of electronic records and signatures.

For a demonstration of how Qualtrax can simplify accreditation, call +44 (0) 1908 920 608

Qualtrax® COMPLIANCE SOFTWARE

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