F A C I L I W O R K S C M M S

FDA COMPLIANCE AND SOFTWARE VALIDATION

The FaciliWorks Validation Kit and our on-site validation services ensure documentation accuracy and preparedness for successful audits.

21 CFR PART 11 COMPLIANCE SUPPORT

21 CFR Part 11 sets forth the FDA's standard for electronic signatures and tracking of all changes to your database. Companies that wish to have electronic records and electronic signatures accepted as equivalent to the corresponding paper records must comply with this standard.

To assure our customers of compliance with 21 CFR Part 11, CyberMetrics voluntarily undergoes independent 3rd party audit, review and certification. This includes actual on-site inspection of our records, product development practices, testing methods, maintenance procedure as well as specific functional assessment of our software. Copies of our compliance certification letters are available upon request.

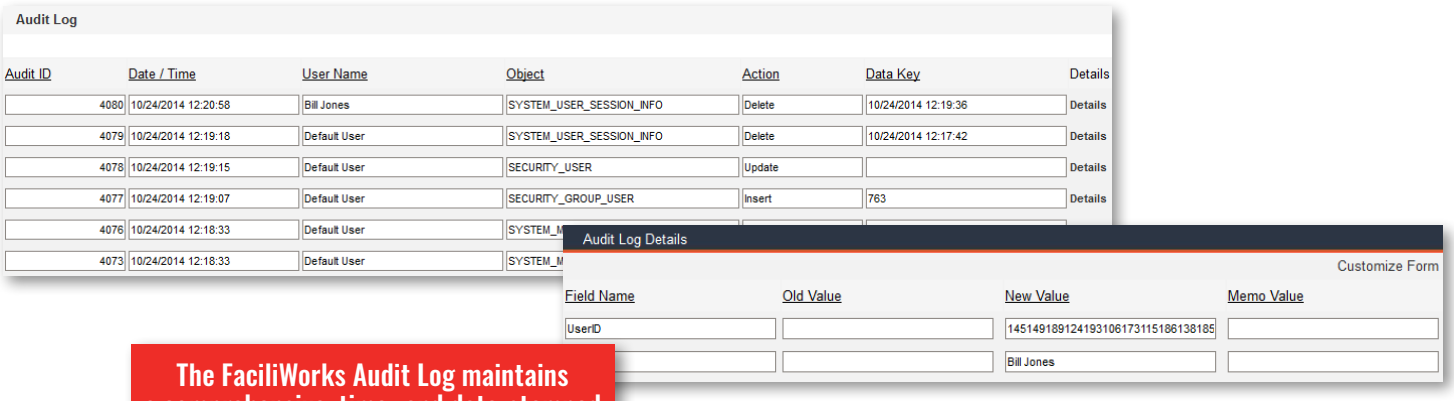
The 21 CFR Part 11-compliant version of FaciliWorks automatically and permanently enables security and the Electronic Signature, Advanced Audit Log and Login Timeout functions.

FACILIWORKS FEATURES

Security: With security enabled, a user's access to forms and fields within forms can be limited; for instance, a user can view the Labor form under Work Orders but cannot view the Cost field in that form. To make security easier to implement, you can create groups with standardized access privileges and assign users to groups as needed.

Electronic Signatures and Approvals: The 21 CFR Part 11-compliant version of FaciliWorks records signatures and approval signatures upon the completion of PMs, work orders, service requests and checklists and the creation of purchase orders. Once a record has been signed, it cannot be modified unless the original signer unsigns it. If the record has been approved, the original approver must first unsign the approval record and then the original signer may unsign the record. FaciliWorks maintains a comprehensive history of all signatures on a given record, including date, time, signer and any comments entered at the time the record was signed or unsigned.

Audit Trail: The 21 CFR Part 11-compliant version of FaciliWorks automatically enables and indefinitely preserves the Audit Trail which maintains a comprehensive history of all user actions such as record modifications, additions or deletions along with the date and time of each action and the name of the user who performed the action. The Audit Log can be viewed on screen or printed and can be filtered to show specific records.



The FaciliWorks Audit Log maintains a comprehensive, time- and date-stamped record of all user actions.

FACILIWORKS VALIDATION KIT

Software validation, as it applies to FaciliWorks Web-based CMMS maintenance management software, involves making sure that FaciliWorks functions as designed and that it works under the purchaser's actual conditions. FDA GMPs require that purchasers of vendor-supplied software perform software validation under normal operating conditions. To assist you in accomplishing this validation, every version of FaciliWorks is validated prior to its release to ensure compliance with international standards.

The FaciliWorks Validation Kit includes a step-by-step validation guide, which serves as the basis by which the software is validated, and a sample validation database to assist you with:

- Testing the software's functionality
- Preparing your SOPs for FaciliWorks
- Training the users of the software
- Documenting the formal validation report

And, because FaciliWorks can incorporate calibration management, our Calibration Validation Kit supports both CMMS and calibration to meet requirements for single-track FDA validation.

ON-SITE VALIDATION SERVICES

Our on-site validation services streamline the validation process, guaranteeing documentation accuracy and minimizing downtime. Our Validation Services expert uses the FaciliWorks Validation Kit to perform the validation at your facility under normal operating conditions and then documents and stores all results within the Kit as preparation for future audits.

BE PREPARED

Compliance auditors recommend our software solutions because of our software's solid, long-standing reputation and reliable, systematic, adaptable and auditable record keeping. Get the FaciliWorks Validation Kit and take advantage of our on-site validation services today to ensure documentation accuracy and preparedness for successful future audits.

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