

FaciliWorks® 8i FDA Compliance



FDA 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. The FaciliWorks 8i electronic security features make implementing 21 CFR Part 11 in your workplace simple, straightforward and secure.

CyberMetrics voluntarily undergoes independent third-party audit, review and certification of FaciliWorks 8i. This includes on-site inspection of our records, product development practices, testing methods and maintenance procedures and specific functional assessment of our software. Copies of our compliance certification letters are available upon request.

FaciliWorks simplifies the validation process with its backup/restore feature, built-in referential integrity checks, field-level input validation and standard reports.

Security

The 21 CFR Part 11-compliant version of FaciliWorks 8i requires security to be active at all times and automatically enables the Electronic Signature and Audit Trail features.

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 8i 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 unapprove the approval record and then the original signer may unapprove the record.

FaciliWorks 8i 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.

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Record: 337

PM No.	PM-Nov-2011-0016	PM Description	
Asset ID	Double Backer003	Asset Description	PH# Double Backer
Task ID	Ro-replace Seals	Task Description	Replace the seals on the shaft bearings

Done By	Signature Name	Date	Time	Mode	Comments
	Frank	11/04/2011	10:07:14	Signed	
	Frank	11/04/2011	10:06:39	Unsigned	forgot to add labor
	Frank	11/04/2011	09:59:05	Signed	

Unsign

Approved By	Signature Name	Date	Time	Mode	Comments
	Sarah	11/04/2011	10:04:37	Signed	

Unsign

Audit Trail

The 21 CFR Part 11-compliant version of FaciliWorks 8i automatically enables 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 Trail is preserved indefinitely in the 21 CFR Part 11-compliant version of FaciliWorks 8i; however the standard version allows the purging of these records after a set number of days.

The Audit Log can be viewed on screen or printed and can be filtered to show specific records.

FaciliWorks 8i Validation Kit

Software validation, as it applies to FaciliWorks 8i CMMS software, involves making sure that FaciliWorks 8i 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, CyberMetrics validated FaciliWorks 8i CMMS software before its original release and continues to validate it prior to each subsequent update release.

And, because FaciliWorks 8i can now incorporate calibration management, our 8i Calibration Validation Kit supports both CMMS and calibration to meet requirements for single-track FDA validation.

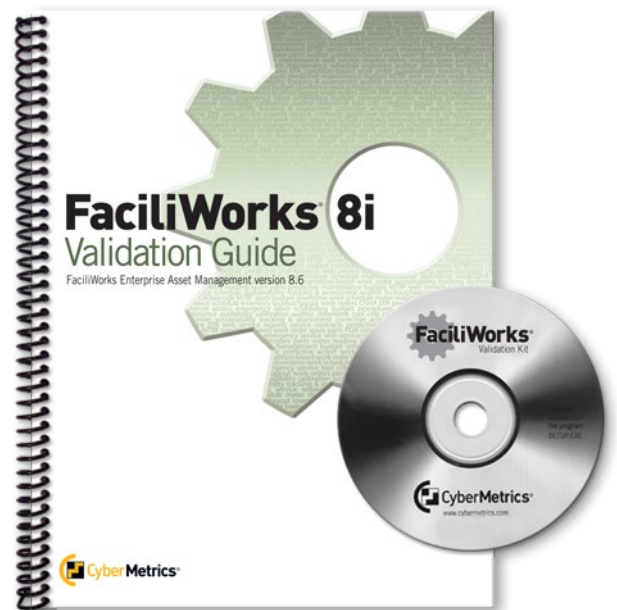
The FaciliWorks 8i Validation Kit includes a Validation Guide, which serves as the basis by which the software is validated, and a sample validation database.

- Test the software's functionality
- Prepare your standard operating procedures (SOPs) for this software
- Train the users of the software
- Document the formal validation report

Audit ID	Date / Time	User Name	Object	Action	Data Key	Details
121818	06/27/2011 11:01:36	Robert Jones	SYSTEM_USER_SESSION_INFO	Update	06/27/2011 10:55:03	Details
121817	06/27/2011 11:01:33	Phil Smith	GROUPING_EQUIPMENT_LINK	Delete	105	Details
121816	06/27/2011 11:01:33	Sandy Davis	GROUPING_EQUIPMENT_LINK	Insert	105	Details
121815	06/27/2011 11:01:33	Sandy Davis	EQUIPMENT_STATUS_HISTORY	Insert	68	Details
121814	06/27/2011 11:01:33	Robert Jones	SYSTEM_WORKFLOW_HISTORY	Insert	44	Details
121813	06/27/2011 11:01:33	Phil Smith	EQUIPMENT_MASTER	Insert	133	Details
121812	06/27/2011 11:01:33	Phil Smith	SYSTEM_USER_SESSION_INFO	Update	06/27/2011 10:55:03	Details

Field Name	Old Value	New Value	Memo Value
SettingValue	2	1	
1			

The FaciliWorks 8i Audit Log maintains a comprehensive, time- and date-stamped record of all user actions.



With our commitment to compliance assurance, it's no wonder that over 12,000 organizations worldwide use our software solutions in virtually every type of industry and organization.

Contact us today for your free trial or personalized web demo to see FaciliWorks 8i in action.

FaciliWorks® 8i
by CyberMetrics

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