

AUDITOR-RECOMMENDED



FDA

GAGETRAK FDA COMPLIANCE MANAGER

The GAGetrak FDA Compliance Manager and our on-site validation services ensure documentation accuracy and preparedness for successful audits.



To ensure compliance with 21 CFR Parts 11 and 820.72, CyberMetrics voluntarily undergoes independent, third-party audit, review and certification. This includes on-site inspection of our records, product development practices, testing methods and maintenance procedures as well as specific functional assessment of our software. Copies of our compliance certification letters are available upon request.

The **FDA Compliance Manager**, a companion product to GAGetrak Pro or GAGetrak Lite, connects to your GAGetrak database and is used to convert the database to FDA mode. It automatically and permanently enables security, audit trails, login timeout functionality and the electronic signature feature. Any GAGetrak install that is connected to an FDA-mode database will have FDA compliance enabled.

The screenshot shows the 'GAGetrak FDA Compliance Manager' application window. The 'Gage Audit Trail' tab is active, displaying a table of audit records. The table columns include Date Change, Custodian, Table, Record Identifier, Change Type, Field Name, Field Change, Previous Val, New Value, User Name, and Parent Table. The table contains 20 rows of data, showing various actions like 'Record Added' and 'Record Deleted' performed by an 'Administrator' on different tables such as 'GageProcedure' and 'GageRefStandarc'.

Date Change	Custodian	Table	Record Identifier	Change Type	Field Name	Field Change	Previous Val	New Value	User Name	Parent Table
11/03/2023 3:11	Administrator	GageProcedure	001E-GBLK CP10E Revision 01/	Record Added	Procedure	Value Added		CP10E Revision 0	Admin	Procedure
11/03/2023 3:11	Administrator	GageProcedure	001E-GBLK CP10E Revision 01/	Record Added	Gage	Value Added		001E-GBLK	Admin	Procedure
11/03/2023 3:11	Administrator	GageProcedure	001E-GBLK CP10E Revision 01/	Record Added	PrintProcedure	Value Added		False	Admin	Procedure
11/03/2023 3:01	Administrator	GageRefStandarc	002E-OMIC 1. Free movement/	Record Deleted	ReferenceGage	Value Deleted	WT2		Admin	GageTestPoint
11/03/2023 3:00	Administrator	GageRefStandarc	002E-OMIC 1. Free movement/	Record Deleted	ReferenceGage	Value Deleted	WT90		Admin	GageTestPoint
11/03/2023 3:00	Administrator	GageRefStandarc	002E-OMIC 1. Free movement/	Record Added	ReferenceGage	Value Added		WT90	Admin	GageTestPoint
11/03/2023 3:00	Administrator	GageRefStandarc	002E-OMIC 1. Free movement/	Record Added	ReferenceGage	Value Added		WT2	Admin	GageTestPoint
11/03/2023 2:57	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		043F-AGB	Admin	GageTestPoint
11/03/2023 2:41	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		042E-AGB	Admin	GageTestPoint
11/03/2023 2:41	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		MSGB1	Admin	GageTestPoint
11/03/2023 2:41	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		L44565-20	Admin	GageTestPoint
11/03/2023 2:41	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		WT90	Admin	GageTestPoint
11/03/2023 2:41	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		WT2	Admin	GageTestPoint
11/03/2023 2:40	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		MSGB1	Admin	GageTestPoint
11/03/2023 2:40	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		L44565-20	Admin	GageTestPoint
11/03/2023 2:40	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		WT90	Admin	GageTestPoint
11/03/2023 2:40	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		WT2	Admin	GageTestPoint
11/03/2023 2:40	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		MSGB1	Admin	GageTestPoint
11/03/2023 2:36	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		L44565-20	Admin	GageTestPoint
11/03/2023 2:36	Administrator	GageRefStandarc	001E-GBLK 01. Flatness/paralle	Record Added	ReferenceGage	Value Added		WT90	Admin	GageTestPoint

Audit Trail: The FDA Compliance Manager automatically enables and preserves the audit trail (pictured above) 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. Audit trails can be viewed on screen or printed and can be filtered to show specific records.

Security: With security enabled, a user's access to forms can be limited; for instance, a user can have read-only access in Gages (or no access), but can have full access to Calibrations in order to create calibration records. 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: 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. GAGetrak 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.

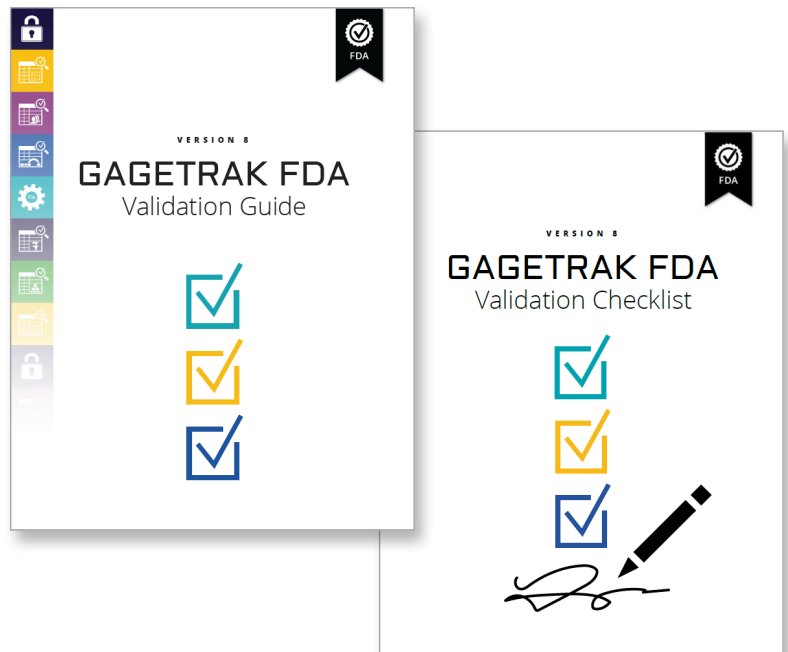
VALIDATION

Software validation, as it applies to GAGetrak calibration management software, involves verifying that GAGetrak functions as designed and that it works under the purchaser's actual conditions. Every version of GAGetrak is validated prior to its release to ensure compliance with international standards. FDA GMPs require that purchasers of the software perform software validation under normal operating conditions.

The FDA Compliance Manager software includes a step-by-step Validation Guide and a corresponding Validation Checklist to streamline these validation efforts. Use the Guide to verify key product functionality and its compliance to the FDA 21 CFR Part 11 and Part 820.72 requirements and use the Checklist to document the results.

- Test the software's functionality
- Prepare your SOPs for GAGetrak
- Train the users of the software
- Document the validation report

After completing validation, the FDA Compliance Manager application can be utilized by GAGetrak administrators to view and manage the audit trail, reference attached validation documents and adjust FDA-specific settings as needed for your training and production databases.



ON-SITE VALIDATION SERVICES

Efficient validation processes are crucial in ensuring compliance and optimal product performance. When you opt for our on-site validation services, our experienced Services team will guide your team through the validation effort. Swift compliance and a quick start will give your organization a competitive edge.

BE PREPARED

Compliance auditors recommend GAGetrak because of its solid, long-standing reputation and reliable, systematic, adaptable and auditable record keeping. Get the FDA Compliance Manager and take advantage of our on-site validation services to ensure documentation accuracy and preparedness for successful audits.

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