

AUDITOR-RECOMMENDED

GAGETRAK FDA COMPLIANCE AND VALIDATION

The GAGetrak 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 FDA Edition of GAGetrak automatically and permanently enables security and the Electronic Signature, Advanced Audit Log and Login Timeout functions.

GAGETRAK FEATURES

Security: With security enabled, a user’s access to forms can be limited; for instance, a user can have read-only access in Gage Entry (or no access at all), but can have full access to Calibration Entry 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: The FDA Edition of GAGetrak records signatures and approval signatures upon the completion of calibrations. 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.

Audit Trail: The FDA Edition of GAGetrak 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.

GAGetrak maintains a comprehensive history of all signatures on a given record, including date, time and signer.

GAGetrak’s Audit Log maintains a comprehensive, time- and date-stamped record of all user actions.

Audit ID	Date / Time	User	Object	Action	Data Key
63	4/15/2014 12:39:02 PM	Admin	Settings	Update	Settings
62	4/15/2014 12:38:53 PM	Admin	Settings	Update	Settings
61	4/15/2014 12:38:01 PM	Admin	Settings	Update	Settings
60	4/15/2014 12:37:48 PM	Admin	Settings	Update	Settings
59	4/15/2014 11:32:07 AM	Admin	Settings	Update	Settings
58	4/15/2014 11:21:49 AM	Admin	Settings	Update	Settings
57	4/15/2014 11:19:05 AM	Admin	Gage Master Entry	Delete	EXTRA
56	4/15/2014 11:18:59 AM	Admin	Gage Master Entry	Delete	NEW
55	4/15/2014 11:17:32 AM	Admin	Gage Master Entry	Update	NEW
54	4/15/2014 11:15:29 AM	Admin	Gage Master Entry	INSERT	CURRENT

Field Name	Old Value	New Value	Memo Value (for Memo field)
LoginInactivityPeriod	1	30	

GAGETRAK VALIDATION KIT

Software validation, as it applies to GAGetrak calibration management software, involves making sure that GAGetrak 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 GAGetrak is validated prior to its release to ensure compliance with international standards.

The GAGetrak 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 GAGetrak
- Training the users of the software
- Documenting the formal validation report



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 GAGetrak 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.

JUST A FEW OF OUR FDA-COMPLIANT CUSTOMERS

DSM Biomedical	Medline	Vention Medical	Medtronic
Cardinal Health	Kaiser Permanente	Cook Incorporated	Zimmer
Catalent	Herbalife	Accellent	Acumed Inc.
Mylan Technologies	Ametek	Becton Dickinson	EMD Millipore
Exsurco Medical, Inc.	West Pharmaceutical	Terumo Cardiovascular Systems	CareFusion

BE PREPARED

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

SUPPORT

+1 (480) 212-1257
1-800-777-7020
support@cybermetrics.com

SALES

+1 (480) 922-7300
1-800-777-7020
sales@cybermetrics.com

