

GAGetrak® 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. GAGetrak's 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 GAGetrak. 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.

Security

The 21 CFR Part 11-compliant version of GAGetrak 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 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 21 CFR Part 11-compliant version of GAGetrak records signatures and approval signatures when calibrations are completed. 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 and signer. If the record has been unsigned, that information is recorded as well.

A screenshot of the 'Calibration Entry' software window. The window has several tabs: 'Calibration', 'Measurements', 'Procedures', 'Signature and Scans', and 'Additional'. The 'Signature and Scans' tab is active. It shows a 'Gage ID' of 'AB-032-210' and a 'Description' of 'Analytical Balance 210g'. Below this, there are two sections: 'Calibrated By Signature' and 'Approved By Signature'. Each section contains a table with columns for 'Signature Name', 'Signature Date', 'Signature Time', and 'Signature Mode'. The 'Calibrated By Signature' table has one entry for 'Robert Jones' on '1/24/2011' at '7:45:51 AM' with a 'Signed' mode. The 'Approved By Signature' table has one entry for 'Susan Smith' on '1/24/2011' at '7:49:56 AM' with a 'Signed' mode. There are 'Unsign' buttons next to each table. At the bottom of the window, there are buttons for 'MSA', 'Graph', 'Certificate', 'Gage Entry', and 'Scan New'. A status bar at the very bottom shows 'Record: 1 of 45'.

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

Audit Trail

The 21 CFR Part 11-compliant version of GAGetrak 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 GAGetrak; 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.

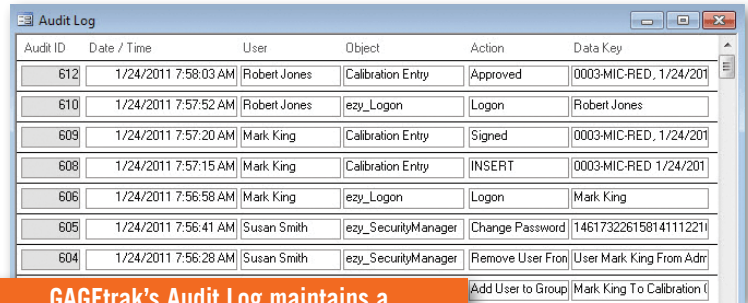
GAGetrak Validation Kit

Software validation, as it applies to GAGetrak calibration management software, involves making sure that GAGetrak functions as designed. Software validation involves assuring that the software itself works properly and that it works under the purchaser's actual conditions.

To assist you in accomplishing this validation, CyberMetrics validated GAGetrak calibration management software before its original release and continues to validate it prior to each subsequent update release to ensure gage standards and calibration compliance with quality standards alongside the FDA regulations.

The GAGetrak 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

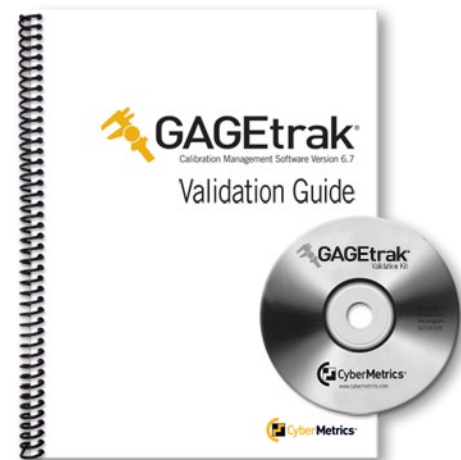


Audit ID	Date / Time	User	Object	Action	Data Key
612	1/24/2011 7:58:03 AM	Robert Jones	Calibration Entry	Approved	0003-MIC-RED, 1/24/2011
610	1/24/2011 7:57:52 AM	Robert Jones	ezy_Logon	Logon	Robert Jones
609	1/24/2011 7:57:20 AM	Mark King	Calibration Entry	Signed	0003-MIC-RED, 1/24/2011
608	1/24/2011 7:57:15 AM	Mark King	Calibration Entry	INSERT	0003-MIC-RED, 1/24/2011
606	1/24/2011 7:56:58 AM	Mark King	ezy_Logon	Logon	Mark King
605	1/24/2011 7:56:41 AM	Susan Smith	ezy_SecurityManager	Change Password	14617322615814111221
604	1/24/2011 7:56:28 AM	Susan Smith	ezy_SecurityManager	Remove User From	User Mark King From Adr
			Add User to Group		Mark King To Calibration

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

Recommended by Auditors

Compliance auditors recommend GAGetrak because of its solid, long-standing reputation and reliable, systematic, adaptable and auditable record keeping... yet another reason GAGetrak is the #1 calibration management software solution in the world.



With our commitment to compliance assurance, it's no wonder that over 12,000 organizations worldwide rely on our software solutions.

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

 **GAGetrak**
by CyberMetrics

1.800.777.7020
www.cybermetrics.com +001 (480) 922-7300