21 CFR 11

VERSION 8

GAGETRAK FDA COMPLIANCE MANAGER

Intro Guide

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TECHNICAL SUPPORT

M-F 6:00 a.m. to 4:00 p.m., MST.
https://gagetrak.com/support/

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CHAPTER 1: INTRO & INSTALLATION

Overview

CyberMetrics has further simplified the validation process with the FDA Compliance Manager, a companion product to GAGEtrak, created to assist you in managing your organization's ongoing FDA compliance requirements. In FDA Mode, the GAGEtrak FDA Compliance Manager will ensure that the specific functionality required to meet FDA 21 CFR Part 11 is enforced. Once implemented, managers will be able to use the FDA Compliance Manager to monitor audit trails, produce compliance reporting and make any configuration changes necessary to meet your organization's compliance needs.

As you read through this guide, keep in mind that the screenshots shown may differ slightly from your software, depending on your operating system and settings. Let's get started!

How to Install

Whether you have downloaded your software or requested it on physical media, launch the **GAGEtrak FDA Compliance Manager setup executable (.exe)** file. It is recommended to install FDA Compliance Manager under computer or domain administrative permissions. Once launched, the FDA Compliance Manager installation wizard will open; simply click **Install** to begin. Follow the on-screen instructions to complete the installation.

During installation, the **Database Type** window will open, giving you the option to connect to your existing database or skip this step and connect to your database later. If you select to connect to your existing database during this installation process, a **GAGEtrak Connect** window will display. Make sure you connect to your existing GAGEtrak core application database by doing the following.

In the **Connection Name** field, name your database connection; this will make the database connection easier to identify, especially if you plan to have multiple databases, e.g., Fixtures and Assembly Data or by a location, such as Memphis Assembly No7.

Select the appropriate **Data Source Type** (use the Standard SQLite option unless instructed by your IT team to select one of the other DBMS options provided). The **Database File Name** field is automatically populated; use the default value unless otherwise instructed. Click **Save and Connect**.

Click **Finish** when the installation completes.

If Installation Fails

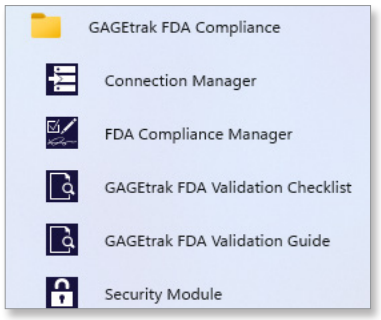
If you are unable to install or you receive any error messages during installation, please run a Windows Update if possible, restart your systems and try again. If the installation fails again, please write down any error messages and call tech support at +1 (480) 212-1257 for assistance.

How to Uninstall

To uninstall, go to the **Windows Control Panel -> Programs and Features -> Uninstall or change a program**, select **GAGEtrak FDA Compliance** and click **Uninstall**. Once it has been uninstalled, simply remove the program group from the Start menu and delete the **GAGEtrak FDA Compliance** directory. Note: The database may be stored locally, so please ensure there are no database files that you want to keep before deleting the GAGEtrak FDA Compliance directory, i.e., the **Gtdata870_FDA.db3** and **Gtdata870_FDA_Archive.db3** database files can contain gage and calibration records. Windows 10 and 11 users: by default, GAGEtrak FDA Compliance Manager installs to C:\Program Files (x86)\CyberMetrics...

Launching FDA Compliance Manager

Locate the **GAGEtrak FDA Compliance** program group in your Windows Start menu; this contains shortcuts to the **FDA Compliance Manager** application along with several other utilities and functions. Please do not modify the properties of these shortcuts, as this may affect the program's ability to correctly launch.



License Registration and Management

A **License Code** is required to run GAGEtrak FDA Compliance Manager. Once launched, the **Register License** dialog will appear and give you the opportunity to enter and validate your **License Code**. Enter the code provided by CyberMetrics or your authorized distributor and click **Check License** to verify and register your account.

GAGEtrak requires a persistent Internet connection for product activation and for ongoing license management. Once activated, you will not be prompted for this code again, unless you completely uninstall and reinstall the product. You can view your license code and other registration information in the **About** window within your GAGEtrak software.

Please Note: Your GAGEtrak application requires a persistent Internet connection. Without Internet, the application cannot verify your license and it will not run.

Troubleshooting License Issues

If you are having trouble registering your license code, then you are likely restricted in some way from reaching our license host. A simple test can be performed to determine if you are blocked by going to my.nalpeiron.com. If you can access this site, then our software is being prohibited in some other way from validating your license. Proxy servers and firewalls can restrict certain inbound and outbound traffic and for certain ports or URLs.

Firewalls

In the case of a firewall restriction, you will need to ask your help desk or IT provider if they are restricting this site and if so, request that they whitelist the following:

GAGEtrak License Host Site and Port Information:
License Activation and Validation URL: my.nalpeiron.com
TCP Port 443 (HTTPS), Allow IP: 184.106.60.185
Note: Wildcard whitelisting "*.nalpeiron.com" should be sufficient.

Proxy Servers

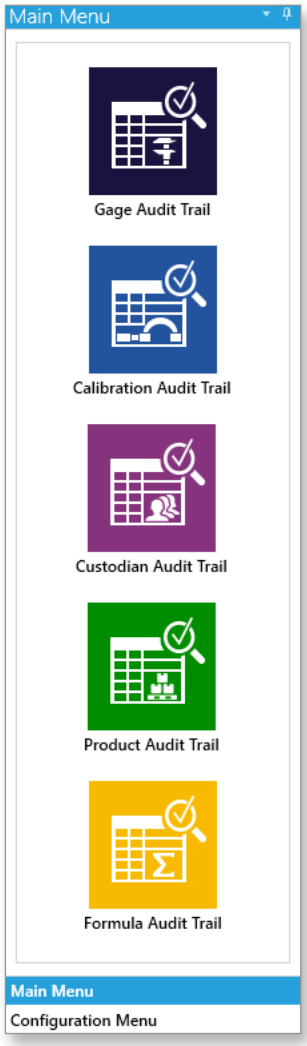
If a proxy server is employed at your location, go to the **About** window (**Help -> About -> License Management -> License Proxy** tab) to enter proxy host and authentication information. This will allow our application to negotiate access to our license host.

CHAPTER 2: CONVENTIONS

To save time and ensure consistency, GAGEtrak uses program conventions, which are standard commands and design elements that make the various windows and forms operate in the same way throughout the application. You should become familiar with these conventions before you begin using GAGEtrak.

Navigation Menu

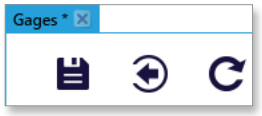
At the bottom of the Navigation Menu, you can access the **Main** and **Configuration** menus. The menu pane can stay visible at all times, or it can be undocked (by clicking the pushpin icon) to access it only when needed, which opens up more workspace. This menu system gives you the flexibility to quickly navigate to each area of the application without having to close out previously opened forms or losing your place while seeking information from other areas.



Tools Menu

Available in all entry screens, the **Tools** menu (in the Ribbon) contains common program functions and by default, is minimized. Click **Tools** to temporarily access the menu, or to make it remain open, right-click anywhere in the bar that contains the **Tools** menu and deselect **Minimize the Ribbon**. Use the **Save** function here (or Ctrl + S) to save all record modifications.

Some **Tools** menu items, like **Save**, **Undo** and **Refresh** are also visible in the header of most data entry views. The **Save** and **Undo** icons will be grayed out until a record is modified. Changes to records will activate these icons and an asterisk will appear on tabs or drop-downs to indicate unsaved changes as well. If you attempt to leave a view with unsaved changes, you will receive a prompt to do so before you can exit.



Please note that most of these options will be disabled in the Audit Trail modules; data in those modules is read only and can't be deleted.

Infotips

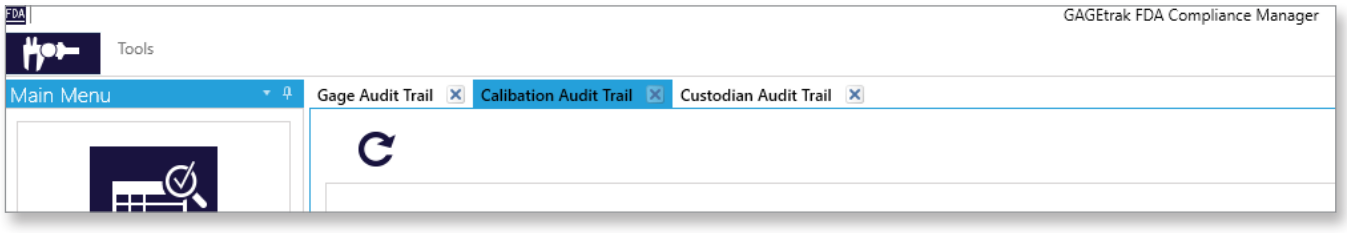
Infotips provide useful information about various features and functions throughout the program. Hover your mouse cursor over an infotip icon to get context-related information for that field's purpose or capability.

Backstage Menu

Click the caliper icon to access the backstage menu area from the upper-left hand side of the Main Menu. The backstage menu provides specific application settings, unique to this computer install. From here, you can control settings such as themes and application performance, as well as manage your database connections, email configuration and access license and help information.

Master Tabs

The **Master Tab** feature permits multiple forms to be simultaneously open, so that you can quickly switch back and forth between them. You can even have multiple instances of the same tab open at once to compare records or view the records in different formats. In the image below, the tab highlighted is the active tab and the asterisk next to the tab name indicates an unsaved record.



Record Navigation Bar

From left to right, the record navigation buttons perform the following functions:

- Go to the first record in the data set.
- Go to the previous record in the data set.
- Go to the next record in the data set.
- Go to the last record in the data set.
- Add a new record.
- Delete the current record (deletion confirmation will ensue).

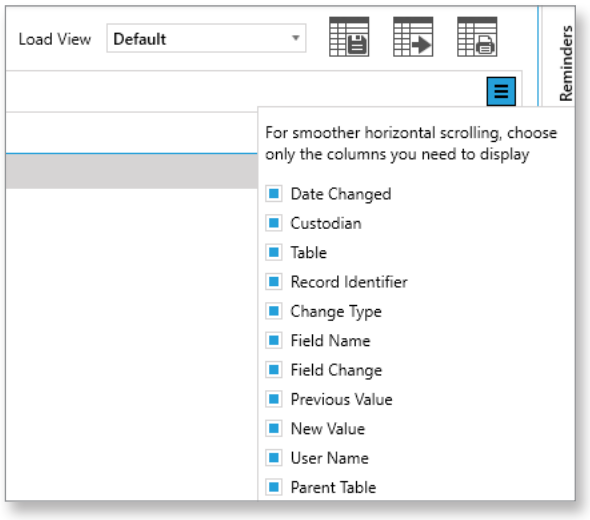
Record View Options

The FDA Compliance Manager displays all records in grid view. The view that was most recently used (positioning of columns, sort order, active filters, etc.) will be retained as the default view the next time you open that entry screen; the default view cannot be deleted.

When you make changes to the default view, such as moving columns in the grid, those changes are retained as your **Current View**. (The **Load View** field will display **Current View**.) The next time you open that screen, your **Current View** will be displayed.

Column Chooser

Located in the upper-right corner of the grid is the **Column Chooser** icon ☰. This is an invaluable tool for setting up your views and ad-hoc report output. You can use drag-and-drop to position columns in your grid view from within the column chooser window or directly from the grid. Use the checkbox to the left of each item on the chooser window to make it visible in your grid or to remove it.

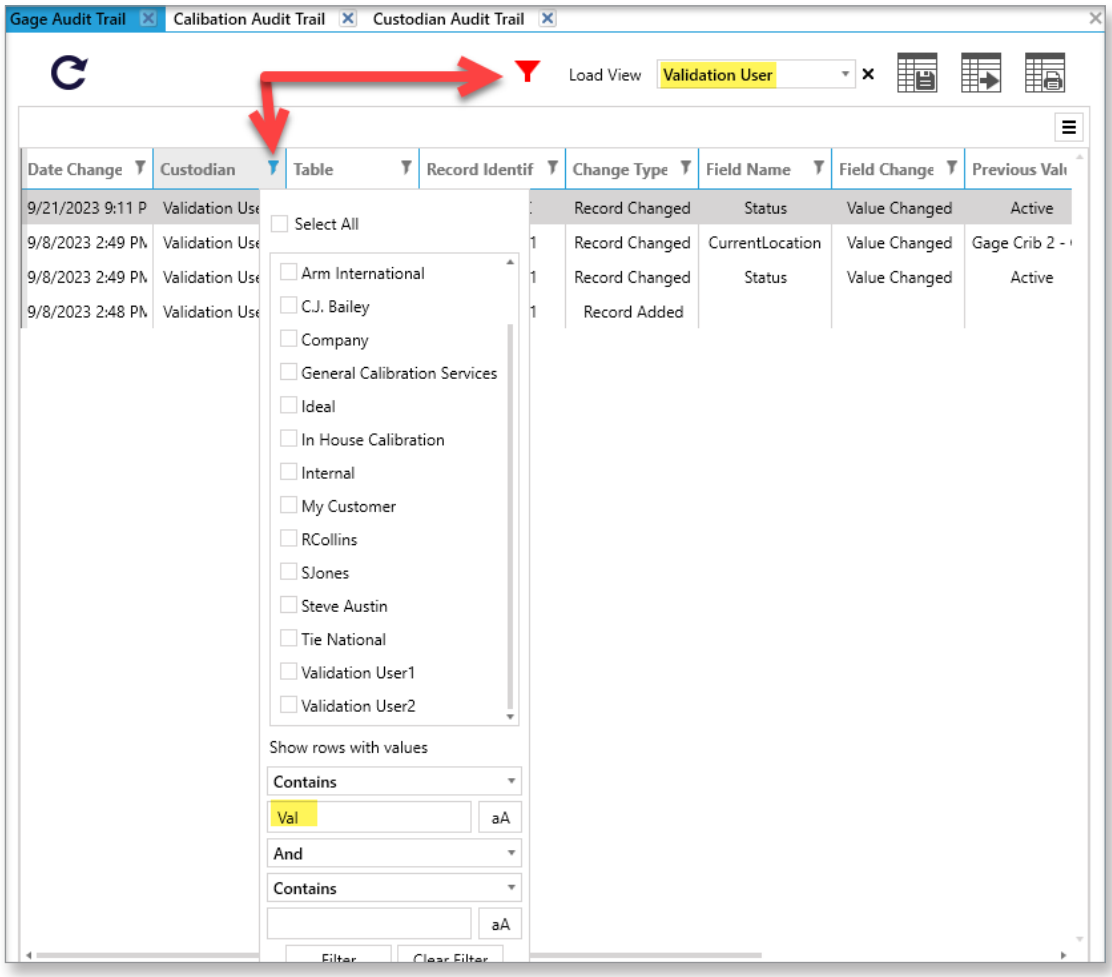


Sorting Records

Each column header contains the name of the field that it represents. When you click a column header, you sort your records by that field. Click once for ascending, again for descending and a third time will remove the sort on that column. A small black arrow is visible on fields that have been sorted by the user. Most views have a default sort order, typically by the identification fields, such as Gage ID or by date, such as Calibration Date. If you change the sort, it is saved automatically and the next time you return to that view, your previously selected sort will remain (see the **Saving Views** section).

Filtering Records

Each column header contains a **Filter** icon ; click the icon to see the filtering options. In the example below, records are filtered to show every record whose **Custodian** contains *Val* (filtering for Validation User). After entering your filter criteria, click the **Filter** button. When no filter is active, the filter icon in that column is gray; when a filter is active, the filter icon is blue and a red filter indicator will be visible in the header (this is to notify the user that the current records are filtered and may not be displaying all of the records in the database). To remove a filter, click the blue filter icon and then click **Clear Filter**.



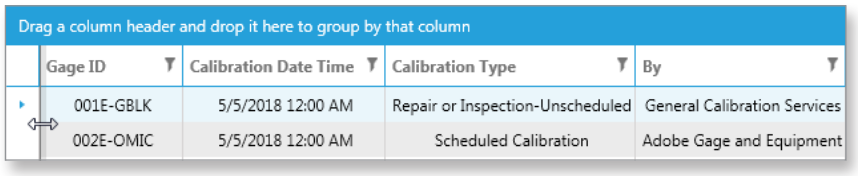
Saving Views

After filtering records, you can save your filter criteria for future access. It is also important to note that saved views are also used to generate reports and email notifications. (Please note, the Notification Manger is available with the core GAGEtrak Pro application, which can be used to schedule and send reports via emails to designated recipients. See **Notifications** in the **Configuration** chapter of your Intro Guide.)

Click the **Save View** icon , enter a name for your filter and then click **OK**. To use that filter later, select it from the **Load View** drop-down list. To delete a previously saved view, select the view and click the red **X**; confirm the deletion. Saved views will only be visible to you, unless you check the **View Sharing** option provided. Once shared, any user can see and manage that saved view. Views are a great option for presenting your data in several ways and we think you will find them to be an invaluable tool for viewing and managing your data.

Freezing Columns

In the data grid, there is a vertical gray bar at the left of the grid. Hovering over the bar with your mouse will change the mouse pointer to a double arrow. Click and drag the bar to the right; any columns of data that remain to the left of the bar will be frozen for scrolling.



Exporting Records

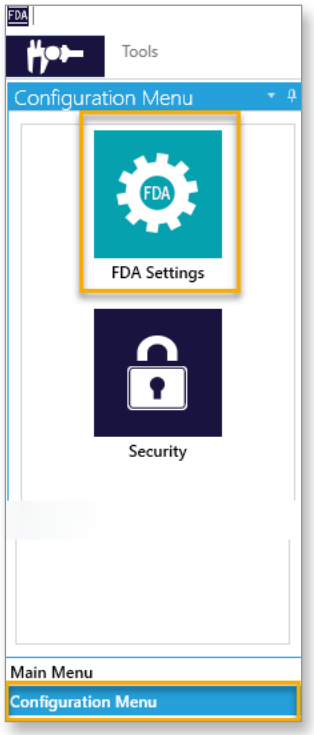
To export records from a grid, click the **Export** icon , select an export format, browse to a destination location, enter a name for your file and click **OK**. Any records that are currently visible in that view will be exported. For example, if your grid view is filtered to show only micrometers, then your exported output will only contain those micrometer records.

CHAPTER 3: FDA SETTINGS

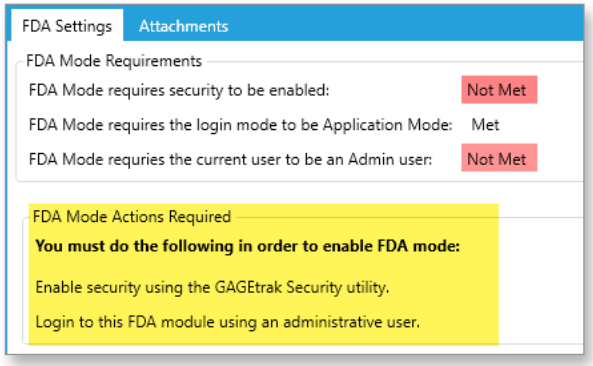
Converting the Database to FDA Mode

Either edition of GAGEtrak version 8 (Lite or Pro) can be made FDA 21 CFR Part 11 compliant by converting the database to FDA Mode. **IMPORTANT:** Once a database has been converted to FDA Mode, it cannot be converted back by any means available to the software.

Click **Configuration Menu** at the bottom of the main navigation panel and then click **FDA Settings**.



The **FDA Settings** tab will make it clear whether or not your database meets **FDA Mode Requirements**. In this example, the database needs an administrative user and security to be enabled before the database can be converted to FDA Mode:



Activating the Administrative User

In the **Configuration Menu**, click **Security**. This will launch the Security Module in a separate application window. Click the **Users and Groups** tab.

Highlight the existing Admin record in **Users** box and click the **Set New Password** button. Once you have entered and confirmed a new password in the pop-up, click the **Set New Password** button in the pop-up. This Admin user is already part of an admin group. Click the **Save** icon.

When you close and reopen the FDA Compliance Manager, you'll log in with Admin as the user name and your new password. In this window, you can add other users when needed.

Enabling Security

In **FDA Settings**, access the **Security Settings** tab. Click the checkbox to **Enable Security** and verify that the **Login Method** is set to **Manual Login to Application**. Save your changes.

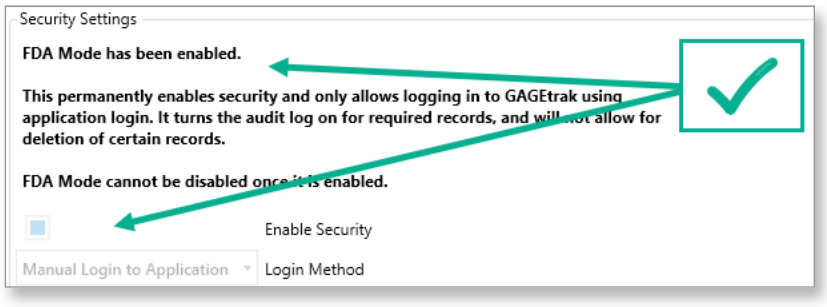
Enabling FDA Mode

Once you have created an admin user and enabled security, close the FDA Compliance Manager and reopen it. Log in with Admin as the user name and the password you created.

Navigate to the **Configuration Menu -> FDA Settings -> FDA Settings** tab. If your database meets all requirements, click the **Enable FDA Mode** button. Review the two ensuing confirmation messages and click **Yes** on each if you wish to proceed. Remember that once FDA Mode is enabled, it cannot be disabled.

The final confirmation message will appear, notifying you that all users connected to this database will need to close and reopen GAGEtrak for FDA Mode to be established on their systems. Click **Ok** on this message and the FDA Compliance Manager will automatically close and re-open to a security prompt.

When the FDA Compliance Manager reopens, login with Admin as the user name and the password you created. Navigate to the **Configuration Menu -> FDA Settings -> FDA Settings** tab and you will see that FDA Mode has been enabled and security is permanently enabled.



Purging Audit Trail Records

As the Audit Trail grows over time, it can have a significant impact on application performance, slowing down data access and save operations. For this reason, you may find it necessary to purge the Audit Trail from time to time. This can improve performance by removing older Audit Trail records from your database, while still retaining them in an external CSV file format. In this format, the Audit Trail records are still readable and can be accessed later if needed.

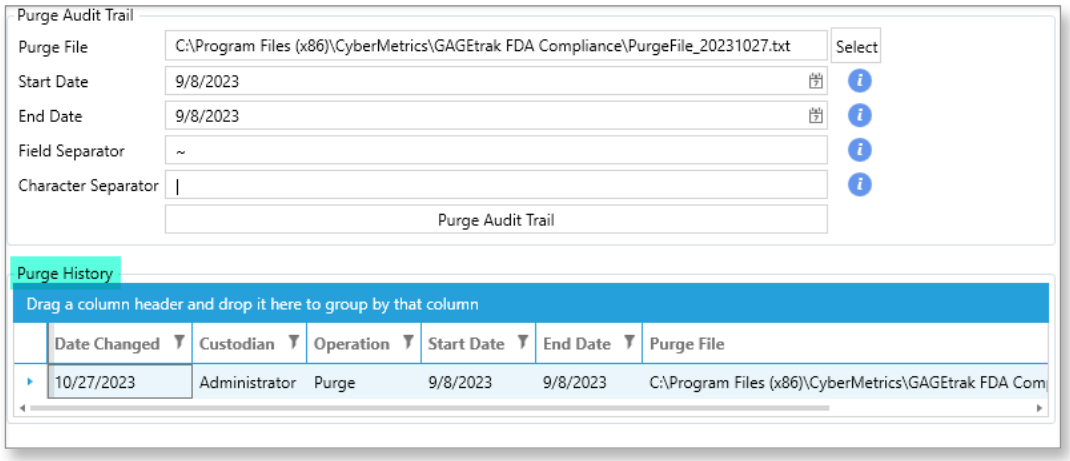
Navigate to the **Configuration Menu -> FDA Settings -> FDA Settings** tab.

In the **Purge Audit Trail** pane, click the **Select** button and navigate to the location where you want to save the purge file. Be sure to either attach the resulting CSV file in the **Configuration Menu -> FDA Settings -> Attachments** tab or store the files in a secure file share where it can be accessed later.

In **Start Date** and **End Date**, enter the date range of the records you need to move to the purge file. The default **Field Separator** and **Character Separator** values for your purge records can be modified if needed.

Click the **Purge Audit Trail** button and in the ensuing confirmation message, click **Yes** if you want to proceed.

A completion confirmation message will display; click **Ok**. The **Purge History** section in the **FDA Settings** tab will be updated with a record indicating when the purge was done, the date range of the records purged and the location of the purge file:



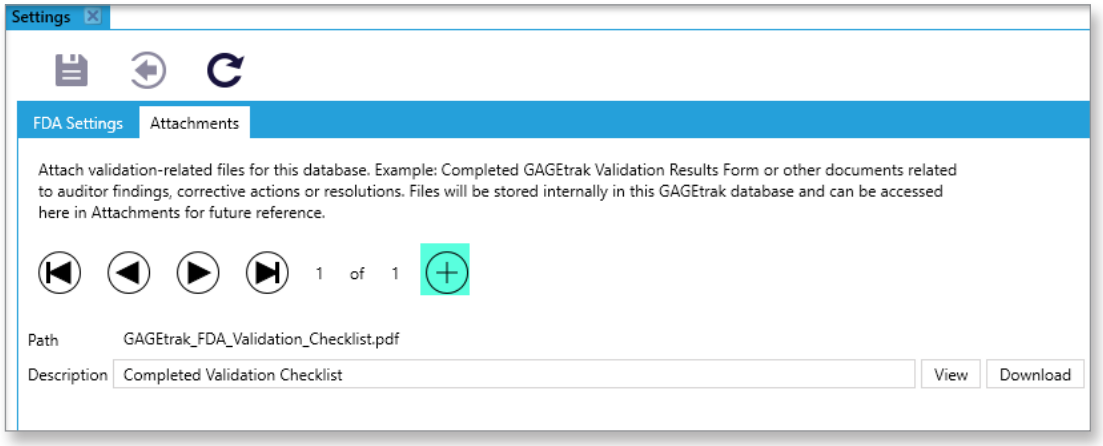
Attachments

The FDA Compliance Manager includes the option to attach any documentation related to your validation process, such as your completed **GAGEtrak FDA Validation Checklist** (access the checklist from the GAGEtrak FDA Compliance program group in the Windows Start menu) as well any documents provided by your auditor.

The files attached will reside in your database and can be retrieved for future reference from this **Attachments** tab.

To attach documents, click on the **New Record** icon ⊕. In the ensuing window, browse to the location of the document, select it and click **Close**. In the **Description** field, enter a brief description about the document.

To consult any of your attached files, click the **View** button to the right of the **Description** or click the **Download** button to download a copy of the document.



CHAPTER 4: AUDIT TRAILS

The Audit Trail contains database actions such as record modifications and deletions for monitored areas of the application that are considered subject to Part 11 regulation. Each component of the Audit Trail was selected for its potential effect on product quality, safety and record integrity. In compliance with Part 11, these Audit Trail records will include the date and time at which each action occurred, including the name of the custodian/user who performed each action, the table containing the changes and when applicable, a previous value and new value for record changes. When in FDA Mode, the Audit Trail is automatically enabled and cannot be disabled by any user, including administrators.

Audit Trail Actions

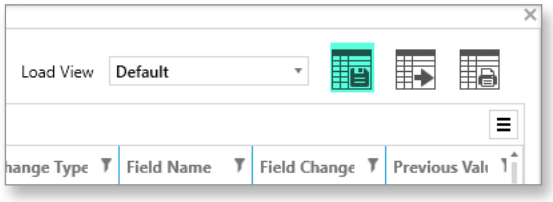
Unless otherwise noted, the software logs creation of records, deletions and edits to all regulated record areas listed below and logs changes to every field in the record. Changes to these records are logged, regardless of the form in which the change is made.

- **Gage Audit Trail** will log record creation, edits and deletions in Information, Specifications, Notes, Custom Fields, Attachments, Schedules (Calibrations, Reminders, Activities, MSA), Test Points, Formulas, Comments, Reference Standards, Procedures, History (no changes are possible from this tab) and Where Used (Products, Authorized Persons, Measurement Ranges). This includes changes to these areas from application module actions that are initiated by users or RESTful API interfaces.
- **Calibration Audit Trail** will log record creation, edits and deletions in Information, Results, Accounting, Miscellaneous, Custom Fields, Attachments, Measurements, Formulas, Comments, Reference Standards, Procedures and Signature. This includes changes to these areas from application module actions that are initiated by users or RESTful API interfaces.
- **Custodian Audit Trail** will log changes to Custodian Name in the Information tab and User Name, Active Login and Maximum Calibration Signature Level in the Security tab. This includes changes to these items from application module actions that are initiated by users or RESTful API interfaces.
- **Product Audit Trail** (Pro edition only) will record changes in Information, Specifications, Notes, Custom Fields, Inspection Points, History (no changes are possible from this tab) and Where Used. This includes changes to these areas from application module actions that are initiated by users or RESTful API interfaces.
- **Formula Audit Trail** will log creation, edits and deletions to Formula records.

Viewing Audit Trails

In the **Main Menu**, select an audit trail. In the grid view, click the **Column Selector** icon to choose the columns you want to display. In the displayed grid, you will be able to verify any changes, additions and deletions to your data; it will display all the columns that were set as visible. Each column includes the filter option to help you find specific data.

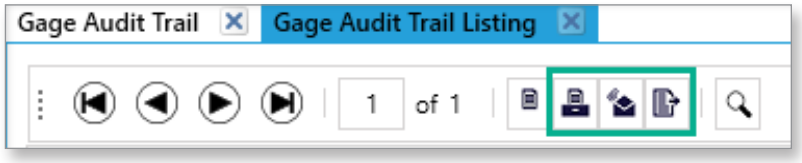
If you filter the data or reorder columns, the view can be saved for future use by clicking the **Save View** icon:



Saved views are available in the **Load View** drop-down.

To export your data, click the **Export** icon . The **Export Data** window will display. Select an export format, browse to the location in which you want to save the file, enter a name for the file and click the **Ok** button.

To view your data in a report format, click the **Print Ad-hoc Report** icon . The report will open in a separate master tab and can be exported, emailed or printed using the buttons at the top of the tab, shown in the image below. In order to email reports from here, **Email Settings** must already be defined.



The Audit Trails are an important component of achieving Part 11 compliance, as users are expected to create, modify and delete regulated records during normal operation of the GAGEtrak software. By providing the sequence of events, time stamps, custodian and user information, the Audit Trails will provide critical information should any of your records be accidentally altered or deleted from the system.

TRAINING

To save time, avoid common mistakes and get the most out of your software, it is imperative to receive proper training and we offer a wide variety of training options to meet every need and budget.

Completion of comprehensive training entitles each participant to a completion certificate in order to provide proof to an auditor that you've received proper training from the software manufacturer.

Go to https://gagetrak.com/training-schedule/ for details about types of training, schedules and pricing.

CONTACT US

Feel free to contact us at any time, for any reason. We're here to help and value your feedback.
1-800-777-7020 https://gagetrak.com/contact-us/