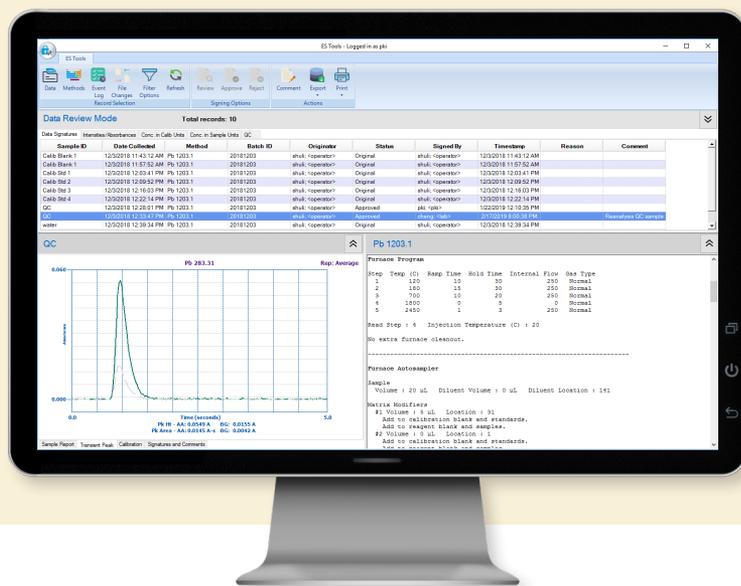


## Atomic Absorption



### Key Features:

- Secure Audit Trail
- Password-Protected Access Control
- Multilevel User Permissions
- Electronic Signatures
- Data Integrity
- Database File Structure

## Syngistix for AA Enhanced Security Software for 21 CFR Part 11 Compliance

### Introduction

In the pharmaceutical manufacturing field, it is mandatory that all computerized systems comply with the regulations of the U.S. FDA's 21 CFR Part 11 to ensure the data accuracy, integrity and reliability.

PerkinElmer's Syngistix™ for AA Enhanced Security™ software (version 4.0 or higher) is designed with extra security features to support the laboratory comply with these regulations. Its redesigned User Setup and ES Tools modules provide a built-in data integrity control system.

Benefits of Syngistix for AA Enhanced Security software (version 4.0 or higher) include:

- Password-controlled access with system login and windows login
- Group permission settings for users
- Login history including failed login detection and lockout
- Electronic signatures and reason codes
- Database file structure
- Backup database
- E-mail and text notifications
- Comprehensive event log
- File change for version control to view differences between methods and Sample Information Files
- Device checks

## User Setup

Launching User Setup from a separate icon outside of the main Syngstix application brings up a simple tool bar which allows the Administrator to set up Users & Groups permissions, assign Data Folders, customize Electronic Signatures and set Notifications with just a few clicks (Figure 1).

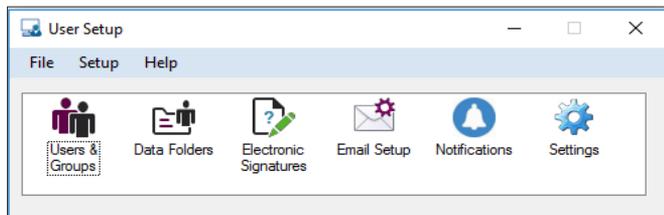
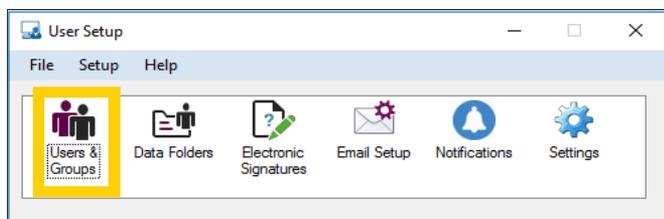


Figure 1. User Setup tool bar – Users & Groups.

## Users & Groups



Through Users & Groups, you are able to create and define user and group permissions, and view login history, audit trail of actions performed in the User Setup applications and user summaries. Logins can be managed through PerkinElmer login controls or Windows/Domain users – the choice is yours.

Figure 2 displays where permissions and settings are defined. A designated user can be assigned to groups to gain a set of permissions. There are 11 pre-defined group permissions which are based on 21 CFR Part 11 regulations (Figure 3). These can be used – or not. Administrators can define, modify, or disable groups as personnel and responsibilities change within a lab – you're not locked in. Any or all permissions can be used for any group – it's up to the Administrator.

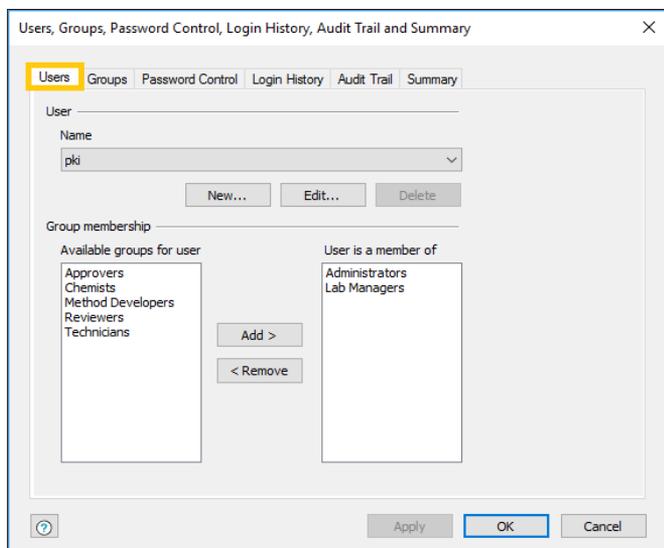


Figure 2. Assigning group membership.

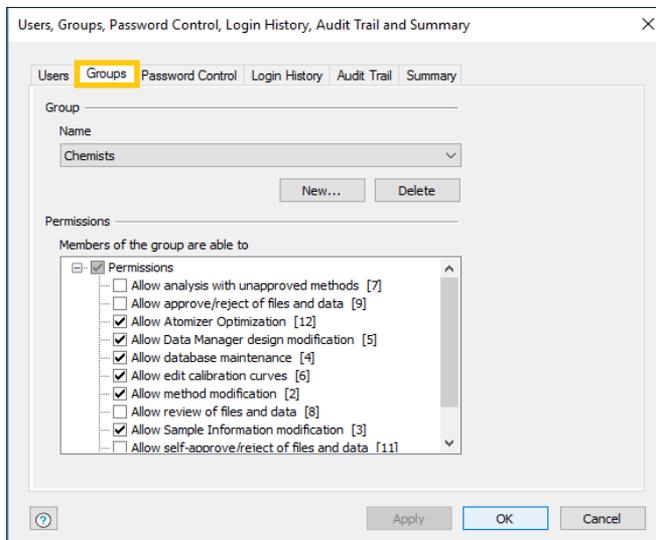


Figure 3. Setting permissions for Groups.

The log-in history is tracked for each user, which can then be printed to PDF and/or archived at any time (Figure 4).

The Administrative audit trail tracks all Global Security Components (GSC), which include function, time-stamp, user name, and computer/domain. The secure audit trail can be printed to PDF and/or archived to a file (Figure 5).

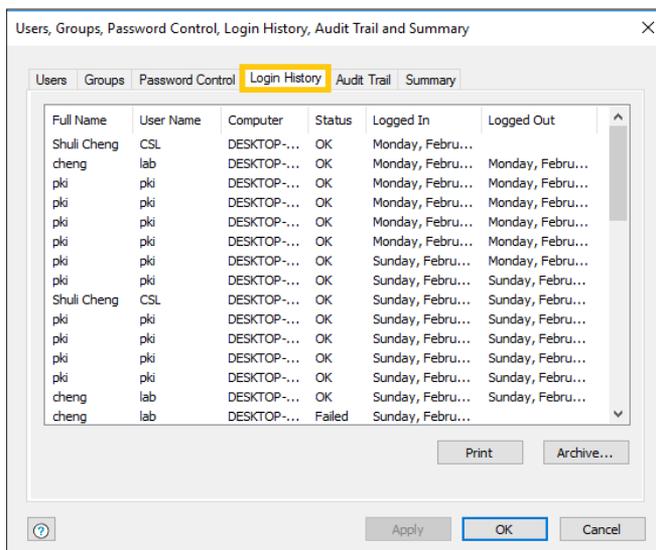


Figure 4. Login History in User Setup.

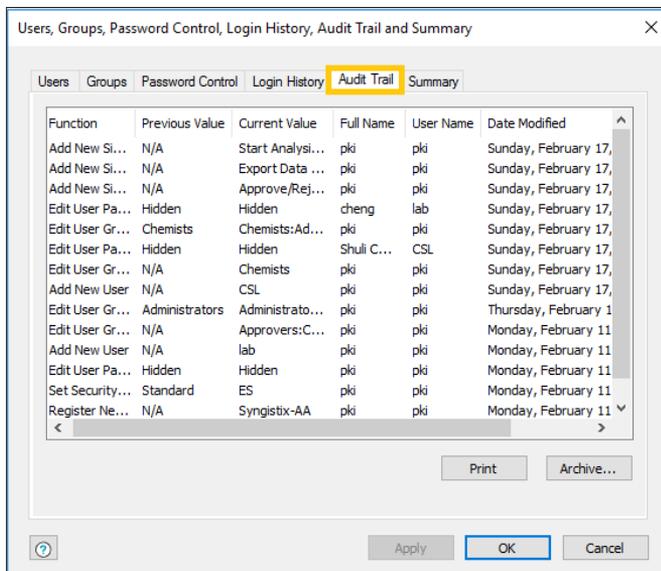
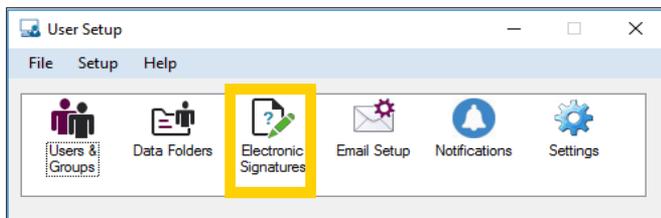


Figure 5. Audit Trail in User Setup.

## Electronic Signatures



Electronic Signatures appear in the main Syngistix application and require the User Name and Password before proceeding. Comments can also be added, if desired. The Administrator can set the criteria for when an electronic signature is required – a selectable list of pre-defined reasons is available, along with the ability to add new reasons (Figure 6).

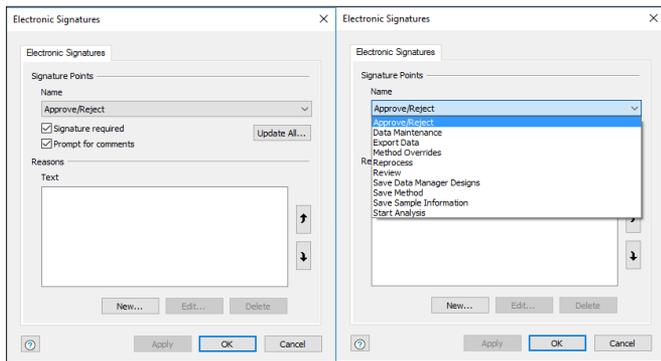


Figure 6. Electronic Signature setup screen.

## Data Manager

Once the analysis data has been acquired and automatically stored in the Syngistix database (ensuring data integrity), Data Manager can be used to perform database functions. Additional features have been included in Syngistix for AA Enhanced Security software version 4.0 or higher:

**Data Integrity Check** – The “Verify Checksums” button checks all records within the database to make sure they are valid. If methods or files are created or altered outside of the Enhanced Security environment, an alert will be shown.

**Backup Database** – It’s now simpler to back up the entire database – the Backup function can make a backup copy of the entire database in a compressed file.

There is no “Delete” function in Data Manager to ensure data integrity, security and traceability.

## ES Tools

The ES Tools module provides the functionalities for FDA inspection in a single environment. After an analysis is complete, the data can be quickly reviewed and signed off through ES Tools, a separate application launched from outside of the main Syngistix application (Figure 7). This user-configurable dashboard interface lets you quickly and easily review data, methods, event logs, and file changes. With the ability to filter and sort entries, it’s easy to find what you’re looking for. Reviewing, approving, rejecting, and adding comments are just a click away, along with the ability to export and print individual samples and batches in a human readable format.

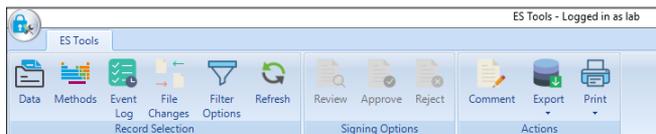


Figure 7. ES Tools tool bar.

## Data and Methods Mode

In the Data and Methods modes of ES Tools, Electronic signatures are applied to the electronic data in a manner consistent with the requirements of the FDA 21 CFR Part 11 regulation for Electronic Records and Electronic Signatures.

Use Data mode to review and compare side-by-side results, transient peak and calibration, as well as signatures and comments. Select what you want to view from the tabs along the top and bottom of the screen and customize the windows how you want to view them. You can also view signatures and comments, the method with which the data was acquired, and approval status.

Selecting the Method icon in the ribbon allows the method to be viewed in detail, including the method Report, Audit Trail, and Signatures and Comments.

## Event Log

Selecting the Event Log, a sortable record of events from Syngistix appears, including electronic signatures and reasons/comments. This comprehensive view lets you see the details associated with the samples. This event log can be printed, exported, and archived.

Time stamp	Originator	Event	Event details	Signed by	Reason	Comment
2/17/2018 10:05:47 PM	phi-cgk	Event Log	Event Log view opened	N/A		
2/17/2018 10:06:30 PM	phi-cgk	Data Review	Data Review view opened: Pb 1203	N/A		
2/17/2018 10:04:21 PM	phi-cgk	Data Review	Data Review view opened: API sam.	N/A		
2/17/2018 10:03:50 PM	phi-cgk	Approve method	Approve "Pb test- ES 7"	phi-cgk	To approve	
2/17/2018 10:02:42 PM	phi-cgk	Method Review	Method Review view opened	N/A		
2/17/2018 10:01:21 PM	phi-cgk	Data Review	Data Review view opened: Pb test 0.	N/A		
2/17/2018 10:00:30 PM	phi-cgk	Event Log	Event Log view opened	N/A		
2/17/2018 10:00:27 PM	phi-cgk	Start ES Tools	Logged into ES Tools	N/A		
2/17/2018 9:59:24 PM	phi-cgk	Exit User Setup	Logged out from User Setup	N/A		
2/17/2018 9:59:23 PM	phi-cgk	User & Group	User & Group edited	N/A		
2/17/2018 9:59:14 PM	phi-cgk	Electronic Signat.	Electronic signatures added	N/A		
2/17/2018 9:58:10 PM	phi-cgk	User & Group	User & Group edited	N/A		
2/17/2018 9:55:39 PM	phi-cgk	Start User Setup	Logged into User Setup	N/A		
2/17/2018 9:54:47 PM	zheng-hab	System shutdown	Logged out from Syngistix AA Furn.	N/A		
2/17/2018 9:54:41 PM	zheng-hab	Warning Message	Do you want to quit using Syngistix?	N/A		
2/17/2018 9:54:37 PM	zheng-hab	Exit ES Tools	Logged out from ES Tools	N/A		
2/17/2018 9:52:22 PM	zheng-hab	Event Log	Event Log view opened	N/A		
2/17/2018 9:52:01 PM	zheng-hab	Approve sample	Approved "QC"	zheng-hab		
2/17/2018 9:51:40 PM	zheng-hab	Review sample	Reviewed "QC"	zheng-hab		
2/17/2018 9:51:01 PM	zheng-hab	Data Review	Data Review view opened: Pb test 0.	N/A		
2/17/2018 9:50:38 PM	zheng-hab	Data Review	Data Review view opened: Pb test 0.	N/A		

Figure 8. Event Log in ES Tools.

## File Changes

Do you want to track and see what's different between two methods and sample information files? How about what's changed between different versions of the same method? File Changes provides this information quickly and easily: in File Change mode, simply select two methods or two versions of the same method and click the Show Differences button. A list of differences between the methods appears.

Name	Version	Status	Signed by	Timestamp	Reason	Comment
Pb 1203 new	1	Approved	shukl-cooperator	1/23/2018 11:58 PM	method has been approved	
Pb 1203	1	Approved	shukl-cooperator	1/23/2018 11:38:29 AM	method has been approved	
Pb- val add	2	Approved	shukl-cooperator	1/13/2018 11:10:59 AM	method has been approved	
Pb 1113	1	Approved	shukl-cooperator	1/13/2018 10:28:35 AM	method has been approved	
Pb test-ES	7	Approved	shukl-cooperator	1/13/2018 10:27:07 AM	To approve	
Pb test-ES	6	Original	shukl-cooperator	1/13/2018 9:50:41 AM		
Pb test-ES	5	Original	shukl-cooperator	1/13/2018 9:50:27 AM		
Pb test-ES	4	Approved	shukl-cooperator	1/13/2018 9:53:27 AM	method has been approved	
Pb test-ES	3	Approved	shukl-cooperator	1/13/2018 8:25:12 PM	method has been approved	
Pb test-ES	2	Approved	shukl-cooperator	1/13/2018 8:30:34 PM	method has been approved	
Electronic	1	Original	shukl-cooperator	1/13/2018 8:30:34 PM	enable new method	

Section	Parameter	Pb test- ES.7	Pb test- ES.1
1 Spectrometer Page-Settings	Number of replicates	2	3
2 Sampler Page-Furnace Program	Step 3 change	Temp=900, RampTime=10, HoldTime=20, GasFlow=	Temp=700, RampTime=10, HoldTime=20, GasFlow=
3 Sampler Page-Furnace Program	Step 4 change	Temp=1300, RampTime=10, HoldTime=5, GasFlow=	Temp=1800, RampTime=10, HoldTime=5, GasFlow=
4 Sampler Page	Stock Standard #1	Conc: 25, Use Stock Std yes, AS Loc: 128	Conc: 100, Use Stock Std yes, AS Loc: 126
5 Calibration Page-Define standards	Added Calibration entry	Name=Calib Std 1, ASLocation=126, Sample Type=	ASLocation 126, Sample Type=
6 Calibration Page-Standard Conc	Calibration entry	Name=Calib Std 2, ASLocation=126, Sample Type=	Name=Calib Std 1, ASLocation=126, Sample Type=
7 Calibration Page-Standard Conc	Calibration entry	Name=Calib Std 3, ASLocation=126, Sample Type=	Name=Calib Std 2, ASLocation=126, Sample Type=
8 Calibration Page-Calls Units & conc	Calls Units and add concs for analyze Pb. 293.31	None	Standard Name Calls Std 4, Conc 40 ug/L
9 Calibration Page-Calls Units & conc	Calls Units and add concs for analyze Pb. 293.31	Standard Name Calls Std 1, Conc 5 ug/L	Standard Name Calls Std 1, Conc 10 ug/L

Figure 9. File Changes in ES Tools.

## Summary

Syngistix for AA Enhanced Security software (version 4.0 or higher) provides regulated laboratories powerful but simple-to-use tools to meet the technical requirements for 21 CFR Part 11 compliance, offering as much flexibility as possible while providing electronic signature points, maintaining data integrity through a database file structure, and implementing a secure audit trail.