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

In the highly regulated pharmaceutical industry, data integrity is essential. Audit trails* are highly scrutinized during regulatory inspections, and being able to produce an audit trail demonstrates that the data life cycle is intact.

Building on our years of experience and leadership in AA, we offer a comprehensive suite of Syngistix™ software solutions that deliver new levels of simplicity, productivity, and data security. Behind the intuitive interface of Syngistix™ for AA software lies a full range of features designed to optimize data security and ensure compliance to help today's laboratories cope with the regulations mandated by government agencies or quality protocols.

And to complement these, our Syngistix for AA Enhanced Security™ software option provides additional capabilities required to comply with the U.S. FDA's 21 CFR Part 11 regulations:

- Master Event Log – records all significant actions performed by the user. Each entry includes the date and time of the action, what was done, the name of the user, and, in many cases, the reason the action was performed.
- File Change Log – adds version numbers to all files and data sets, records the changes between versions, and automatically moves old versions to a history directory.

Will your existing audit trail pass an FDA inspection?

With PerkinElmer's Syngistix for AA Enhanced Security software your lab can rest assured it has the right solution for compliance, requiring absolutely no workarounds in order to meet regulatory requirements.

Syngistix Enhanced Security software includes user access controls to prevent analyses from being performed without saving data and to allow analyses only with saved methods, ensuring a complete audit trail is maintained for all activities.

For more information, visit www.perkinelmer.com/SyngistixAAES

*The FDA defines audit trail as a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record.

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