DATA INTEGRITY NO COMPROMISES

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

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

Building on our years of experience and leadership in atomic spectroscopy, 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 and ICP software lies a full range of features designed to optimize data integrity and ensure compliance to help today's laboratories cope with the regulations mandated by government agencies or quality protocols.

And to complement these, Syngistix for AA and ICP Enhanced Security™ software (version 4.0 or higher) provides the functionality to fully meet the technical requirements for 21 CFR Part 11 compliance:

Access Control

- Password-controlled access ensures that only authorized individuals can access system, which can be configured using Windows or software login.

- With multilevel user permissions, user groups can be created and assigned different privileges consistent with their different responsibilities.

Comprehensive Audit Trail

- Master Event Log automatically records all significant actions performed by the operator. Each entry includes: date, time, user ID, user name, action performed, action details, electronic signature information, and reasons for the actions where appropriate.

- File Change Log adds version numbers to all files and data sets and records the changes between versions; the old versions are automatically moved to a history directory. No files or data can ever be deleted.

Electronic Signatures

- E-signatures are implemented through fully configurable electronic signature points, which include approving the method and results sign off. The signed data records are viewable on the application screen and in printed reports along with the signatures.

- Administrators can set the criteria for when an e-signature is required and a selectable list of predefined reasons is available.

Syngistix Enhanced Security software delivers best-in-class capabilities for the data security required by regulated laboratories performing elemental analyses.

For more information, visit www.perkinelmer.com

For a complete listing of our global offices, visit www.perkinelmer.com/ContactUs