



Agilent ChemStation Plus Security Pack and NuGenesis ARCHIVE® — A Comprehensive Lab-Wide Solution for 21 CFR Part 11 Compliance

Application Note

The Call To Compliance

The U.S. Food and Drug Administration's (FDA) 21 CFR Part 11 regulations have driven suppliers of software to the pharmaceutical industry to meet specific requirements in their data handling products to comply with the new regulations. With ChemStation Plus Security Pack software Agilent Technologies continues to lead the industry in supplying tools that specifically address the compliance needs of the analytical laboratory. For laboratories with Agilent and other vendor's analytical equipment, NuGenesis ARCHIVE software has become a significant part of many companies' overall compliance solution. It provides a fully automated backup, archiving and cataloging system for all software-based instruments in a lab or enterprise, satisfying a key component of the 21 CFR Part 11 regulations.

Agilent ChemStation Plus Security Pack

Agilent ChemStation Plus, which includes the ChemStation and database module, provides centralized, simple management. ChemStation Plus Security Pack provides the additional security and other features for full compliance with 21 CFR Part 11 for data acquisition, result calculation and storage of raw and meta data.

System and Data Security within ChemStation Plus Security Pack
ChemStation Plus Security Pack provides access and privilege control to data within the system, ensuring that only authorized individuals get access to data within the ChemStation and database module. ChemStation Plus Security Pack offers session locks for unattended operation and an advanced user management with numerous user roles and user privileges.

Data Integrity within ChemStation Plus Security Pack

The ChemStation Plus Security Pack database provides a link between all raw data, processed results and the methods that produced them, ensuring full data integrity. It also stores all re-analysis copies of one original injection as revisions together with the raw data, such that no data is ever overwritten.

Audit Trail within ChemStation Plus Security Pack

ChemStation Plus Security Pack documents all activities in an audit trail. It tracks changes to acquisition parameters, new result versions and the application-specific activities in log-books and audit-trail tables. The audit-trails are user independent and ensure compliance with 21 CFR Part 11 requirements.



Agilent Technologies

NuGenesis ARCHIVE Software

NuGenesis ARCHIVE software provides direct automated, data backup, archiving and catalog support for the analytical data. It also enhances compliance with the 21 CFR Part 11 requirements over the entire data retention time.

Archiving within NuGenesis ARCHIVE Software

NuGenesis ARCHIVE software backs up archive units, raw data, associated methods, and results files to many different types of media. While doing this, it creates a catalog that includes context-sensitive or meta data keys extracted from the files or their locations. Context-sensitive data are user-definable fields that enable end-users to search the catalog for specific files which facilitates locating data files for restoration. Administrators may fully automate the archive process, letting scientists work uninterrupted.

Archive Devices supported by NuGenesis ARCHIVE Software

NuGenesis ARCHIVE software interfaces with CD jukeboxes, Zip drives, JAZ drives, hard disks, RAID drives and magneto optical media. NuGenesis Technologies offers these hardware systems to integrate with NuGenesis ARCHIVE software, providing a complete archival solution.

Retrieving Data with NuGenesis ARCHIVE Software

The NuGenesis ARCHIVE catalog provides a means to quickly find and restore data from the near line storage media. The Quick RESTORE browser allows files to be located and then restored to the same or a different designated path.

How NuGenesis ARCHIVE software works with ChemStation Plus Security Pack

ChemStation Plus Security Pack creates what is referred to as an "archive unit". An archive unit is a collection of user-defined data, results and methods identified within the ChemStation Plus Security Pack database. The creation of the archive unit effectively serializes these data into a single file that is typically stored in a directory or set of directories on a network drive.

NuGenesis ARCHIVE software automatically scans those directories and backs up the ChemStation Plus Security Pack archive units immediately, to safe, stable media such as CD/R, magneto optical media, CD jukebox or RAID drive. At the same time NuGenesis ARCHIVE software creates a database catalog allowing ChemStation Plus Security Pack users to quickly locate and restore archive units as needed.

Advantages of NuGenesis ARCHIVE software and ChemStation Plus Security Pack

ChemStation Plus Security Pack provides comprehensive compliance with 21 CFR Part 11. NuGenesis ARCHIVE software provides a compliance-based archiving strategy.

NuGenesis ARCHIVE software provides direct automated data backup, archiving and catalog support for the ChemStation Plus Security Pack. This strategy provides an opportunity for complete data management from acquisition to data review to long-term data archiving. It also enhances compliance with the 21 CFR Part 11 requirements over the entire data retention time. ChemStation Plus Security Pack and NuGenesis ARCHIVE software offer complete and accurate copies of machine-readable data and timely data retrieval for archived data. The system is fully automatic and allows for a true data archive to be performed.

The key benefits of ChemStation Plus Security Pack include remote instrument control and monitoring, central data management, and 21 CFR Part 11 compliance.

The key benefits of NuGenesis ARCHIVE software include:

- Lab or enterprise-wide automated data backup and archiving strategy
- Data back up to safe stable media such as CD/R, magneto optical media, CD jukebox or RAID drive
- No user interaction required; archiving is automatic (backup and delete) based on user-defined criteria
- Database catalog of archived data for quick lookup and restore
- User-defined context-sensitive data; user-definable fields that enable end-users to search the catalog for specific files
- Ability to browse the database catalog or search using targeted queries
- Enterprise-scalable architecture

The combination of NuGenesis ARCHIVE software and ChemStation Plus Security Pack provides the most comprehensive compliance solution for users of Agilent Technologies equipment.

Literature

NuGenesis ARCHIVE software product description

"Using Agilent ChemStation Plus to make sure chemical analysis data complies with FDA 21 CFR Part 11," Technical Note, Agilent publication number 5968-7930E

"Using Agilent ChemStation to make sure UV-visible spectroscopy data complies with FDA 21 CFR Part 11," Technical Note, Agilent publication number 5980-1051E

"Good Laboratory Practice & Current Good Manufacturing Practice," Primer, Agilent publication number 5968-6193E

"Regulations and Tools to Comply with FDA 21 CFR Part 11", CD-ROM, Agilent publication number 5980-1050E

NuGenesis, the NuGenesis logo and NuGenesis ARCHIVE are registered trademarks of NuGenesis Technologies Corporation.

www.agilent.com/chem/nds

The information in this publication is subject to change without notice.

Copyright © 2001 Agilent Technologies, Inc.
All Rights Reserved. Reproduction, adaptation or translation without prior written permission is prohibited, except as allowed under the copyright laws.

Printed in Germany, March 1, 2001
Publication Number 5988-2320EN



Agilent Technologies