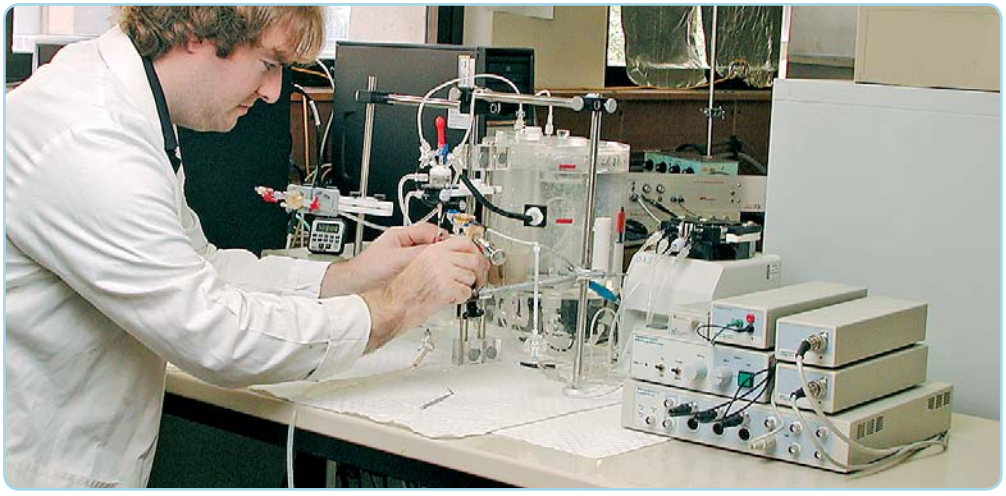
GLP & 21 CFR Part 11 Compliance

ADINSTRUMENTS
making science easier

Data Acquisition Solutions



Meeting the requirements of GLP does not need to be a time-consuming or frustrating exercise. ADInstruments offers an easy and reliable data acquisition solution for a GLP and 21 CFR Part 11 compliant environment.

The ADInstruments GLP Client enables you to satisfy the requirements for non-repudiation of data. Features include a comprehensive audit trail, secure signing, preservation of raw data and date/time stamping. The GLP Server software provides a centralized user authorization system. The two GLP software components work with any PowerLab® data acquisition unit and LabChart® software to facilitate GLP and 21 CFR Part 11 compliance.

Installation, Validation & Training

ADInstruments offers installation and training services that incorporate the use of hardware and software to optimize data acquisition and analysis. We also provide services for periodic calibration of your PowerLab hardware to confirm that the system is operating within manufacturing specifications. The ADInstruments Validation Unit is available for customers wishing to perform in-house validation of PowerLab systems. It includes all the hardware, software programs and documentation required for validation purposes.

Online Support & Hardware Warranty

Free email, phone and online GLP technical support is available to all customers in the first year. All research PowerLab data acquisition systems come with a standard five year warranty.

Proven Quality & Reliability

ADInstruments is a leader in computer-based data acquisition systems for life science research. We have installed over 34000 PowerLab systems worldwide in pharmaceutical companies, research organizations, hospitals and universities. Our products are also manufactured under the international ISO 9001:2008 Quality Management System.

Features & Benefits

- Data acquisition compliant with GLP and 21 CFR Part 11 regulations
- Centralized authorization system that supports an unlimited number of users
- A system that does not allow unauthorized access or tampering of files
- Public key Private key user validation to guarantee user authentication
- Easy installation, administration, maintenance and record keeping
- User-friendly system that does not hinder research

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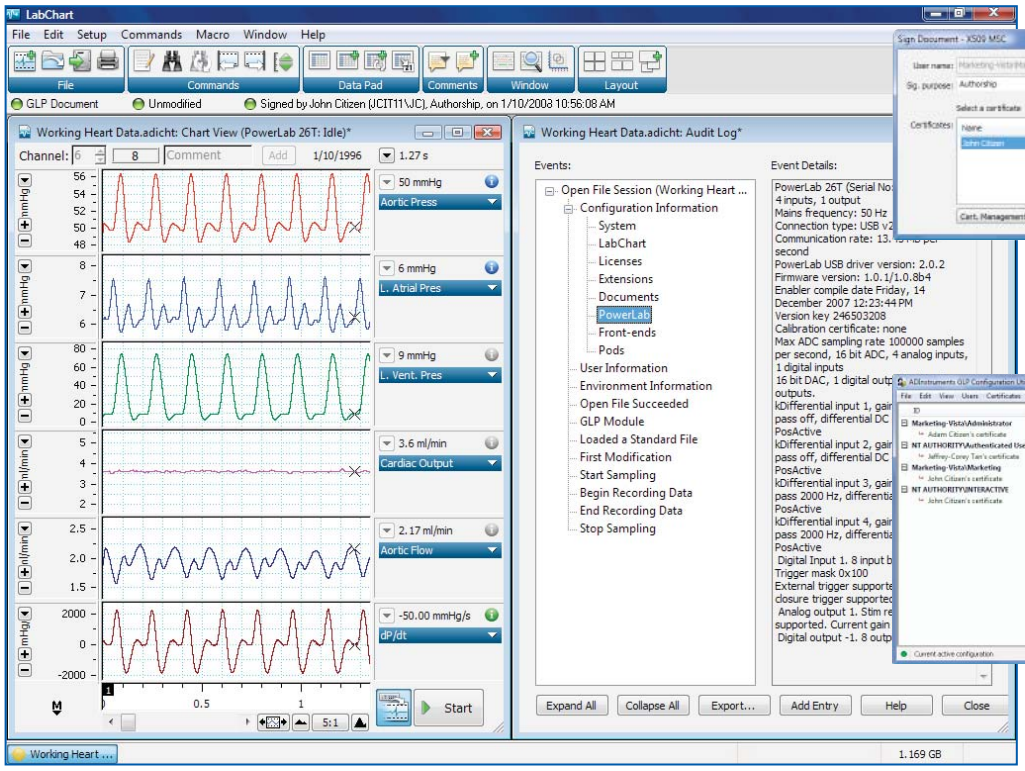
GLP Client and GLP Server Software

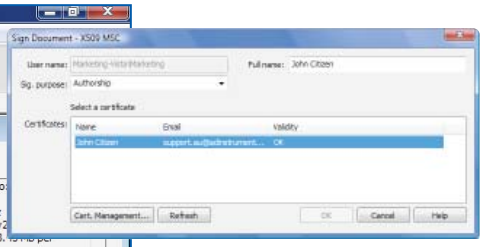
GLP Client Features:

- Secure signing of data files to eliminate unauthorized access and tampering (public key private key)
- Association of any changes to the data file with the registered individual making them
- A non-editable audit trail records all file operations
- Preservation of raw data
- Exportable (TXT, HTML, XML) and printable audit trail
- Incorporation of date and time stamping

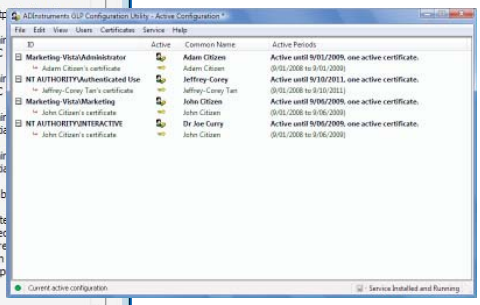
GLP Server Features:

- Centralized user and signature authorization system
- Verification of signature validity when files are opened
- Use of digital signatures when saving data files
- Support for an unlimited number of users
- Access to remote configuration
- Extensive and customized logging
- Underlying configuration file suitable for scripting and automating batch processing





The Sign Document window allows the signing and verification of LabChart Documents.



The GLP Configuration Utility allows for the addition or deletion of users or changing of user privileges.

Above: The GLP Client adds a GLP Status Bar to the LabChart application window and an Audit Log (right panel) that records the user, GLP status, configuration and recorded data information.

For more information on how ADInstruments systems can expedite your research and facilitate GLP and 21 CFR Part 11 compliance, contact your nearest ADInstruments representative.

GLP 21CFR Part11 Compliance

ADINSTRUMENTS.com ISO 9001:2008 Certified Quality Management System

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