confirm™ Software

For the 21 CFR Part 11 Environment

micromeritics®

The Science and Technology of Small Particles™

21 CFR Part 11 Solution

confirm Software

The Code of Federal Regulations Title 21, Part 11, was implemented by the U.S. Food and Drug Administration (FDA) Department of Health and Human Services in an effort to reduce time-to-market of new products that are subject to FDA rules. Under 21 CFR Part 11 rules, the FDA will accept electronic signatures and a paperless record system as the basis for the Agency's decisions regarding the safety and efficacy of new human and animal drugs, biological products, or medical devices. The code also applies to electronic records submitted to the agency under the requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act and the Public Health Service Act.

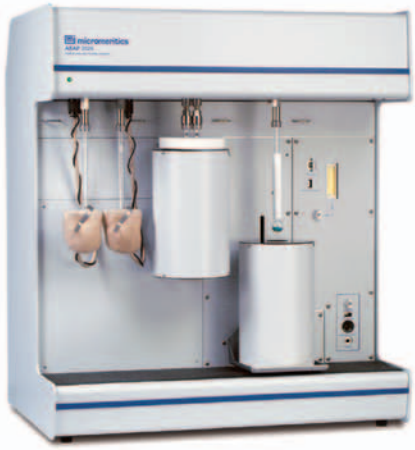
The regulation addresses issues pertaining to computerized systems used to create, modify, maintain, archive, retrieve, or transmit data intended for submission to the Food and Drug Administration. The regulation's controls are designed to ensure the authenticity, integrity, and confidentiality of electronic records.

Put simply, it applies to computers associated with analytical instruments that produce and manage electronic records (raw and reduced analytical data and metadata) for submission to the Agency. For applications in the pharmaceutical industry, this instrumentation includes Micromeritics' **ASAP™ 2020** Accelerated Surface Area and Porosimetry System, **Saturn DigiSizer® 5200** High Resolution Particle Size Analyzer, **TriStar™ 3000** Surface Area and Porosimetry Analyzer, and **Gemini™ V Series** Surface Area Analyzers. Micromeritics' ***confirm*** software has been designed for use with these instruments within a 21 CFR Part 11-compliant laboratory system.

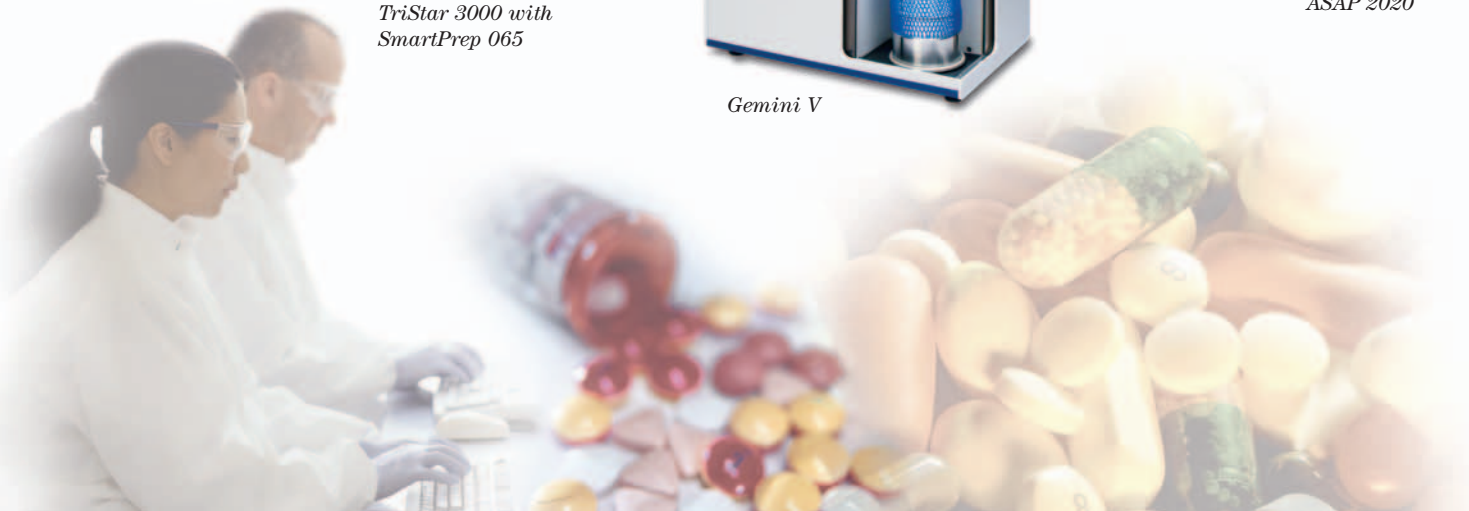
Saturn DigiSizer 5200

TriStar 3000 with SmartPrep 065

Gemini V

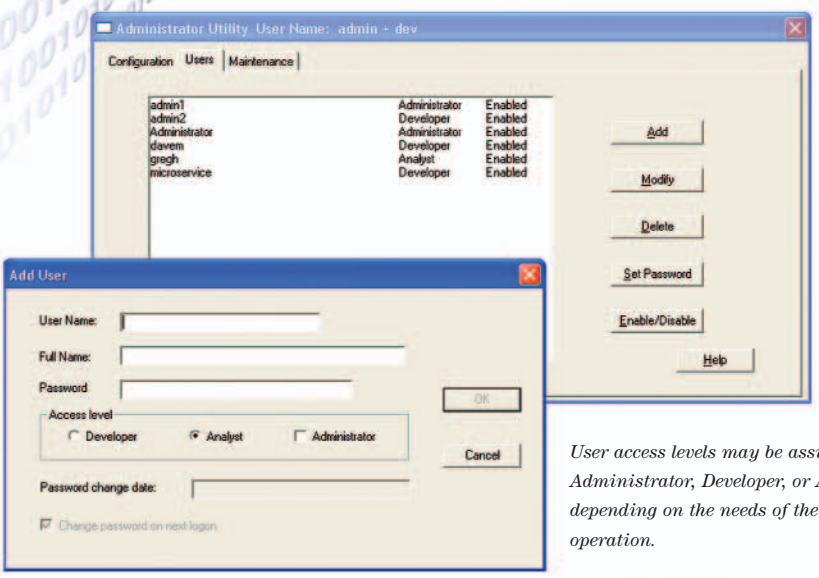


ASAP 2020



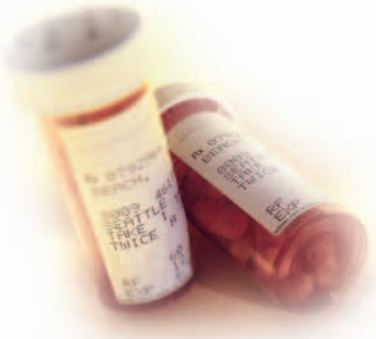
Easy-to-Use, Intuitive Software

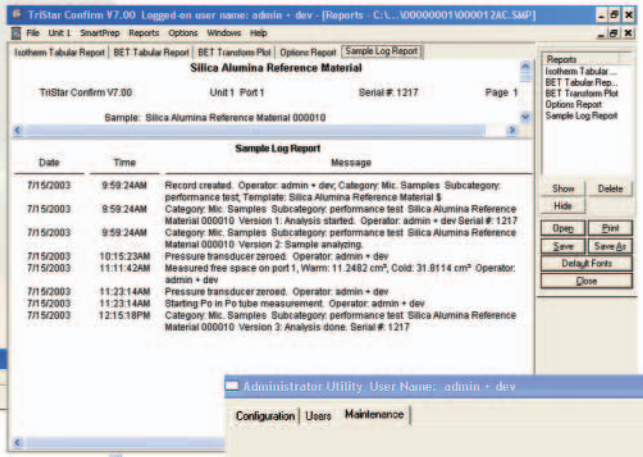
Micromeritics' ***confirm*** software is designed to make easy work of the compliance process. User levels usually are assigned by the laboratory manager working with the Windows® 2000 or XP system administrator. Once security is configured at the operating system level, the Micromeritics Administrator application is used to assign access levels to users of Micromeritics' 21 CFR Part 11 software. When an operator logs into the instrument software, he or she can control only those analytical functions associated with their particular level of security, and access only the records and templates that reside in their secured file storage areas.

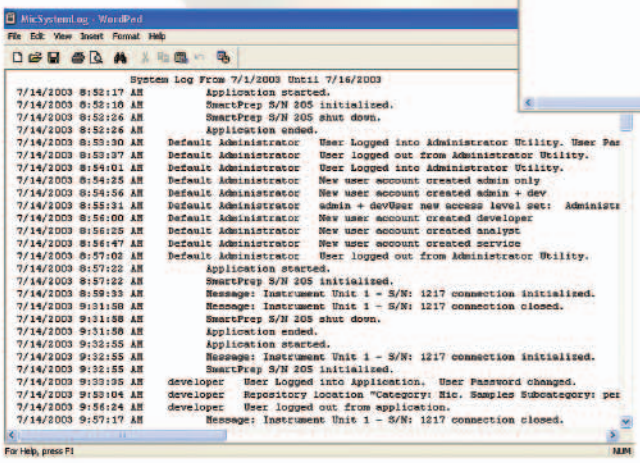


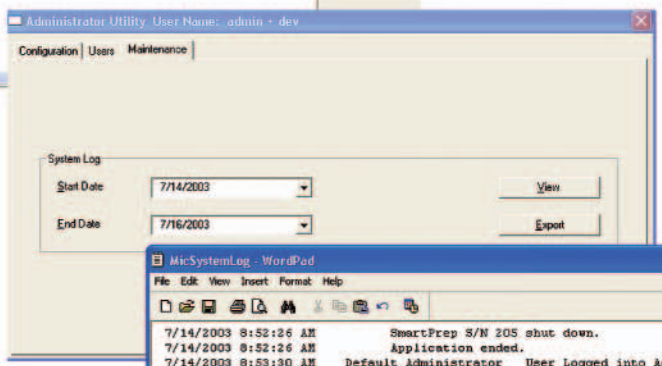
User access levels may be assigned as Administrator, Developer, or Analyst, depending on the needs of the individual operation.

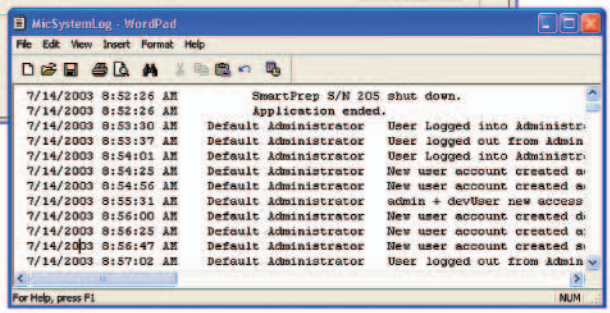
Every aspect of 21 CFR Part 11 pertinent to the instrument system has been thoughtfully integrated into a simple yet powerful, cleanly designed software package. Rule compliance operations are seamlessly built into normal operation of the instrument.







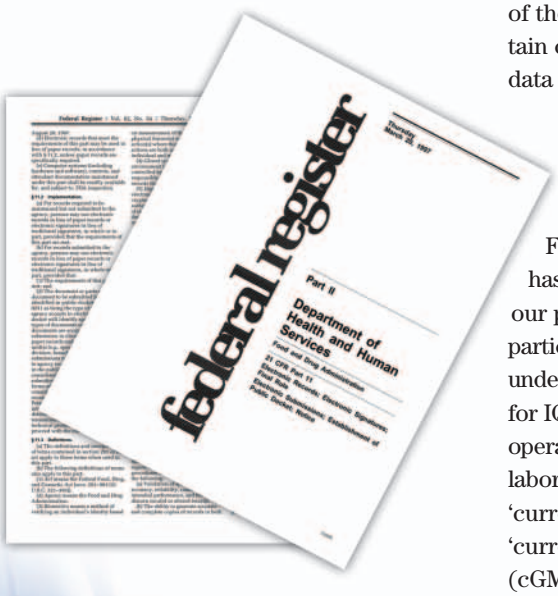




Log files include complete information on user access, routine changes to sample files, and complete report generation - all time-stamped for optimum data integrity.

Take Your Data to New Levels of Validation

While the 21 CFR Part 11 regulation is a requirement of the FDA for particular aspects of the pharmaceutical industry, many companies who may be providers to, or indirectly associated with, the industry have found it valuable to maintain compliance with the rule. Further, the excellent record-keeping and validation capabilities of ***confirm*** software make it extremely useful across all industries. It's a great way for all companies to keep track of their data and provide verification of their analyses.



Validation, Certification, and Compliance

Regarding analytical instrumentation, 21 CFR Part 11 is designed to take optimum advantage of the use of electronic records for the validation and certification of data subject to the rule. Note that under the regulation, neither an instrument nor its corresponding software is deemed "compliant"; rather, the term "compliance" here refers to the overall process of fulfillment of the requirements of the rule.

Is your company compliant?
confirm software addresses FDA's 21 CFR Part 11 requirements with features assuring data security, maintenance of time-stamped audit trails, authority checks, password aging, and data reporting. You can rest assured that we have provided you with all of the features and tools necessary to maintain compliance with the highest level of data integrity possible.

Optional Installation and Operation Qualification (IQ and OQ) services

For many of our customers, validation has become a necessary step in integrating our products into their laboratories. This is particularly true for customers who operate under 21 CFR Part 11 guidelines, but the need for IQ/OQ is not limited to that standard of operation. Validation also is important to laboratories or facilities that operate under 'current Good Laboratory Practice' (cGLP), 'current Good Manufacturing Practice' (cGMP), or other standards of practice. Each IQ/OQ service and accompanying documentation is tailored to fit a specific Micromeritics product model or configuration.

The Installation Qualification service is paired with the Operation Qualification service. The IQ assures that the instrument system is installed correctly in the user's environment from the moment it is unpacked to the point it is ready for operation – documenting the completeness of shipping, the operating environment, and the components of the system. IQ provides documented evidence that all key aspects of the system installation adhere to the appropriate codes and design intentions, and that the recommendations of Micromeritics have been suitably considered. IQ services also include training on operation and basic maintenance.

OQ is performed to verify and document that the instrument meets specified functional and performance criteria. The OQ service includes verification of instrument calibration and a comprehensive test of the complete system using established conditions and well-characterized reference materials. The OQ package provides documented evidence that the equipment or system operates as intended in the user's environment.

At the conclusion of the IQ/OQ, you are given a signed set of documents verifying that each step of the installation and operation tests was performed, as well as results of those tests.

An Operation Qualification service also is available for those laboratories that require periodic revalidation of the proper performance of analytical systems. Instrument validation will be maintained using Micromeritics' instrument services designed to meet the demanding needs of the pharmaceutical industry.

What is compliance all about?
Compliance with 21 CFR Part 11 involves more than just the creation, modification, maintenance, archiving, retrieval, and transmission of electronic data intended for submission to the FDA. It involves all laboratory practices associated with these tasks. Laboratory policies and practices ultimately define the path to compliance. Features in Micromeritics' ***confirm*** software help make compliance easier.

Examples of how Micromeritics' *confirm* software addresses 21 CFR Part 11 requirements.
A complete checklist is available upon request or on the Micromeritics website at www.micromeritics.com

What 21 CFR Part 11 mandates:	How Micromeritics *confirm*® software and associated services help you conform:
Sec. 11.10 Controls for closed systems.	
(a) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	Records are protected from unauthorized access and deletion while under control by Micromeritics' ***confirm*** software. However, it is strongly recommended that these records be offloaded to a central data repository such as a system network or data management system.
(b) Limiting system access to authorized individuals.	Access is limited to those individuals who have been assigned logons and passwords. Once logged on to the Micromeritics instrument by ***confirm*** software, access to certain instrument functions are determined by prescribed user rights.
(c) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	Micromeritics' ***confirm*** software employs an extensive set of log functions to create an accurate time-stamped audit trail to record user access to files and manipulation of information within files.
(d) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	Micromeritics' ***confirm*** software controls the sequence of the analysis. The software enforces instrument operation as defined in secure analysis template files.
(e) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	Microsoft's Windows 2000 or XP provides the first level of security at the operating system level to assure that only authorized individuals can use the computer system. Two additional levels of security are provided by Micromeritics' ***confirm*** software: 1) software access is limited to those with a unique logon/password combination, and 2) a level of authority is assigned by the system administrator to each logon/password, limiting the user to a certain range of operations within the software.
Sec. 11.300 Controls for identification codes/passwords.	
(a) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	Micromeritics' ***confirm*** software allows the administrator to control password aging. The administrator has authority to recall, lockout, or otherwise prohibit the use of a particular login/password combination.
(b) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	Micromeritics' ***confirm*** software employs only keyboard entry of user names and passwords. Users will be "locked-out" after a predetermined number of unsuccessful login attempts. Only the administrator can reinstate the account. The administrator has authority to recall, lockout, or otherwise prohibit the use of a particular login/password combination.
(c) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	After a predetermined number of failed attempts to log into Micromeritics' ***confirm*** software, the application will be locked to that login name and a message prominently displayed on the screen announcing a potentially unauthorized attempt to enter the system. Other logins and passwords are still allowed, however a series of unsuccessful attempts to log in under different passwords will lock the application to all but the administrator.

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