

Regulatory Industries

Regulatory and Compliance Software for the Food and Pharmaceutical Industry

Designed for 21 CFR Part 11 e-Signature Compliance

Helps make FDA electronic records compliance a Plug and Play operation

Secure Audit Trails Track Operator Control Changes

Automatically track and log operator actions into a secure database

Security Server Enforces Logins and Restricts Access

Ensure that only authorized personnel access the system

One Software System Reduces Development Time

Common development tool for creating workstation, server, Pocket PC, Web, Terminal Server and mobile applications

Record and Report Operator Comments

Log, track and trace reasons for operator adjustments

Scalable Data Logging to Secure Standard Databases

Maintain industry standard databases, such as Microsoft® SQL Server, MSDE, Microsoft Access and Oracle®, to aid in record retention

Create Operational Sequence Checking for Operators

Enforce operation process steps with advanced visualization tools

Configuration and Runtime Password Revision, Control and More

Complete set of password tools with automated timeouts and more

Integrated Security Restricts Access with Biometric Technology

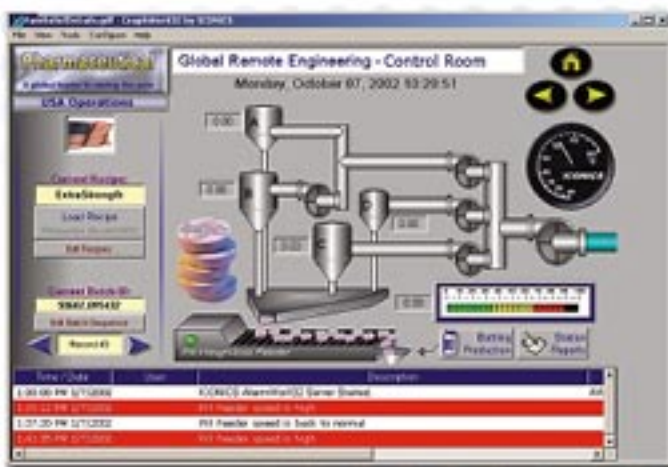
Synchronizes with Windows NT® security across corporate LANs with Biometric authentication

International Language Switching Technology

Easily deploy reports and documents globally in any language

Traceable Alarm and Event History

All operator actions, system events and alarms are retained

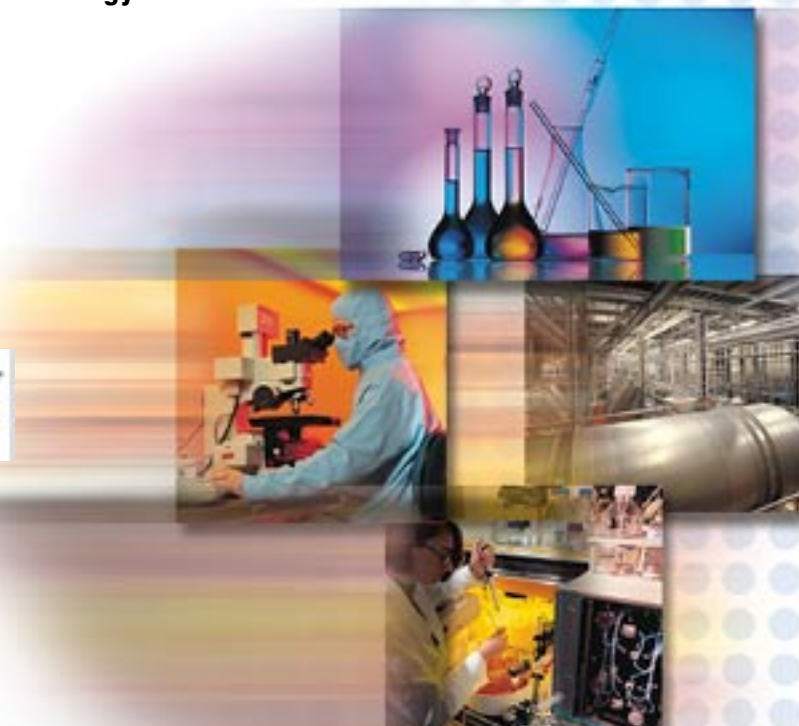


"ICONICS' ability to quickly collect, visualize and report OPC data, and the mix of robust OPC clients are the reasons we selected GENESIS32"

Eric Bellas – Director of Engineering
Cyberlogic Automation



Visualize Your Enterprise!™



ICONICS' suite of applications offers features and functions specifically designed to aid in complying with the FDA 21 CFR Part 11 regulations that are now sweeping the globe.

Industries Served

For systems requiring FDA oversight, the following industries benefit from ICONICS' solutions:

- Drug and Pharmaceutical
- Food and Beverage
- Medical Device Manufacturing
- Blood Handling
- Cosmetics
- And Many More ...

Benefits

Customers who deploy ICONICS Software in an FDA 21 CFR 11 application enjoy these benefits:

- Maximum security with integrated popular biometrics
- Operational accountability through sequence checking
- Accurate audit trail information of who did what, when, where, and why
- Applications that are designed for the FDA 21 CFR Part 11 regulation



For further information, call
508-543-8600
or visit our website
www.iconics.com



Visualize Your Enterprise!TM

Regulatory Industries

Regulatory and Compliance Software for the Food and Pharmaceutical Industry

Overview

The Food and Drug Administration has recently started enforcing the rules of compliance as outlined in the FDA 21 CFR 11 (Code of Federal Regulations: Food and Drug Administration Title 21, Chapter I, Part 11) – "Electronic Records; Electronic Signatures." GENESIS32TM offers many features that will help you build a system that complies with FDA 21 CFR 11. It enables proper handling and recording of FDA-regulated electronic information and applies "electronic signatures" such that the FDA considers them to be "equivalent" to that of handwritten signatures and documents.

Designed for FDA 21 CFR 11 Compliance and Accountability

ICONICS makes it easy to create applications that comply with the latest FDA regulations. Audit trails, enforced logins and restricted security access are integrated into every ICONICS Solution.

Secure Audit Trails Track Operator Input and Control Changes

Using the ICONICS GenEventTM Server, it's easy to keep track of operator input changes. This tracking system records the date and time stamp along with the name of the person performing the action, as well as the value entered and the tag name being affected. In addition, GENESIS32 also captures the node name, thus recording information pertaining to who, what, when and where.

One Software System Reduces Development Time

ICONICS software suites run on Microsoft[®] Windows[®] NT, 2000, XP, Windows Server[®] 2003 and Windows VistaTM operating systems. Web-enabled applications run on Web browsers and Terminal Servers, as well as dedicated wireless Pocket PCs, Windows CE, Embedded NT and Embedded XP devices.

Record and Report Operator Comments

When an alarm or event is acknowledged, operators can enter a comment explaining the alarm and/or event for inclusion as part of the permanent record. GENESIS32 can force the entry of operator comments.

Scalable Data Logging to Secure Standard Databases

Both the AlarmWorXTM32 Logger and the TrendWorXTM32 Logger record their information to industry standard databases, including Microsoft[®] SQL Server, MSDE, Microsoft Access and Oracle[®]. Using such standard corporate databases provides long-term maintenance, reporting and retrieval throughout the retention period.

Create Operational Sequence Checking for Operators

For applications that require operational system checks to enforce permitted sequencing of steps and events, GraphWorXTM (visualization component) is ready to help.

Configuration and Runtime Password Revision, Control and More

ICONICS' suites of applications offer many standard features. From password revision controls to timeout enforcement, from document revision control to unauthorized access detection and prevention, ICONICS' products are ready to assist in the overall management and accountability of today's pharmaceutical industry, related to meeting FDA 21 CFR 11 regulations.

Integrated Security Enforces Logins and Restricts Access with Biometrics

ICONICS offers a powerful Security Server component designed to restrict user access rights to various parts of the system. Not only are certain files and/or applications restricted, but specific features within each module may also be restricted on a per-user basis. Central to the FDA 21 CFR 11 is the absolute confirmation of users' unique IDs and the association of these with each employee's actions. ICONICS Security Server seamlessly integrates Biometric mice, hand, face and eye recognition as well as other Biometric technologies, providing the most comprehensive identification system available.

International Language Switching Technology

Companies needing to deploy their reports and documents anywhere in the world can now define multiple languages with automatic engineering units conversion.

Traceable Alarm and Event History

Record operator set-point and control changes using the GenEvent Server component. The GenEvent Server also creates a traceable history of other "system events." Include important items such as startup/shutdown sequences and times, operator login events, security issues, trouble reports and much more.

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