# Pharmaceuticals
## Software for FDA 21 CFR Part 11 Applications

### Designed for 21 CFR Part 11 e-Signature Compliancy
*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*
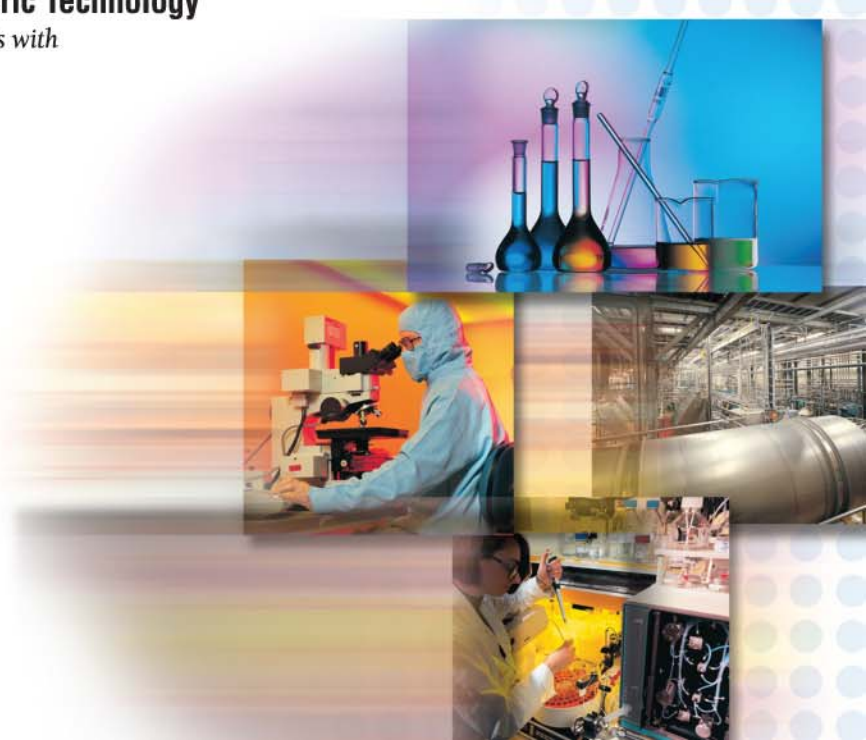
### Traceable Alarm and Event History
*All operator actions, system events and alarms are retained*

**"Makes FDA compliance a Plug and Play operation!"**

**Microsoft® GOLD CERTIFIED Partner**
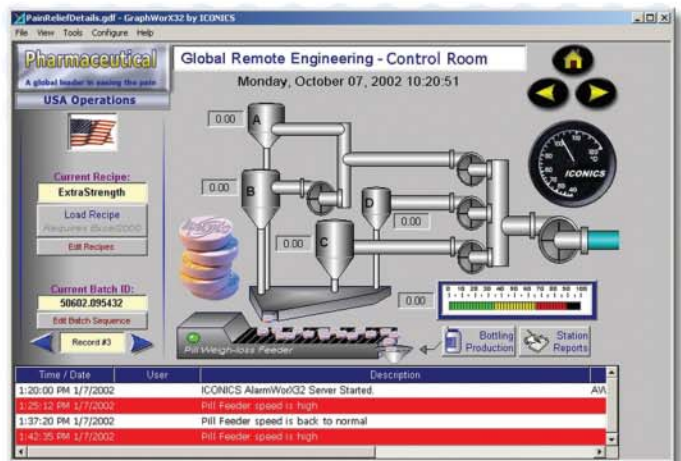
## ICONICS

**Visualize Your Enterprise!™**

ICONICS' GENESIS32™ 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 are deploying GENESIS32 in an FDA 21 CFR 11 application will enjoy these benefits:

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

GENESIS 32™

BizViz™
Bridging the Plant Floor to the Enterprise

Certified For
Microsoft Windows
Windows 2000 Server
Windows 2000 Professional

Designed for
Microsoft Windows XP

Microsoft Windows NT
Windows 98

Microsoft
GOLD CERTIFIED
Partner

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ICONICS
**Visualize Your Enterprise!**™

# Pharmaceuticals

*Makes FDA Compliance a Plug and Play Operation*

## 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." GENESIS32™ 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

GENESIS32 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 GENESIS32 software system.

## Secure Audit Trails Track Operator Input and Control Changes

Using the GenEvent™ Server, a standard part of GENESIS32, keeping track of operator input changes is automatic. 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

Create applications with one common development studio and deploy them to popular Microsoft® Windows® operating systems such as Windows 98, ME, 2000, 2000 Server, XP and Windows NT®. Deploy applications to Web browsers such as Microsoft Internet Explorer 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 AlarmWorX™32 Logger and the TrendWorX™32 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, GraphWorX™32 (the visualization component of GENESIS32) is ready to help.

## Configuration and Runtime Password Revision, Control and More

The GENESIS32 suite of applications offers 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

The GENESIS32 suite 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. GENESIS32 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.