MDT AutoSave

Automation Change Control for the Life Sciences Industry

SECURE RESTORE SAVE PROTECT DISCOVER TRACK CONTROL TRACK RECOVER MANAGE UNIFY SECURE RESTORE SAVE PROTECT MANAGE

Increasing Quality and Compliance

Due to high regulatory scrutiny on the life sciences industry, manufacturers are seeking ways to be assured their processes have not been altered without approval or documentation.

MDT AutoSave is part of the change control and audit infrastructure that ensures regulatory compliance. Tracking changes in PLCs, human-machine interface systems and workstations is integral to protecting your processes, people, and end-products. AutoSave's unique features, including internal security capabilities, have long been beneficial to regulated industry sites in meeting the requirements of the FDA.

To further increase the level of change control, our latest version of AutoSave provides workflow approval routing and electronic signature functionality in support of 21 CFR 11 guidelines.



Changes happen. Control them.

MDT AutoSave empowers users to protect, save, restore, discover, and track changes in industrial programmable devices and plant-floor documents. AutoSave unifies automation software under one common user interface and results in a secure, well documented, controlled environment that dramatically reduces coordination constraints, wasted effort, and safety issues. AutoSave allows users to:

Verify Programs Have Not Been Modified

MDT AutoSave periodically queries automation devices and compares the code running in the processor with the code on file to verify that the correct version of the program is running in the device.

Reduce Errors and Downtime

The key to rapid recovery is the ability to access and download the correct program to the device. In providing a common central repository of all changes, MDT AutoSave can ensure that if a device fails, the most current copies of program logic and documentation are available so plant operations can be restored quickly and correctly.

Improve Security

AutoSave is designed to manage access to program areas and programs via a flexible privileging system. When physical access to automation devices is prohibited (ensuring changes can only be made through MDT AutoSave) all changes in program logic are recorded by user, date, time, location and specific change detail. When physical access to the devices

MDT AutoSave: 21 CFR Part 11 Support for Regulated Industries

- Electronic signatures and records, timestamps of changes
- Computer generated (system administration and enduser) permanent audit trails: who, what, when, where, why of changes
- Secured access to different areas and programs permitted to the user and the client PC
- Automatic notification of changes
- Scheduled program verification

White Paper:

Go to <u>www.mdtsoft.com/industries/WhitePaper_Pharma.pdf</u> for more information on the rules set forth in FDA regulation 21 CFR Part 11 and how MDT can help manufacturers comply with the rules.

is possible, AutoSave periodically compares the program running in each device with the program copy on file in AutoSave and identifies any differences. An email notification is then sent highlighting these differences.

MDT AutoSave: Automation Change Control

Increase Productivity

There can be numerous disks and laptops located throughout the plant, each containing different program and document versions. Inefficiencies are inevitable, costly and even dangerous. In providing a common central repository of all changes, historical changes can also be analyzed to identify bottlenecks and observe trends in programming practices so operational improvements can be made.

AutoSave Supported Devices

AutoSave supports the most comprehensive range of devices and programming software in the industry including:

- Schneider Electric
 - ABBModicon
- InvensysSiemens
- Omron
- Mitsubishi
- GE Fanuc
- Rockwell Automation/Allen-Bradley
- Bosch Rexroth and more

Complete Control over Device Programs

MDT AutoSave's client modules are integrated with your programming editors to offer both an interactive environment and background monitoring. You have complete control over your device programs including:

- Secure on- and off-line editing with immediate, central library archival of changes
- Historical tracking and audit trails
- Automatic change discovery and real-time notification
- Rapid disaster recovery
- Comparison on demand and automated comparison
- Version-specific modules for your editors

Our Customers

As a trusted provider of disaster recovery and change management solutions, over 4,700 end users in numerous industries worldwide have selected products from MDT Software to effectively manage an increasing array of software on the plant floor. MDT's AutoSave is the corporate standard for plant automation device management in many of the most advanced manufacturing facilities in the world. Our customers include:

- 3M
- Abbott Nutrition
- American Sugar
- AstraZeneca
- BAA (Heathrow Airport)
- Bausch & Lomb
- BHP Billiton
- Budweiser
- Bristol-Meyers Squibb
- Campbell's Soup Company
- Chevron
- Chrysler
- Coca-Cola
- Eli Lilly
- Fonterra

- Ford Motor Company Genetech
- General Mills
- Genzyme
- GlaxoSmithKline
- Honda
- Hospira
- Johnson & Johnson Vision Care
- Johnson Matthey
- Mars
- Merck & Co.
- Miller Brewing
- Millipore
- Nestlé Pet Care
- New Zealand Dairies
- Orthoplastics, Ltd.

- Pepperidge Farm
- Proctor & Gamble
- Rio Tinto
- SAB Miller
- Sydney Airport
- Synlait
- Tamko Asphalt
- Toyota
- TransAlta
- Veolia Water
- Vistakon
- Visteon Automotive Systems
- Weyerhaeuser
- Whirlpool
- Wyeth



For More Information

To find out more how MDT AutoSave can help you gain plant-wide control of your automation environment, please visit <u>www.MDT-Software.com</u>.

