Solution Note

Experion® HS and HC900:
Effective Solution for Regulated Industries

Honeywell has a proven and reliable automation solution for regulated industries with its Experion HS software platform and HC900 process and logic controller. Together, they provide enhanced capabilities for change management, electronic signatures and version control — enabling manufacturers to meet strict regulatory requirements.

The United States Food and Drug Administration (FDA) is responsible for ensuring drugs are safe and effective. This is accomplished by requiring manufacturers maintain detailed records of their production processes. The FDA regulations concerning manufacturing and related record keeping are known as the Current Good Manufacturing Practices or cGMPs. Specific requirements for electronic records and signatures are addressed in the 21 CFR Part 11 regulation.

The objective of 21 CFR Part 11 is to allow manufacturers to take advantage of electronic record keeping while making sure electronic records and signatures are equivalent to paper versions. Electronic records must be reliable, trustworthy, and authentic to be considered equivalent to paper records and handwritten signatures for FDA purposes.

Manufacturers in regulated industries must meet a host of strict regulatory requirements.

Companies involved with pharmaceuticals, food & beverage and biologics need a proven and reliable solution for meeting FDA 21

CFR Part 11 requirements in process automation applications. This includes secure recordkeeping in the areas of project engineering, manufacturing operations, system administration, and system maintenance.

Enhanced Capabilities for Manufacturers

Honeywell combines its Experion® HS software platform with the HC900 process and logic controller to meet the rigorous demands of regulated industries. Together, they satisfy 21 CFR Part 11 requirements, including change management, electronic signatures and version control. This solution also implements robust security features to safeguard applications where control of data is critical.
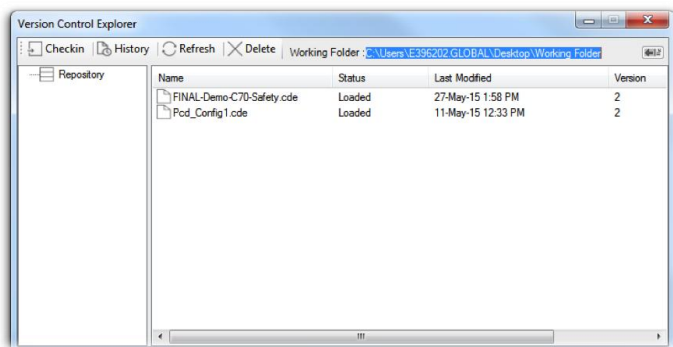
The Experion HS human-machine interface (HMI) enables manufacturers to monitor and control their production environment using real-time data. An onboard historian archives valuable information from across the plant. Configuration data as well as production data such as recorded history, audit trails and batch reports can be easily exported or archived.

The system also supports electronic signatures to improve the traceability of actions within process operations. This capability, along with trend backfill, is intended for applications with strict compliance requirements. Users can store and archive process data, and provide backfill in the event connection is lost to the controller.

In addition, Experion HS has various levels of security for operators, supervisors, managers and other plant personnel to restrict access based on job function. Password requirements can be made very stringent.

Paired with Experion HS, HC900 is a reliable and proven controller employing a modular, scalable design that can be sized to meet the automation needs of a wide range of process equipment. Its touch screen operator interface provides user-friendly, pre-built or custom displays, along with trending, data archiving and a host of other capabilities.

The HC900 has been upgraded to optimize version control and change management. For example, personnel are required to sign-in with a date and time stamp to modify the controller program. The HC900's change management capability tracks multiple configurations at once to indicate the history of any changes that are made. Users can compare configurations to determine additions or deletions by specific individuals.

The HC900 has been upgraded with new features to optimize version control and change management.

From a security standpoint, the HC900 has key protection on hardware, which puts the controller into a "RUN" locked mode that cannot be altered without opening the cabinet. Worksheets and configuration files are dual password protected to prevent changes without the correct code. Additionally, the system logs all alarms and events in an effective manner.

For More Information
Learn more about how Honeywell can improve your performance and regulatory compliance, visit our website www.honeywellprocess.com or contact your Honeywell account manager.

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Electronic Records for Regulatory Compliance

Manual methods of document version control are difficult and prone to error, and mistakes are costly. There may be copies of a document on the network or on a user's hard drive, and paper copies as well—making it virtually impossible to determine which the correct version is.

Electronic records in an automation system are easier to keep than manual records. At the same time, manufacturers can protect electronic records from alterations by non-authorized persons.

Powerful Software for Version Control

Honeywell's automation solution for the regulated industries employs powerful software to help manufacturers optimize validation and version control. The software serves as a central point for document access and automatically ensures users always access the latest version of any file. It saves previous versions of documents and maintains historical metadata to provide a snapshot in time as well as the complete document history. An audit trail is also maintained for each document throughout its lifecycle.

Using the software, project teams can upload inputs to customers, drawings, graphics and Quick Builder files for easy management. The first page of the software also maintains a version control detail on the changes made to the configuration file.

Versatile Tools for Easier Engineering

Users of the Experion HS and HC900 solution realize additional benefits through easier engineering and a lower total cost of ownership. For instance, function blocks can be grouped in a single library, which is exported and saved as a master file for replication on future projects. Plus, a bulk edit capability allows function blocks to be re-named on a mass basis.

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