

Product Information Note

PlantCruise by Experion[®] Qualification and Version Control System (QVCS)



Honeywell's PlantCruise by Experion Qualification and Version Control System (QVCS) simplifies system qualification by establishing and enforcing a user-defined development lifecycle.

Key Benefits

The PlantCruise by Experion[®] Qualification and Version Control System (QVCS) establishes well-enforced lifecycle and implementation procedures and reduces the number of Standard Operating Procedures (SOPs) while eliminating manual signatures and paper trails.

QVCS supports U.S. Food and Drug Administration (FDA) Title 21 Code of Federal Regulations (21 CFR Part 11) compliance and provides the following key benefits:

- User-defined development cycle for easy process control management and compliance
- Comprehensive version history and audit trail for system protection and accountability
- User-defined electronic signature qualification

This solution also provides detailed check-in and checkout facilities to protect the change control process.

State	Name	Version	Modified	Modified By	Qualification State	Comments
Checked in	Cascade_PID	1.01	11/19/2002 8:01:2...	Default login	Non_regulated	Server display name changed
Checked in	CMIO3	1.00	11/19/2002 9:55:1...	Default login	Non_regulated	First creation
Checked...	Elec_Sgn	1.00	11/19/2002 2:24:5...	Default login	Non_regulat...	
NOT in VCS	example_motor	N/A	N/A	N/A	N/A	

QVCS tracks procedural changes and electronically completes the approval process.

Features

QVCS is a lifecycle management solution for PlantCruise by Experion that tracks procedural changes and electronically completes the approval process through electronic signatures, simplifying the change control system. This allows engineers to follow a predefined change control procedure that ensures regulatory compliance.

QVCS is ideal for regulated industries because it manages the lifecycle, not just the version. This means the user can control who has the authority to make changes, approve transitions to the next step in the lifecycle and limit configuration installation to authorized individuals. QVCS also has several built-in security mechanisms for embedded 21 CFR Part 11 compliance.

Features unique to QVCS, not contained in a manual system, include qualification lifecycle support, version control traceability, support of a version control system toolbar, and a full version history and audit trail. The history and audit trail allow the system to keep detailed records that meet FDA regulations and GAMP guidelines.

Honeywell's technical excellence and clause-by-clause analysis of 21 CFR Part 11, 210 and 211 have helped develop a system that reflects functionality and usability, while delivering a groundbreaking best-in-class product that will maintain regulatory compliance and reduce the cost of compliance.

User-Defined Development Lifecycle

At the end of each lifecycle stage, approval is required before the process can continue. QVCS allows you to define who is authorized to approve each step and how the transition to the next step will occur. By creating these clear definitions, your

control process is not only compliant with FDA regulations, but also easier to maintain and manage.

State	Fallback State	Restricted Signing	Load To Controller Allowed
Non_regulated	Non_regulated	Non_regulated	Yes
Implemented	Implemented		No
Ready_For_Test	Implemented		Yes
Tested	Implemented		Yes
Ready_For_verification	Implemented		Yes

Honeywell's QVCS solution ensures your control process is not only compliant with FDA regulations, but also easier to maintain and manage.

21 CFR Part 11 Compliance Tools

Within the QVCS system are embedded 21 CFR Part 11 compliance tools that automatically structure your change control system to be compliant. Electronic signatures and a detailed paper trail are required for every change that is made to the system. In addition, QVCS includes an alarm system that will warn you when a process is in violation of FDA regulations.

To further protect your change control process, the QVCS system has built-in time-out period and signature requirements for revert functions. And to make configuration management easier, the user can apply revert labels to specific versions of one or more objects, and then easily retrieve them via the revert label. Labels can be assigned in bulk or individually.

For More Information

Learn more about how Honeywell's PlantCruise by Experion solution can improve plant performance, visit our website www.honeywellprocess.com or contact your Honeywell account manager.

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Version History and Audit Trail

The QVCS history window displays all sets of logs associated with any object. Complete logs provide managers with the opportunity to track who has been in the system and what actions they took.

For each configuration object, the system maintains an individual audit trail and stores each version. The user is able to retrieve specific versions into the project side of the Control Builder.

The QVCS also allows a specific version of an object to be compared with the checked-out version, the version currently on the monitoring side of Control Builder, the previous version or a specific version selected in the QVCS. The difference report will indicate the changes, additions and deletions that have occurred between the two versions.

In addition, the QVCS system allows you to quickly track changes between two versions of any process through visual imaging. Users can pull up screenshots of the previous and revised process to see what changes were made, when they were made and who made them.

Detailed Check-In and Checkout Requirements

The QVCS system has developed a detailed check-in procedure that further protects your change control process. Once an object is checked-in by an authorized user, the document becomes read-only and may not be modified. All documents that are checked in must have details such as comments and revision type. This mandatory interaction further strengthens your ability to easily manage all the changes occurring in your system.

The checkout system relies on similar actions. Once an authorized employee checks out an object, it can only be changed by that same user.

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