



System replacement provides major improvements:

- Recipe management system
- Reduced report generation time
- User friendly report setup

Lyophilization SCADA System Provides Reliability and Easy Maintainability

BACKGROUND

21 CFR Part 11 Remediation Spurs SCADA System Replacement

A well-designed validation effort combines regulatory compliance with improved quality assurance.

Producers must meet the FDA's process validation guidelines requiring a high degree of assurance that a specific process will consistently produce a product meeting predetermined specifications and quality attributes. A large pharmaceutical manufacturer pinpointed their lyophilization manufacturing area as a high-risk area. They retained CQSI to help them establish a remediation program for the control systems on existing equipment. The equipment had limited control system documentation and a legacy hardware and software.

The legacy Report and Recipe System needed replacement to provide an audit trail and ease of change control. The new system was to be based on open, industry-standard software, which would also ease modifications and maintenance.

CHALLENGE

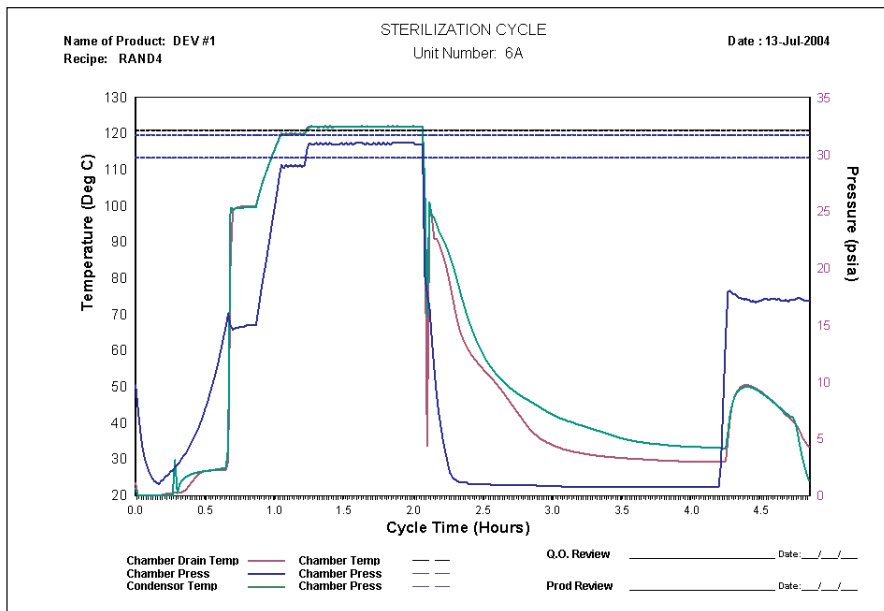
Designing a System with Validation in Mind

Working closely with customer Quality Assurance, Engineering, Operations and Validation staff, CQSI created a team environment to get the best information to everyone as quickly as possible. CQSI also met with the customer to understand the company's corporate standards and worked with them to improve the Validation Master Plan.

A GAP analysis was written, approved and conducted to determine the extent of the remediation effort. A new control system would be required to fully meet the requirements of FDA guidelines. To begin the remediation process, the customer worked closely with CQSI to develop a User Requirements Specification (URS). The URS included the following requirements of the new system:

- Built-in FDA Compliance
- Minimal Downtime for Installation
- Increased Processor Capacity
- Minimal Re-Training of Operations Staff
- Reliable Human-Machine Interface (HMI)
- Improved Report Generation
- Recipe Management System

The system had to be reverse engineered to prepare the Functional Specification (FS) and Design Specification (DS). CQSI worked closely with the customer's Engineering staff to determine the best way to meet the requirements of the URS. It was decided that a prototype needed to be developed and fully tested out-of-plant to minimize installation downtime. Also, due to the large number of nearly identical systems, a prototype with built-in flexibility to replace all of the systems without re-engineering was highly desirable.



◀ Sample Batch Report

SOLUTION

FDA-compliant and easier to maintain system.

The entire system was designed with FDA compliance in mind -- reliability and redundancy are key features for the customer. All software uses Windows domain-based user accounts with special privileges to communicate to each other. Due to security policies limiting interaction with the Windows desktop, each HMI computer automatically starts and executes the HMI software with no human intervention allowed.

Users are grouped into security areas with specific screen access. Each user, from Operator to System Administrator, is managed from the Domain Controller and is automatically synchronized down to the control system with no assistance from Engineering. All of the components of the system are accessible from the secure HMI interface, and predetermined functions of the system require point verification, such as cycle initiation.

The system is built on advanced, industry-proven platforms:

- Server-class computers with Intel Processors and RAID storage technology for reliability and increased uptime
- GE's iFIX SCADA
- Domain-based user account for increased security and centralized account management
- ORACLE relational database for Recipe Management
- Redundant Network Design to ensure multiple data paths between data collection and data storage computers
- Reporting utilizing Crystal Reports™
- GE's iHistorian captures analog data and recipe parameters. Automatic audit trails are maintained, which are reported to the SCADA computer on demand.

The CQSIRecipe Manager (vaiRM™), a client-server program, interfaces to a database and allows a user to define templates and process units. These templates can then be made into recipes by assigning values to the parameters defined in the templates. The system can handle multiple templates and multiple recipes based on each template. This provides a common validated and 21 CFR Part 11-compliant recipe database for all of the lyophilizers as well as reports for recipe history and audit trails.

RESULTS

Prototype saves validation and installation time.

A prototype of the entire system was built at the CQSI Engineering Center, allowing Factory Acceptance Testing (FAT) to be completed without affecting production. By fully validating graphical screens, security, recipe operations, reporting and all other functionality not directly tied to the operating machinery, the extensive FAT also reduced installation time significantly. Each system was tested completely with the actual computer hardware and software to be installed on site, and I/O simulation allowed for actual product processing simulation. The off-site prototyping and testing resulted in a much faster installation time at the customer site, which minimized production downtime.

While the primary goal of the customer was meeting the FDA requirements for validation, the system is also much easier to maintain and upgrade. Additional benefits include:

- Documented traceability of system development for FDA requirements
- Improved maintainability of control systems and manufacturing processes
- Complete, accurate validation documents for FDA inspection
- Industry-standard, maintainable, expandable system with built-in reliability and ease of use
- Greatly improved recipe management

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