



Upgraded subsystem provides:

- Centralized server with limited access
- Improved troubleshooting
- Reduced maintenance

HMI Subsystem Upgrade Provides Part 11 Compliance and More

BACKGROUND

A Part 11 compliance gap analysis of HMI systems on liquids manufacturing tanks at a midwestern pharmaceutical manufacturer revealed deficiencies in the software's security functions, data storage and retrieval and supporting documentation. The Engineering Department decided to upgrade to the current version of the software to solve problems with:

Access Security - Passwords were stored and authenticated on a local Access database, but not on the company's primary domain controller.

Data Security - The HMI software stored production records on an unsecured computer. The Batch Record data could be altered without detection or audit trail. Data transmissions from computer to computer were unreliable, raising the issue of data being lost forever.

Operational Sequence - No means of controlling or recording the sequence of operations was provided.

Reports - The current HMI application had no configured batch end reports that could be viewed or printed by the operators. In addition, comments input by the operator did not appear on the current reports.

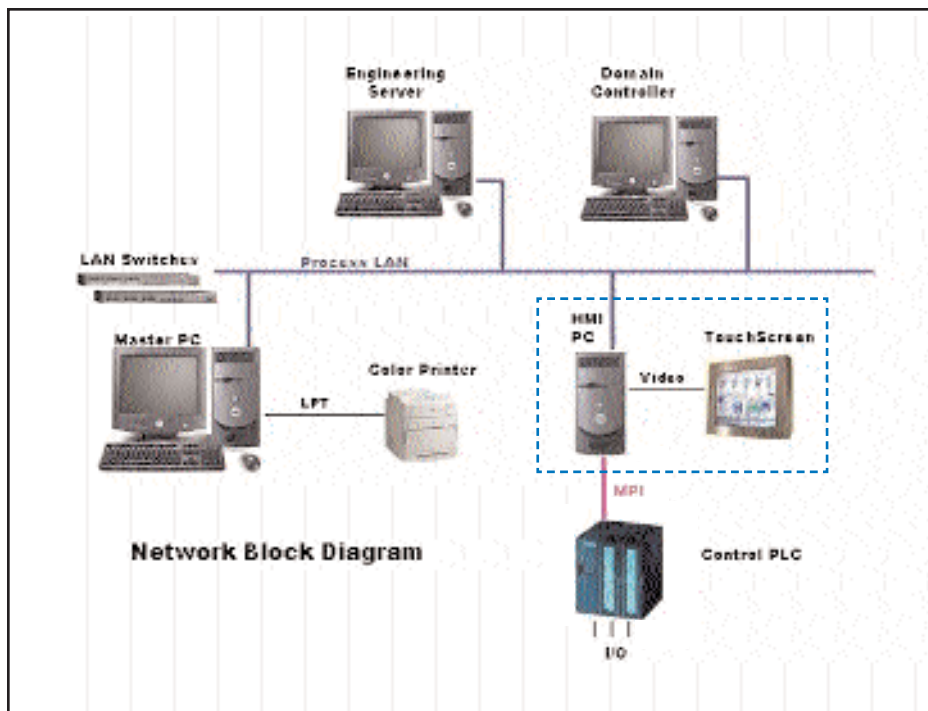
Specifications - No Functional or Design Specifications existed to document the functionality of the HMI application.

HMI Application - The application was written and sparingly documented in German, making it hard to follow, understand and troubleshoot. The application code also included multilingual support, which the customer wanted removed.

CHALLENGE

CQS Innovation's team worked with the customer's engineering department to define the requirements and design specifications for upgrading and modifying the access security, data security and reporting functions to meet the requirements of Federal Regulation 21 CFR Part 11. The two teams defined the requirements for seven different functions:

- New security authentication requirements for the HMI application.
 - New data storage and retrieval requirements.
 - Local data buffering requirements to compensate for the loss of communications with a secured engineering server. This existing engineering server has audit trail and security functionality to document and prevent the unauthorized manipulation of data.
- Reporting requirements.
- Wonderware application tags and scripts. This effort required reverse engineering of the application software and the translation of existing German comments to meaningful English text.
 - Describe both the new and existing functionality in Functional and Design specifications.
 - Eliminate multilingual screen text support code from the software.
 - Prepare qualification protocols for validation.



◀ Minimal changes in physical hardware were required to produce dramatic improvements in overall system functionality.

Secure data on a centralized server

SOLUTION

CQS Innovation upgraded the HMI PC component of the control system with new hardware and software to resolve the customer-identified deficiencies. The existing control system consisted of a Siemens S7 PLC, an integrated Pentium 2 computer with touch-screen display, and a PC running proprietary recipe and configuration software provided by the tank manufacturer. The new control system consists of the original PLC, a new computer with touch-screen monitor, and the existing recipe and configuration PC.

CQSI delivered new capabilities with the HMI PC's software:

- Upgraded the operating system to support the upgrade of the Wonderware InTouch software.
- Reconfigured the HMI PC application to redirect its security requests to the site's primary domain controller for security authentication.
- Configured the existing Engineering server to collect data from the HMI PC for batch records.
- Set up InSQL-IDAS modules on the HMI PC for local buffering of data during loss of communications with the Engineering server.
- Configured reports using Active Factory for the reporting of Batch Step Data, Batch Alarms, Batch Events and Trends.
- Wrote a Functional Specification and a Design Specification to document functionality of the HMI PC.
- Documented all changes to the HMI Software with English language comments.
- Eliminated multilingual support from the HMI screens.

RESULTS

The customer received significant, measurable benefits from their new HMI PC:

- Security requests are now authenticated through a centralized primary domain controller, which greatly reduces the maintenance of security services for the HMI.
- Batch data is stored on a secure Engineering server set up to prevent unauthorized access to the data and to document any changes to the data by authorized personnel.
- The HMI application allows the operators to view and print preconfigured batch reports.
- Batch reports were validated to correspond to the actual actions of each sequential step.
- The functionality and design of the HMI application is now documented in Functional and Design Specifications.
- The English language comments, added to the scripts and tags changed during the upgrade, have greatly enhanced the customer's ability to upgrade and troubleshoot the HMI application in the future.
- The operating system is now supported by the IT department.

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