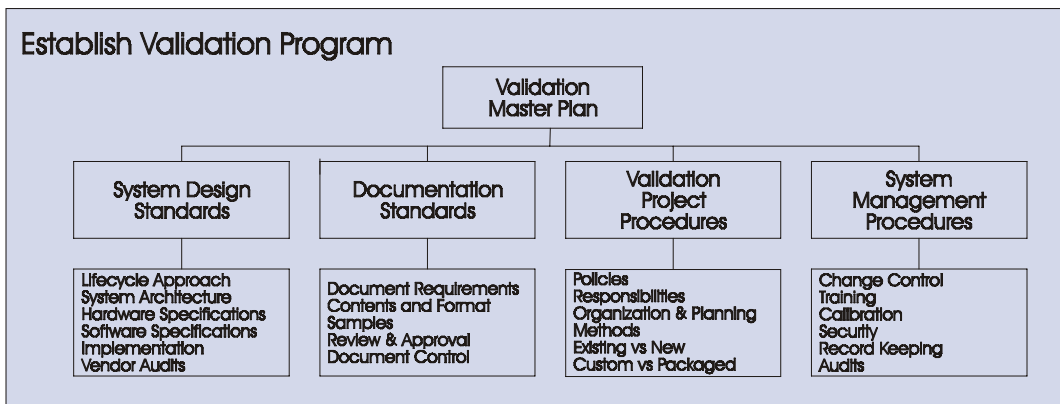


Validation of Active Pharmaceutical Ingredients (API)

Active pharmaceutical ingredient production facilities need to be validated:

- reverse engineer control systems
- produce needed specs and protocols
- execute qualifications tests and write report



◀ Steps to establish a Validation Program

Background

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 its predetermined specifications and quality attributes”. A large manufacturer of bulk pharmaceuticals engaged CQSI to establish a validation program for control systems on existing production lines. Their plant uses four major processes comprised of 25 different control systems.

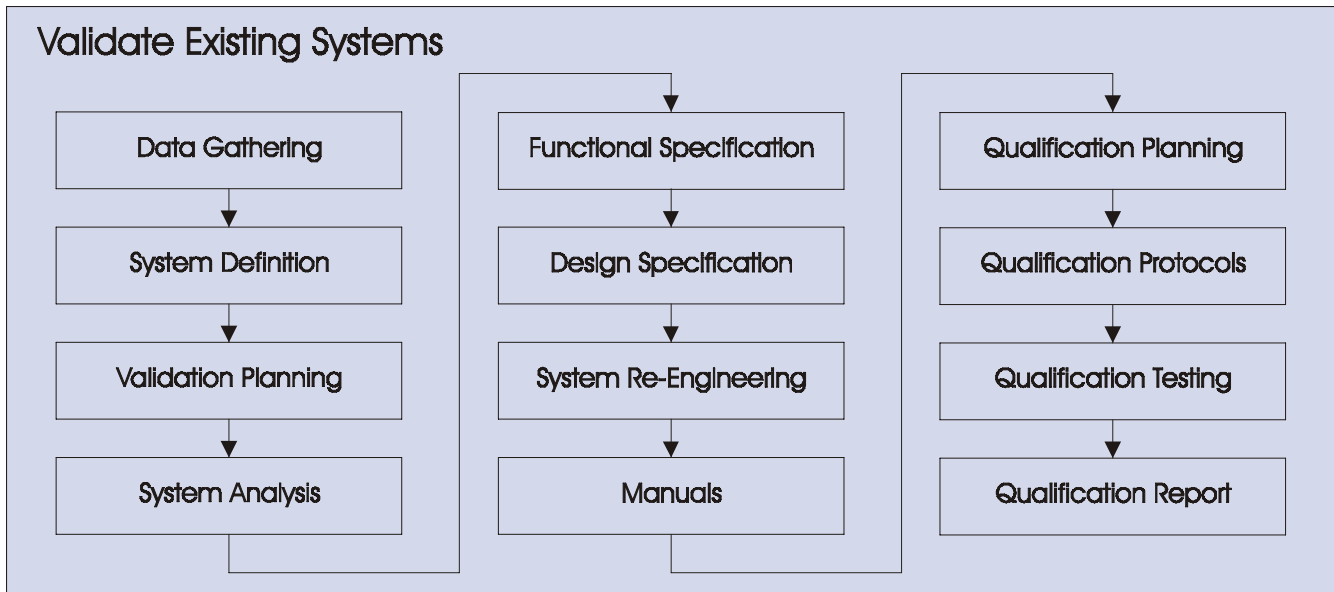
The regulatory agency had been inspecting their plant for years, but announce on the most recent trip that future inspections would require evidence that the existing process control systems had been validated. This meant developing or finding documents needed for requirements, design specifications, test protocols and test results to provide the evidence required.

The funds for such an undertaking were not budgeted and the plant was not familiar with validation processes. CQSI has delivered validation documents for control systems we built, so we are familiar with the process.

Challenge

Working closely with customer Quality Assurance, Engineering and Operations staff, CQSI created a team environment to get the best information to everyone as quickly as possible. The team directed CQSI to the information available on the systems to be qualified and the methods to be used. Protocol content and formats were specified from existing corporate SOPs relating to similar facilities. Sample documents were developed and submitted for review and approval to verify the content and format would be adequate. Once approved, the rest of the control systems were documented and tested.

There was no validation, we had to start from scratch a master plan to describe the documents and the tests necessary to meet regulatory compliance. CQSI staff met with the customer to understand the company’s corporate standards and plant operating procedures. Following the planning meetings, the effort was expanded to include all devices within each control system, not just the PLC. Next, a review of each of the existing systems’ documentation and current PLC code determined which systems needed what documents. Once the extent of the effort was known, a project plan was developed.



▲ Steps used to validate an existing system.

Solution

The major effort was production of missing design documents, manuals and the protocols for Installation and Operation Qualification testing. Where multiple control systems functioned similarly, the existing controller code was rewritten into common modules which proved to be more economical than documenting the unique code in each controller. This new common module library will also reduce maintenance effort on all these systems by the uniformity of code and function.

Results

The CQSI project provided numerous benefits for the manufacturer, including:

- Documented traceability of system development for FDA requirements
- Improved maintainability of control systems and manufacturing processes
- Complete, accurate validation of documents for FDA inspection
- A complete and practical methodology to follow for future control system validation programs

While meeting FDA requirements for validation was the manufacturer's primary goal, their engineering staff took the opportunity to improve the maintainability and quality of the control systems. One of the company's engineers noted that the level to which CQSI took the validation work allowed them to survive the FDA audit, structure their records and modify their procedures for the validation of future systems.

CQSI Provides World-Class Solutions for Manufacturing

CQS Innovation, Inc. provides validation program services for new and existing information and control systems to manufacturers of pharmaceuticals, OTCs and health care products subject to FDA regulation.

CQSI also provides complete systems of computers, controllers, networks and software to improve product quality, production flexibility and product quality data recording.

We specialize in meeting the needs of pharmaceutical, food, consumer packaged goods and metal manufacturers. For more information, call (800)860-1968, ext. 385.