

# ABB Automation Systems: Your Validation Partner



ABB Automation



# Validation in the Pharmaceuticals Industry

Throughout the world, the production of pharmaceuticals is subject to strict governmental controls.

Production processes and facilities are carefully inspected, and conformance with applicable regulatory directives is constantly monitored.

Each manufacturer is required to provide documentary evidence that the production process is capable of producing and continuing to produce a product that meets the corresponding specifications and quality requirements. This process is called validation. Validation typically covers all methods and procedures, facilities and equipment used in the production of pharmaceuticals.

Because the quality of the product can be significantly influenced by the process control system, that system is also subject to validation or qualification requirements and must be up to the regulators' high standards.

For manufacturers of pharmaceutical products, validation is a difficult challenge.

Only through cooperation with a competent and reliable partner, validation is effectively possible at reasonable cost.

**ABB Automation Systems is that partner, and we will support your validation efforts.**

Validation has its origins in the USA. In the early 1980's the Food and Drug Administration (FDA), an agency of the US Department of Health, released directives for the production and importation of pharmaceuticals. Similar requirements regarding all pharmaceutical processes have been in force in the European Union and many other countries since the beginning of 1992.

## Regulations

The FDA's "Good Manufacturing Practices" (GMP) and the corresponding "national legislation in each country" from the German Health Ministry describe the philosophy behind proper and reliable production of medications.

Extensions of these guidelines have special provisions regarding validation of computer-aided processes.

## Validation Procedure

The operator of the production plant is responsible for validation. For new plants, validation runs parallel to the planning, setup and even the maintenance process.

The validation procedure is described in the "V-Model" recommended by cGMP/NAMUR. This procedure is divided into several phases: those carried out by the facility operator, those carried out by the system supplier, and those carried out by both.

In the V-Model, the planning activities and the corresponding qualification measures are laid out side by side.

## Master Plan

The basis for all activities is the "Validation Master Plan" produced by the plant operator. This plan covers:

- Plant planning, system design and specification as based on operational and legal requirements.
- Validation plan for the different phases and costs.

## Supplier Auditing

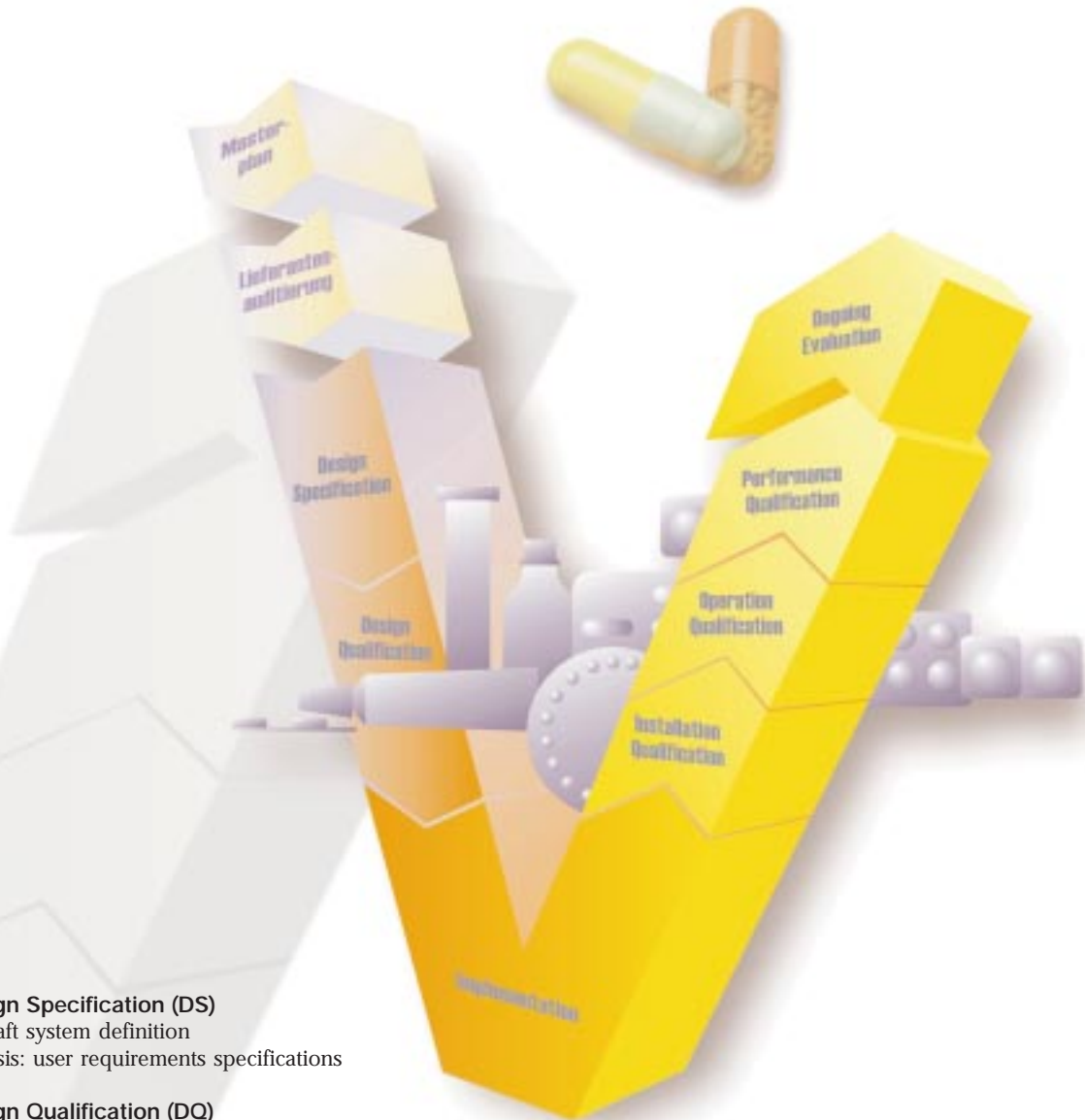
The plant operator chooses the system supplier, weighing the following points: product characteristics, company capability in supporting validation, such as organization, quality management and project management, work methodology and control mechanisms. Preferred suppliers are those which have already qualified by passing an audit, such as, for example, ABB Automation Systems.

## Qualification

As system provider, we meet the needs of the customer in a step-by-step process derived from cGMP/NAMUR recommendations. Documentary evidence is created, showing that the process control system functions in a reliable and reproducible manner.

The conclusion of the validation process is the "Performance Qualification." In this step, the interaction of process and automation is tested according to the Master Plan. This, for example, can consist of a systematic test run, or tests of system functioning under both normal and exceptional conditions.

**The result is the validation report.**



#### Design Specification (DS)

- Draft system definition
- Basis: user requirements specifications

#### Design Qualification (DQ)

- System layout of hardware and software components
- Control system functional specifications
- Testing instructions for IQ and OQ qualifications

#### Implementation

- Implementation of system hardware and software
- Writing application software
- Module testing
- Module integration

#### Installation Qualification (IQ)

- Hardware testing
- Physical installation of the control system
- Firmware and application software installation
- Technical function checking

#### Operation Qualification (OQ)

- Functional testing of software and application software
- Control system commissioning
- Comprehensive test of the full control system

#### Performance Qualification (PQ)

- Plant commissioning
- Systematic test operation
- Test batch operation
- Stress testing
- Validation report

#### On-going Evaluation

- Maintenance measures
- After sales support
- Change control

# An Experienced Validation Partner

## Validation with ABB Automation Systems

ABB is not only a supplier of products and services, but also your partner when it comes to automation of facilities and processes. As such, we are also qualified to support you in validation.

Validation support, a field of expertise in its own right, is based on:

- Experience and competence
- A certified quality assurance system for products and services
- Project management using procedures suitable for validation, as based on the "Validation Manual"
- Reliable, validatable system technology
- Experience with production plant projects in the pharmaceutical industry
- Wide range of service offerings

## Our Expertise

ABB Automation has decades of experience in the field of process automation and is one of the leading suppliers worldwide. We have had a decisive influence on the development of process control technology.

Our process control systems are installed and proven around the world, and include many in the chemical and pharmaceutical industries.

All of this know-how is applied in the development of new systems and equipment.

## Quality Assurance

As the company who developed the basic skills and programming languages for Batch Control and Recipe Management, ABB sets a high standard. With over 15,000 Application Engineers, many of who are Batch Control specialists, ISO 9000 certified implementation centres around the world, ABB has become the logical choice for most of the major pharmaceutical and Batch processing companies around the world.

For us, quality is more than just a statement on paper. The quality management concepts implemented have become second nature throughout the company. Together with employee training, they allow continuous improvement of the high standard of quality assurance.

Our process control systems are designed, implemented and tested according to a well-established quality assurance program.

Proper execution of development and production procedures is documented in accordance with the requirements of the Quality Assurance Manual.

## Validatable Project Management

All control system orders are handled on the basis of effective project management, including:

- Design and planning
- Engineering and testing
- Installation and commissioning

A project manager with overall responsibility is assuring central active project coordination and continuity. In this effort, the project manager receives full support from various technical departments. Responsibility and authority is explicitly established, even for subtasks. Any changes are reviewed, and, if necessary, approved, by an authorized individual; activity is summarized in a detailed project log. The documentation management system stores this information and thus ensures project transparency and continuity.

Projects requiring validation are handled according to directives in the company's own "Validation Manual."

This guideline takes the special requirements of validation in all project phases into account. Feedback from previously completed projects is incorporated into the Validation Manual, leading to continual improvement of the process.

### Supplier Qualification

ABB has been audited around the world both in the system development centres and implementation companies by such companies as Merck, Kemper-Masterson etc.

These audits covered the following areas:

- System development
- Quality management
- Application development and project management
- After sales support

In addition, we have had the opportunity of proving our validation competence on the occasion of numerous supplier audits carried out at the initiative of our other customers.

**We have proven ourselves to be qualified system suppliers!**



### Partnership with Plant Operators

A cooperation agreement has been concluded with the renowned pharmaceuticals company Hoechst Marion Roussel (HMR) and others. This partnership will pursue the following goals:

- Exchange and development of automation and product know-how
- Minimizing of acquisition and operating costs
- Development of engineering standards for cost reduction.

### Service Offerings and After Sales Service

Even after the control system is commissioned, we can assist you in maintaining the validated status of your plant according to the master plan.

We offer an extensive spectrum of services, and guarantee easy availability of the technology employed during its full life cycle. We will gladly assist you with system checks, plant expansion or modification.

**Validate your plant with us. We have the management know-how and the validatable control technology.**



# ABB Process Control Systems – Reliable and Validatable

What characteristics must a control system, PLC, or DCS have in order to make its use permissible in a facility which is subject to a validation requirement?

In response to this questions, a working group of the Standardizing Organization for Measurement and Control (GMA/NAMUR) published the NAMUR NE 72 recommendation titled "Control System Implementation Validation Support."

This report specified that three major criteria must be tested when a control system is validated:

- Reliable operation in accordance with the design parameters
- Prevention of unintentional alteration and unauthorized access
- Documentation meeting the needs of the process in question

Similarly the compliance to FDA regulations (21 CFT Part II), the ABB process control and EBR products, support clients to fulfil these requirements.

The validation of control systems is greatly facilitated by the modular structure of the hardware and software. Only the application-specific configuration elements need to be tested, because all important functions are carried out by standardized software function modules.

These function modules are type-tested and used repeatedly. Even complex multi-thread, multi-product batch recipes are implemented using the standard modules. Details are specified on a case-to-case basis in the "Design Specification/Qualification" documentation.

**We support your validation with robust, reliable systems technology. Let us show you how!**



# System Functions Supporting Validation

## Structured system design, unambiguous labeling

- Separate processing of tag and operation/observation functions
- Modular hardware and software structure
- Clearly designed and implemented field connection system

## Input control, change control and access authorization

- Configurable user profiles
- Separate authorizations for configuration/parameterization
- Input plausibility checks
- Logging of operation and configuration actions
- Forward documentation of configuration changes

## Processing and safety

- Processing with fully tested, standardized hardware and software modules
- Configurable redundancy
- Status monitoring of the hardware
- Alarm management system
- Integrated online diagnostic system

## Fault location and handling

- Configurable response to fault conditions
- Measuring point monitoring with provision for default values
- Orderly restart after power loss
- Decentralized processing
- Configurable system architecture
- Remote diagnostic capability

## Efficient alarm system

- Alarm messages cannot be covered up
- Rapid access to detailed information
- Configurable acknowledgment requirements
- Explicit acknowledgment
- Chronologically correct alarm display/recording
- Disturbance course log

## Data integrity and protection

- Battery backup power memory
- Automatic archiving of curves, configuration and system data

## Extensive documentation

- Operation documented in logs
- Special logs for batch operation
- Forward documentation for configuration
- Product documentation
- Online help

The illustrations on the front cover and on pages 3 and 4 were provided courtesy of Hoechst Marion Roussel.





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