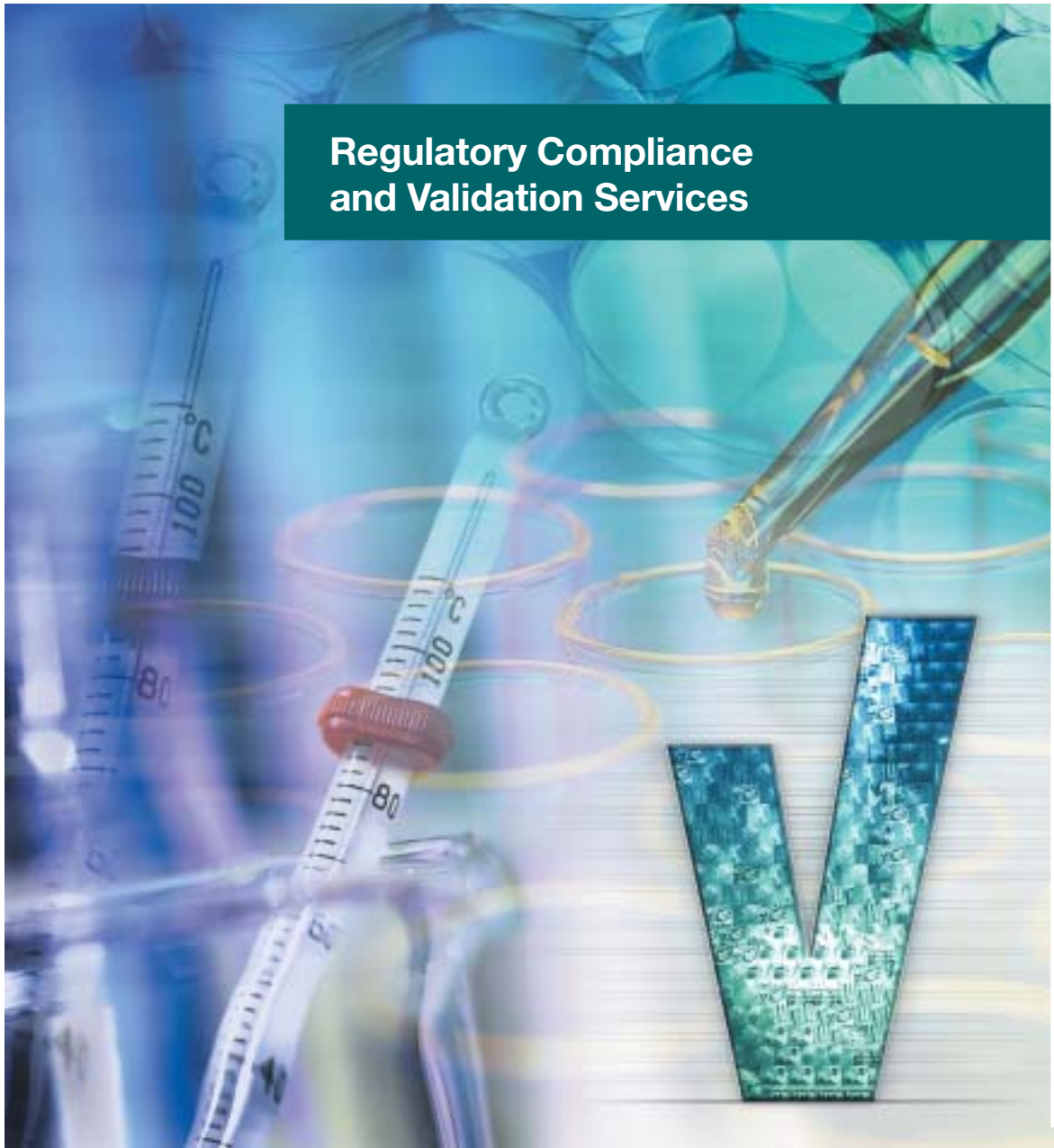


Industrial^{IT} Solutions for the Life Sciences Industry

**Regulatory Compliance
and Validation Services**



ABB's regulatory compliance services assist you in dealing with the increasing demands and complexity of national and international regulations.



Regulatory compliance in the Life Sciences industries

Throughout the world, Life Sciences manufacturers are subject to strict governmental control. Pharmaceutical, biotechnology and medical device manufacturing must observe national and international legislation to increase product safety and ensure the health of consumers.

The challenges

This situation creates several industry wide challenges:

- How to balance on-going changes in the industry and the implementation of new technologies with the need for compliant solutions.
- How to find the time and resources to stay up-to-date with regulatory developments and to be constantly prepared for an inspection.
- How to meet consumer demand for high quality standards at good prices in tougher economies.

Time and costs are crucial to success. Time to market is driven by the limited patent life of new drugs or the resources needed for drug discovery and clinical trials.

Concerns about time and costs force Life Sciences companies to focus continually on ways to add value, improve performance and increase profitability in a regulated environment.

Validation professionals

ABB's regulatory compliance services assist you in dealing with the increasing demands and complexity of national and international regulations.

Our validation teams keep up to date through our liaison with international clients, contacts with regulatory authorities, participation and attendance at conferences, and strategic involvement with the GAMP forum.

Practical, defensible solutions

ABB's technical and regulatory compliance experts rescue you from over-engineered solutions. We develop practical but defensible solutions that stay within your budget. Your partnership with ABB will help you produce competitive quality products that are not too costly and that come to the marketplace quickly.

Your partner in success

Focusing on regulatory developments and validation activities consumes time and resources that you need to speed your products to market.

Our team wants to partner with you to take care of:

- Validation strategic planning
- Validation project management
- Specialized validation training
- Validation outsourcing

Our services give our customers confidence in a compliant solution.

Choosing the right partner

Life Sciences manufacturers must plan, implement and document validation activities. These activities must be assessed against the regulations that are applicable and legally enforced for the specific product manufactured.

Validation has given the pharmaceutical industry many benefits:

- Assurance of safe and quality products
- Reliable equipment and systems
- More reproducible procedures

Streamlined validation

However, projects are also governed by budgets and timelines. The earlier you set the course for cost-effective validation, the better. Otherwise, the project scope and regulations become mired in confusion and misinterpretations, resulting in unrestrained bureaucracy and paperwork. The costs of compliance soar.

ABB can help you lower validation costs right from the start, using methods like risk analysis, gap analysis and impact assessment based upon GxP significance.

Pragmatic, risk-based approach

ABB has developed a pragmatic and risk-based approach to compliance issues. The main characteristics of this approach are consistency, rationale and risk reduction:

- Assessments are brief and directed towards the highest risk.
- No assessment is complete until the remediation is identified and carried out.
- Regulatory, inspection and business criticality are determined.
- Prioritization is based on criticality, cost and economic life cycle.

All actions are justified with a rationale, both those that are to be implemented and those that are not. Our validation teams deliver compliance appropriate to your needs at a sensible price.

International scope

Pharmaceutical manufacturers work globally in today's rapidly changing healthcare environment. They sell their products globally, maintain manufacturing sites in many countries or buy equipment and ingredients from globally operating suppliers.

Thus, it's important to have a validation partner with the same global perspective and coverage. ABB validation experts are a phone call away and can help you solve problems at short notice, no matter what regulations you operate under.

Experienced project management

Our validation and regulatory compliance experts cover all validation disciplines and levels.

Project managers are senior specialists with experience in quality management, technology and engineering. They minimize iterations and facilitate communications with technical and quality assurance personal. Experienced project management ensures that your validation projects will be completed on time in full.

For your convenience this brochure contains a glossary of terms associated with regulatory compliance and validation.



ABB understand the needs of the Life Sciences industry, and we bring you more than one-hundred years of experience with the regulated industry.



Validation outsourcing

The majority of pharmaceutical companies already outsource validation to some degree. The vendor services may range from procuring laboratory systems with vendor templates for installation and operational qualification (IQ/OQ), to specifying the validation elements for a new system or facility, through to complete operational qualification.

Recruitment and development of in-house validation personnel is a costly proposition. By contrast, a partnership with a validation specialist organization allows you to meet the cyclical validation requirements of your organization while freeing you to make maximum use of your in house resources.

The rewards of a partnership

Developing a partnership with a single organization with the critical mass to support your outsourced needs may sound like a bold step but the potential rewards are significant, including:

- Access to a pre-qualified work force who understand your company policies, procedures and templates, yet are available on an as-needed basis
- Predictable validation costs through the implementation of clear role and competence frameworks and fixed cost structures
- De-bottlenecking of validation, by taking it off the critical path of your projects – which means faster project completion
- Continual analysis and implementation of methods to reduce validation-driven risks and costs
- Clear quality and compliance governance remit for internal staff
- Direct access to a body of subject matter experts reflecting current thinking in a broad spectrum of validation areas
- Access to an independent auditing group
- Ongoing collaborative review of validation procedures, securing timely opportunities to implement risk-based pragmatic validation at reduced cost

An invitation to partner

We would like to invite you to partner with ABB. Our team understands the needs of the Life Sciences industry, and we bring you more than one-hundred years of experience with the regulated industry.

As a leading group of validation and regulatory compliance specialists, ABB covers all validation disciplines. We deliver the level of validation that you want.

Consider ABB as your representative in the regulatory arena and as your validation partner for regulatory compliance. ABB's industry expertise, excellence in execution and global resources guarantee stability and a continued commitment.

Computer systems validation

Computer systems facilitate the daily work of Life Sciences manufacturers. They are used during the whole life cycle of human or animal drugs, biological products, medical devices and even certain food and color additives.

Computers are found more and more in research and development departments, in manufacturing sites, and in storage and distribution and quality control areas. They create, modify, maintain, archive, retrieve or transmit data.

Computer systems are a central factor determining work sequences; they are faster and less expensive than manual interventions. Where a computer replaces a manual operation, there should be no resultant decrease in product quality or quality assurance.

Key challenges

Any computerized system that could influence the safety and quality of pharmaceutical products must be validated.

A validation program must verify whether:

- The computer and its application works as intended and according to the specifications and regulatory requirements.
- The computer data is protected from unauthorized access and changes, as well as unintended losses.

The validation documentation specifies requirements, evaluates risks and records the

implementation type and procedure, including the test results. This documentation is an important proof of regulatory compliance and quality; the manufacturer needs it when government authorities inspect the research and development process, the manufacturing site and the business or other systems.

Comprehensive validation assistance

ABB bases validation planning, implementation, or evaluation upon a review of laws, regulations, and guidelines that are applicable to your product, process and country. In addition, our validation program covers:

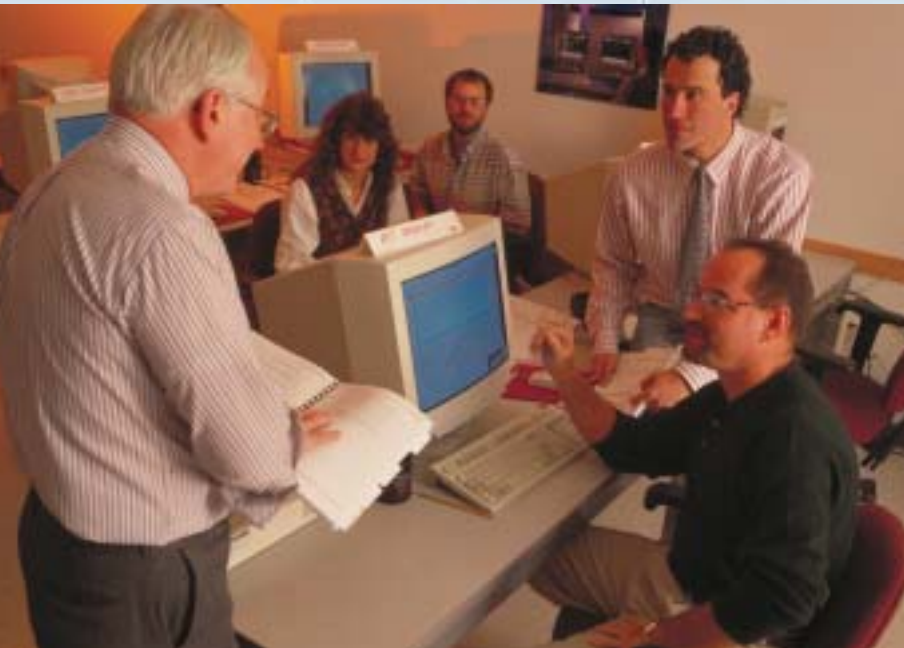
- Validation master plan
- Risk assessment
- Traceability matrix
- User requirement specifications
- Functional requirement specifications
- Source code review
- Installation qualification
- Operational qualification
- Performance qualification
- Standard operation procedures
- Validation documentation

Training, guidance, leadership

ABB helps you meet the goals of your computer system validation program by training your existing staff or supplying qualified consultants. Our teams can assume leadership in project planning and in executing your compliance program. We work directly with your operational personnel, the IT department or your contractors staff.



ABB helps you meet the goals of your computer system validation program by training your existing staff or supplying qualified consultants.



GMP and GAMP

GMP regulations and Good Automated Manufacturing Practice (GAMP) guidelines embrace regulatory requirements for computer infrastructures. These requirements cover the suitability of the design, construction and performance, as well as the need for documented verification of inputs and outputs.

When a computer infrastructure is being introduced in pharmaceutical processes, the implementation includes not only hardware components (like servers, switches or routers), but also features like:

- Access management
- Alarm and event reporting
- Back up and recovery strategies
- Electronic records and archives
- Encryption and integrity controls
- Entity and message authentication

Computer infrastructure qualification

Whether you develop, test, manufacture or deliver active pharmaceutical ingredients, vaccines or other pharmaceutical products, your software applications are based on an infrastructure, including:

- Servers, that host data, databases or files, applications or special services
- Client workstations
- Network components and protocols

The computer infrastructures coordinate and allocate resources to users and applications to enable data sharing, and also provide communication services. Before the computer system can be validated, the infrastructure must be qualified to prove its security, availability, reliability and usability, and to ensure that data is transferred accurately.

Once the validation qualification is available, it can be referenced in all validation programs, and doesn't need to be repeated for each application supported by the infrastructure.

Both IT and regulatory expertise

Our experts understand both the technical aspects and the regulatory requirements. They'll help you qualify your computer infrastructure or conduct the complete validation, including:

- Design and selection of equipment
- Equipment and infrastructure installation
- Configuration management
- Evaluation and testing of equipment

The infrastructure documentation consists of design documentation and diagrams, equipment configuration worksheets and qualification testing. In addition, our experts help you:

- Develop change control, maintenance and training records.
- Set up an audit track on databases
- Implement recovery plans.

ABB's combination of IT expertise and compliance proficiency improves your business processes.



Business systems validation

Increasing demands for time-to-market and for manufacturing effectiveness are just two of the factors driving the development of business systems in the pharmaceutical research and manufacturing industries.

Business systems and applications are increasing in complexity and integration, so that companies can deliver real-time manufacturing, engineering, sales and accounting information across the entire enterprise. These systems and applications include:

- Computerized Maintenance Management Systems (CMMS)
- Document management
- Enterprise Resource Planning (ERP)
- Laboratory Information Management System (LIMS)
- Manufacturing Resource Planning (MRP/MRP II)

Integrated systems

Integrated computerized systems have a direct impact on the quality of pharmaceutical products. As a result, pharmaceutical manufacturers face issues with:

- Mixed GxP and non-GxP critical functionality
- Wide range of data types, from master data to dynamic real-time data

- Complex and enterprise wide business processes with many users, SOPs and interfaces.

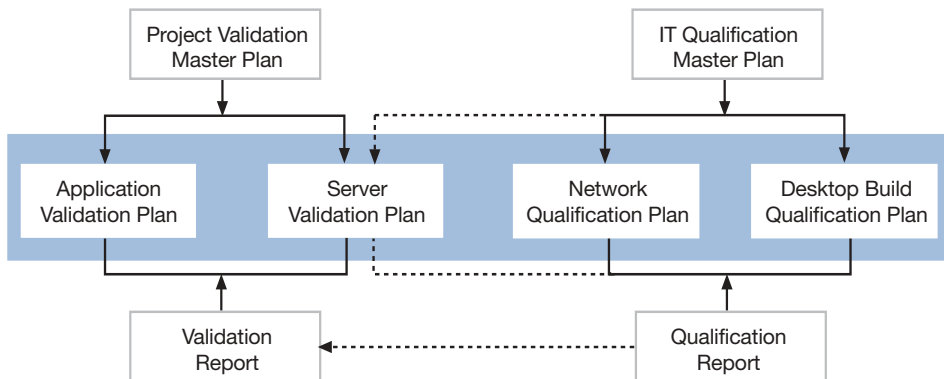
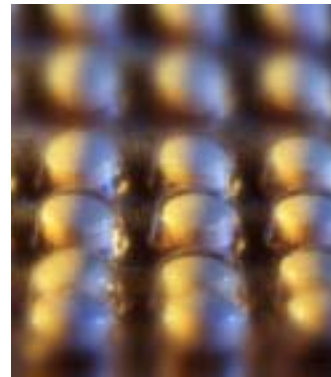
Business systems are usually highly configurable and customized to fit your needs. Replacements and upgrades, data migration and cut-over (going live) must all be considered during compliance validation. These issues can affect your project schedule and your ability to complete your validation project on time in full.

Informed business decisions

ABB takes the fear out of validation by helping you understand the risks so that you can make intelligent business decisions while meeting your investment and compliance requirements.

We help you to implement new technologies and still maintain compliant systems. We provide services such as:

- 21 CFR Part 11 assessment
- Business readiness evaluation
- Cut-over planning and management
- GxP assessment
- Project management
- Risk and gap analysis
- System retirement planning
- Validation and implementation



Our validation experts convert or develop your spreadsheets and deliver fully validated applications so you can continue to use the flexibility, familiarity and interconnectivity of Excel.



Electronic records and electronic signatures

FDA 21 CFR Part 11

The U.S. Food and Drug Administration rule 21 CFR Part 11 applies to electronic records and signatures. It covers all pharmaceutical products manufactured in the United States, and also products manufactured elsewhere but distributed in the United States. Many other jurisdictions also have or are setting directives in place that enable the use of electronic records and signatures.

A paperless world with fully electronic data handling promises cost savings from improved efficiency and reduced physical handling and storage. Electronic signatures are given legal equivalence with traditional “wet ink” signatures on paper.

Key areas of the regulation which require attention are:

- The definition of an electronic record
- Access control, security and data consistency
- Audit trails
- Electronic copies for inspection
- Retention and maintenance of records
- Application of electronic signatures

It's not possible for any equipment vendor to offer a turnkey “Part 11 compliant system.” Any vendor who makes such a claim is misleading you. Part 11 requires you to put into place both procedural controls (i.e., notification, training, SOPs) and administrative controls, in addition to the technical controls that a vendor can offer.

The focus of inspections

21 CFR Part 11 affects most computerized systems and is increasingly the focus of inspections. It applies to existing systems, as well as new systems.

Key steps to achieve compliance with 21 CFR Part 11 include:

- Establish a consistent company-wide Part 11 interpretation
- Integrate Part 11 with corporate policies and guidelines
- Take inventory. Identify and prioritize the systems that are subject to Part 11 for inspection
- Introduce and execute assessment and gap analysis
- Identify non-compliant systems and the tools and solutions for bringing them into compliance

Solutions for compliance issues

ABB offers a number of services to assist you. Acting as your 21 CFR Part 11 compliance team or in support of your in-house team, we:

- Develop and execute 21 CFR Part 11 training programs.
- Verify and ensure that corporate policies address all compliance issues.
- Introduce a compliance program based on a reasonable schedule.
- Execute the program according to the plan.
- Provide ongoing services to maintain the compliance status.

Spreadsheet validation

Are you using spreadsheets in a regulated environment? Does your Life Sciences company regularly use Microsoft® Excel for GxP purposes, whether as an operator interface, as a data manipulation tool or for data storage?

How do you deal with log-on security for the application and spreadsheets, independent audit trail, electronic signatures? Is your data secure? Can your saved data be accidentally overwritten?

Inspectors are now increasing their focus on 21 CFR Part 11. In particular, the U.S. FDA is sending a strong message that Part 11 compliance should include Excel spreadsheets.

Warning letters are being sent that cite, for example, a company's "failure to use fully validated computer spreadsheets to calculate analytical results for in-process and finished product testing." Responding to such situations can impact your time-to-market and your manufacturing efficiency.

A fully defensible response

If you're using Excel for GxP activities, you must validate each GxP critical spreadsheet to demonstrate the security and traceability of your data.

Start assessing your spreadsheet inventory and apply risk assessment technology to determine gaps. The range of the inventory assessment program can extend from individual applications or systems to the full plant or company.

Highlight those spreadsheet applications that most threaten your operations because of GxP, business and inspection criticality. Then establish a remedial action plan that shows regulators your commitment to 21 CFR Part 11.

ABB can assist. Our aim is to help make your position fully defensible in the shortest time possible.

Fully compliant applications

We help bring your non-compliant spreadsheet applications into full compliance. ABB supplies and installs the DaCS™ software on your equipment or across the network. Each spreadsheet will be moved into the controlled DaCS environment to ensure:

- Logical security for the application and spreadsheets
- Independent audit trail of operator and system actions
- Use of electronic signatures on individual spreadsheets to fit the data flow processes
- Secure yet portable data, protected by the DaCS digital integrity features

Our documented validation includes:

- Spreadsheet specification
- Spreadsheet qualification (IQ, OQ)
- Installation and environment security
- Spreadsheet administration
- Procedures for maintenance and operation

Our validation experts convert or develop your spreadsheets and deliver fully validated applications, so you can continue to use the flexibility, familiarity and interconnectivity of Excel. You'll receive more than just spreadsheets – you'll receive the assurance of full FDA 21 CFR Part 11 compliance.

Our partner Wimmer Systems provides the technology that enables Excel to be used in regulated environments. Wimmer Systems' DaCS™ is the technology we use to put your Excel spreadsheet into compliance.



Validation Life Cycle

All validation projects are carried out gradually in defined phases. The planning phases result in specification documents. A detailed report is produced after each qualification phase. In the case of a failed qualification, retests will be performed until the qualification test has been passed successfully. The validation process ends with the final system acceptance and the validation report.

- Generate validation master plan
- Set up project management
- Specify user requirements
- Schedule validation trainings

Validation Planning

- Assess GxP criticality
- Conduct Part 11 assessment
- Plan supplier audits
- Document risk assessment

Risk Analysis

- Specify functional requirements
- Include infrastructure prerequisites
- Initiate requirements traceability matrix
- Implement change control procedures

Detailed Planning

- Design hardware and select equipment
- Specify software design
- Set up configuration management

Design Specification

Implement

Validation Review Management

- Maintain the validated state
- Manage change control procedures
- Use revalidation measure



Validation Report

Performance Qualification

- Verify user requirement specifications
- Ensure availability of approved documentation
- Conduct system acceptance testing

System & User Documentation

- Generate templates
- Document prerequisites
- Document the system and application procedures

Operational Qualification

- Commission the system
- Verify functional specification
- Ensure SOPs are in place
- Conduct operational testing

Standard Operation Procedures

- Assess global SOPs
- Write related SOPs
- Include requirements
- Organize SOPs

Installation Qualification

- Verify design specification
- Generate test plans
- Produce test specifications
- Conduct installation testing

- Build system
- Engineer and execute coding
- Review source code
- Conduct software integration testing

ation

ABB works closely with you to bring early success and payback from your automation investment.



One of the key benefits of GAMP are the life cycle documents, which have proven their effectiveness as communication tools along the entire validation and life cycle of drug products.

User Requirement Specification (URS)

The URS describes the end user's expectations with regard to features and functions as well as the overall model of the automation system, the process equipment, and associated operations. Typically, the user is the author of the URS. The later performance qualification implies that the URS was tested successfully including plant commissioning, test of batch operations, stress testing, and finally the validation report.

Functional Specification (FS)

Based on the URS either the user or the supplier identifies the system requirements and specifies the functional demands. The FS describes how the system should function and may also include instrument lists, P&I diagrams, or requirements for data management and interfaces. The FS sets system design objectives without defining how to do the detailed design or engineering. After the commissioning, the system acceptance testing verifies that all functional requirements are met.

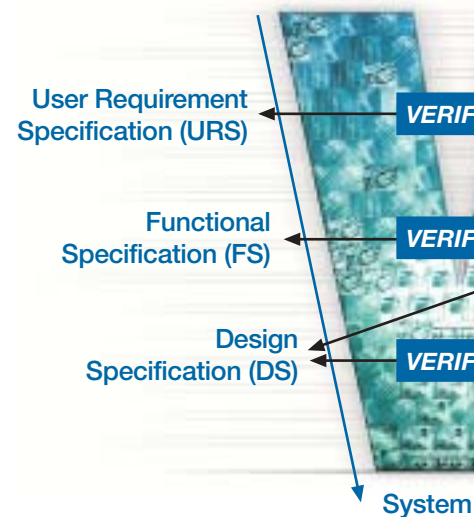
Automation systems validation

In the pharmaceutical industry GMP-relevant manufacturing processes are increasingly automated and supported by control systems. Like any other computerized systems, these automation systems must be validatable in compliance with regional and international guidelines.

Standardization through GAMP

In addition to the GMP requirements that refer to drug product types, a comprehensive reference of good practices was tailored specifically to automation systems: the Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems.

The GAMP guide establishes validation deliverables and provides a common language, terminology and procedural task flow for project implementation and maintenance.



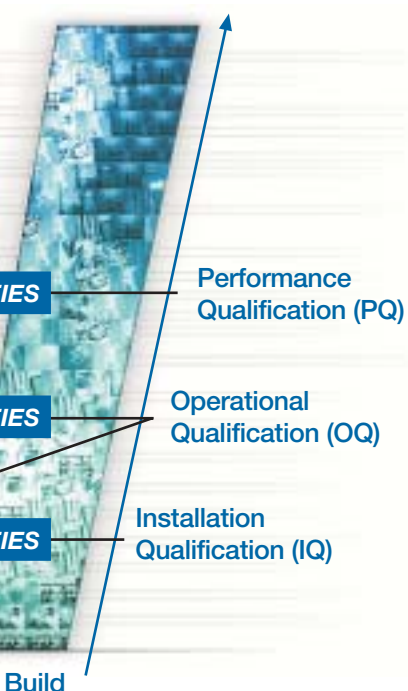
Design Specification (DS)

The system layout incorporates hardware and software components. The hardware design specification clearly defines all system hardware requirements, for example, operator workplaces, controllers, redundancy requirements, as well as how the system interfaces to other systems.

The completed software design specification (SDS) restricts the engineers to stay within the intent of the agreed upon requirements and design. The SDS describes what the software should do and how, in order to avoid ad hoc design decisions.

In automated systems, the software design includes system configuration. Configuration management guidelines may also include procedures on how to design, test, document and release system configuration data or how to organize versioning, for example, in project libraries.

Detailed written test procedures will later, after the system build, help to verify the installed system hardware and software against the design specifications.



Early success and payback

We work closely with our clients to bring them early success and payback from their automation investments. No matter what types of automation systems and control units are installed in your plant, our consultants will help you achieve compliance with services such as:

- Automation systems validation
- Application of GAMP guidelines
- Specification development
- Risk-based analysis
- SOP development
- Qualification documentation
- 21 CFR Part 11 compliance
- Electronic batch record compliance

Faster project execution

You face ever stronger demands to bring products to market ever faster while remaining profitable. Combine our validation services with ABB's Industrial IT System 800xA and speed your products to market.

With full audit trail included throughout the system, it helps shorten project lead times due to a fully integrated engineering environment and reuse of intellectual assets. Smart engineering tools allow building blocks to be designed, engineered, documented, validated, and then reused multiple times. You duplicate your solution, not the engineering and validation hours.

System 800xA offers you a faster path to manufacturing efficiency and compliance:

- System 800xA is designed for use in regulated environments
- Automation systems engineering and validation services, both from a single partner
- Automation retrofit delivery and cutover management and validation

You save on costs for engineering and documentation and you reduce project risks.



Our strength in validation processes, process engineering and control systems can help you achieve the right level of validation.



Facility and equipment validation

Facility validation is the foundation for assuring success in manufacturing process validation. It ensures that you have acceptable facilities, utilities and equipment to support manufacturing operations before you begin validating the manufacturing process itself.

The qualities of a successfully validated process – reliability, repeatability and robustness – also depend heavily on the repeatability and reliability of the process equipment.

Process equipment is usually delivered with an embedded control system. So process validation and computer validation are part of the same package.

Right first time compliance

For a GMP facility, manufacturers need to validate:

- Facility design, installation and function
- Critical process support utilities (HVAC, water purification, dust extraction, etc.)
- Process equipment design, installation, and operation, including calibration when applicable
- Computer systems

Once the facility is validated, manufacturers must concentrate on employee training, validation of the manufacturing process, and validation of the building and equipment cleaning procedures.

The benefits of experience

ABB's strength in all these areas – validation processes, process engineering and control systems – can help you achieve the right level of validation. We help you to establish a project team to manage and execute each phase of the validation project as required to satisfy the regulatory authorities. We combine technical knowledge with our compliance expertise to help you lower overall costs. We cover these key validation phases and GMP issues:

- Requirements phase
- Validation planning
- Project team formation
- Supplier audit
- GMP risk assessment
- Design review and qualification
- Installation, operational and performance qualification
- Preventative maintenance
- Periodic review, change control and revalidation
- Training

We work to develop a long-term partnership with you, providing a consistent and practical approach.



Education and training

Well-trained employees are essential for your business planning. ABB is proud to offer a range of regulatory compliance training programs. All courses can be customized to the needs of your professionals, from quality

management and validation to IT, engineering, manufacturing and supply chain. Fundamental or in depth training seminars are delivered on-site or at your nearest ABB office. For example:

Course	Participants will learn about ...
21 CFR Part 11	<ul style="list-style-type: none"> 21 CFR Part 11 The rule and methodology Applying the rule
Business Systems Validation	<ul style="list-style-type: none"> Terminology and specific application of validation principles Information technology (IT) compliance components Vendor selection and qualification
Cleaning Validation	<ul style="list-style-type: none"> Cleaning processes Cleaning validation principles and practices Associated analytical methods
Computer Validation	<ul style="list-style-type: none"> Basic concepts of validation Computer systems validation and risk assessment Process control systems validation using GAMP 4
Equipment and Facilities Validation	<ul style="list-style-type: none"> Regulations and guidelines for facility design related to cGMPs Practical approaches to equipment qualification and calibration
GAMP 4	<ul style="list-style-type: none"> Good Automated Manufacturing Practice (GAMP) principles and applications Guidance for Validation of Automated Systems Applying GAMP 4 (workshop)
GMP Fundamentals	<ul style="list-style-type: none"> Interpretation and application of current Good Manufacturing Practice (cGMP) Applying risk-based approach to cGMPs
Infrastructure Qualification	<ul style="list-style-type: none"> Applying prospective or retrospective qualification Network infrastructure qualification Qualification of servers and data centers Qualification of desktop (user) computers
Risk-based 21 CFR Part 11 Compliance	<ul style="list-style-type: none"> 21 CFR Part 11 regulations 21 CFR Part 11 key issues Risk-based approach to 21 CFR Part 11 compliance Compliance program implementation plans
SOPs for GMP Operations	<ul style="list-style-type: none"> Regulatory impacts to Standard Operation Procedures (SOPs) Writing and organizing SOPs
Spreadsheet Validation	<ul style="list-style-type: none"> Assessing spreadsheet inventory Applying risk assessment technology to determine criticality Reformatting spreadsheets and developing fully validated solutions using best practice guidelines



Our validation and regulatory compliant experts cover all validation disciplines and levels. We are only a phone call away.



Glossary of terms

This glossary is an overview of the most often used compliance and validation terms. It will help you maintain consistency in describing the requirements of the law and regulations, validation activities and compliance services.

Term	Description
21 CFR Part 11	Criteria under which the FDA considers electronic records, electronic signatures and handwritten signatures executed to electronic records to be trustworthy, reliable and generally equivalent to paper records and handwritten signatures executed on paper.
Archive	A lasting collection of computer system data or other records that are in long term storage for later research or verification, for security purposes, for historical or legal purposes, or for backup.
Audit	The independent examination of a sample of records, activities and/or systems to assess the state of governance, to comply with established controls, policies and procedures, and to recommend control improvements where judged necessary to reduce risks. Role performed by internal and external auditors.
Audit event	A discrete action detected by the system that may or may not generate a record in the audit log. Depending on audit rules (parameters) in the system's logical security policy, the system determines whether or not to record each audit event in the audit log.
Audit trail	A chronological record of audit events, linked to user IDs, that is used to reconstruct and verify an historical sequence of actions.
Authorization	The granting of permission of a resource owner to an authenticated individual to access the resource for a specific purpose.
Availability	The assurance that data or information, data processing functions and communications will be ready for use by authorized users when and where expected or required without unacceptable delay.
Backup, restore	The process of making a duplicate copy of data and/or systems for safe storage (normally in a fireproof-safe, often off-site), such that if the original data or systems are lost or unavailable, the backups may be retrieved and reloaded, possibly at a secondary (recovery) site.
Certification	Documentation by qualified authorities that a system's qualification, validation or revalidation has been performed appropriately and that the results are acceptable.
CFR	U.S. legislation: Code of Federal Regulations
cGMP	Current Good Manufacturing Practice (cGMP); a collection of high quality standards for drug manufacturing, and a law for companies subject to Food and Drug Administration (FDA) jurisdiction. This quality standard became legislation in many other countries as well.

Glossary of terms (continued)

Term	Description
Change control	A formally documented monitoring system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status to determine the need for corrective action to retain its validated state.
Computer-related system validation	The procedure of establishing documented evidence which provides a high degree of assurance that a specific computer-related system will consistently operate in accordance with pre-defined specifications.
Configuration management	The process of identifying and defining the configuration items in a system, controlling the release and change of those items throughout the system's life cycle, recording and reporting the status of configuration items and change requests.
Cutover management	Application-to-application migration management, including data migration planning, data cleansing, application retirement planning, reconciliation design and management, risk management, cutover process selection and delivery management, cutover validation.
Document control	System of procedures and practices that ensures proper change control and approval of documents, consistent with regulatory requirements and security of proprietary information.
Electronic record	Any combination of text, graphics, data, audio, pictorial or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.
Electronic signature	A computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
FDA	Food and Drug Administration; a U.S. Agency that drives the legislation for pharmaceutical industries (www.fda.org).
Functional requirement	A requirement that specifies a function that a system or system component must be able to perform.
GAMP guidelines	Good Automated Manufacturing Practice guidelines for validating automated systems. They contain information for both users from the pharmaceutical industry and suppliers of systems to the industry. (www.ispe.org/gamp)
GxP	Good Practice Guidelines, also referred to as "predicate rules," including: <ul style="list-style-type: none"> ■ GCP: Good Clinical Practice ■ GDP: Good Distribution Practice ■ GLP: Good Laboratory Practice ■ GMP: Good Manufacturing Practice
Good Manufacturing Practices (GMP)	Regulations that define high quality standards for the manufacturing, processing, packing or holding of medicinal products for human or veterinarian use or biologics.



ABB's industry expertise, excellence in execution and global resources guarantee stability and a continued commitment.



Glossary of terms (continued)

Term	Description
Handwritten signature	Traditional “wet ink” signature on paper or an electronic signing using an electronic stylus pen on electronic media.
Inspection	A formal and documented assessment of all or parts of drug discovery, development, testing, manufacturing or distribution against the requirements of the relevant governing regulations and procedures.
Installation qualification (IQ)	Documented evidence that the plant has been installed correctly to the design specifications, drawings and manufacturer’s or designer’s recommendations
Life cycle	An approach to computer system development that begins with identification of the user’s requirements; continues through design, integration, qualification, validation, control and maintenance; and ends when commercial use of the system is discontinued.
Master plan	A high level document which specifies the validation approach for a given system. It would normally define the validation procedures and standards, and the roles and responsibilities of key persons involved in the process.
Operational qualification (OQ)	Documented evidence that the plant, the process, the system or the equipment operates correctly to the design, specifications, drawings and manufacturer’s or designer’s recommendations, and that it has sufficient range and robustness to continue doing so.
Performance qualification (PQ)	The act of establishing documented evidence that the plant, the process, the system or the equipment performs its intended use and specified function in a reliable, reproducible manner.
Periodic review	The act of formally assessing and documenting that a given system is still being used for its original intended purpose and has been operated and maintained in line with the relevant governing procedures. The purpose is to ensure that the validation of the system is still appropriate and valid.
Prequalification	Credible portrayal of a product (software/hardware/services) by a supplier. It includes tests conducted by the supplier on the specific product or applications which are employed in precisely this form in various installations of a supplier’s customer.
Procedure	A directive usually specifying how certain activities are to be accomplished.
Process validation	The act of establishing documented evidence providing a high degree of assurance that a specific process will consistently yield a product meeting predetermined specifications and quality attributes.
Prospective validation	Validation conducted prior to the distribution of either a new product or a product made under a revised manufacturing process, where the revisions may affect the product’s characteristics.





Glossary of terms (continued)

Term	Description
Qualification	A phase of validation that provides documented verification that any system or equipment works correctly and consistently leads to the expected results.
Reliability	The ability of equipment or a system or component to perform its required functions under stated conditions for a specified period of time.
Requirements traceability matrix	The matrix provides assurance that the user requirements were covered in the validation documentation. It allows quick verification that all relevant functionality was tested during validation.
Retrospective validation	Validation of a process for a product already in distribution, based upon accumulated production, testing and control data.
Revalidation	The process of evaluating changes to the computer-related system or equipment and of executing those validation activities that will maintain or re-establish the validated status.
Risk	A measure of the probability and severity of undesired effects. Often taken as the simple product of probability and consequence.
Risk assessment	A comprehensive evaluation of the risk and its associated impact.
Risk-based approach	A systematic evaluation of the risk of a process by determining what can go wrong (risk identification), how likely is it to occur (risk estimation) and what the consequences are.
SOP	Standard Operation Procedures. The specific operating procedures that personnel have to follow in pre-defined situations and in sequence.
System life cycle	The course of developmental changes through which a system passes from its conception to the termination of its use; e.g., the phases and activities associated with the analysis, acquisition, design, development, test, integration, operation, maintenance and modification of a system.
User requirement specification (URS)	Definition of end user expectations with regard to features, functions and overall model of proposed process equipment and associated operations.
Validation	The act of establishing documented evidence providing a high degree of assurance that the manufacturing process (including buildings, systems and equipment) will consistently produce the desired results according to predetermined specifications and quality attributes.
Validation plan	A strategy to develop documented evidence of what the process, facility system or equipment is supposed to do and whether it indeed does what it is supposed to do. It also includes a strategy for maintaining a validated state.
Validation report	The documentation of detailed results of the validation efforts, inclusively test efforts, are provided in the validation report.



Industrial^{IT} for the Life Sciences Industry



An overview of Industrial^{IT} products and services for the Life Sciences Industry

Analysis and Instrumentation Equipment

- At-line analysis of powder blend homogeneity, and solid dosage from content uniformity
- On-line moisture analysis
- On-line monitoring of API manufacturing process, and solvent recovery process
- Raw material identification

Automation

- Batch control and management
- Building and facility automation
- Discrete control and package unit automation
- Electronic batch records, including manual operations
- Engineering and optimization software
- Fieldbus device and maintenance management
- Integrated information management
- Process automation and visualization

Robot-based Manufacturing

- Robots to pick, pack and palletize

Regulatory Compliance Services

- Automation systems validation
- Business systems validation
- Computer infrastructure qualification
- Computer systems validation
- Electronic records and signatures
- Facility and equipment validation
- Laboratory systems validation
- Risk assessment
- Spreadsheet validation
- Standard operation procedures
- Validation outsourcing

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