



# Computer systems validation Intelligent solutions

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Control systems are becoming increasingly essential to pharmaceutical production. Whether they are embedded in process equipment or a stand alone system, many are critical to achieving product quality.

ABB Process Solutions offers an industry leading capability in the validation of all computer systems. With our considerable track record in managing automation technologies and projects, we can deliver both regulatory compliance and optimal business benefit.

Both the MCA (Medicines Control Agency) and the FDA (Food and Drugs Administration) have been training large numbers of people in the inspection of control systems. The FDA recently estimated that in a few years more than half of all citations will be computer related.

Do you have concerns about:

- Rework on projects involving automation?
- Achieving GAMP (Good Automated Manufacturing Practices) compliance?
- Electronic records and signatures (21 CFR part 11)?
- Retrospective validation issues?

## If so ...ABB can help

ABB delivers because:

- We have led computer systems validation from the start
- We are flexible in our approach meeting both your requirements and those of the regulators
- We are experienced in specifying our own automation projects from a user's perspective
- We work with our clients' and their suppliers so that all parties understand validation requirements in full



ABB's pre-eminence in this field is exemplified by our role as initiator, sponsor and chair of the GAMP Supplier Forum.

As your system approaches production we will ensure that the following GMP (Good Manufacturing Practice) issues are covered:

- Procedures
- Training
- Preventative maintenance
- Back up and restore
- Periodic review
- Electronic records and signatures

## Outcome

You will achieve a successful project with an assurance of a system that meets the requirements of the regulators, the users and production managers.



## Real world experience at your fingertips!

ABB delivers leading edge guidance and global services in asset management and operations improvement. We deliver, improve, assure and maintain the performance of our clients' manufacturing operations and associated infrastructure, managing all the technical, process, operational and regulatory problems to optimise manufacturing and project performance, output and profit.

- Improving business and supply chain performance
- Improving regulatory performance and compliance
- Improving variable cost performance
- Increasing operational competitiveness
- Optimising asset base

Our in-house capabilities mean that our clients benefit from a uniquely comprehensive range of services relevant to their needs, all from one company.

ABB Automation Technologies division serves the automotive, cement, chemical, distribution, electronics, food and beverage, life sciences, marine, metals, mining, paper, petroleum, printing and telecommunications industries with application-specific power and automation technology. The division has strong domain expertise to create Industrial IT-enabled products and services for its customers in these industries.

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