



# Pharmaceutical process and equipment validation

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Pharmaceutical manufacturing, packaging and warehousing equipment is becoming increasingly complex, often having embedded or linked control systems. Validation and qualification considerations are now critical factors during the specification, procurement and implementation of new equipment and systems.

## ABB your partner for compliance

Whether you are subject to FDA or EU/MCA inspections or are audited by your customers, ABB Process Solutions will work with you to achieve a defensible level of validation or qualification for your equipment or systems.

## How ABB life sciences can help you

ABB life sciences have significant experience of working with our clients achieving the right balance between process and computer systems validation for process equipment. ABB's strength in process engineering, knowledge of the ISPE baseline guides, and control systems and robotics places us in a unique position to devise and deliver the complete validation package.

We will help you to assess the GMP criticality of your systems or equipment, and for your critical systems we will ensure that the following GMP issues are considered:

- User requirements specification
- Design review and qualification
- IQ and OQ documentation including calibration and materials certificates, weld documentation, challenge testing...etc
- Registration of the equipment into the site asset register and set up of change control and configuration management
- Operation, maintenance and cleaning manuals and procedures
- Training
- Periodic review
- Computer system administration procedures
- Electronic Records / Electronic Signatures requirements as necessary



ABB has a wide range of examples and template documents covering primary manufacturing, actives manufacturing, sterile manufacturing, oral dosage form manufacturing, metered dose inhaler testing and manufacture, packaging, labelling and warehousing.

### Major client benefits

- Your production managers will receive process equipment or systems which are predictable and fit for purpose and which meet the needs of the operators and maintenance staff
- Our experience and proven validation approach delivers increased assurance that your process equipment or systems will be delivered on time, to cost and to the required specifications
- We are backed by an extensive engineering strength including, process, control, materials science, piping, vessels, robotics, instrumentation, civil engineering...etc
- We provide advice and regulatory judgements which are independent and which put the interests of our client first
- Our company culture is orientated towards the delivery of successful projects, not towards selling man-hours



## 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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