



Pharmaceutical equipment and facilities validation

Accurately building in validation costs and resources and minimising validation on the critical path of your project is a significant challenge. It involves applying a pragmatic approach to defensible compliance, which allows the facility to move into beneficial operation to planned time and cost

ABB your partner for compliance

Validation and compliance must be an intrinsic element of a new build or refurbishment project at steering group level from the earliest stage. It is essential to fulfil the needs of the regulator without allowing the validation process to become bureaucratic and overbearing.

How ABB Engineering Services life sciences can help you

ABB life sciences have significant experience of managing and delivering the validation component of equipment and facilities projects based upon a thorough understanding of the ISPE baseline guides. Through a clear campaign of communication and training we ensure that all parties (including suppliers) know what is expected of them and what role they have in the provision of validation-ready products and documentation. The validation document collation, testing and reporting then become faster and more predictable.

Our pragmatic approach to validation is based upon a documented assessment of GxP risk, which directs resources to high risk elements of your design.

Our logical procedures are geared towards ensuring that a validation activity occurs only once to the required format. For example where possible we would manage factory acceptance testing, installation and commissioning such that it fulfils some or all of the requirements of IQ and OQ.

The co-ordination, management and planning of the validation activities is a critical element of our service offering. We have experienced validation program managers with proven track records who recognise the need for effective and dynamic integration of the validation activities with the planned activities governed by the higher project plans.



Major client benefits

- Our experience and proven validation approach delivers increased assurance that the project will be delivered on time, to cost and to the required specifications
- We can work with you to remove validation activities from the critical path for your project, saving you time and money
- We have a wide range of examples and template documents, which can form the basis of many of your potential User Requirements Specification (URS), Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ) documents.
- We enable you to appoint a single organisation with clear responsibilities for the strategy and leadership of compliance project deliverables.
- 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
- We tailor the integrated validation approach to enable adherence to the higher business and project aims



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

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