Project Compliance and Validation Support
Helping you deliver successful projects cheaper and faster
How can I take advantage of the latest risk-based approaches to validation to deliver successful projects and reduce the cost of compliance?
How can I ensure that I have the right skills available at the right time during my project?
How do I keep validation off my project critical path and deliver on time?

ABB have wide experience of validation projects and use well tested processes to ensure successful project completion which have been perfected and proven with key pharmaceutical clients world wide.

Exploit the opportunity

For regulated industries, GMP compliance is an essential element of maintaining a viable business. Systems must be demonstrably fit for intended purpose and must be deployed and used to minimise patient risk. The regulators have opened the door for regulated companies to achieve these objectives at reduced cost and work burden using targeted risk based approaches.

Focus on the risks manage the costs

In order to gain maximum project benefit from risk based integrated commissioning and validation concepts, then compliance and validation needs to be designed into the project from day one. The lean, targeted, “test once” strategies can only really be applied and leveraged if all of the relevant project stakeholders have a clear understanding and appreciation from the onset.

We can contribute to a wide variety of projects

Examples of typical projects:

- New build
- Expansions
- Upgrades and refurbishments
- Laboratories and systems
- Post acquisition integration
- Divestment cut out
- IT Implementations
- Training
- Retrospective validations
- Gap analysis / benchmarking
- Facility and utilities upgrades
- SOP development
Extending your capability

At times your projects may require some access to specific Subject Matter Experts in order to maintain progress and manage risks. In Europe ABB are a leading consulting force participating in many forums which help to shape the regulatory and guideline landscape in the areas of safety, engineering integrity and validation. By working with us you can secure access our bank of key individuals to provide short but high added-value contributions on an as needed basis.

Potential compliance and validation aspects

<table>
<thead>
<tr>
<th>Requirements Definition</th>
<th>Scoping Planning Costing</th>
<th>Procurement Design Development</th>
<th>Integration Commissioning</th>
<th>Start up Go live Handover</th>
<th>Operation Beneficial use</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Draft user requirement specification</td>
<td>- Confirm user requirement specification</td>
<td>- Roll out strategies across the project</td>
<td>- Support retirement of GMP systems being replaced</td>
<td>- Execute PQ</td>
<td>- Recommend periodic review and PQ frameworks</td>
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<tr>
<td>- Draft project quality plan</td>
<td>- Draft validation master plan</td>
<td>- Brief and train relevant persons</td>
<td>- Develop and implement commissioning and testing strategies</td>
<td>- Resolve test failures</td>
<td>- Participate in the projectwrap-up and lessons learned exercises</td>
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<td>- Set business and project objectives</td>
<td>- Define lean testing / commissioning strategy</td>
<td>- Lead GxP risk assessment and management</td>
<td>- Develop and implement GMP systems and data cut over and migration plans</td>
<td>- Write validation summary reports</td>
<td>- Support ongoing system change</td>
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<td>- Define key milestones</td>
<td>- Define risk-based validation strategy</td>
<td>- Co-ordinate validation activities</td>
<td>- Participate in GxP design reviews</td>
<td>- Provide additional start up support and training as necessary</td>
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<td>- Approve initial investment</td>
<td>- Define validation ready purchasing strategy</td>
<td>- Audit the project</td>
<td>- Audit vendors during project</td>
<td>- Manage and lead the production of the validation batch</td>
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<tr>
<td>- Generate preliminary commissioning and validation plan</td>
<td>- Devise PAT role in manufacturing license application</td>
<td>- Participate in GxP design reviews</td>
<td>- Review procurement specifications</td>
<td>- Support the optimisation and trimming activities</td>
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<tr>
<td>- Identify quality related business readiness aspects</td>
<td>- Audit vendors for selection</td>
<td>- Implement GMP testing strategies</td>
<td>- Support change management process</td>
<td>- Participate in the definition and handover of GMP related maintenance schedules and spares</td>
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<td>- Audit vendors for selection</td>
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<td>- Write validation protocols IQ and OQ</td>
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Hand us the problem

Whatever the scale of project or your preferred project execution model we could provide resources or manage your verification, testing and validation requirements on your behalf using a cost effective blend of our permanent staff and a network of proven and pre-qualified associates.

Turnover of key people can be a key challenge during an ongoing project and when this occurs it can have a major impact on your costs and timelines. Not having access to the appropriate experience and skills may also pose a threat to your projects success. Plan your project in advance with ABB and we will help you assemble the “A” team so that you can manage risks and minimise the cost of success.

“ABB defined a practical validation strategy and a detailed implementation plan which paved the way for a very smooth implementation resulting in on-time delivery and reliable user-friendly systems.”

Project manager, Pfizer
The services we offer

We offer compliance expertise in the following areas:

- Validation Programme Manager
- Validation Co-ordinator
- Commissioning Manager
- Commissioning Engineers
- Training and Development Lead
- Laboratory Systems Validation Specialist
- Offshore Technical Authors
- Equipment Validation Engineer
- Process Validation Engineer
- Utilities Qualification Engineers
- Computer Systems Validation Specialist
- Supplier Auditors

Our wider capabilities include:

- Validation and regulatory compliance services
- Pharmaceutical business process optimisation
- Information system project management
- Risk assessment and management
- Manufacturing performance improvement
- Environmental consultancy services
- Safety management
- Reliability and maintenance improvement
- Organisational development and change management
- Energy and utilities management
- Project consultancy services

ABB Engineering Services as part of ABB Global Consulting provides technical services to improve performance in the areas of compliance, operations and engineering to customers in the chemical, petrochemical, oil & gas, power, pharmaceutical, metals and consumer industries worldwide.

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