



IS / Life sciences

When it comes to “speed-to-market” there are many influencing factors the pharmaceuticals research and manufacturing industry have to take into account.

ABB’s combination of capability and credibility in the life science sector uniquely positions us to help you meet your business and regulatory needs.

Validation strategy

Industry is now being told that they have to use fully validated methods in all stages of drug development to manufacture and distribution. Ensuring that every process that impacts on GMP manufacturing will enable the fastest possible ROI made in products.

ABB Engineering Services has the capability to cover in depth, all aspects of regulatory compliance from R&D to production to warehousing and inventory management.

Business systems validation

Business systems are increasing in complexity and their integrated nature is leading to them having a direct impact on product quality. ABB can offer complete solutions to your compliance needs in the area of MRPII and MES.

Computer systems validation

Control systems are becoming increasingly essential to pharmaceutical manufacture. Whether they are embedded in process equipment or standalone systems, many are critical to achieving product quality. ABB offers leading capability in the validation of all computer systems. With our considerable experience in managing automation technologies and projects, we can deliver both regulatory compliance and optimal business benefit.

LIMS

With increasing use and focus in LIMS, your project is a prime target for regulatory scrutiny. Recent inspection reports have cited laboratory systems as being the main area of deficiency. ABB can help turn your regulatory challenges into compliance successes.

Process equipment

Process equipment is increasingly supplied with embedded control systems. The FDA and MCA are expecting a high level of validation on all packages. ABB’s strengths in both process engineering and control systems places us in a unique position to deliver the complete validation package.

21 CFR Part 11 ER/ES

Compliance with 21 CFR Part 11 has become essential for the health care industry. The rule applies to computerised systems used in equipment that can have an impact on final product quality.

ABB are recognised as being one of the leading suppliers of consultancy services on part 11, providing a wide range of services to a number of blue chip pharmaceutical companies and suppliers.

Facility validation

Sterile manufacture

ABB has considerable knowledge of validation sterile facilities. We also provide the best solutions to the equipment compliance used within it.

Whether it be autoclaves, depyrogenation ovens, vial wash and fill, form-fill-seal to packaging and labelling there is every chance ABB has experience in validating it.

Oral dosage

Again our experience place ABB as a leader in independent validation. Services range from dispensing to mixing/granulation, coating, encapsulation, packaging and labelling.

Active pharmaceuticals.

ABB works with API manufacturers in all aspects of validation, identifying which stages are critical to enable appropriate validation programs to be developed.

ABB brings comprehensive knowledge of the latest requirements of the FDA on API manufacture.

Services

- Compliance consultancy
- Audit
- Validation master planning
- Validation project planning
- Protocol generation/execution
- Training

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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