



# Pharmaceutical business systems

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Increasing demands for time-to-market and manufacturing effectiveness are just two of the factors driving the significant development of business systems in the pharmaceuticals research and manufacturing industries.

A combination of technical, compliance and operational knowledge uniquely positions ABB Engineering Services to help you meet both your regulatory obligations and your business needs.

In recent years, the pharmaceutical regulators have focussed on business and information systems. The number of citations and warnings arising from the quality impact of business systems has been increasing.

The key to implementing business systems is to: -

- Implement efficient business processes while ...
- Maintaining a compliant system and ...
- Controlling project and validation costs ...
- Using a risk based approach

ABB can help ...

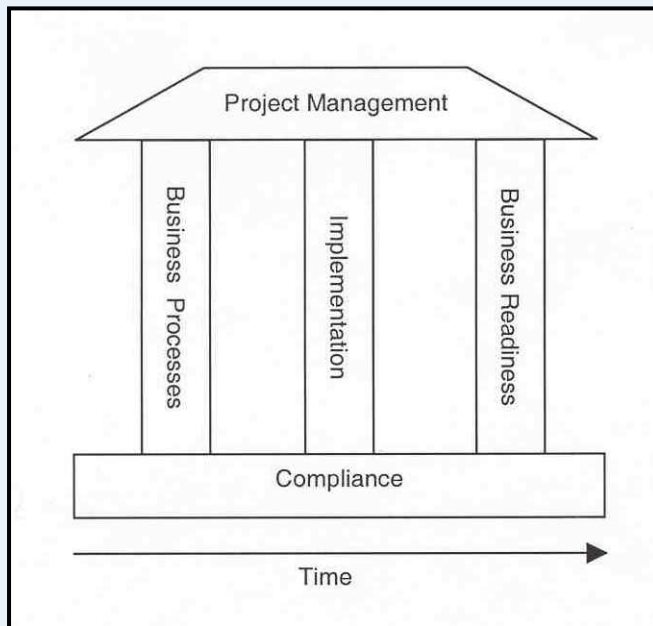
We have leading expertise in all areas of business systems including:

- Supply chain, Asset management and ERP Systems (e.g. SAP, Oracle and Datastream)
- Laboratory Information Managements Systems (LIMS)
- Manufacturing Execution Systems (MES)
- Document Management Systems (e.g. Documentum and Lotus)
- IT, Network Infrastructures and Security Management Systems (e.g. Tivoli, SMS)
- Electronic Records and Electronic Signatures (21 CFR Part II)

Our approach is to tailor a service to meet the specific needs of each customer, and such services may include:

- Supplier audit
- Validation and data migration strategies
- Business process definition and specification
- GxP risk assessment to focus validation effort
- Implementation
- System qualification
- Data migration specification and qualification
- Cutover planning and management
- Business readiness (SOPs and training)
- Support during system operation
- Compliance leadership

Our risk-based approach is specifically designed to define and implement efficient business processes and to focus compliance effort where it is needed.



### Client endorsement

#### Pfizer Ireland

*"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."*

*Matt O'Sullivan, Project Manager*

## 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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