



# Pharmaceutical risk assessment and management

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In August 2002 the FDA announced that they expect:

*"The most up-to-date concepts of risk management ... while continuing to ensure product quality"*

FDA Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach.

Other regulators have already accepted a risk based approach and are assessing the best approaches available.

ABB Process Solutions has recently trained MHRA (previously MCA) inspectors in risk assessment and management techniques.

ABB has developed a structured approach which assesses risk AND gives business benefit:

- Industry proven approach - based on the GAMP risk assessment methodology
- Flexible approach - can be utilised on all types of system
- Scalable approach - can be utilised all levels of pharmaceutical operation
- Speeds up whole process by:
  - Identifying and excluding non-GxP systems and functions at an early stage reducing risk assessment and validation time.
  - Minimising the number of validation deliverables.

## Background

For over a decade, we have successfully applied our GxP assessment process to repeatedly deliver project and business benefit simultaneously with achieving improved levels of compliance.

In addition, from its heritage as ICI's engineering consultancy group, ABB Process Solutions has unparalleled capability in applying risk assessments to personnel safety and projects. With the push from the FDA, we have now combined our experience to develop efficient mechanisms for applying risk assessment/management processes on a company/site wide basis and within projects.

## Solutions and benefits

### Apply company / site risk assessments to focus resources where risk is highest

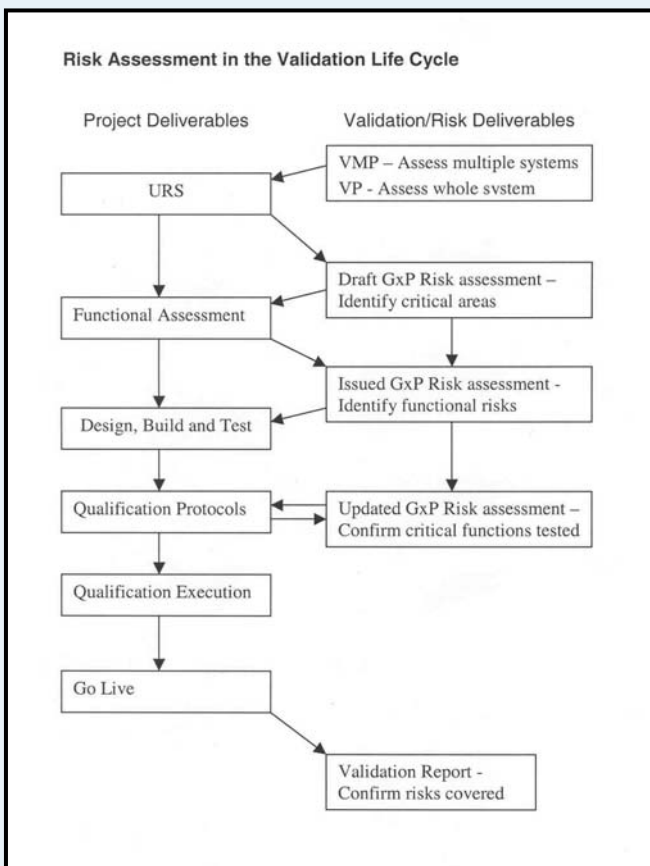
A bottom up approach to Part 11 has been taken by many companies and has left them with many assessments and few benefits. ABB has already applied risk based approaches to help companies focus resources where the risk is highest. These same approaches have been extended to areas outside Part 11.

### Apply project risk assessments to minimise downstream effort

The ABB methodology has used the hazard study approach to filter the risks at an early stage so that detailed assessments are only carried out where there are clear benefits. Also the assessments are later used to only qualify functional areas where there is GxP risk (standard testing can be used for non-GxP areas).

### Training in risk assessment to empower your people

ABB can provide consultants trained in the ABB risk methodology. However risk assessment benefits can best be achieved by the adoption of a team approach comprising ABB staff and client organisation staff trained in the risk based approach – hence we offer a range of standard training packages which can be tailored to your particular organisation.



## 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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