



# Process Analytical Technology (PAT) Site Readiness Assessment

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Senior site management need to ensure that globally driven (corporate) and locally developed PAT initiatives deliver their promised benefits at site level. The benefits may measured in financial terms by realising an improvement in manufacturing efficiency (increase in throughput, increase in yield or reduction in cycle time or waste) or in terms of a balanced scorecard which includes a broader range of KPIs.

Each site that embarks on a PAT project should first consider how well prepared it is to successfully execute the project and deliver the desired return on investment at that site.

ABB Engineering Services will provide a PAT lead consultant and subject matter experts who will deliver a series of workshops and audits. We will work with your PAT team in all relevant areas, to facilitate the assessment of the opportunities and the threats to success to your site PAT project and help you define appropriate site level KPIs. Our input is based on our extensive background in project assurance and operations improvement projects. We will also share with you our expertise in risk based quality management in the pharmaceutical environment using techniques optimised since the early 1980's, in particular as applied to project, validation and qualification and quality decisions. The science and risk based quality management approach is central to PAT ( as described in ICH Q8,9 and 10) and ensures that the effort expended is proportional to the risk.

## Benefits

ABB's expertise will position your site to enjoy PAT project success.

- Able to gain full commercial advantage from a planned PAT initiative due to site specific ROI scenarios and definition of site KPIs
- Project outcome risk reduced by targeting high ROI production processes and product lines
- Project implementation risks reduced by identifying and addressing
  - Organisational barriers to success
  - Required changes to site business and quality processes before project execution
  - Required changes to technical infrastructure before project execution
  - Identifying resource / training and expertise gaps
- Project timescale and cost reduced as site now prepared and ready to accept project execution
- Long term return on investment optimised as
  - Site personnel are clear about the PAT project goals and priorities
  - Site infrastructure is compatible with planned technology change
  - Early identification of site specific opportunities and threats allows the full realisation of the benefits behind the global or local PAT initiative

## For further information please contact:

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