



# Facilities Validation

Client: Pharmaceutical Company

Location: UK

Value: n/a

## Background

ABB Process Solutions provided validation consultancy and project management for a £ multi-million investment in a new Pharmaceutical Development Facility (PDF) for a major UK pharmaceutical company. The facility would provide for the manufacture, testing, storage and distribution of materials for clinical trials, stability and safety assessment.

Working alongside the main contractor and the client team, ABB were responsible for all of the validation services required for regulatory and legislative compliance. The primary regulatory bodies in this case were the US Food and Drug Administration (FDA) and the UK Medicines Control Agency (MCA).

The scope of the validation work covered all aspects of the PDF design, installation and operation. This included materials handling, dispensary, sterile filling, process development equipment, environmental systems, clean utilities and building services.

The ABB validation project team was responsible for the following activities:

- Review of Validation Master Plan
- Design Qualification
- Factory and Site Acceptance Tests
- Installation and Operational Qualification
- Standard Operating Procedures
- Preparation of final documentation

## Benefits:

- Validation built into the project program from day one, with designers and suppliers understanding their contributions and responsibilities from day one.
- Independent validation of the facility against a planned and predictable budget.
- Hand-over of a fully compliant facility to a trained client user group.
- Effective management and integration of the validation activities within the wider project.

## For further information please contact:

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