ABB Engineering Services CASE STUDY

Business systems validation

Client: Pfizer Ireland | Location: Loughbeg, Cork, Ireland | Value: ABB Euro 200K

The Drug Product Plant at Loughbeg is a flagship site for Pfizer producing Lipitor, the world's biggest selling drug with turnover >$6Bn per annum.

Pfizer needed to maintain their excellent regulatory compliance record at the plant during a major transition from their existing SAP system to Pfizer's standard business systems.

Client endorsement

"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.

Background

The existing SAP system was to be replaced by a combination of Pfizer proprietary systems and an externally supplied system. Around one million items of data had to be transferred and verified during a weekend when the new system went live. Pfizer needed personnel that were experienced in validation of business systems to provide validation deliverables and guidance for internal and external resources. The project had a team of 50 people working on it.

Pfizer Ireland chose ABB Engineering Services after a recommendation by two other sites. ABB already had extensive experience in validating one of the Pfizer proprietary systems. Pfizer wanted a detailed strategy for validation including data migration. They also had a firm requirement for project completion by the end of September.

Pfizer Loughbeg site near Cork, Ireland

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Solution

ABB brought best practice examples from other Pfizer sites and other clients. The validation strategy was developed jointly with Pfizer colleagues to match their policies, terminology and standard practices. The key benefit of ABB's initial involvement was to integrate the data migration activities with the rest of the validation life cycle. This brought out such issues as environments for testing. The validation plan was developed to capture this detail.

ABB were also involved in the review of specifications produced by Pfizer and suppliers (Datastream and IBM) to ensure technical quality and traceability. In accordance with ABB's recommendation, these specifications were then used as the basis for an ABB led GMP (Good Manufacturing Practice) assessment which defines GMP criticality of the many functions and brings focus on the areas that will matter to the pharmaceutical regulators. The assessment was updated during testing to ensure that all critical functions were formally tested.

ABB then took on the role of qualification managers, responsible for standards and for meeting time scales in testing. The role included defining the test strategy and overseeing the production and execution of test protocols. Testing covered the usual IQ, OQ, PQ and also Cutover Qualification (CQ) which controls and documents the flurry of activities during the 'go live' stage.

The project was completed on schedule and within budget.

Pfizer colleagues discussing some of the key issues of the project

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CST226a/07/05