

Contracting good health

A leading pharmaceutical company has outsourced its maintenance operations at a new production facility in Italy to ABB

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ABB is one of the world's largest providers of solutions to the life science industries, with a capability and product portfolio that ranges from advanced control, optimization and manufacturing execution systems, to process analytics, packaging line robotics, and plant electrification and automation systems.

A key element of this offering is the ABB Full Service® maintenance contract, more than 150 of which are in operation in a variety of industries worldwide. One of the most recent is a leading international pharmaceutical company, which outsourced its maintenance operations at a new production facility in Italy to ABB.

Outsourced performance services

The company, which is one of the largest pharmaceutical corporations in the world, awarded the contract to ABB in July 2007. The five-year contract covers a variety of maintenance activities, including routine maintenance and calibration, asset monitoring and optimization, and the supply of production resources to assist plant operation personnel. It also includes performance-based bonus payments to ABB for its contribution to the customer's bottom line.

The customer site utilizes a biopharmaceutical batch process to produce an active pharmaceutical ingredient (API). The final product is an antibiotic for infusion into the human bloodstream. The plant employs approximately 20 people in production operations, supported by an additional 12 under the ABB Full Service® maintenance regime **Factbox 1**.

For batch changeover (a new batch is started every 15 days), extra personnel are subcontracted by ABB to accomplish the additional work required in a regulated and validated environment.

Although ABB was awarded the contract in July 2007, a substantial number of tasks were accomplished beforehand, including 12 months of maintenance engineering studies, the drawing up of a maintenance manage-

ment master plan, and training of personnel. A detailed analysis of the technical documentation was carried out by ABB experts in Full Service and pharmaceutical processes, and an onsite survey performed with the customer. On the basis of these detailed preparations, ABB proposed a two-phase approach consisting of a design phase and an operative phase.

The partnership between the customer and the ABB site teams shows a high level of mutual trust and respect with clearly defined boundaries of responsibility.

The design phase

The design phase started in June 2006, during which ABB carried out essential maintenance engineering activities in three key areas: maintenance system implementation, maintenance activities management, and continuous improvement **Factbox 2**.

In addition, ABB manages the subcontractors who perform activities such as coordination and supervision of routine maintenance, metrology calibration, corrective or extraordinary maintenance activities, and spare parts management.

Factbox 1 ABB Full Service®

An ABB Full Service® partnership is a long-term, performance-based agreement in which ABB commits to maintain and improve the customer's production equipment.

In a Full Service agreement, ABB takes over responsibility for the engineering, planning, personnel provision, execution and management of an entire plant's maintenance activities.

Benefits

- Improves plant performance
- Increases the reliability and life cycle of production equipment
- Manages maintenance as a business
- Manages change and creates a service culture
- Gives access to resources and knowledge of ABB's global network
- Simplifies the sourcing of suitably qualified personnel

Customers also benefit from ABB's global expertise, technology and industry best practices from more than 150 ABB Full Service® active partnership agreements around the world.

Site quality operating manual

Based on information gathered during the design phase, ABB prepared a site



Outsourced performance services



quality operating manual that defines the maintenance service quality policies and specifies how organizational and operative procedures are to be verified and implemented.

The document aligns and integrates the quality policies and manuals of the customer and ABB, and defines and indicates how to implement the “nonconformity” procedure.

In addition, the scheduling of quality audits is also addressed with regard to: operative flows, structure, internal personnel, external personnel, analysis of the quality manual, internal methods, and organization.

ABB organization and resources

Three full-time maintenance engineers were present at the site during the design phase. They were managed by an ABB site manager and supported by local ABB technical and financial resources based in Milan. ABB also started to recruit and train the core site maintenance management for the operative phase.

The operative phase

The operative phase began in January 2007 when ABB assumed control of the maintenance activities that had

been jointly defined by the customer and ABB during the design phase. These activities were many and varied, and included those involving calibration as well as reactive, preventive and condition-based maintenance.

Also included were the management and maintenance of the computerized maintenance management system (CMMS), as well as management of the site quality operating manual and the performance of activities risk analysis. ABB also assumed responsibility for the spare parts warehouse and spare parts procurement; the implementation of maintenance, quality and safety-improvement projects; the complete PDCA (plan, do, check, act) continuous improvement process for maintenance engineering; the execution of engineering studies looking into operational improvement potential; and, when required, the execution of return on investment (ROI) studies.

ABB then took over the task of updating the existing site key performance indicators (KPIs) and all technical documentation drawn up during the design phase – in particular, the maintenance standard operating proce-

dures (SOPs) and maintenance plans. ABB informed the customer of any changes made in the technical design documentation. Updating and maintaining these documents remains the responsibility of the customer for process validation reasons.

In addition, ABB managed the legal documentation and compliance process regarding health, safety and environmental items such as fire protection and pressure relief audits on plant protection equipment.

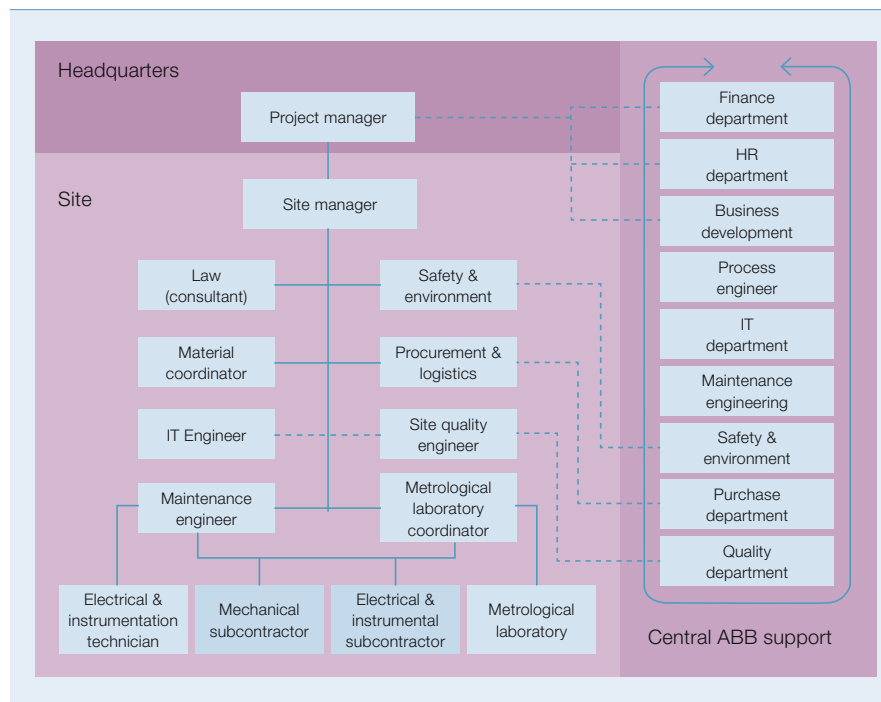
Finally, in July 2007, ABB assumed responsibility for the planning, management and execution of all maintenance activities at the customer site under its ABB Full Service® agreement. During the last six months of 2007, the customer and ABB jointly defined the KPIs and related targets that set the baseline and direction for the performance-based partnership, including bonus and penalty clauses, for the coming years.

Good working relationship

The partnership between the customer and the ABB site teams shows a high level of mutual trust and respect with clearly defined boundaries of responsibility. Weekly information meetings

Outsourced performance services

ABB Full Service® site organization for the project



with production, quality and maintenance personnel review disturbances and the previous week's activities, as well as forthcoming activities and improvement opportunities. Monthly reports are generated containing all business-relevant figures, performance indicators and activities.

A well-structured equipment hierarchy record is maintained for the automation scope, maintenance SOPs and maintenance plans, with calibration plans in place for all major equipment to allow management of the assets. The CMMS is owned by the customer and is used to log all equipment-related activities. Work orders can be opened by ABB or the customer but can only be closed by the customer, once all required activities have been confirmed.

ABB's capability in life sciences

ABB's scope of supply capability to the pharmaceutical industry includes the supply of control, optimization and safety solutions; instrumentation, analytics, robotics, and automation; and electrical equipment, from motors and drives to medium-voltage and low-voltage distribution equipment. ABB also provides solutions for process analytical technology (PAT), as

well as consulting and validation services.

ABB's service capability extends from ad hoc support to fully outsourced maintenance of the complete production and electrical assets of a plant. This is enhanced by an ABB system that provides integral asset management and a bi-directional interface with CMMS, thereby allowing the automatically generated asset triggers to prompt predictive maintenance as an integrated record within the CMMS to be created. These triggers are highlighted to the operational personnel on the screen displays and can be sent as SMS messages to maintenance personnel when immediate attention is required.

Additionally, the combined system supports asset optimization by the customer or ABB staff, as well as work-order control, full asset audit tracking of process modifications, asset recalibration, and generation of electronic batch records in compliance with 21CFR Part 11. Products and services from ABB also support the total life cycle of automation assets and include the provision of ABB and third-party hardware, as well as integration responsibilities and applica-

Factbox 2 Maintenance engineering activities

Maintenance system implementation consists of:

- Complete equipment and instrument data inventory
- Detailed analysis of the installed equipment/instrumentation operational and calibration status
- Standard operating procedures (SOP) design
- Detailed maintenance activities design, consisting of 800 preventive maintenance plans and 1,500 metrology calibration plans
- Computerized maintenance management system (CMMS) implementation and startup
- Spare parts supply inventory and warehouse flow design
- Safety and quality procedures design

Maintenance activities management involves:

- Organizational design of maintenance
- CMMS management
- Preventive and extraordinary maintenance operations management
- Reporting

Continuous improvement comprises:

- Ongoing review of the maintenance plan on the basis of root cause analysis (RCA) methodology
- Drafting and discussion of technical conditions for a global service contract

tion software to cGMP (current good manufacturing practice) standards and the recommendations of ICH 8, 9 and 10.

For more information on ABB's Full Service offering, see "Outsourced maintenance" on page 79 and "A head start to profitability" on page 88 of this *ABB Review Special Report*.

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