Johnson & Johnson’s Centocor/Global Biologics Supply Group (GBSG) (Malvern, Pa.) manufactures a key bulk biopharmaceutical ingredient that is used to formulate the drug Remicade, an injectible biologic therapy used during the treatment of rheumatoid arthritis and other inflammatory diseases. Due to strong market demand for Remicade in recent years, J&J recently completed more than $100 million in capital expansions at its Malvern facility. Such effort underscored the need for improved maintenance and reliability management.

The company sought to implement a world-class Computerized Maintenance Management System (CMMS) to automate and streamline many of the reliability-related activities at the site — such as the monitoring and collection of operating data, instrument calibration, planning and scheduling of maintenance activities, costing, purchasing and management of spare parts. J&J’s goal was to optimize process efficiency and productivity, improve equipment reliability, minimize unplanned downtime and reduce operating and maintenance costs. One overarching goal was to create a streamlined, secure, paperless environment to carry out many of these maintenance-related activities.

To ensure the successful deployment of the new CMMS, the ABB/J&J team spent considerable effort re-engineering the underlying business processes, in order to identify gaps between existing practices and best practices, eliminate non-value-added steps, and identify opportunities for improvement. Equally important was the need to manage the change management and training activities required to create a workforce that could both optimize the use of the system and sustain the improvements over time.

With its proven expertise in SAP technical and reliability engineering, ABB was selected by J&J to manage the CMMS implementation and carry out the associated change management activities and training at the site.
Business challenges
To meet strong market demand for its biopharmaceutical products, J&J established a corporate mandate to keep its plant running safely and efficiently at all times, in order to maximize safe, reliable production while meeting rigorous international regulatory requirements associated with pharmaceuticals production and cleanroom operation.

The plant’s existing CMMS provided only the most rudimentary capabilities and thus created significant compliance risk. And due in part to the limitations of the existing CMMS, the Malvern site did not meet the requirements of the J&J’s Manufacturing Equipment Excellence (ME2) program.

The objective was to implement a new CMMS that could streamline and optimize key maintenance-related activities, such as materials management, costing, capacity planning, maintenance scheduling, costing, purchasing and materials management). J&J’s goal was to improve overall plant reliability by enabling better maintenance practices. Ultimately, J&J is working to harmonize and standardize its reliability-related practices across other GBSC manufacturing sites.

J&J partnered with ABB to evaluate CMMS options, and once the SAP system was selected, ABB managed the implementation and adoption of the system.

The primary challenge of this initiative was two-fold:
− To customize and implement a validated, paperless CMMS that would manage maintenance-related activities at the Malvern site without violating strict regulatory requirements pertaining to biopharmaceutical manufacturing and cleanroom operation, and
− To re-engineer the underlying business processes and maintenance practices to optimize the capabilities of the new installation

To do this, ABB translated the business process requirements into the SAP configuration, incorporating feedback and suggestions from plant personnel along the way.

One of the most powerful tools that ABB configured into the SAP CMMS is a “calibration dashboard,” which enables maintenance personnel to carry out all calibration transactions — with access to more than 5,000 underlying instrumentation calibration formats and protocols — on one user-friendly screen. The design of the dashboard template allows maintenance personnel to fill in the blanks and choose the most appropriate calibration standard. With the push of a button, the system carries out the calibrations.

Benefiting from value-added capabilities
Among the challenges that had to be addressed by ABB when configuring the SAP CMMS for J&J:
− To create protocols and capabilities for paperless practices, including electronic routing and approval of documents — Maintenance technicians now use wireless tablet PCs to both perform real-time transactions in SAP and access other business applications.
− To identify and establish the right maintenance-related data types — Working with the facility’s process-and-instrumentation diagrams (P&IDs), the team worked to establish standardized definitions and nomenclature to describe all equipment and tank lists, functional location tags and hierarchy, calibration parameters and reports, maintenance plans, spare parts and materials, vendor masters information, failure catalogs and so on.
− To manage the cultural challenges associated with the new CMMS implementation — The adoption of new business processes require new roles and responsibilities for key personnel, new terminology, and training in not only the new CMMS itself, but in the new business processes and paperless workflow protocols as well

Results
Since installing its new CMMS, maintenance personnel at J&J’s Malvern facility have been able to carry out real-time maintenance and reliability transactions in the SAP environment, and take advantage of a fully integrated, paperless system to streamline many of the maintenance-related activities.

The overall $3.2 million investment made at the J&J/Centocor at its Malvern facility was paid back in less than two years.

The ability to increase equipment reliability and reduce costs, the facility realized savings of $1.3 million in Year 1 and $1.1 million in Year 2.

After the implementation of the new SAP CMMS, productivity at the facility has increased by 30%, and the facility is enjoying recurring savings of $300,000/year.

And, the new SAP CMMS and improved business practices have enabled the Malvern facility to meet the rigorous standards of J&J’s Manufacturing Equipment Excellence (ME2) program and led to significant recurring savings every year.

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