

Case Study of Corporate Account

Mallinckrodt Baker's Migration to Web-based MasterControl™ System Helps Globalize Company's Quality Management

Chemicals are the molecular building blocks of drug products, making them critical in pharmaceutical manufacturing. Mallinckrodt Baker Inc. (MBI) has built a reputation for excellence in this important field, providing specialty chemicals and high purity products not only for the pharmaceutical industry, but also for laboratory, microelectronic, and industrial markets.

Mallinckrodt, founded more than 130 years ago, merged with J.T. Baker in 1995. Tyco International Ltd., a diversified manufacturing and service company, bought Mallinckrodt Baker in 2000. MBI occupies a 70-acre property in Phillipsburg, N.J., consisting of 40 buildings (including R&D laboratories) and manufacturing space of 170,000 square feet. It has plants in Kentucky, the Netherlands, and Mexico.

Mallinckrodt Baker produces and supplies chemical specialties, including inorganic salts, acids, solvents and chromatography products. Some of these products are classified as bulk pharmaceutical chemicals, which are regulated by the FDA. The company also develops custom chemical manufacturing processes. In the past 20 years, MBI has been awarded more than 380 patents in such diverse areas as purification of biomolecules, environmental analysis, and photolithography.

Regulations and Standards

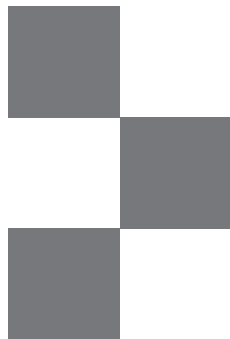
Given Mallinckrodt Baker's highly specialized products, the company complies with the strictest regulations and the highest quality standards. Its facilities are FDA-registered and ISO-certified.

The company adheres to the FDA's "Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients." It is intended to help ensure that APIs meet the quality and purity characteristics that they purport to possess. The Q7A guidance emphasizes the importance of keeping manufacturing operations in constant state of control to ensure that drugs are safe, pure, and effective.

MBI also conforms to ISO 9001 quality standards, which are widely used by manufacturers and companies worldwide. Adherence to ISO standards is voluntary, although certain countries require ISO certification and many customers prefer vendors and suppliers that are ISO-certified.

Manual Quality System

Compliance with FDA regulations and ISO standards require an effective quality management system, which entails establishing, documenting, and controlling quality processes. For years, Mallinckrodt Baker used a simple database management system to number and date SOPs and other documents. The numbers allowed employees to track documents.



“We maintained paper files that held the master copy. Then we manually routed photocopies of the master copy,” said Gary Jerabek, senior quality engineer at MBI. The manual system was manageable back then because routing involved only two people to approve documents.

When Mallinckrodt Baker decided to automate its system in 2000, the company chose MasterControl. The company bought the client/server system, which was standard at the time. “Our goal back then was to control documents electronically and to have them all in one place,” said Jerabek. While the client/server system automated MBI’s manual processes, Jerabek said it was not fully utilized because of speed issues and complaints from some users.

Migration to Web-based MasterControl

In the summer of 2004, Mallinckrodt Baker began to consider a Web-based quality management system. There were two key factors that prompted the move. “It became our corporate policy to use Web-based products,” said Jerabek. “We also wanted to globalize our operations.”

By then, MasterControl had introduced a Web-based software solution, which uses the Internet to provide unprecedented connectivity for companies with multiple facilities in different locations. “I saw a demo of the new MasterControl software and I really liked it,” recalled Jerabek. “I felt it was the right direction for us to take.”

Later in 2004, Mallinckrodt Baker prepared to switch to a Web-based MasterControl system, choosing MasterControl Documents™ and MasterControl Forms™, integrated applications of the MasterControl™ quality management suite. The MasterControl Professional Services team mapped a detailed implementation plan for MBI. The meticulous process of migration began with Mallinckrodt Baker having to verify individual documents (formats, characters, titles, etc.) before sending its database to MasterControl for testing. Then MasterControl sent the database back to MBI for its own testing.

In January 2005, the Web-based MasterControl software was installed. The same month, Jerabek attended a comprehensive training for system administrators in MasterControl’s training facility in Salt Lake City. The Professional Services Team went onsite to conduct the actual migration of 2,000 documents, SOPs, stability profiles, product information, technical reports, and other documents. While onsite, the team also trained MBI’s “power” users, employees whose jobs called for frequent use of MasterControl. Jerabek then taught the rest of the company’s system users.

Under FDA’s 21 CFR Part 11, organizations such as Mallinckrodt Baker that choose to use an electronic system to comply with predicate rules must validate their electronic record-keeping systems. In February 2005, MBI validated its system utilizing MasterControl’s Validation ToolKit, which provides detailed, pre-written IQ (installation qualification) and OQ (operational qualification) validation test protocols and scripts. “We could not have done it without those protocols,” said Jerabek. In addition to the Toolkit, MasterControl offers comprehensive consulting services, including writing PQ (performance

qualification) protocols for customers and conducting all validation tests.

Successful Results

After a successful validation, Mallinckrodt Baker went live with MasterControl Documents™ in March 2005 and with MasterControl Forms™ in September 2005. The new system integrated the company's quality processes, strengthened its compliance efforts, and connected the different departments.

Integrated Quality Processes

MBI automated and integrated its document control and change control processes. Using MasterControl Forms, the company created four best-practice forms for different types of changes and revamped the entire change control workflow. MasterControl Forms streamlined MBI's process of review and approval, tracking, and communication of changes both internally and externally. "We have vastly improved our change control process and this is, in no small measure, because of MasterControl Forms," said Jerabek.

With MasterControl, the company was able to globalize its quality management, connecting the separate systems of different plants. "We can now approve documents globally," said Jerabek. The new system has allowed the inclusion of more people in the approval process when required. For example, quality managers at each MBI site and the quality director are now part of the approval process, something that was not possible before.

The MasterControl Web-based system is everything that MBI needed in terms of speed and accessibility. After documents are approved, all MasterControl users are automatically notified of the documents' availability via e-mail. Electronic approvals are also particularly helpful for a company like Mallinckrodt Baker. "Everybody is impressed by how fast we can accomplish things now," said Jerabek.

Sustained Compliance

Mallinckrodt Baker has ISO conformance assessments every six months. Since the company's migration to a Web-based MasterControl system, it has been audited twice — in May and November 2005 — for the purpose of maintaining its ISO certification. "The auditors gave very favorable comments about our MasterControl system," said Jerabek. "They noticed that everything was easily traceable, documents were readily available, and electronic signatures were all there."

MasterControl has helped increase MBI's control over quality processes. "The fewer hard-copy documents we have, the less chance there is of having obsolete SOPs [on the shop floor]," said Jerabek. MasterControl's advanced revision control means that when a document is being corrected or revised, no other user can work on it. This ensures that only the current version is available. And when a user makes a change in the InfoCard (the MasterControl tool that provides basic information for every document or record), the user must enter a reason for the change. The system tracks these changes and makes them available through reports.



Connectivity Throughout the Enterprise

Mallinckrodt Baker currently stores 3,000 documents in its MasterControl system. The number of users has increased from 50 under the client/server system to about 300 at present. The departments using MasterControl include Quality Assurance, Quality Control, Production, Purchasing, Marketing, Technical Support, and Distribution. The plants in Kentucky and the Netherlands are currently using MasterControl Forms and are expected to use MasterControl Documents in the near future.

Mallinckrodt Baker employees like using MasterControl because it is intuitive, according to Jerabek. Even those who did not previously use MasterControl client/server learned the system quickly. Moreover, even the most critical users praised the new system. For Jerabek, the latter was the true measure of the success of the company's new MasterControl system.

Jerabek noted that Mallinckrodt Baker maintains an excellent relationship with MasterControl personnel, from Sales to Professional Services to Technical Support. "The people at MasterControl are committed to solving any issue in a timely manner," he said.

Conclusion

At Mallinckrodt Baker, MasterControl has become integral to quality management. New employees are trained on the system using a MasterControl user's guide. Jerabek plans to use this guide as a basis for developing MBI's own user's manual, which would add the company's customized applications.

The tremendous change in Mallinckrodt Baker's quality management system did not go unnoticed. In August 2005, MBI's management recognized the effectiveness of the change control process utilizing MasterControl Forms. Jerabek received the Excellence in Execution award as leader of the team that developed the process. The team was composed of employees from the New Jersey, Texas, and Netherlands sites and represented the Quality, Plant Support, Sales, Marketing, and Environmental Health and Safety departments.

Mallinckrodt Baker continues to find new ways to optimize its quality processes with the help of MasterControl. "Our users come up with new ideas about how to use MasterControl all the time," Jerabek said. And when people outside the company ask him about MasterControl, he said he usually has the same answer: "I'm very happy with it."

About MasterControl

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit www.mastercontrol.com, or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 6801 6147 (Japan).