

GlaxoSmithKline Confronts Industry Challenges with Datastream



THE COMPANY

GlaxoSmithKline (GSK) is a world-leading, research-based pharmaceutical company formed by the merger of Glaxo Wellcome and SmithKline Beecham. With a powerful

combination of skills and resources, the new company has a platform to deliver strong growth in today's rapidly changing healthcare environment. GSK is an established industry leader, with an estimated 7% share of the world's pharmaceutical market. GSK's Global Manufacturing and Supply organization is playing a crucial role in its success and helping the company achieve its mission to improve the quality of human life by enabling people to do more, feel better, and live longer.

GSK has over 100,000 employees worldwide with headquarters in the UK and major operation bases in the United States. Around 40,000 of those employees work at 115 manufacturing sites in 41 other countries.



THE CHALLENGES

GSK's Global Manufacturing and Supply organization has clear objectives. Its mission is to ensure a secure source of high quality products, comply with regulatory

requirements and customer expectations, offer best-in-class costs, and develop leading-edge practices and performance in procurement and in other global functions at all sites. As a result, plant maintenance must ensure that all equipment is reliable, available for manufacturing, and operating properly and cost-effectively. However, the primary challenges GSK faces in terms of maintenance are twofold—containing costs while delivering improvements in methods and systems and maintaining consistency and visibility across all operations.

In addition, GSK, along with all other pharmaceutical companies, operates in a highly regulated environment. They needed a comprehensive asset management system—one that could help them meet their objectives and satisfy the requirements of the FDA and other regulators.

"As the products we manufacture and supply must be safe and effective for both patients and the general public, we must prove that systems and activities are 'fit for purpose,' or functioning in the way intended—consistently and reliably. The asset management systems in seven of the UK manufacturing sites were not year 2000 compliant, and several different products were being used across different areas of business, making support and sharing of best practices difficult," explains Alan McBirnie, applications consultant at GSK.

TECHNOLOGY

- > Functionality to meet regulations of the pharmaceutical industry
- > Asset management tools to streamline maintenance and operations
- > Ability to create enterprise-wide visibility

FUNCTIONALITY

- > Audit trail and extensive documentation capabilities
- > Multi-organization tools to make enterprise practices consistent
- > Migration software to ensure accurate data transfer from old applications
- > Integration capabilities with existing applications

BENEFITS

- > Comply with FDA regulations to avoid penalties.
- > Compile accurate records to reduce audit expenses.
- > Optimize inventory with an enterprise view of what supplies are available.
- > Streamline maintenance practices to create consistency and efficiency.



THE SOLUTION

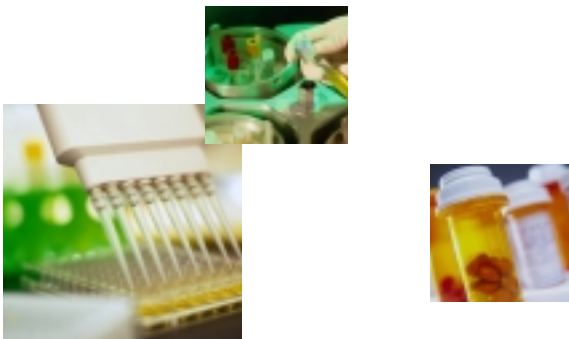
"Computer validation . . . establishes competency records for all staff involved in the product development cycle and includes continuous auditing to ensure that all staff fully comply with approved operating procedures. The key word in this process is 'evidence,'" says Bernard Verkooijen, Datastream project consultant.

GSK chose a Datastream asset management solution, the first fully Web-architected application in the industry, to help the seven UK sites comply with FDA regulations, satisfy good manufacturing practices, and help keep accurate records of transactions and assets. The Datastream solution is based on the Oracle Database and the Oracle Developer toolset. Full integration with other systems, such as Oracle Financial applications, is also possible through the application's programming interfaces.

GSK implemented Datastream software at the sites, enabling them to maintain an inventory of all plant items and track their history. Datastream software also enables the plants to manage all routine and unplanned maintenance activities.

THE RESULTS

Datastream provided the UK sites with a product that would help them meet critical regulatory requirements. Previous products used by these sites were not year 2000 compliant, but Datastream software met the criteria and could be installed and fully integrated quickly. Software set-up and the integration process were aided by Datastream's development of specialized migration software to transfer data from the old systems into the new database.



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ALAN MCBIRNIE
Applications Consultant
GlaxoSmithKline (GSK)

"Through intensive audits, Datastream not only became a compliant supplier but also improved efficiencies internally. It resulted in excellent documentation and improved staff development and training. Our determination has paid off as a result of this validation." comments Verkooijen. "The sites have a system provided by Datastream that is highly configurable and adaptable, and, most importantly, will help GlaxoSmithKline satisfy compliance requirements for many years to come."

For more information on Datastream products and services, call 1.800.955.6775 (USA and Canada) or 1.864.422.5001 (direct) or visit www.datastream.net.

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