

## CUSTOMER PROFILE:

# World Leading Pharmaceutical Company



### Background

A world leading research-based pharmaceutical company with 100,000 employees across the globe in more than 38 countries has a rich history of pharmaceutical research and product development dating back several centuries. Its

broad product line includes widely used prescription medications and consumer products such as toothpaste, smoking cessation tools and antacids. The company also manufactures vaccines for a variety of diseases.

### The Goal

This large pharmaceutical company needed an asset management solution that could be deployed across two US-based research and development sites. Workers at these plants develop new drugs and manufacture them for clinical trials, using precise equipment that requires periodic calibration and maintenance to keep it performing up to government standards. Thus, the asset management system needed functionality that could meet these specific requirements and, most importantly, automate the process of complying with the U.S. Food and Drug Administration's critical 21 CFR Part 11 standard.

The system also needed to provide automated capabilities for purchasing, inspection scheduling and auditing, inventory, data collection and system validation. Lastly, the company needed an asset management solution that was easy to implement and could integrate seamlessly with the company's existing enterprise application infrastructure.

### The Challenge

The FDA's 21 CFR Part 11 regulation governs pharmaceutical companies' electronic systems and strives to modernize the regulation of pharmaceutical manufacturing and product quality. Under 21 CFR Part 11, pharmaceutical companies are required to validate electronic signatures and their computer systems, track audit trails, limit system access and control revisions.

## QUICK FACTS:

- > Among world's largest pharmaceutical companies
- > More than 100,000 worldwide employees
- > Deployed Datastream 7i across two R&D campuses
- > Uses Datastream 7i to optimize asset management for scientific, process and facilities related equipment in compliance with FDA regulation 21 CFR Part 11

Pharmaceutical companies that fail to comply with this regulation expose themselves to FDA regulatory action such as warning letters of violation or even plant closures.

A world leader in pharmaceuticals and technical innovation, the company had been using a Computerized Maintenance Management System (CMMS) since 1992, but the system could not extend beyond a single organization and did not include automated functionality for 21 CFR Part 11 compliance. As such, the company had been using cumbersome paper-based processes to comply with the standard. The company's QA department performed an internal audit. They wanted to get away from the paper-based system and also adopt a method to validate existing software. To accomplish this, the company sought out an automated solution that would ensure compliance while also enabling multi-organization Asset Performance Management.

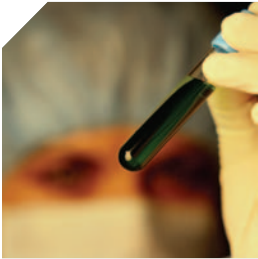
### The Solution

This world-leading pharmaceutical company had been using Datastream products since the early 1990s and was pleased with the high level of service provided by Datastream. Because of this level of satisfaction, the company upgraded to Datastream's Web-architected Asset Performance Management solution, Datastream 7i. The company knew that Datastream 7i was the most technologically advanced, easily deployed and cost-effective solution on the market. Additionally, Datastream was able to point to more deployment and upgrade successes than any of its competitors which further solidified the company's comfort level with its selection of Datastream 7i.

## The Results

The Web architecture of Datastream 7i makes it easy for both plants to work under a single application, allowing the company to easily add new users, standardize work processes across plants and optimize inventory, resulting in cost savings.

Datastream 7i interfaces with essential software that the company uses, including Lotus Notes for work orders



and JD Edwards for purchasing and receiving of goods and services. With the product's Web architecture, employees can access asset data, issue work orders, check inventory for parts and procure replacement parts and other items from any Internet connection. Because

the plants are connected through a single multi-site deployment, they can compare costs and productivity across plants and identify abnormalities and problems. Also, because changes and updates are reflected immediately in the system, users can make better business decisions in real-time.

Datastream 7i collects information on assets that the pharmaceutical company uses on a daily basis, such as eyewashes, fire extinguishers and shuttle service vehicles. The company uses this information to track assets and schedule regular preventive maintenance. Datastream 7i also lets the company simplify the invoicing and budgeting processes. Because Datastream 7i allows the company to create custom reports, it can specify exact budget information needed. This personalization provides more accurate information on operations costs and inventories.

Improvements to the invoicing process have resulted in tremendous time savings. It previously took the company six days per month to process its invoicing report. However, with Datastream 7i, the company is able to run a report in Excel that details the labor costs associated with work orders.

The data is then uploaded into the JDE financial system. This whole process now only takes a few hours per month to complete versus the previous six days.

Datastream 7i also helps the company with audit trails required to meet 21 CFR Part 11 requirements. Audit trails are configured to track procurement and receiving activities as required by the financial services department. In light of recent financial scandals, the company had found the audit trail functionality in Datastream 7i is critical to show compliance.

Part of the project also included validation of the company's own Oracle database software, computer server hardware and networks to show how the entire system architecture functioned. The whole process was extremely smooth—on budget and on schedule. The company is constantly looking for further uses of Datastream 7i. In the near future, the company plans to implement the Datastream 7i Calibration module to eliminate all paper files for work orders and rely completely on the product's electronic signature functionality.

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