



TEVA Strengthens Security for Software Assets with MKS Integrity



“One of the main measures for success in the implementation of the MKS Integrity Suite was the reduction in the amount of paper and forms that get manually pushed from person to person. By simply automating service request forms and routing them via electronic workflows we have become much more effective, and dramatically reduced our time spent managing projects.”

Tom Loane, Chief Information Officer , TEVA Pharmaceuticals

Company Overview

TEVA USA is a wholly-owned subsidiary of TEVA Pharmaceutical Industries Ltd., Israel's largest pharmaceutical manufacturer operating globally in 30 countries on 5 continents. TEVA is among the top 20 pharmaceutical companies and the largest generic pharmaceutical companies in the world. The company has approximately 14,000 employees worldwide with production facilities in Israel, North America, Europe and Mexico. TEVA USA has an aggressive Research & Development effort and one of the best overall ANDA approval records in the industry. The company's mission is to play a leading role in the transformation of the U.S. healthcare system through its preeminence in the development, manufacturing and marketing of pharmaceuticals.

The Challenge

As a pharmaceutical company operating in the U.S., TEVA must comply with Food and Drug Administration (FDA) regulations. The FDA requires stringent application development and change control practices surrounding software registration, phlebotomy, component processing, testing, and distribution of applications. A particular compliance challenge is FDA 21 CFR Part 11, concerning electronic records and electronic signatures. All pharmaceutical companies are subject to audit by the FDA and face scrutiny with respect to their systems and processes, including computer systems.

A pharmaceutical company is obligated to follow the basic principles of validation. They must specify intended use and user requirements, of the software; make sure and verify that the software meets the requirements through proper design, implementation and testing and maintain proper use through an on-going performance program.

The goal for TEVA is to reduce the burden and cost associated with compliance to FDA regulations. In parallel, TEVA has experienced significant operational growth. With completely manual, paper-based change processes, the organization's ability to adopt less burdensome and low cost processes was limited. With respect to change controls, the transition from the actual work products implemented, and deployment to production was not a smooth process. As a result, TEVA staff was spending a disproportionate amount of time on change control activity.

TEVA's manual processes also made it difficult for management to conduct root cause analysis, identify potential bottlenecks and anticipate potential problems. The manual Change Control Request Forms (CCRFs) resulted in an inefficient change control process with disconnects to internal reporting systems, reducing management visibility and control over

TEVA Pharmaceuticals USA



The Solution

the status of work in process. This was detrimental to management's ability to efficiently manage and allocate resources.

Inefficient configuration management and security policies around how software assets were versioned further complicated compliance objectives. The problem affected all business critical applications in the distributed clientserver environment (Oracle, LIMS, as well as other Java and HTML based applications).

With an ever-increasing rate of change, disconnected tools, and manual processes, the IT organization was challenged to remain efficient and meet compliance requirements.

Initial Steps for Compliance

TEVA's IT department identified requirements for a change control process that is more efficient and compliant with Good

Manufacturing Processes (GMP). Good Manufacturing Practices are standard guidelines set out by the FDA to ensure drug development is carried out in safe and quality processes, to avoid contamination and ensure repeatability.

In support of this compliance effort, TEVA evaluated change and configuration management solutions. Following a thorough evaluation process, MKS Integrity was selected for four primary reasons:

- Flexibility – the solution could support any process that TEVA had implemented or would implement
- Ease of development – TEVA recognized that MKS's solution was the easiest to install, administer and use

➤ Customer support – MKS's team had a proven track record of providing fast and effective technical support

➤ Cost – it was determined that MKS's solution would provide a lower total cost of ownership when compared to the other solutions

Another primary concern for TEVA was finding a solution that could be linked with other technologies in TEVA's environment, such as Oracle, Microsoft, and Mercury Interactive, just to name a few.

Implementation

The U.S. implementation consisted of six phases: planning, specification, design, construction, testing and operation use (production). An MKS services consultant was brought onsite to provide a process assessment and map appropriate workflows into the tool before the solution was deployed to the first projects. During meetings with various stakeholders of the MKS project, TEVA personnel provided sponsorship of the newly designed workflows by reviewing and suggesting changes to the system. These changes were discussed, and based on a team consensus, were implemented into the workflow.

It was important for TEVA personnel to verify and sponsor changes made to the workflow in order to elicit personal buy-in to the new process. With this sponsorship from all of the team leads and department heads, transition to the new system went smoothly. After initial projects were fully deployed, MKS Integrity was then rolled out across all application development areas.

Business values realized by TEVA

Since implementing MKS Integrity, TEVA has achieved:

➤ Improved operational efficiencies from tighter integration between lines of business, development and IT operations. This has been achieved through process automation and seamlessly linked change control and configuration management processes;

The FDA has enforced validation of software and computer systems pharmaceutical manufacturing since the mid eighties. Computer validation in the eyes of the FDA means: “Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through the software can be consistently fulfilled.”

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