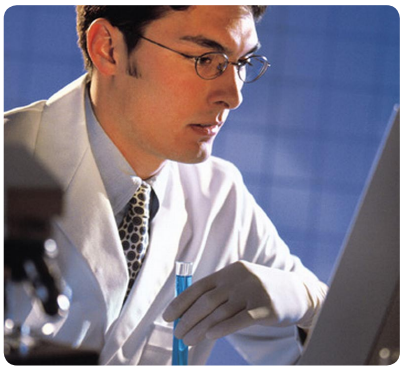
CUSTOMER PROFILE

JHP Pharmaceuticals

Compliance “peace of mind” in a highly regulated environment

Benefits

- Title 21 CFR Part 11-compliant solution ensures compliance with U.S. and European regulations for controlled documents
- Personnel on the factory floor can be assured they’re always accessing the most current versions of SOPs and other critical documents
- System enables streamlined, accurate, and efficient processes for routing and approving documents
- Automation of formerly paper-based processes reduces costs



Business overview

JHP Pharmaceuticals is an integrated specialty healthcare company that manufactures and sells sterile injectable pharmaceutical products to hospitals and clinics. JHP also provides contract manufacturing for global pharmaceutical companies. JHP’s own product portfolio includes leading diagnostic, women’s health, and anesthesia products, all of which have a long track record of “gold standard” service and are at or near the front line of treatment in their therapeutic indications. The company’s contract manufactured products include some of the leading global biologic products.

Challenges

In order to bring a new drug to market, a pharmaceutical company must undergo a lengthy and complex regulatory filing process and provide detailed documentation of every step in the product’s development, through clinical trials and testing. The challenge is even greater for a global pharmaceutical company such as JHP, which must comply with the regulatory requirements of each country where it does business.

When JHP’s founders created the company in 2007 through the acquisition of selected products from King Pharmaceuticals, they knew they would require a powerful enterprise content management system to support the regulatory filing process. By providing a centralized repository for storing, reviewing, approving, and managing revisions to important controlled documents such as manufacturing standard operating procedures (SOPs), JHP wanted to avoid the inefficiencies and high costs involved in paper-based and manual document processes. In addition, the company sought a content management solution that complies with the FDA’s Title 21 CFR Part 11 regulations for controlling and managing electronic documents and signatures.

EMC solution

Controlled documents for the newly acquired products from King Pharmaceuticals had been successfully managed by EMC® Documentum® Compliance Manager for many years within King’s content management infrastructure. Therefore, for JHP, the quickest path to its new content management objectives was to migrate King’s legacy Compliance Manager system to a new hardware infrastructure owned by JHP. Compliance Manager is a robust solution designed to automate the sharing and management of controlled content for organizations in life sciences and other highly regulated industries. Compliance Manager enables companies to create, review, approve, and distribute content within an audited, tightly managed environment.

Business profile

JHP Pharmaceuticals

Manufacturer of sterile injectable pharmaceutical products; also provides contract manufacturing

Industry

Healthcare

Geographies

Headquarters in Parsippany, NJ with manufacturing facility in Rochester, MI.

Business solution

SOP management, regulatory compliance

EMC products

EMC Documentum Compliance Manager

Deployment summary

Automated content management solution enables JHP to manage, route, and approve controlled documents electronically and provides an audit trail of actions taken on documents.

EMC partner

Impact Systems

Up and running in record time

Based on the transaction completion date of the King purchase, JHP had only 90 days to migrate the previous Documentum application into the new Compliance Manager environment and become independent of King's support for the system. JHP enlisted systems integrator Impact Systems to provide implementation services. "All critical documents and their associated histories needed to be migrated in their exact form for future manufacturing and quality audits; in other words, we needed to exactly mirror the system that had been in place at King," said Paula Del Papa, documentation supervisor at JHP. "Impact Systems did a phenomenal job on all aspects, from consulting on hardware purchases to migrating configurations, critical documents, and associated metadata, to system validation, without any loss in business continuity and in only 45 days—well within our deadline."

Impact's Q-Config™ and Q-Transfer™ Designed for EMC proprietary software tools were used to support JHP's migration, which saved an estimated four to six months of manual configuration and content transfer time. In addition, Impact accelerated deployment through its templated validation scripts, which enabled JHP to jump-start the validation process—a critical and time-consuming component of any compliance solution.

A smooth and controlled workflow for document revisions

Today, JHP controls and manages all critical manufacturing documents within the Compliance Manager framework. These include SOPs, test procedures, materials specifications, training records, and other documents that support the regulatory documentation process for each product. These controlled documents are closely audited, and regulations require that the effective versions be made available to plant personnel at all times.

To support compliance, Compliance Manager automates all of the processes involved in updating the documents, routing them for approval, and then releasing the effective versions to users on the factory floor. More than 75 reviewers have been given "contributor" access, enabling them to check out documents for editing and then manage the approval process. Compliance Manager manages all access levels ranging from full editing to read-only access.

> "The Documentum Compliance Manager plays an essential role in keeping us compliant by ensuring that our plant personnel are always accessing the most current versions of critical documents, and by supporting us during regulatory audits."
>
> **Paula Del Papa, Documentation Supervisor**

The Compliance Manager system automates many processes that have been paper-based, time consuming, and inefficient in a traditional pharmaceutical manufacturing environment. "If we had to rely on a paper system, we would have to hire at least five additional employees to manage the workload we currently process with Documentum," said Del Papa. "Routing and approvals would be much more complicated, because we'd have to distribute paper copies to reviewers and develop manual systems for managing and releasing the latest versions to the factory floor. The margin for error would be much higher, which would expose us to greater risk of violations and fines."

A validated and compliant solution for streamlining audits

JHP is subject to periodic audits of its manufacturing procedures by regulatory agencies as well as customers, and the Compliance Manager system plays a critical role. "Since Compliance Manager is a 21 CFR Part 11-compliant and validated solution, it's like having an insurance policy going into an audit. Often, we aren't scrutinized in the document area as much because of our Compliance Manager implementation," said Del Papa. "We are audited sometimes up to twice a month, and, thanks to Compliance Manager, it's rare that I get called in to address document-related questions. The system gives us peace of mind by providing an instant audit trail that shows every action taken on a document."

Since JHP distributes its products in Europe, the company is also regulated by the European Medicines Agency (EMEA). "The EMEA regulations closely match those of the FDA, so the Part 11 compliance of Compliance Manager makes it that much easier for us to comply with overseas rules and continue to expand the global reach of our company," said Del Papa. "In fact, the system gives us important marketing leverage with potential clients who are able to see we're running a compliant operation not only for the U.S. but also for Europe."

Moving forward: an enterprise solution

With the initial success of Compliance Manager for controlled manufacturing documents, JHP is looking at ways to expand the system to other document types such as stability protocols, batch records, and security documents. In addition, JHP is looking at additional document processes that are currently manual and could be significantly improved through automation with Compliance Manager. One example is a series of forms that must be sequentially numbered for a laboratory notebook. "Compliance Manager has features that would allow us to sequence and manage these documents electronically, instead of having to rely on our quality assurance department or laboratories to do it," said Del Papa.

Longer term, JHP is exploring expanding the system to control and manage the actual document assembly process for a new drug submission, a concept that has received support from the company's upper management. "As we gain more experience with the system, we're really starting to understand just how extensive its capabilities are and how many different document types we can manage throughout the organization. Long term, we really view Compliance Manager as an overall company solution for managing any type of controlled document," said Del Papa.

Summary

The compliance system based on the EMC Documentum platform has enabled JHP to avoid the pitfalls and inefficiencies associated with manual, paper-based processes for managing controlled documents in a regulated manufacturing environment. "The Documentum Compliance Manager plays an essential role in keeping us compliant by ensuring that our plant personnel are always accessing the effective versions of critical documents, and by supporting us during regulatory audits," said Del Papa.

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