Success Case

Soft Expert ®
Software for Performance Excellence

KLEY HERTZ
FARMACÊUTICA

Website:

www.kleyhertz.com.br/en

Sector: Pharmaceutical

Products used:

SoftExpert Document

SoftExpert Differentials:

• Low complexity implementation

• Great cost-benefit relationship

• Integrated components

• 100% web-based

Benefits/Results:

• Enhanced traceability of processes.

• Improved regulatory compliance.

• Provided operational and
  productivity gains.

• Increased agility across the
  document approval process.

• Facilitated control of revisions in
  Quality Assurance.

• Allowed more demands to be met.

• Guaranteed a reliable, traceable
  and dynamic document
  management process.

Kley Hertz enhances processes, guarantees information security and boosts productivity with SoftExpert

Kley Hertz is one of the 10 largest Brazilian-owned OTC pharmaceutical companies. It has a portfolio of over 60 medication brands, including Over-the-Counter medicines, herbal remedies, supplements, cosmetics, dermocosmetics and prescription medications, producing and distributing over 20,000,000 units annually. ®

Its factory has Good Manufacturing Practice – GMP certification, guaranteeing that the company meets all pharmaceutical industry standards required by law for the manufacture of medications.

Challenge

Although it has a document management process spread across all areas, management of this process was done manually. All documents implemented at Kley Hertz were updated in a master list controlled using an Excel spreadsheet, which was also used to control the expiration of documents.

Control of documents under revision was cumbersome and there was no way to control how long a document remained with each responsible party (creator, consensus and approval). This caused delays in approvals and greater involvement of Quality Assurance at each step of the process and in asking the areas to return documents. Considering the large amount of documents that the company has, expiration control was not applied to all documents.

According to Márcia Valiati, Technical Manager at Kley Hertz, it was impossible to know which documents were most accessed and revised and they only became aware of new versions after e-mails were sent.

In addition, watermarks were manually added and documents were converted into PDF format in order to make them available electronically for consultation. The texts had no keyword search, which demanded time for research.

The Solution

In light of this situation, Kley Hertz began a detailed assessment process to adopt an electronic management solution for its documents and records, considering the strict regulatory and validation requirements for systems that the pharmaceutical industry must have. At the end of the process, the SoftExpert Document solution was selected. This product is part of a suite of applications for enhancing processes, regulatory compliance and excellence in management, provided by SoftExpert.

As differentials, Valiati points to the traceability and security of SoftExpert solutions. "We consider the software to be educational and its parameters can be set according to the company's need," she adds.

SoftExpert Document is part of the collaborative workflow technologies, such as indexing, recovery and visualization of content, in a single web application. The software allows for simple and immediate access to documents by the company's departments, customers and suppliers, assuring that up-to-date versions are available. In addition, all actions executed in relation to the documents throughout their life cycle are 100% monitored.

The Results

With the SoftExpert solution, Kley Hertz has enhanced the traceability of its processes and regulatory compliance with electronic management of documents and records. The organization currently manages processes and over 10,000 documents electronically, with operational and productivity gains.

"Today, we have around 10,000 documents, including current and obsolete documents, stored on the system," says Valiati.

The solution serves 273 registered users, allocated to the Production, Quality Control, Quality Assurance, Research and Development, Engineering, Environment and Logistics areas, in addition to Administrative areas such as HR, Marketing, Sales, Finance and IT.

Among the gains obtained with SoftExpert Document, Valiati mentions involvement of areas and agility across the document approval process. "This has facilitated control of revisions by Quality Assurance and allowed for greater compliance with demands," she says.

Keyword searches in the body of documents, awareness of which documents are most accessed and management of the document expiration period were also highlighted by Valiati.

"SoftExpert Document guarantees that the document management process is reliable, traceable and dynamic. This is of the utmost importance at a company like ours, where compliance with procedures and standards is essential to the success of the business," she says.

Next Steps

According to the Technical Manager, management of production orders, contracts and supplier documents could migrate to SoftExpert Document. In addition, Kley Hertz is interested in implementing SoftExpert's Action Plan Management solution to manage instances of non-compliance and corrective and preventive actions, in an effort to allow for greater integration of the system and more traceability and involvement of the interface areas in the quality deviation process.

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>
> Márcia Cruz Valiati – Technical Manager, Kley Hertz

About SoftExpert

Operating in the business management software market, SoftExpert emerged in 1995 in southern Brazil. Currently, the brand has over 500 employees, 2,000 customers, 600,000 users spread across 50 countries, 300 partners worldwide, including strategic alliances with companies such as AWS, Bakertilly, Deloitte, Kodak Alaris, and DocuSign, in addition to business units in 9 countries. This is because SoftExpert has solutions for companies ranging from business management and corporate quality to environmental, project and government management in just one contract for its customers, providing them with greater efficiency, agility, and cost-effectiveness. Its global presence shows that SoftExpert adapts its range of services according to the needs of companies, as well as their locations. The platform offers a set of multi-language modules that are integrated to automate processes and optimize different business areas of organizations.