OPENTEXT™

Pharma International Improves the Health of their Content-Centric Business Processes

Process automation, easy version comparison, and a single, central content repository drive efficiency and ease compliance burden

Pharma International Co. (PIC) offers a range of pharmaceutical products and services, focused on generics, starting from the earliest stage of research & development, and including large-scale commercial manufacturing operations, quality testing, distribution, and marketing in the Middle East and North Africa (MENA) region and Europe.

Their pharmaceutical portfolio covers a variety of production lines of different dosage forms; tablets, capsules, injections, syrups, dry suspensions, suppositories, medicated shampoos, creams, ointments, and gels. The diverse portfolio covers most therapeutic classes, with extensive specialization in cephalosporin antibiotics. PIC is one of only a small number of companies with dedicated cephalosporin manufacturing capabilities in the region. PIC launched their first product in 2001 and now reaches more than 20 countries.

The pharmaceutical industry is renowned for being heavily regulated. Consequently, pharmaceutical companies rely heavily on a substantial volume of documentation to track and manage every aspect of research, manufacturing, testing, distribution, packaging, labelling, and quality assurance. PIC meets the stringent requirements of the Food and Drug Administration (FDA) and World Health Organization (WHO) and their Good Manufacturing Practices (GMP). In order to do so, they needed to address shortfalls in their existing document and other content management provisions, especially that of product packaging and labelling.

Reduce Time Spent on Regulatory Returns and Enable Version Comparison

Among the challenges that PIC faced was the length of time it took them to collate information for regulatory submissions. The old system lacked the ability to provide quick, easy-to-view document comparisons, which are required to track changes coming from multiple sources. There was also no way of performing systematic comparisons of image files, such as drawings, for product packaging and labelling.

Consequently, human errors became commonplace and manual comparisons became time consuming.

INDUSTRY

Pharmaceutical

CUSTOMER

Pharma International Co.

CHALLENGES

- *Meeting evolving compliance requirements is difficult and time consuming with existing system*
- *Manage, track, and compare packaging document and image file revisions*
- *Lack of business process automation workflow adversely impacts efficiency*

SOLUTIONS

- *OpenText™ Content Suite Platform*
- *OpenText™ Brava!™*
- *OpenText™ Extended Workflow (including OpenText™ Electronic Signatures)*

BENEFITS

- *Workflow-driven processes speeds up regulatory submissions with greater accuracy and reliability*
- *Packaging document and image version comparison capabilities greatly reduce time spent managing changes*
- *43% improvement in overall efficiency of business processes*

"When replacing the existing system, we engaged all areas of the business to ensure we captured comprehensive requirements. By doing this, we were able to set a vision for the future, and we began to look for a solution that would meet our needs today and long into the future," explains Ahmad Alshami, IT Manager at Pharma International.

With a clear vision and requirements documented, PIC set about looking for a solution. They considered a number of possibilities, but only one offered the diversity and breadth of capability that is needed to meet their long-term goals: OpenText™ Content Suite.

"We were impressed that OpenText has the ability to provide the most complete, end-to-end Enterprise Information Management solution. Being able to cover everything from scanning, document creation, workflow, records management, document and image comparisons, electronic signatures, and out-of-the-box integration to other enterprise systems, meant that OpenText was the only choice for us," adds Alshami.

An Efficient and Effective Implementation

Continuing on the theme of inclusivity, PIC involved representatives from across the business in the implementation project. This ensured that their needs would be taken into account. Representatives from marketing, artwork, administration, production, quality assurance, IT, finance, and legal worked with the established local OpenText partner, Mediterranean Sea & Gulf for Computer Services (MGS).

"Having a project team comprised of representatives from across the business, with backup and support from OpenText and MGS had a positive impact on our implementation. The combination worked well and provided the knowledge and flexibility we needed to deliver the solution into production," says Alshami.
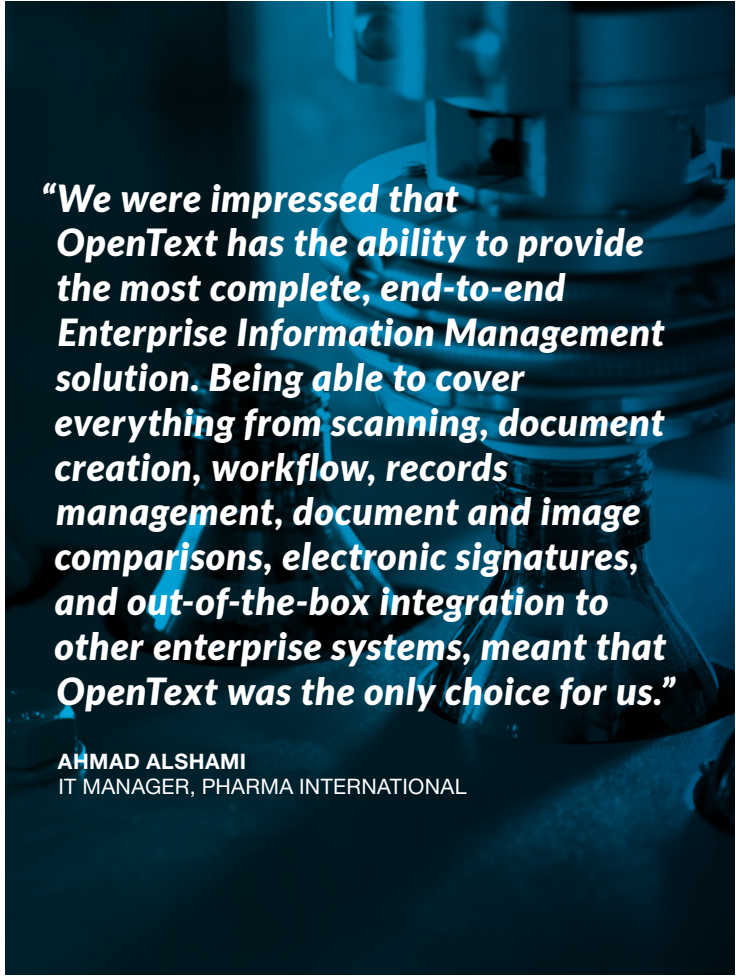
The majority of the functionality that PIC sought is provided by the Content Suite Platform out-of-the-box. However, PIC had specific needs around their business processes, such as automatic batch number generation and integration of their own HTML forms, that were easily addressed using the Content Suite developer tools.

Reduce Risk of Non-Compliance and Speed Time to Market

OpenText helps PIC resolve a number of significant challenges, including performing visual comparisons of packaging design and labelling. The solution provides dynamic document workflows that offer parallel, rather than sequential approval steps.

"Using the intuitive and flexible graphical workflow design tools, we are able to quickly set up our complex packaging design, review, and approval processes. A key part of this process is the ability to compare changes made between two versions of a document or drawing using OpenText™ Brava!™ This saves us time and reduces errors," notes Alshami.

In the area of product labelling and packaging, PIC interacts with numerous external parties, and develop various versions for different markets. Brava! helps PIC streamline the process of managing review and approval cycles, while the workflow capabilities of Content Suite automate process steps, notifications, alerts, and provide reporting.

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> **AHMAD ALSHAMI**
> IT MANAGER, PHARMA INTERNATIONAL

"Using OpenText Brava! helps us compare the text and layout for two different pieces of artwork, even if it is just a single letter or number," adds Khalid Elyan, Planning Manager, Pharma International.

Approval of packaging involves numerous external parties, which can vary by region. Using OpenText™ Extended Workflow, PIC can track and manage these interactions, maintaining an audit trail of correspondence, drawing versions, and the final approvals using electronic signatures. This helps PIC meet their compliance obligations and ensures they can produce the necessary submissions to regulators.

"One of our key performance indicators (KPIs) is the average process time of a workflow. We see an improvement time of 43% when comparing present day times with the old system. In addition, tracking and follow-up of tasks are improved due to multiple ways of tracking processes either by establishing a custom report, visual workflow process mapping, or dynamic search in workflow names," notes Elyan.

Once documentation and drawings are approved, they are stored in Content Suite. This provides a single source for all content, rather than the previously disparate storage silos. When a regulation changes in a particular market, users can now quickly access the entire package of content relating to any product, see the history, and initiate any necessary actions.

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> **KHALID ELYAN**
> PLANNING MANAGER, PHARMA INTERNATIONAL

Building on Benefits and Planning for the Future

PIC set out a vision for the future of their enterprise information, and with OpenText Content Suite they are well on the way to realizing that vision. Process efficiencies and automation, ease of tracking approvals, and fast, accurate comparison of content versions all contribute to a better information management culture at the organization.

Plans are in place to extend the use of OpenText software into other areas and processes across the business. The next phases will consider records management, integration with other systems such as Enterprise Resource Planning (ERP), and the use of mobile devices.

"With OpenText, we have established a solid, reliable, and effective base from which to build," concludes Alshami.

Mediterranean Sea & Gulf for Computer Services (MGS) is a dynamically growing company and leader in providing specialized enterprise business and IT solutions and services. MGS focuses on ECM solutions for unstructured data and ERP for structured data. With over 15 years of experience in OpenText™ and SAP® product and solutions, MGS has built a solid implementation methodology in order to ensure success and quality services for ECM for SAP. The range of services we offer, from classic consulting services to implementation and operational support, provide great benefit to our clients because of our team's deep project experience. In the end, we have one objective: a cost effective, profitable utilization of ECM technologies – focusing on meeting your business objectives, not technology for technology's sake.

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