opentext™

Success story

Almac Clinical Services Limited

Industry
• Life Sciences

Solutions
• OpenText™ Content Server
• OpenText™ Regulated Documents
• OpenText™ Remote Cache
• OpenText™ Electronic Signatures

Results

Reliable, single source of the truth and robust document control.

User confidence that documents retrieved are current, helping ensure compliance.

Reduction in time spent searching for documentation alone saved £350k in first year

Ability to quickly deploy new workflows using a globally defined standard base. Can now handle any document type.

ALMAC
Diagnostics

Almac Clinical Services' document health improves with OpenText

OpenText Content Server provides single source of the truth, with quick search and retrieval, improved compliance, collaboration, rapid workflow deployment and cost savings

"Locating documentation also became much quicker, saving up to 360 hours per week or £350k per year. To help users better understand the file plan layout, we provided them with mouse mats, printed with the plan—simple yet effective, something many still use today."

Paul O'Connor
Global VP Quality
Almac

The Almac Group provides a comprehensive range of services from research through pharmaceutical and clinical development to commercialization of product. Headquartered in Craigavon, Northern Ireland, where around 2,000 of their 3,600 global employees are based, the company generates an annual turnover of half a billion dollars.

Over 600 companies worldwide, including all the market leaders, use Almac's services, a testament to the quality, innovation and efficiency of the business over the past 30 years. Almac has operations in the United Kingdom, United States and Asia Pacific regions. Almac's Clinical Services business unit specializes in providing a global service for the manufacture, packaging, labeling, distribution, return and analysis of clinical trial supplies.

Like any organization working in the global pharmaceutical industry, Almac is heavily regulated within an ever-evolving regulatory environment. With dozens of new laws passed each year, generating, capturing, storing and retrieving the multitude of documents, including Standard Operating Procedures (SOP), labelling and approvals generated on a day-to-day basis, poses a significant on-going challenge.

Almac identified the need to move from difficult to monitor and control paper-centric processes to more systematic and reliable processes, improving efficiency. They set out to identify a robust, scalable solution for their growing volume of content. Moving to workflow driven processes would also enable improvements around audit and compliance.

Andrew Hillis, group head of Information Services at Almac, expanded: *"Internal collaboration was too reliant on paper documents. This led to questions around the reliability of documents being up-to-date and current which is critical in our environment. Working with external collaborators only compounded the problem. For example, obtaining labelling approval signatures meant numerous exchanges of paperwork and often involved a costly international courier. Approvals could take up to 18 weeks."*

OpenText provides solid Content Management platform, with opportunity for future expansion

An internal project looked in closer detail at the needs of the business: document capture, storage and retrieval, collaboration, workflow and electronic approvals. Almac set about identifying potential solutions in the marketplace.

Paul O'Connor, global VP, Quality at Almac, and the business sponsor, elaborated on their ultimate selection: *"Many of the solutions we evaluated offered strong document filing and storage, but OpenText stood out from the crowd. Of particular immediate interest to us were the capabilities OpenText™ Content Server provides around workflow, collaboration and electronic signatures, as well as the future possibilities for our enterprise information needs."*

The OpenText track record and understanding of heavily regulated industries, in particular pharmaceutical, gave Almac confidence they had selected the solution best suited to their needs. A project team with representation from the business, IT, quality assurance and OpenText themselves began the implementation.

"One of the first areas to be moved to the OpenText solution was documentation relating to our quality systems, a crucial aspect of our business. Change control, SOP, policy and batch record documentation were migrated and made available to users. Following training, users began to benefit from the carefully designed file plan, providing improved structure and control," added Paul O'Connor.

> *"OpenText provides the flexibility we need to apply the 90 percent commonality of lifecycle management across the globe, and take into account the 10 percent of local nuances."*
>
> **Andrew Hillis**
> Group Head of Information Services
> Almac
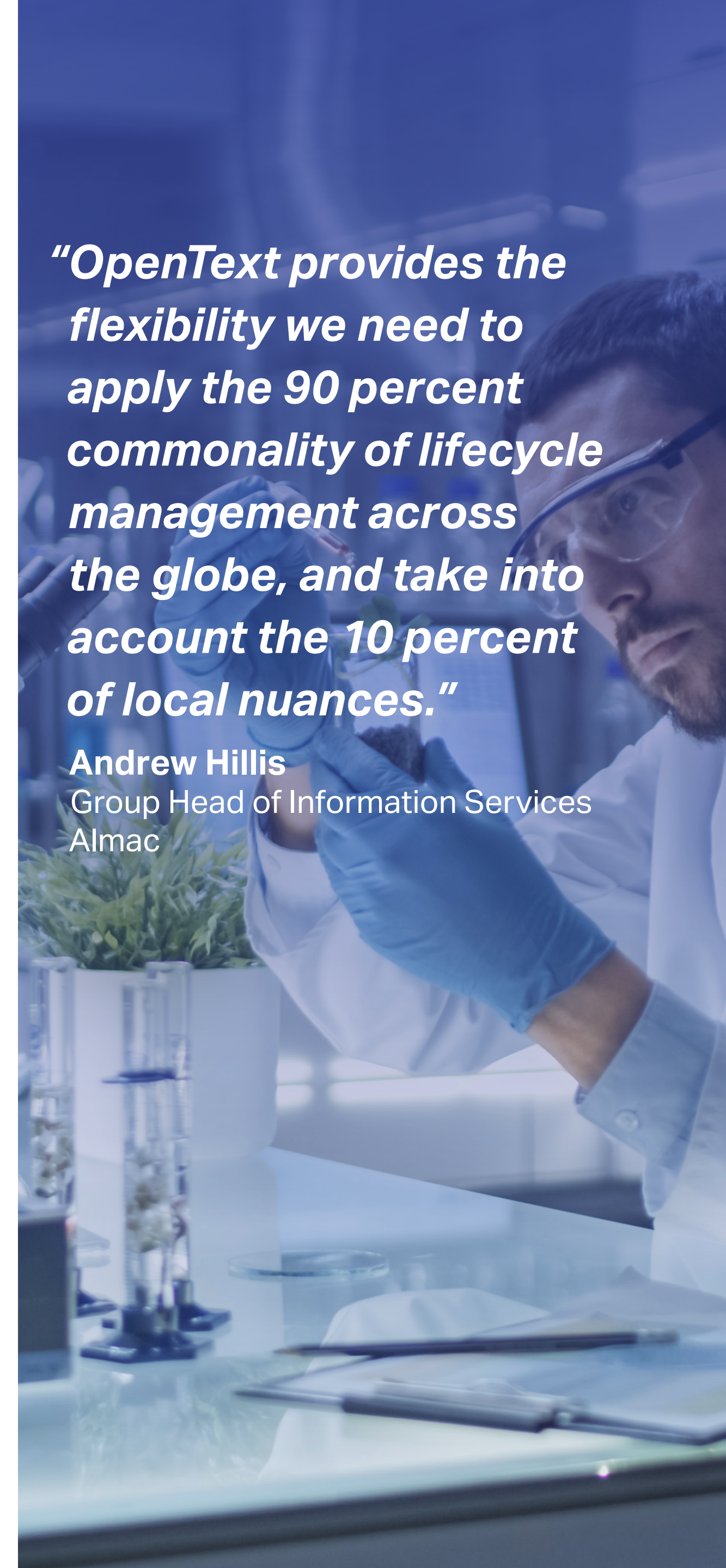
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Meeting the needs of a distributed user community and providing both local and global compliance

Almac continues to grow globally, storing up to 8,000 new documents each week, and they recently added operations in Singapore. The OpenText solution is providing the flexibility and agility they sought as part of their vision surrounding some 1.5 million documents to date.

"The OpenText solution has proven to be highly scalable. It fundamentally does what OpenText said it would. A lot of enterprise solutions promise a lot but fail to deliver, Content Server does not disappoint. For example, when we recently began operations in Singapore, we simply made the necessary adjustments to the file plan and were up and running. No fuss, no cost," added Andrew Hillis.

Keeping pace with and meeting compliance requirements on a global basis requires flexibility. While there is a high percentage of commonality across territories, there are, however, important differences.

"OpenText provides the flexibility we need to apply the 90 percent commonality of lifecycle management across the globe, and take into account the 10 percent of local nuances. Using OpenText™ Regulated Documents we're able to ensure compliance throughout the lifecycle," added Andrew Hillis.

With an increasingly distributed workforce of some 1,200 users, Almac also needs to ensure optimum performance. Using OpenText™ Remote Cache provides seamless local replication of content to any location,

maintaining security profiles. This minimizes retrieval delays, while ensuring everyone is working consistently and reliably from the latest document version, a critical measure for compliance and audit.

Using the highly configurable workflow capabilities of Content Server, avoiding custom development, allied to OpenText™ Electronic Signatures, Almac has improved efficiency and reduced costs. With over 1,100 workflows initiated weekly, and many more child processes spawned, this is helping in areas such as labelling approvals. Significantly, approvals now typically take just two weeks, down from 18.

Passing external audit with flying colors, critical for the business

Almac regularly undergoes external audits and was recently inspected by the UK medicines regulatory agency at their headquarters in Northern Ireland. With fast retrieval from a well-defined file plan, Almac was able to satisfy the inspectors that they are in complete control of their documentation, and passed with flying colors.

Andrew Hillis expanded, *"Reputation is everything in our industry and a poor audit can have serious detrimental effects. However, the auditors praised us, saying our provisions around documentation were the highest quality they had come across."*

One of many key document types that come under scrutiny at audit is shipping or distribution documentation. Almac has to have the ability to trace any single shipment through batch numbers, dates and a variety of other data points. With distribution a 24-hour-a-day, seven-days-a-week, operation, they put their trust in OpenText, storing each and every piece of documentation which may need to be retrieved at a moment's notice.

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Andrew Hillis
Group Head of Information Services
Almac

Future plans to expand on the solid OpenText platform

Since implementing OpenText™ Content Suite Platform, Almac has benefitted in many ways. But OpenText continues to innovate and so they are now planning to update to the latest Content Suite Platform, including OpenText™ Records Management,, greater provision for mobile device use, and greater collaboration, especially with customers.

"The relationship with OpenText has without doubt been mutually beneficial. It doesn't follow the usual purchase order driven motivations we see all too often. OpenText go out of their way to keep us informed of their roadmap developments, and the account management team act as an advocate for us. It's all about doing the right thing for the customer," concluded Andrew Hillis.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit opentext.com.

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