

opentext™

SUCCESS STORY

Ascentage Pharma

Industry

- Pharmaceuticals

Solutions

- OpenText™ Documentum™
- OpenText™ Documentum™ for Quality and Manufacturing
- OpenText™ Documentum™ for Life Sciences
- OpenText™ Brava!™ for Documentum™ D2

Partner support

- Shanghai Zonysoft Co. Ltd.

Results



Ensured compliance requirements are met



Improved efficiency of document approvals



Secured corporate IP



Reduced reliance on paper



Ascentage Pharma meets compliance requirements with OpenText

Biopharmaceutical company secures IP, improves efficiency and drives up compliance standards with OpenText Documentum for Life Sciences

“Without the OpenText Documentum for Life Sciences solution, we would not be compliant and this would impact our ability to take new products to market. We have great confidence that the solution will meet our needs in the future too, as we grow.”

Mr. Leo Sun
Associate IT Director
Ascentage Pharma



Ascentage Pharma is a globally-focused, clinical-stage biopharmaceutical company developing novel, small molecule therapies for cancer, hepatitis B virus and age-related diseases. Founded in 2009 and headquartered in Suzhou, China, the company has set out to pioneer a new class of medicines that can address the most difficult-to-treat diseases to improve the lives of patients in both China and globally.

As with all pharmaceutical companies, Ascentage must adhere to strict compliance and regulatory frameworks, notably FDA CFR 21 Part 11 for the storage of electronic records and signatures. The business has undergone rapid growth in recent years. Relying on physical paper documents, files stored on local drives and email for standard operating procedure (SOP) documentation and approvals, had become increasingly cumbersome, difficult to track and likely to result in compliance breaches. As the Chinese pharmaceutical market is extremely fast-paced, IT solutions are heavily relied upon to avoid delays in bringing products to market caused by non-compliance.

Mr. Leo Sun, Associate IT Director at Ascentage Pharma, explained the challenges the company faced. ***“As well as needing to comply with various regulations and compliance frameworks, we also need to protect our intellectual property as we grow. This means we must have a scalable, secure and compliant solution to capture, store, track and retrieve our documentation. We could no longer rely on paper and passing documents around to staff one by one to gather signatures, which was both ineffective and non-compliant.”***

Having defined its business requirements, Ascentage looked at a number of vendors, including both local and global solution providers. A number were invited on site to conduct testing to establish if their respective solutions were aligned to the business’s needs.

“We wanted a solution that would meet our needs today and into the future. Having evaluated numerous options, one solution stood out, OpenText™ Documentum™ for Quality and Manufacturing,” said Mr. Sun. “Our decision to select [an] OpenText™ Documentum™ for Life Sciences [solution] was based on the outstanding reputation of the solution, the global presence of OpenText and the large number of implementations in the pharmaceutical and wider Life Sciences market.”

Another reason for selecting Documentum for Life Sciences was its built-in industry best practice. Working with local OpenText implementation partner, Shanghai Zonysoft Co. Ltd., Ascentage brought together a team from its IT and quality departments, where the solution has been initially deployed.

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“Thanks to the knowledge of the local OpenText implementation partner, Shanghai Zonysoft, and the close cooperation with our team, our taxonomy was designed and the solution was successfully implemented in just a few months. Following training and knowledge transfer, the solution has been fully adopted in our quality department with little, if any, impact on IT,” added Mr. Sun.

Ascentage has also implemented OpenText™ Brava!™ for Documentum™ D2 to enable users to collaborate on documents, regardless of the document type. Users can annotate documents and sections can also be redacted for security reasons, protecting sensitive information. User access rights are strictly controlled, protecting IP, with a comprehensive audit trail maintained at all times.

To date, approximately 200 staff are using the solution, significantly reducing the amount of paper used and saving considerable time.

“Our primary objectives of compliance and efficiency are being met with OpenText™ Documentum™. However, as we bring products to market, the true return on our investment will be realized, as our entire document lifecycle, quality processes and associated workflows will be compliant,” stated Mr. Sun.

A further key element of compliance for Ascentage under FDA requirements is computer system validation (CSV). Documentum for Life Sciences provides the quality and accuracy of data needed to ensure that critical processes are functioning properly, with quality built into the solution at every step and not just as a final output of the process.

Having successfully completed the implementation in the quality department and following good user experience feedback, thoughts are now turning to the future and how Documentum can provide benefits to a wider userbase.

“Without the Documentum for Life Sciences solution, we would not be compliant and this would impact our ability to take new products to market. We have great confidence that the solution will meet our needs in the future too, as we grow,” said Mr. Sun. ***“We also plan to widen our usage of OpenText Documentum to other parts of the business, including implementing additional Documentum modules, helping us expand on our vision of a single platform for content throughout the entire company. Modules, such as OpenText™ Documentum™ for eTMF (Electronic Trial Master File), will allow us to improve our inspection readiness and compliance for clinical trials.”***

About Shanghai Zonysoft Co. Ltd.

Shanghai Zonysoft Co. Ltd. is a focus on unstructured data lifecycle management and application of information technology companies.



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](https://www.opentext.com).

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