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Success story

Syngene International Limited

Industry

- Contract Research Organization

Solutions

- OpenText™ Documentum™
- OpenText™ Documentum™ for Quality and Manufacturing
- OpenText™ Documentum™ for Life Sciences

Implementation Partner

- Impact Systems

Results



Improved customer service, enhanced audit compliance and greater automation



Implemented an enterprise-wide paperless platform for client and regulatory audits and support future growth

Syngene

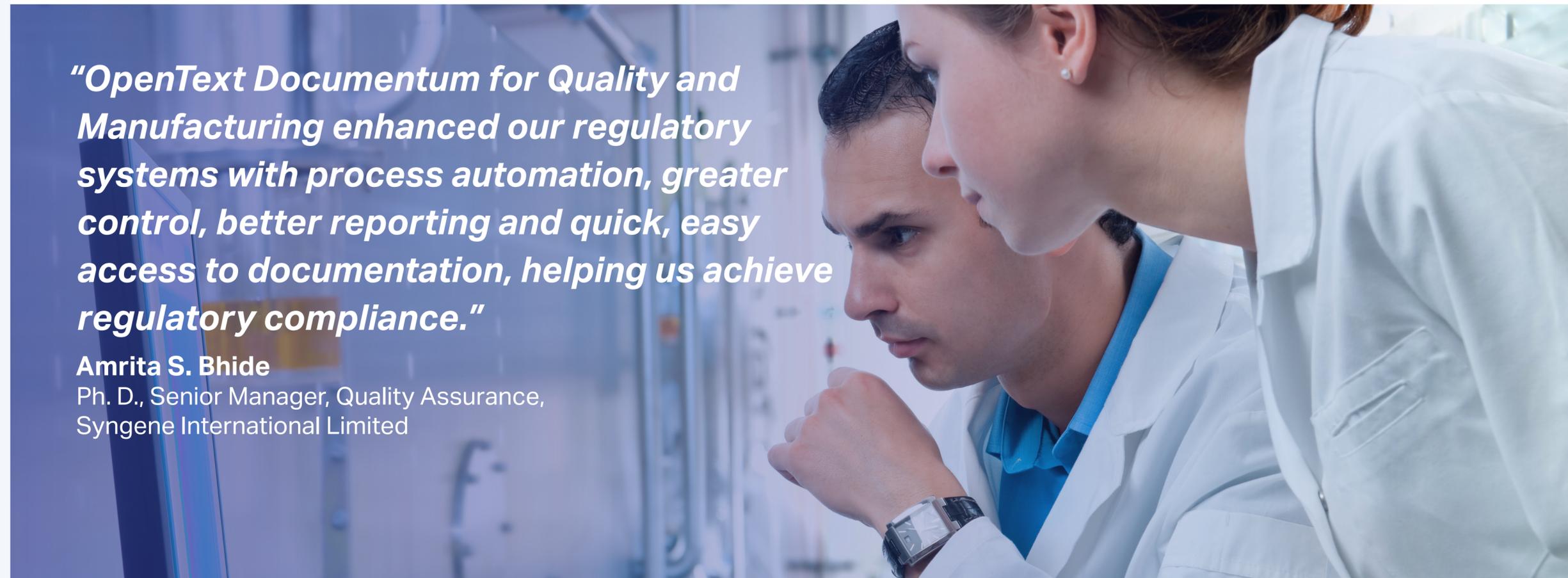
Research & manufacturing organization improves compliance processes

Syngene International undertakes digital transformation with OpenText Documentum for Life Sciences.

“OpenText Documentum for Quality and Manufacturing enhanced our regulatory systems with process automation, greater control, better reporting and quick, easy access to documentation, helping us achieve regulatory compliance.”

Amrita S. Bhide

Ph. D., Senior Manager, Quality Assurance,
Syngene International Limited



Syngene International Limited is a global scale Contract Research and Manufacturing Organization offering integrated discovery, development, and manufacturing services for novel molecules. It has over 360 clients in pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical industries around the world. Its world-class research and manufacturing facilities spread across 1.9 million square feet area and house nearly 4200 scientists who are engaged in cutting-edge scientific projects.

As the scientific research partner of many leading global organizations, Syngene must comply with regulatory requirements of India, where it is headquartered and operated, and those of the markets where its clients operate. This necessitates detailed and meticulous documentation of trial data, test results, product formulae, manufacturing processes, and more in a secure and easy to access manner.

Amrita S. Bhide, Ph.D., Senior Manager, Quality Assurance at Syngene International Limited expanded on the challenges the business faces: ***“On average, we have 15 audits taking place each month. Earlier we had a paper-based system that involved maintaining physical record of all documents, including getting physical signatures of relevant authorized team members. Needless to say, this system had many limitations: difficulties in maintaining audit trails, lengthy document retrieval times and others.”***

To maximize efficiency Syngene embarked on a company-wide digital transformation initiative to transition away from a paper-based system in its quality, audit, and manufacturing processes. After evaluating several solutions, Syngene selected OpenText Documentum as its enterprise document management system.

“Our choice was based on the extensive capabilities of Documentum, allied to the robustness of the platform and a proven track record of successful implementation. OpenText Documentum provides us with enterprise document management designed specifically for the life sciences industry. The Quality and Manufacturing modules provide specific capabilities needed for the regulated markets we operate in,” explained Bhide.

Syngene selected Impact Systems, a Pune-based OpenText Documentum partner, to implement the solution and the project went live in just eight months from initiation.

“The flexibility of the solution has allowed us, quite straightforwardly, to easily fine tune processes to suit our needs, enabling us to achieve the process improvements we sought,” explained Bhide.

Accessing all documentation via OpenText Documentum means users always have the latest version, and they no longer need to maintain paper copies of any document. The team ran an internal communication campaign to inform and sensitize employees on the benefits of going digital, including the harmonization and alignment of processes in different departments.



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With Documentum for Life Sciences, Syngene tracks the movement of every document, identifying bottlenecks or causes of delay and taking prompt corrective actions to maintain a proper audit trail. All access is controlled and recorded and can be granted programmatically to users through predefined access rules. The solution has also been integrated to the TrackWise Quality Management System and plans are underway to integrate with Syngene's Learning Management System (LMS).

“OpenText Documentum for Quality and Manufacturing enhanced our regulatory systems with process automation, greater control, better reporting and quick, easy access to documentation,” summarized Bhide. ***“We firmly believe we are on track to reduce cost, improve efficiency and above all, continue to achieve compliance.”***

About Impact Systems

Impact Systems provides software products and services for implementing, migrating and validating Documentum, on premise or in the cloud. In partnership with OpenText, Impact has developed a proprietary suite of interoperability products to connect the “best of the breed” Enterprise systems such as TrackWise EQMS, LMS, etc. to Documentum. The products connect in a way that allows the enterprise to leverage critical capabilities of existing systems.



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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