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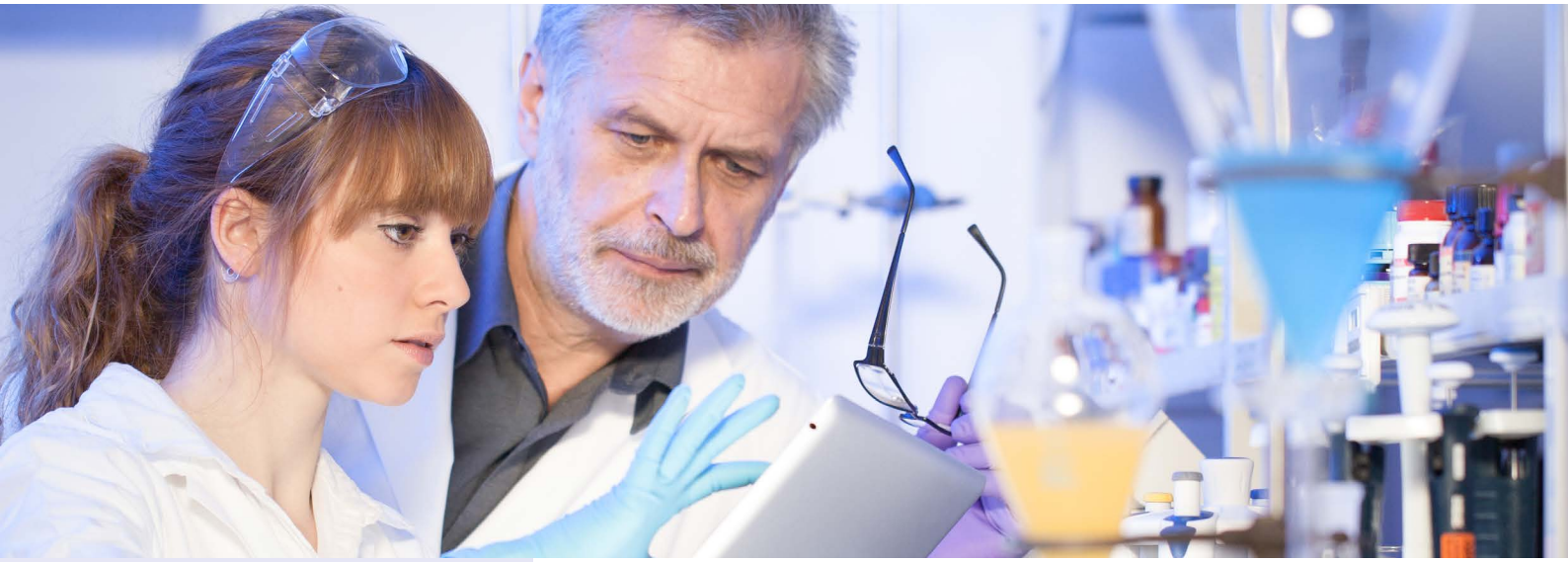
SERVICE OVERVIEW

Regulated Information Management Solution FasTrak

Accelerate life sciences quality management and regulatory compliance initiatives by rapidly deploying the Regulated Information Management Solution (RIMS)



Unifying quality
Maximized business user adoption

Go live faster
Accelerates control of GxP documents

Best practices
Solution capability and deployment approach

15+ years
Regulated information management process and solution knowledge

For Life Sciences companies, the challenge of reducing time-to-market for new products is even greater than for other industries due to the strict regulatory environment in which they must operate. Functions across the life sciences value chain, such as regulatory affairs, quality, R&D, commercial operations, marketing, legal, manufacturing and distribution are all under strict directives to maintain documents and records of high integrity and careful compliance to GxP, ISO, USP and other standards and regulations.

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OpenText Professional Services implemented and deployed Regulated Information Management System as a Managed Service for Pharmascience, a large Canadian pharmaceutical manufacturer. The solution improved time-to-market, quality for pharmaceutical manufacturing and regulatory compliance including reduced SOP deviations.

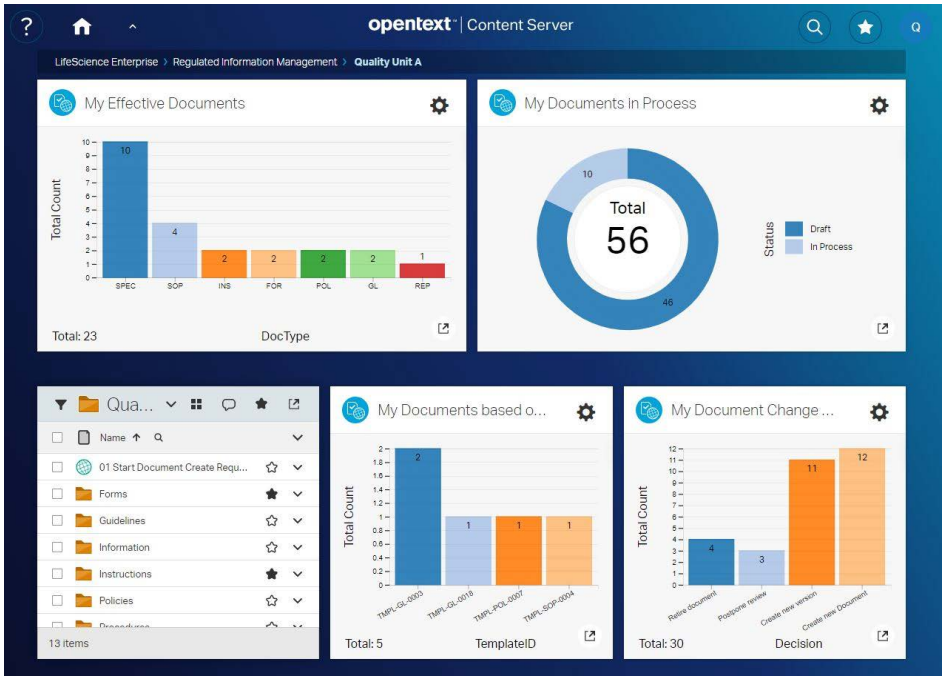
"OpenText is a real partner the service they brought to the table was not only the knowledge of the application, but also all the project management. They knew how to deliver this project."

Denis Beauchemin
Head of IT
Pharmascience

Read the full Success story and watch the video

Go live faster, accelerated GxP control

Quickly establish good quality practices for eDMS, SOP Management and other processes. Going live faster reduces the time-to-value from your solution investment and yields opportunities to learn from initial use of the solution. We can deploy faster because we offer pre-built product functionality extensions, pre-configuration transports, documentation templates to support system validation, and expertise regarding industry and solution specifics.



RIMS Quality dashboard

Best practices, solution capability and deployment approach

The FasTrak project methodology is field proven to significantly simplify the validation of the configured solution. The predefined User Requirements Specification (URS) and Functional Specification (FS) for the solution are tuned using inputs from business workshops identifying customer-specific requirements. This package also provides customers key templates such as Installation Qualification (IQ) and Operational Qualification (OQ) to support system validation related regulator audits. Appropriate validation support following the GAMP 5 approach is included in the FasTrak to support the customer.

15+ years, regulated information management process and solution knowledge

The OpenText team has field-proven experience guiding organizations and delivering effective GxP solutions such as RIMS. They understand the life sciences business, the governing regulatory framework, and how to collaboratively address opportunities and challenges for information management. Knowledge and expertise is informed from working with organizations such as B. Braun, Vifor Pharma, and Pharmascience to name a few.

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Blogs
How prepared are you for the EU MDR?

To talk to a Professional Services expert, please contact **Profservices@opentext.com**

The RIMS offering builds upon OpenText's market leading EIM Content Suite Platform and can be expanded to leverage OpenText Extended ECM integrations to other leading applications such as SAP, Salesforce and Microsoft Office 365. Controlled content sharing is part of the OpenText Core Share Content Server integration. Further, OpenText Content Suite's REST API and OpenText Extended ECM Platform enables integration with QMS, LIMS or LMS applications. The flexibility of the underlying Content Suite Solution enables many customer specific requirements without the need of customization, addressing many additional use cases.

As the product vendor, OpenText delivers as one team. Professional Services has unparalleled access to Customer Support and Product Engineering teams who share mutual accountability to customer success and satisfaction.

OpenText Professional Services offers a comprehensive portfolio of learning services to support effective use and operation/administration of the OpenText product software. **Consultation about user adoption and change management best practices** along with **Learning On Demand (LoD) self-paced learning** and **Instructor Lead Training (ILT) courses and certification exams** are available on **www.opentext.com.**
Related to RIMS we recommend the following courses & certifications:
• Training: **Content Suite Platform, Extended ECM for SAP**
• Certification: **Content Suite Platform and Extended ECM for SAP**
OpenText offers a range of **managed services** offerings for our customers to reduce the burden on customer's IT organization expertly manage solutions, stabilize/save costs, whether on-premises, in hybrid, or full cloud models.

At 3,000 staff, OpenText Professional Services is the world's largest pool of EIM product certified experts on OpenText products/solutions and deployed globally with product engineering teams.

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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