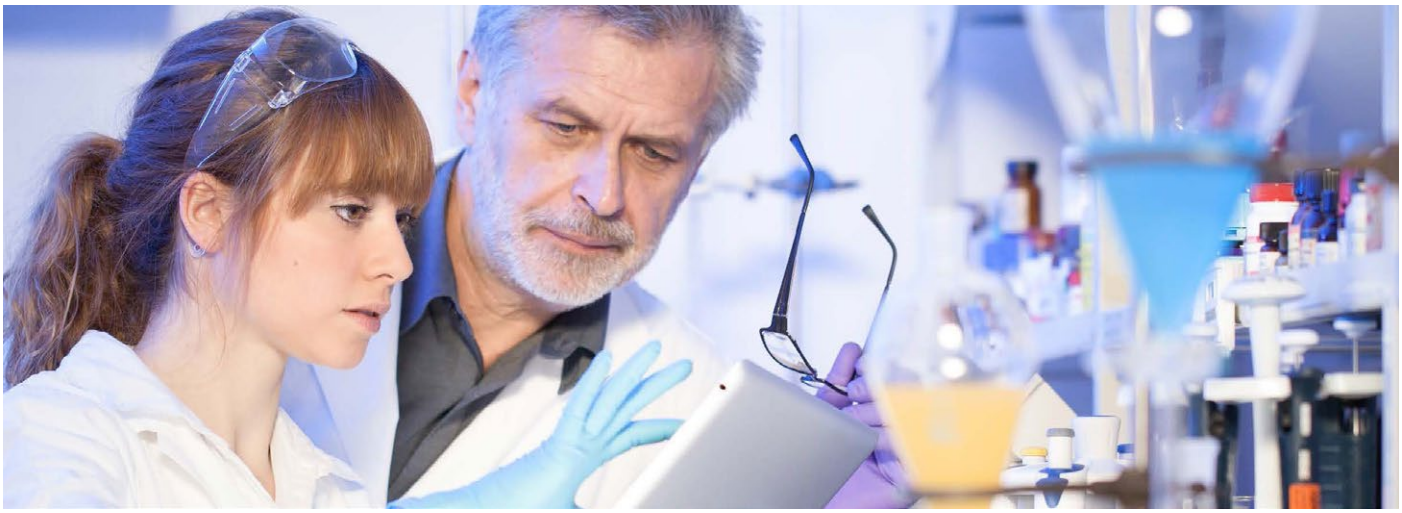
OpenText Content Management for Life Sciences FasTrak

Accelerate Life Sciences quality management and regulatory compliance initiatives by rapidly deploying the Professional Services Life Sciences solution for OpenText Content Management



Benefits

- **Unify quality** and maximize business user adoption
- **Go live faster** with accelerated control of GxP documents
- **Employ best practices-driven** solution capability and deployment approach
- **Rely on 15+ years** of 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.

The OpenText™ Content Management for Life Sciences FasTrak is part of a Professional Services (PS) solution extending OpenText Content Management with solution accelerators and featuring best-practice configuration and deployment methods. The complete solution consists of software extensions, pre-packaged and documented configurations, and consulting services to implement and deploy the solution. It has been developed over the past decade to address common requirements from customers in the Life Sciences industry (pharma and medical device) and is aligned to compliance regulations from authorities such as the FDA, EMA, and others. The OpenText Content Management for Life Sciences PS solution helps Life Sciences companies manage electronic records and signatures across the value chain in compliance with 21 CFR Part 11 or PIC/S Annex 11.

OpenText Professional Services implemented and deployed the OpenText Content Management for Life Sciences solution 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.

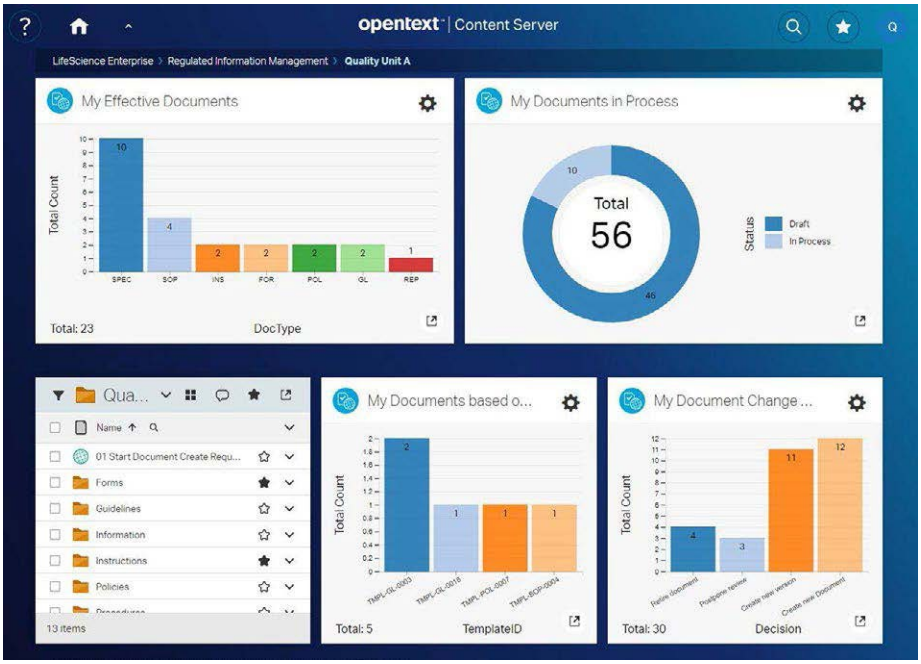
"OpenText is a real partner The service they brought to the table was not only the knowledge of the application, but also all the project management. They knew how to deliver this project."

Denis Beauchemin
Head of IT
Pharmascience

Read the full success story and watch the video >

Unify quality and maximize user adoption

The OpenText Content Management for Life Sciences PS solution provides greater visibility and control of your regulated documents. The ease-of-use increases user adoption to eliminate paper and assure compliance and quality. Predefined best practice workflows enable efficient document control processes, which help business users to stay on task with approval, periodic reviews, training, and withdrawal. Quality managers can monitor status and collect metrics based on flexible reports and dashboards adopted to your requirements.



Quality dashboard

Go live faster with 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, preconfiguration transports, documentation templates to support system validation, and expertise regarding industry and solution specifics.

Employ best practices-driven solution capability and deployment approach

The FasTrak project methodology is field-proven to significantly simplify 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.

Rely on 15+ years of regulated information management process and solution knowledge

The OpenText team has field-proven experience guiding organizations and delivering effective GxP solutions, such as the OpenText Content Management for Life Sciences PS solution. They understand the Life Sciences business, the governing regulatory framework, and how to collaboratively address opportunities and challenges for information management. They have built knowledge and expertise through working with organizations such as B. Braun, Vifor Pharma, and Pharmascience to name a few.

OpenText Content Management for Life Sciences PS solution

The complete solution is comprised of two key Professional Services components, each designed to work together with the OpenText Content Management Platform. Investing in all these elements unlocks the full potential.

The OpenText Content Management for Life Sciences PS solution builds upon OpenText's market leading OpenText Content Management Platform and can be expanded to leverage integrations to other leading applications, such as SAP®, Salesforce® and Microsoft® Office 365®. Controlled content sharing is part of the OpenText™ Core Share Content Management integration. Further, the OpenText Content Management platform enables integration with QMS, LIMS, or LMS applications. The flexibility of the underlying OpenText Content Management platform enables many customer-specific requirements without the need of customization, addressing many 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.

Products/Services

OpenText Content Management for Life Sciences FasTrak Implementation

Professional Services Solution Tools and IP modules

OpenText Content Management Platform

Resources

Blogs How prepared are you for the EU MDR?

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

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 Subscriptions providing self-paced learning and Instructor Led Training (ILT) courses and certification exams are available on opentext.com.

Related to the OpenText Content Management for Life Sciences PS solution, we recommend the following courses and certifications:

- **Training:** Content Management Training
- **Certification:** Content Management Certifications offers a range of managed services offerings for our customers to reduce the burden on customer's IT organization, expertly manage solutions and stabilize/save costs, whether on premises or in hybrid, or full cloud models.

With over 3,000 staff, OpenText Professional Services is the world's largest pool of IM product certified experts on OpenText products/solutions and is deployed globally alongside 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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