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Product overview

OpenText Core for Regulatory Plans

Simplify dossier planning with automated content assembly that accelerates complex regulatory submissions to Health Authorities.

- **Orchestrate complex multi-regional regulatory activities**
- **Leverage existing regulatory content**
- **Integrate** using open, repository-agnostic architecture
- **Deploy and upgrade in the cloud**

Evolving regulatory submissions standards promised flexible content reuse and streamlined reviews. For pharmaceutical companies operating on a global level, it amplified the complexity in the planning and execution of regulatory activities. Existing technologies envisioned at the dawn of the electronic submission era are insufficient in their ability to help sponsors to effectively navigate modern regulatory complexities. Compounding these challenges, regulatory affairs organizations around the world are experiencing constant and increasing corporate pressure to improve their operating efficiency and drive down cost. There is a clear and present need for a new solution to help the sponsors meet their regulatory obligations with the accuracy, agility, and cost efficiency the stakeholders demand.

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OpenText™ Core for Regulatory Plans is designed to reduce these complexities, so Life Sciences companies can focus on their regulatory objectives rather than the steps to achieve them. Core for Regulatory Plans offers an intuitive user interface and powerful capabilities to plan, execute and manage submissions that make up global regulatory activity. Once the submissions are created, leveraging the regulatory content amassed in OpenText Documentum for Life Sciences or other repositories is easy with automated document assignment to the appropriate eCTD structure.

As an OpenText OT2 platform cloud-based application, Core for Regulatory Plans easily provides complete, real-time visibility, access, and control over your regulatory submission portfolio to internal and external contributors, partners and stakeholders globally. Turn-key deployment and seamless upgrades allow you to rapidly respond to global regulatory guidance changes with current best practices, all with the same rigor of GxP compliance.

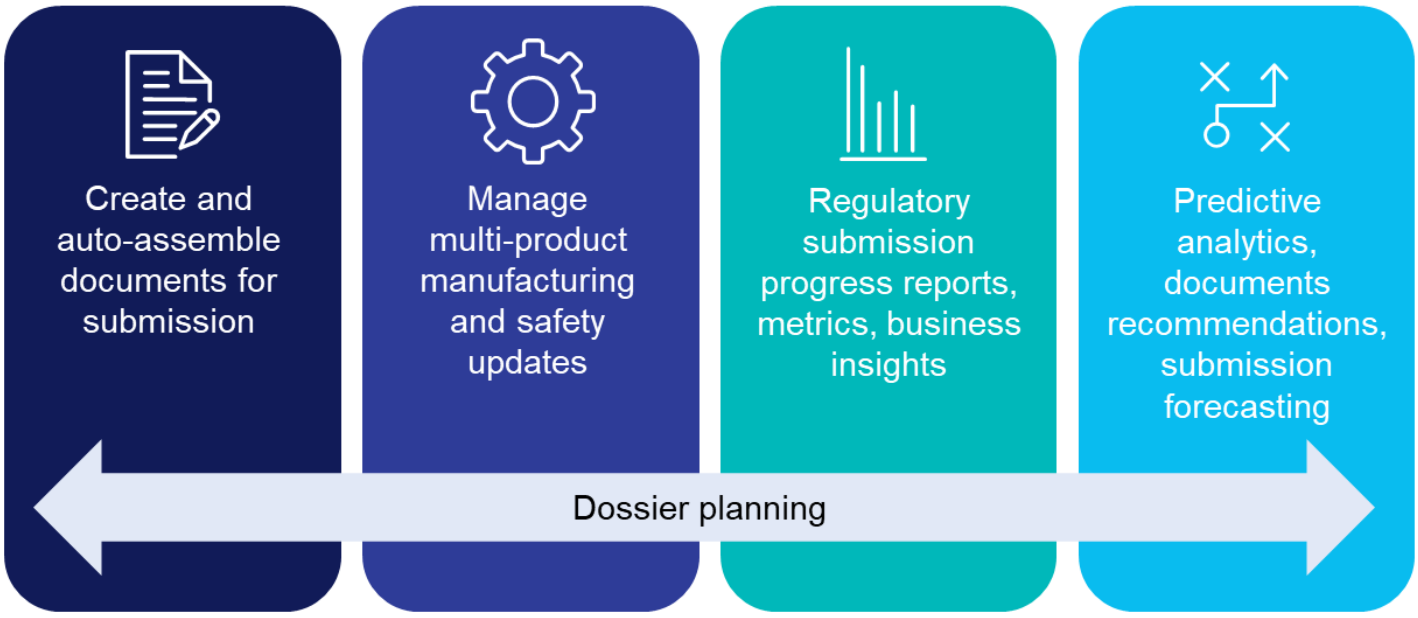
Recurring submissions

Pharma companies are required to send regular updates to government health agencies on long term use and safety of products. Companies must manually manage and track recurring submissions to know when these updates are due, when to get started working on them, and which documents need to be included in the filing. Most rely on tediously created and maintained spreadsheets to do this critical work. Core for Regulatory Plans enables users to automatically create a recurring submission, provide notifications, and automatically assemble starter documents for the submission.

Manufacturing change notifications

When a Pharma company makes a manufacturing process change, they are legally required to notify the government health agencies. Often, this change impacts several marketed products. It is difficult to track what documents need to be updated and assembled in the submission. Core for Regulatory Plans identifies impacted products and their regulatory applications. With a few mouse-clicks, all the regulatory submissions needed can be created to keep these products compliant in multiple jurisdictions.

Core for Regulatory Plans dramatically simplifies the planning of complex multi-application, multi-region and recurring regulatory submissions. It promotes submission content reuse, streamlines eCTD assembly, and tracks submission progress to help customers deliver timely and accurate regulatory submissions.



Manage regulatory events—Using industry best practices, easily manage submissions required to respond to internally-and externally-driven regulatory events across regulatory jurisdictions

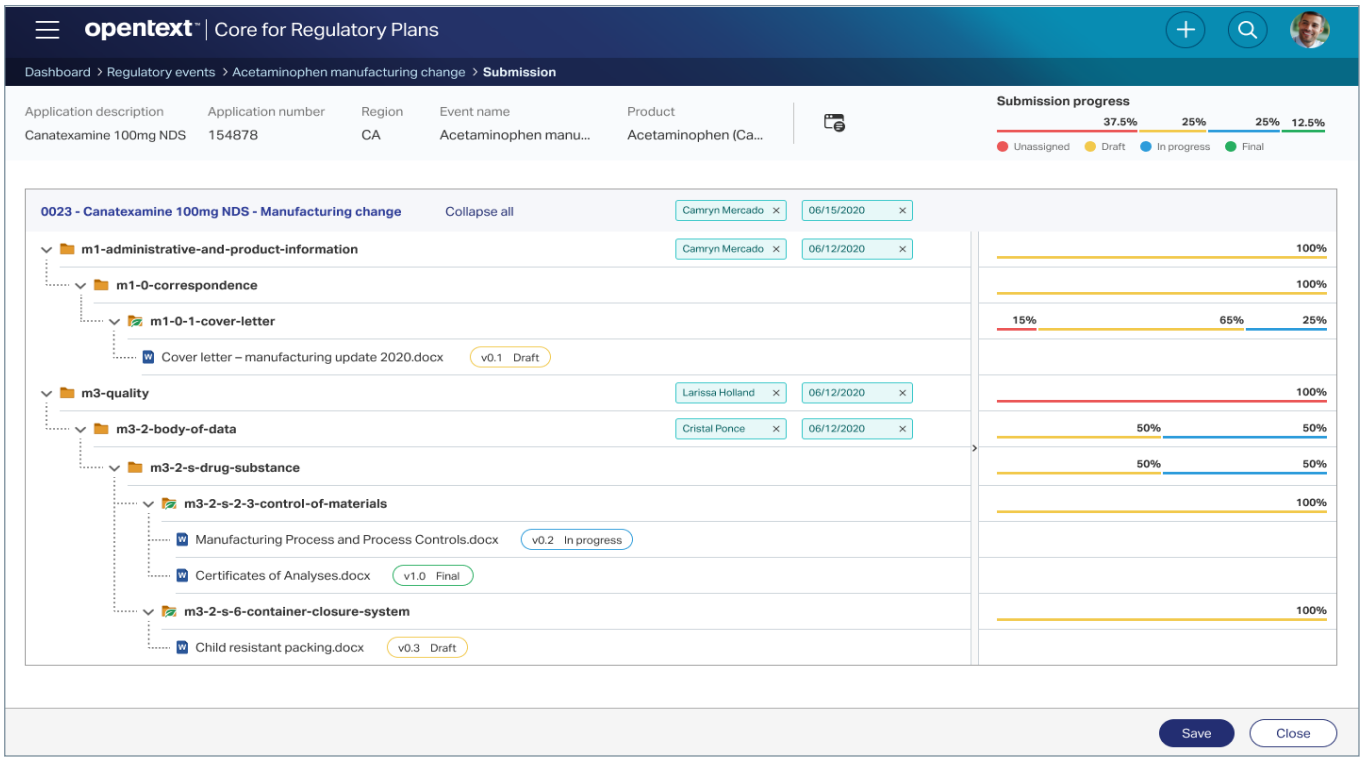
Faceted application search—Rapidly and accurately identify registrations and applications impacted by a regulatory event

Submission progress tracking—Stakeholders have detailed and real-time visibility into the status of submissions in development

Submission creation wizard—Quickly guides users through the submission creation process with intuitive user interface and automated document assignment

Master data management—Simplifies integration with OpenText Documentum for Life Sciences and third-party content management systems

SaaS delivery model—Turnkey onboarding and seamless upgrades minimize deployment risk with continuously delivery of new features and functionalities



Core for Regulatory Plans guides the user through creating new submissions with an intelligent wizard and displays submission progress.

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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