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White paper

# Breaking down information silos

## A shared, single source of regulated content in Life Sciences

Faced with declining blockbusters, rising generics and stringent regulations in the environment, Life Sciences companies must drive innovation that benefits patients, while controlling costs and optimizing operational efficiencies. Bringing safe, high-quality products to market faster at a lower cost requires unifying processes that extend across domains, divisions and external partners. This white paper explores how companies can achieve an information advantage to improve patient outcomes by removing silos to create a single authoritative source for regulated content across their organization and extended network.

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## Introduction

In Life Sciences today, patents are expiring, competition is intense, and organizations are compelled to continually speed time to market for new medicines. Organizational responses vary, but most are adopting new business models, expanding globally, entering into alliances and partnerships, outsourcing, aggressively pursuing acquisitions—or all of the above.

Life Sciences companies are executing on these initiatives against a backdrop of regulations and government reforms that are not only in a state of constant flux, but shift from one market to the next. At the same time, they must find ways to lower costs and maximize efficiency across the full drug lifecycle.

Meanwhile, these initiatives give rise to another set of challenges. Mergers and acquisitions often result in a myriad of disjointed systems, many running custom applications designed for specific departmental needs and typically set up with varying data models. Multiple systems seriously inhibit collaboration and the ability to harmonize and share data internally and with partners in key business processes. Fostering a culture of teamwork across individual domains becomes impossible. IT lacks the agility to respond quickly to changing business needs, while the cost of maintaining these disparate system landscapes takes a big bite out of limited IT budgets.

## Documentation: The common thread

In fact, bringing safe, high-quality products to market faster at a lower cost requires unifying processes that extend across domains, divisions, and external partners. Taking a drug or device from research and development (R&D) all the way to market requires assurance that the product is safe, effective, and developed and manufactured in accordance with GxP requirements. One of the greatest challenges is ensuring that documentation is complete, accurate, and carefully controlled in accordance with each phase of the drug's lifecycle.

Achieving this assurance requires the ability to link and seamlessly share documentation, from discovery and regulatory approval to commercial production. This ability is also an essential path to improving efficiency and worker productivity.

Unfortunately, many companies are still not meeting their goals for efficiency, cost control, and productivity. Despite a diverse range of tools and processes in place to help analyze, interpret and share information, what is typically missing is a coordinated effort across the enterprise, supported by an integrated content management system. There is no question that Life Sciences companies must become more strategic in how they manage regulated content across their organization and extended network. Yet IT managers are often hesitant to propose a more sophisticated approach to content management without a strong business case because of high investment costs, resource requirements, or a combination of both.

Fortunately, solutions are available that address all these issues—including the demands on IT resources—for large enterprises and mid-size companies alike. Often, best-in-class solutions enable companies that already have an enterprise content management solution in place to leverage their existing investments, while smaller firms with tight budgets can start with a single solution that addresses their most pressing needs, and then scale up. Integration of the various modules is the key.

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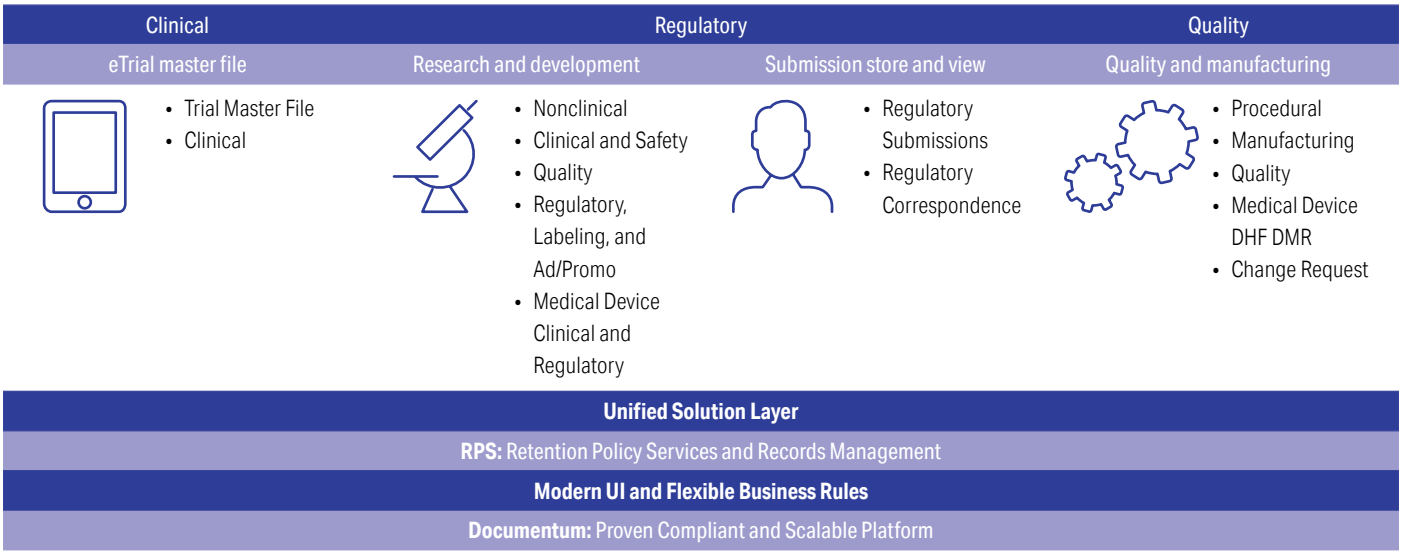
## Unified solution layer

To tackle their challenges, Life Sciences companies should look for a solution that provides a single authoritative source for regulated content across the extended enterprise. The benefit is a single source of content that eliminates the process breakdown in the handoff from one domain to another. From a technology standpoint, this "unified solution layer" is achieved by way of a shared enterprise information architecture with common, industry-standard inventory and data models. This enables IT teams to install multiple solution modules in a single repository; users can then perform cross-domain searches and linking, ensuring they are always accessing the most up-to-date and appropriate content.
To illustrate: instead of wasting time with multiple log-ins, searching and exporting documents from one application to another, users can log in once with a single account for a single view of the content they are authorized to access based on their role and permissions. This approach dramatically simplifies the user experience, and provides essential traceability back to source documents and proactive notifications to affected parties when the shared document is modified.




### Seamlessly linking content

The following are two examples of how this linkage between business domains actually works to help drive efficiency and reduce compliance risk.

**Between clinical and regulatory:** Currently, a number of documents are required for inclusion in both the electronic Trial Master File (eTMF) for audits and regulatory marketing applications for submissions: protocol, clinical study report, and informed consent forms, for example.

Most organizations export and import these documents from one system to another, resulting in version control and traceability issues, multiple copies, and manual processes that result in extra work. Some companies have developed custom integrations to share documents between the eTMF and R&D systems. But these are exactly the type of custom integrations that are so costly to maintain.

The unified solution layer, on the other hand, seamlessly links the approved, current version of the document in the clinical system, for example, directly to the R&D solution. This allows both clinical and regulatory stakeholders to access the same source document, eliminating version-control questions. And, if a change is made to the source document, all stakeholders can be proactively notified.

**Between regulatory and quality:** Similarly, scale-up and knowledge transfer activities mean many types of documents used in regulatory submissions must be transferred to the commercial production realm. Once transferred to production manufacturing, documents are subject to good manufacturing practices (GMP) requirements.

R&D and quality and manufacturing (Q&M) documents are often managed by different groups in different systems or repositories because they require different lifecycles, security, and controls. However, once documents are transferred from R&D to manufacturing, key stakeholders on either side typically lose visibility. This imposes a significant risk of non-compliance if resubmission is required but not communicated or performed. There is no automated traceability or notification when exporting and importing copies between solutions, which can lead to errors, out-of-sync documents, and compliance risk.

The unified solution layer enables the seamless transfer of content from the R&D to the commercial manufacturing domain:

- An authorized user transfers content from a source R&D document to a target Q&M document
- Metadata is exchanged and captured between the documents to maintain traceability
- A relationship is created to link the source and target documents
- Specified users and/or groups in both R&D and Q&M are notified of changes in state to either document

### Driving efficiency, productivity, and reduced cost

Unification is the operative principle. For IT, sharing common configurations for document lifecycles and workflow types, shortens development times; essentially, build once and apply consistently to multiple business areas. This minimizes testing effort, with a single validation rather than testing in each solution. That means fast deployment, and later, simplified updates and troubleshooting.

In addition, property registrations can be shared across solutions, ensuring the same values are used across the organization—such as drug name, dosage, and type (tablet, liquid, capsule)—to support data governance. Finally, unification of configurations eliminates compliance gaps across the solution modules to simplify adherence to corporate quality management policies.

Ease of deployment, reduced testing, simplified maintenance—it all adds up to reduced costs, less strain on IT resources, and increased responsiveness to the needs of the business.

### Simplifying and enhancing the user experience

While the benefits to IT are clear, so too are the benefits for the business user. Users today are sophisticated and tech-savvy, and they expect a modern, consumer-like experience in a professional environment that requires minimal training. By providing users with easy access to key applications, and with an interface tuned specifically for their role, the unified solution layer enables them to easily and intuitively accomplish their work. Whether it's authoring a clinical study report, searching for approved content to include in a submission, or reviewing a standard operating procedure—they can get it done, working on-site or via mobile devices while on the go. As drugs move throughout their lifecycle, business users can easily identify the approved versions of documents, trace back to source documentation when necessary, and collaborate across teams when regulatory or other changes require an impact analysis.

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## OpenText™ Documentum™ for Life Sciences

Documentum for Life Sciences breaks down information silos to transform how organizations access, manage, and share regulated content. Available on-premises or in the cloud, the solution is designed to offer you choice and flexibility with the ultimate goal of unifying and streamlining processes while reducing complexity.

The fully integrated suite of pre-configured solutions includes the following:

- OpenText™ Documentum™ for eTMF: Effectively plan, collect, track, and maintain essential GCP-compliant clinical trial documentation
- OpenText™ Documentum™ for Research and Development: Manage the creation, review, and approval of regulatory submission documentation
- OpenText™ Documentum™ Submission Store and View: Store and manage published submissions in a controlled environment together with related correspondence, while improving security and compliance
- OpenText™ Documentum™ for Quality and Manufacturing: Control quality and manufacturing documents, automate workflows, and ensure GMP compliance

For more than 25 years, OpenText has helped Life Sciences organizations meet compliance requirements, increase productivity, and securely collaborate across the extended enterprise. For additional information about Documentum for Life Sciences solutions, please visit www.opentext.com.

## 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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