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POSITION PAPER

Breaking down information silos

A shared, single source of regulated content for Life Sciences

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Introduction

The consistent march of patents reaching their expiration creates a backdrop of heightened competition in Life Sciences. Organizations are under constant pressure to accelerate the time-to-market for new medicines. While responses differ across entities, common trends involve adopting new business models, global expansion, forming alliances and partnerships, outsourcing, and pursuing acquisitions—sometimes employing a combination of these strategies.

Life Sciences companies are implementing these strategies amid a backdrop of ever-changing regulations, which also vary from one market to another. Simultaneously, they also face the challenge of reducing costs and enhancing efficiency throughout the entire drug lifecycle.

Meanwhile, mergers and acquisitions often result in a myriad of disjointed systems. Many are running custom applications designed for specific departmental needs and typically set up with varying data models. These can seriously inhibit the ability to harmonize and share data internally, as well as with partners in key business processes. Fostering a culture of teamwork across individual domains becomes impossible.

Stuck trying to maintain the balance, IT lacks the agility to respond quickly to changing business needs. The cost of maintaining these disparate systems takes a big bite out of limited IT budgets.

Documentation: The common thread

Bringing safe, high-quality products to market faster at a lower cost requires unifying processes that extend across domains, divisions, and external partnerships. Taking a drug or device from research and development all the way to market requires assurance that the product is safe, effective, and developed and manufactured in accordance with GxP requirements.

A significant challenge is ensuring that documentation remains comprehensive, accurate, and meticulously controlled at each stage of the drug's lifecycle. Documentation must be connected and seamlessly shared throughout the entire journey, encompassing discovery, regulatory approval, and commercial production. This ensures compliance and serves as a crucial avenue for enhancing efficiency and worker productivity.

Many companies are falling short of efficiency, cost control, and productivity objectives. Despite a diverse range of tools and processes to help analyze, interpret, and share information, what is frequently lacking 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 the organization and extended network. However, 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 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

Life Sciences companies should look for a solution that provides a single authoritative source for regulated content across the extended enterprise. A single source of content eliminates process breakdown in the handoff from one domain to another.

From a technology standpoint, this “unified solution layer” is achieved through 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.

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. Instead of wasting time with multiple logins, 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.

Information architecture with common, industry-standard inventory and date models			
Clinical	Regulatory	Regulatory	Quality
eTrial master file	Research and development	Submission store and view	Quality and manufacturing
• Trial Master File • Clinical	• Nonclinical • Clinical and Safety • Quality • Regulatory, Labeling, and Ad/Promo • Medical Device Clinical and Regulatory	• Regulatory Submissions • Regulatory Correspondence	• Procedural • Manufacturing • Quality • Medical Device DHF DMR • Change Request
Unified solution layer			
RPS: Retention Policy Services and Records Management			
Modern UI and flexible business rules			
Documentum: Proven compliant and scalable platform			

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Seamlessly linking content

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

Between clinical and regulatory:
Currently, a number of documents are required 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.

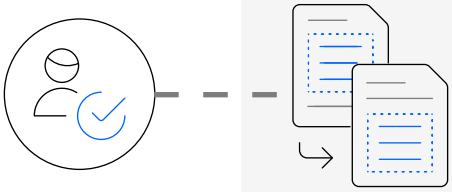
Most organizations export and import these documents from one system to another, resulting in version control and traceability issues, multiple copies, and manual processes that result in extra work. Some companies have developed custom integrations to share documents between the eTMF and R&D systems,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

A 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 staff to access the same source document, eliminating version-control questions. If a change is made to the source document, everyone involved 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.

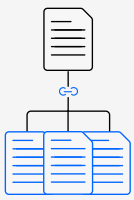
R&D and quality and manufacturing (Q&M) documents are often managed by different groups in different systems or repositories because they require different lifecycles, security, and controls. However, once documents are transferred from R&D to manufacturing, key participants on either side typically 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.

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

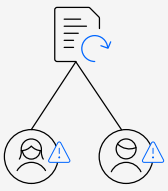


An authorized user transfers content from a source R&D document to a target Q&M document.

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.

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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, staff can 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.

Property registrations can also be shared across solutions, ensuring the same values—such as drug name, dosage, and type (tablet, liquid, capsule)—are used across the organization 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, and simplified maintenance all add 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, 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 a tablet 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 choice and flexibility with the goal of unifying and streamlining processes while reducing complexity.

The fully integrated suite of pre-configured solutions includes:

- **OpenText™ Documentum™ for eTMF:** Effectively manage essential GCP-compliant documentation to accelerate clinical trials.
- **OpenText™ Documentum™ for Research and Development:** Manage documentation to accelerate regulatory submission readiness.
- **OpenText™ Documentum™ Submission Store and View:** Efficiently access archived submissions with associated correspondence.
- **OpenText™ Documentum™ for Quality and Manufacturing:** Manage critical quality and manufacturing documents to 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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