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SPOTLIGHT

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An integrated document management strategy can ensure compliance, drive collaboration, and weave a digital thread of intelligence across the product life cycle.

How an Integrated Document Management Strategy Is Fueling Collaboration in Life Sciences

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Is Intelligent Document Management Transforming the Life Science Industry?

Data intelligence is driving the life science industry today — data is indeed the new gold. Data comes in many shapes and sizes — structured and unstructured data, big data and granular data, clinical trial data, and manufacturing data — and it exists in many different formats. It resides in multiple locations, including on premises, in the cloud, in databases, and in documents, literally everywhere.

To be a market leader, organizations need real-time, controlled, and secure access to data and content to drive critical business decisions. Robust enterprise document management systems (DMSs) that orchestrate the distribution of that content across its life cycle, from its capture through its archival, are essential so that an organization can use its content effectively, which is otherwise usually sitting around in silos, lost somewhere within the organization. Compliance is also critical for the life science industry. The ability to provide the necessary documentation during an FDA inspection can make all the difference between passing or failing an inspection.

The availability of a robust, centralized cloud-based document management platform can serve as a game changer for organizations in a world grappling with:

- An accelerated state of disruption
- Organizational restructuring

AT A GLANCE

KEY STATS

According to IDC's June 2023 *State of Content Services Survey*:

- 54% of the life science industry has experienced or expects to experience increased visibility, auditability, and accountability, and 46% of the industry has experienced or expects to experience improved business decision-making by adopting enterprise content management systems or content sharing and collaboration applications.
- 78% of the life science industry plans to seek solutions that incorporate generative AI for content-centric workflows and use cases in the next 12 months.

KEY TAKEAWAY

The life science industry has been battling to scale global operations, and accelerate time to market, in a sector that is led by innovation and disciplined by regulatory compliance. Timely and controlled access to content is everything, and an enterprisewide integrated content strategy and intelligent document management systems can shape the future of the industry.

- Frequent mergers and acquisitions (M&A), with biotechs establishing licensing partnerships
- Pressure on pharma to be more competitive

Such a platform is a "must-have" to establish governance, streamline document and data workflows, and ensure timely access to content as needed.

Definitions

- **Good documentation practices (GDPs):** This is a term in the pharmaceutical and medical device industries to describe standards by which documents are created and maintained.
- **21 CFR Part 11:** 21 CFR Part 11 is a set of regulations from the FDA that outlines the current good manufacturing practice (cGMP) requirements that govern electronic records and electronic signatures.

Articulating the Value of Intelligent Document Management Systems

Intelligent DMSs offer a multitude of benefits to the life science industry, including:

- **Regulatory compliance:** According to IDC's June 2023 *State of Content Services Survey,* about 40% of the life science industry considered the top driver for component content management system adoption to be increased regulatory compliance. Other drivers of note include higher content reuse, reduced duplication, and centralizing content creation, management, and delivery. The life science industry is highly regulated; hence compliance is top of mind. 21 CFR Part 11 mandates that manufacturers must establish and maintain procedures to control all documents that are required by this set of regulations. Thus the lack of adequate documentation can be a cause for failing an FDA inspection. Poor recordkeeping and the failure to retain records for the required duration frequently result in Form 483s and warning letters from the FDA. The inability to ensure good documentation practices has frequently resulted in the shutdown of manufacturing plants. This impacts not only revenue but also the brand equity of an organization. Detailed analysis of current good manufacturing practices warning letters issued by the FDA from 2010 to 2020 reveal three major types of violations: deficiencies in process validation (26%), documentation practices or data integrity (21%), and quality control (15%).
- **Mergers and acquisitions:** EY has reported that there were 118 completed deals in 2023, with 69% of M&A investment coming from big pharma, compared with just 38% in 2022. EY has forecast that M&As will continue to grow in 2024. M&As are complex, with many moving parts. Having a robust DMS in place can help in driving a successful integration, since information plays a critical role in due diligence, valuation, and integration. Access to critical information can help maximize the deal value.
- **Migration to the cloud:** Declining drug pipelines and expiring patents have put enormous pressure on the life science industry to do more with less. While the cloud offers many benefits, the life science industry has been a slow mover owing to concerns around data security and integrity, though this is now changing. According to IDC's May 2023 *Life Sciences Digital Transformation Survey,* 90% of life science organizations rank the cloud as the top technology enabling their digital transformation efforts and two-thirds consider it to be important to very important for driving the success of their clinical trial strategy. The survey also indicated that half of the life science industry, including 67% of biotechs and 71% of contract research organizations (CROs), considered the intelligent supply chain to be a primary use case for focusing their digital transformation efforts.

Despite life sciences being a tightly regulated industry, IDC's survey found that over half of the sector is deploying up to 25% of its workloads on the hybrid cloud, which unifies public cloud, private cloud, and on-premises infrastructure to create a single, flexible, cost optimal IT infrastructure. With the focus on hybrid cloud in the life science industry growing quickly, it is evident that data is going to be moved around very rapidly. Cloud-based enterprise content management (ECM) systems can reduce IT overheads, address concerns around data security, and enable secure data sharing. There's a whole new level of compliance that organizations need to think about as they move their documents to the cloud. Intelligent ECM systems can make all the difference.

- **Workforce collaboration:** As a result of the COVID-19 pandemic, the industry underwent disruption. Patients and employees both went remote, and decentralized trials became the new norm. This created a burning urgency for the implementation of intelligent content management systems that could simplify content workflows, improve traceability, and increase accessibility to critical business documents from anywhere and at any time. Even with the receding of the pandemic, there is still a need for these systems because the new mode of operating is hybrid, whether one speaks about decentralized clinical trials, regulatory affairs, or distributed manufacturing. Pharmas are increasingly expanding their global footprint. Intelligent DMSs are key to enabling collaboration between a global workforce.
- **Reduction in the duplication of content in the life science industry:** According to IDC's June 2023 *State of Content Services Survey,* 59% of the life science industry believes that up to 75% of content is unnecessarily replicated. This results in undue complexity as different people may be working on updating duplicate copies of a document at different locations. Efficient use of a DMS can eliminate duplicate copies, improving traceability, quality, and compliance.

Considerations

- Generative AI (GenAI) is playing a very important role in knowledge management. According to IDC's November 2023 *Life Sciences Generative AI Survey,* 41% of the life science industry considers knowledge management as the most promising GenAI use case. Its applications in content management are diverse, ranging from legal, contract management, and procurement to marketing. In fact, the survey found that 43% of respondents believe that in the next 18 months, marketing/public relations will be the third most impacted area by GenAI, following product development/design and software development/design. Other applications include the generation of intelligent patient summaries, responses to health authority queries, supporting regulatory submissions, and developing standard operating procedures. Embedding AI to generate manufacturing documentation can help avoid a lot of inspection findings. However, data security and privacy, as well as intellectual property, are top of mind for the life science industry. Care should be taken to implement the necessary guardrails to ensure compliance and patient safety.
- It is important to establish a defined document management strategy and ensure that it aligns with business processes. Failure to do so could impact business outcomes negatively rather than drive business efficiencies. Pharmas and biotechs should select experienced document management partners that bring to the table not only the technology but also the expertise in implementing the right document management strategy.
- "You can lead a horse to the water, but you can't make it drink" is an old adage. People are mired in their old ways of operating. Manual, paper-led processes have been the norm for years, and it is not easy to drive change. Care

should be taken to ensure that there's careful messaging and training to drive enterprisewide engagement and buy-in for using a modern, intelligent DMS.

- Real-time access to content is critical to the success of the life science industry. While the industry is moving toward leveraging cloud-based DMSs, it is important to ensure data security and integrity, address data sovereignty concerns, and tag data assets appropriately to ensure quick access.

Industry Challenges

Life science companies face the following market challenges and opportunities, many of which can be addressed by innovations provided by document management vendors:

- The life science industry is in a state of accelerated transformation — and not just from a technology perspective. Operating models are also evolving across the life science value chain, ranging from decentralized clinical trials to intelligent supply chains to address the needs for the manufacture of cell and gene therapies. Life science companies need to carefully examine what transformation journey stage they are in before selecting a solution.
- GenAI solutions could serve as game changers for the life science industry. However, AI is only as good as the data it possesses. The quality and diversity of data sources vary across organizations and even within an organization. Thorough due diligence is needed when implementing solutions, including the choice of using public or private large language models (LLMs). All plausible scenarios need to be evaluated and necessary guardrails need to be put in place to monitor for model decay, bias creep, and other challenges.

Considering OpenText

OpenText is positioned to enable life science organizations to navigate the intricate complexities of the document-intensive life science industry. Established over three decades ago, OpenText offers an integrated cloud-based information management platform. In addition to modular solutions that span the life science value chain, from R&D to electronic trial master files (eTMFs) to manufacturing, its solutions help instill compliance into the DNA of the life science industry. It plays a crucial role in managing the information life cycle while integrating with other key enterprise applications, bringing all the information within an organization under a centralized span of control.

OpenText Content Aviator, which now seamlessly integrates with OpenText Documentum, leverages GenAI for conversational search, discovery, summarization, and translation to help the life science industry transform the way it interacts with and gains value from enterprise content.

Challenges and Opportunities

- OpenText needs to approach big pharma differently from the way in which it would approach innovative, fast-moving biotechs. While big pharma has well-established DMSs, young biotechs often lack well-established DMSs and are still evolving their standard operating procedures.

Conclusion

Life sciences has become a data-centric industry. Intelligence is the DNA driving growth of pharmas and biotechs. IDC believes that ECM systems are the backbone on which these organizations will thrive. ECM systems help the industry scale innovation, accelerate time to market, drive global collaboration, and ensure compliance with rapidly evolving global regulations in a turbulent geopolitical environment. To the extent that OpenText can address the challenges described in this paper, IDC believes the company has an opportunity to pave the way for the life science industry to move beyond disconnected legacy systems and siloed data sets to architecting agile, connected, compliant, and mature organizations.

Intelligent content management systems will play a critical role in helping the life science industry navigate a complex diaspora of siloed and exploding content and will help build intelligent, compliant, and learning organizations.

About the Analyst

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MESSAGE FROM THE SPONSOR

Build a Better-Connected Drug Development Value Chain with Smarter Document Management

Proper document management is critical for life sciences companies to avoid regulatory non-compliance fines, delayed product launches, and product recalls. A robust document lifecycle management system can significantly improve efficiency, boost compliance, and contribute to faster drug and device development by:

- Integrating content management and business processes to break down information silos
- Effectively controlling and governing business-critical documentation according to regulatory guidelines
- Optimizing document access and collaboration across an extended workforce, including contract research organizations (CROs), contract manufacturing organizations (CMOs), authorized partners, and health authorities

How can OpenText help? Check out our collection of life sciences blogs to learn more.

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