DOCUMENT MANAGEMENT STRATEGIES FOR R&D INNOVATION

Lessons from Implementing an Enterprise Electronic Document Management System

USE CASE

THE CUSTOMER: A DYNAMIC BIOPHARMA WITH A GLOBAL RESEARCH NETWORK

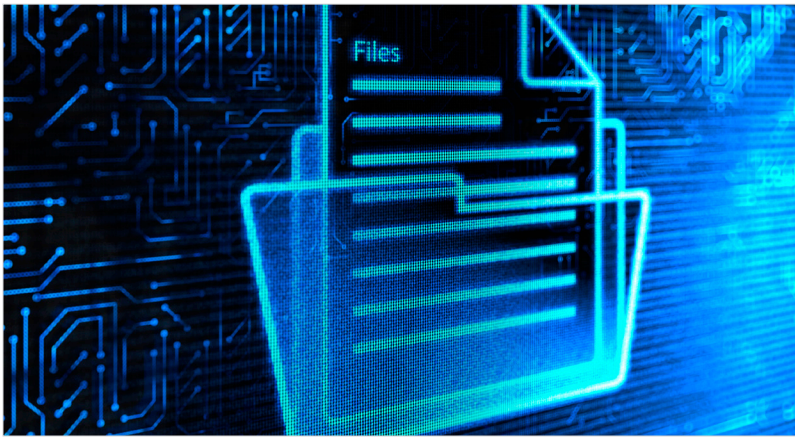
This major biopharmaceutical industry customer of BIOVIA offers a diverse portfolio covering a range of debilitating disease areas including hepatology, oncology, rheumatoid arthritis, pain management, spinal cord injuries and influenza. With several thousand employees and many collaborative partners around the world, they manage every aspect of product development, from early discovery through commercialization. This case study shows how the R&D group of this company benefited from a comprehensive, commercially available document management solution, Dassault Systèmes DocCompliance.

R&D SOFTWARE CHALLENGES

In the past, this company's technology landscape included a legacy Enterprise Resource Planning system and a Dassault Systèmes DocCompliance implementation for Quality Management. The system provided an internal platform for communicating and collaborating on critical documents such as standard operating procedures and work instructions.

Their R&D organization wanted to leverage the benefits of a similar document management solution to improve the efficiency of regulatory submissions, protect intellectual property (IP) and accelerate time to market along the drug development value chain. Protecting IP is a critical initiative in the biotechnology sector. As the associate director at this company stated, "Our IP is what makes us what we are. If this content is not managed in a controlled environment, it does not only increase inefficiency but also risk of loss."

After an unsuccessful start and stop with one system, the company's R&D and IT groups collaborated in a robust search process covering numerous systems including the Dassault Systèmes DocCompliance which had already been implemented in Quality Management. In the end, for a variety of cost, complexity reduction and functional reasons, the team decided to extend the Dassault Systèmes DocCompliance from Quality into R&D.



> "Once the system was implemented, **it never failed us**"
>
> Biopharma Associate Director

IMPLEMENTING DOCUMENT MANAGEMENT IN R&D

According to the associate director at the company, "We went live with Dassault Systèmes DocCompliance to automate internal creation, review and approval of the group's regulatory and quality documents." He also noted, "Once the system was implemented, it never failed us," which is especially impressive since the R&D group has decided to position itself as an early adopter of new capabilities and functionality over time. The group has even gone so far as to join BIOVIA's steering committee, staying on the newest software version and volunteering to be a beta customer for many pieces of new functionality not yet released to the larger customer base.

This early adopter approach has proven to fit the culture of the R&D group well, allowing scientists to proactively innovate while providing a number of additional benefits. Since the first go-live,

Challenges:

- Inefficient processes slowing time to market
- Disjointed data flow across external partnerships
- Worries about securing IP

Solution:

Dassault Systèmes DocCompliance

Benefits:

- **Increased Efficiency**: Streamline quality tasks by standardizing procedures
- **Reduced Risk**: Improve regulatory compliance by managing all documents in a controlled environment
- **Improved Collaboration**: Easily share quality documentation with internal colleagues and external partners

the company has added many new capabilities. These include an enhanced search tool for documents, eliminating the need for scientists to have an in-depth understanding of document types as well as reducing training requirements for new employees. They also leveraged the ability to streamline the process for large-scale approval of document packages using metadata and nested documents.

The early adopter approach entailed some challenges but as the associate director explained, "A key component to our strategy has been to manage the internal reputation of the system." Working as a beta customer allowed the company to work collaboratively with BIOVIA to address roadmap requirements, actively manage scientists' perceptions of the system and react quickly to challenges as they arose. This was especially beneficial for managing the impacts of new functionality on other groups in the company like Quality Management.

DELIVERING BUSINESS VALUE AND NEXT STEPS

Since the original Quality Management implementation and subsequent expansion into R&D, the company has gained business value in a number of areas, including:

- **Increasing efficiency**: The company now has the ability to do more with less within its Quality Management and R&D groups, ultimately supporting the potential delivery of new drugs to market as quickly as possible.
- **Reducing risk**: Eliminating paper and managing documents electronically has reduced the risk of IP loss and/or regulatory action by managing all regulatory content in a controlled environment.
- **Enabling communication and collaboration**: The solution is improving the company's competitive advantage in a fully commercial biopharmaceutical environment that leverages internal and external collaboration while remaining lean internally.

Subsequent deployment of a web-based EDMS solution has further improved the company's ability to securely collaborate when working on controlled regulatory and GxP documents with external partners, extending the efficiencies and compliance benefits of the new document management system beyond the company's walls.

KEY TAKEAWAYS

For companies competing in highly regulated markets, the ability to improve efficiency while remaining compliant can be a major differentiator. With today's powerful software solutions, it is becoming increasingly viable ***and*** beneficial to deploy a document management solution that builds compliance into processes. This company's R&D group has followed this strategy and taken it a step further by deploying a solution that extends to external partners. The company's key takeaways are:

- For R&D organizations in life sciences, a document management system accelerates time to market, protects critical IP, reduces regulatory risk and improves collaboration with partners.
- An organization with a strong "innovation" culture can better focus on its core competencies by leveraging commercial-off-the-shelf, purpose-built software and developing a deep, strategic relationship with the software vendor.
- Life sciences companies that have already deployed a document management system in their quality group should consider extending the same solution to other groups like R&D or regulatory affairs to create a shared, inter-disciplinary, end-to-end innovation environment.

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Dassault Systèmes Corporate
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

BIOVIA Corporate Americas
BIOVIA
5005 Wateridge Vista Drive,
San Diego, CA
92121
USA

BIOVIA Corporate Europe
BIOVIA
334 Cambridge Science Park,
Cambridge CB4 0WN
England