Case Study

Vertex Pharmaceuticals: Document Management Strategies for R&D

Based out of South Boston, MA, with additional research programs in the UK and Canada, Vertex Pharmaceuticals has spent the past 25 years working to improve the lives of patients with serious diseases. With nearly 1,800 employees, its focus is on discovering, developing, manufacturing, and commercializing small molecule drugs. Since its inception, Vertex has made significant advancements in the treatment of hepatitis C, cystic fibrosis, and rheumatoid arthritis, as well as a variety of other life-threatening diseases.

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Vertex's growth and success has been driven by a unique corporate culture that highly values innovation as well as internal technical expertise in software development. Although this approach has done wonders in the areas of drug discovery and overall success of the firm, it has also laid the foundation for challenges when it comes to technology adoption and enterprise application deployments. This case study zeroes in on how Vertex's R&D group specifically overcame those challenges by adopting a comprehensive document management solution.

R&D Software Challenges

In 2006, Vertex was a company with a complex technology landscape, including an ongoing ERP software implementation and a new document management solution implementation for the Quality Management department. The document management solution implementation helped to create an internal platform for communicating and collaborating on critical documents such as standard operating procedures and work instructions.

In 2008, the R&D organization began a search for its own document management solution. This search was prompted by a number of reasons. Fundamentally, time to market is a key metric for success of any R&D organization and inefficient processes regarding document management and regulatory submissions were identified as a risk factor in the critical path for drugs moving from innovation through commercialization. Additionally, for companies like Vertex and others in the biotechnology industry, intellectual property is often the very essence of an organization.

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After an unsuccessful start and stop with one system, the business and IT groups began working together and launched a robust search process that included evaluating the current document management system already implemented in the Quality Management department along with other entirely new systems. In the end, for a variety of cost, complexity reduction, and functional reasons, the same system was chosen for R&D that was already implemented in the quality organization.

Implementing Document Management in R&D

According to Wickert, “In 2009, we went live with BIOVIA QUMAS EDMS to automate internal creation, review, and approval of the group’s regulatory and quality documents.” He said, “Once implemented, the system has never failed us,” which is an especially impressive claim given the fact that 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 the vendor’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.

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This early adopter approach has proven to fit the culture of the R&D group well, allowing it to quench its thirst for innovation while providing a number of additional benefits. Since the first go-live, Vertex has implemented many new capabilities. These include a noteworthy new user interface that improved the search process for documents and removed the need for users to have an in-depth understanding of document types as well as a new user interface that has reduced training requirements for new employees. It also provided the ability to streamline the processes for large-scale approval of document packages through metadata and nested documents.

There have of course been challenges with the system as well, many of them stemming from the early adopter approach. As Wickert explained, “A key component to our strategy has been to manage the internal reputation of the system.” Because Vertex deploys functionality as a beta customer it discovers more bugs then other customers would. Although this allows the organization to work more collaboratively with the vendor to drive the roadmap and address its requirements, it also needs to actively manage users’ perception of the system and react quickly to any challenges users experience. This is especially true for managing the impacts of new functionality on other groups in the company like quality.

Delivering Business Value and Next Steps

Since the original implementation in 2009, Vertex has gained business value in a number of different areas, including:

- **Increasing efficiency:** The organization now has the ability to effectively do more with less within the R&D group because of increased efficiency, ultimately supporting the potential delivery of new drugs to market as quickly as possible.
- **Reducing risk:** The solutions streamlined capabilities create a reduction in risk of IP loss or regulatory action by ensuring all R&D regulatory content is managed within a controlled environment.
- **Enabling communication and collaboration:** The solution has increasingly created a foundation for competitive advantage, helping Vertex move towards a fully commercial pharmaceutical environment that uses collaborative and outsourced relationships while remaining lean internally.

  Recently, the biotechnology company has deployed an upgraded version of this technology, a new web-based solution for securely exchanging and collaborating on controlled regulatory and GxP documents with the external partner network. This new solution easily extends the efficiencies and compliance benefits of Vertex's document management system outside of its four walls.

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Key Takeaways

For companies such as Vertex that are competing in highly regulated markets, the ability to improve efficiency while remaining compliant can be a differentiator. With the powerful capabilities found in today's software solutions, it is becoming increasingly more beneficial to deploy a document management solution that builds compliance into processes. Vertex's R&D group has followed this strategy, only taking it a step further by deploying a solution that can extend to external partners. These benefits as well as others are summarized in several key takeaways below:

- For R&D organizations in life sciences, a document management system can offer significant business benefits, including increased time of drugs to market, reduced risk of IP loss, reduced risk of regulatory action, and improved ability to collaborate with partners.
- Implementing homegrown systems can be challenging in a highly regulated environment. Rather than taking on this challenge alone, if your company has an innovative culture it may be better to leverage purpose-built software and develop a deep and strategic relationship with the vendor.

When this approach is taken it is important to have a strong working relationship between internal IT and line of business organizations.

- Many life sciences companies today have already deployed similar document management systems in the quality group. Although it is important to conduct a thorough and robust search when other groups like R&D or regulatory affairs are looking to deploy their own systems, it is important to consider the benefits of using the system already implemented in terms of ease of burden on internal IT resources and usability across internal business groups.

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