Expert's Opinion The Rise of Virtual Models to Speed Development

By Mike Jovanis, VP of Vault Quality, Veeva Systems | November 10, 2016

The need to create specialty drugs to treat complex diseases is driving greater pressure among life sciences companies to develop more treatments and medicines faster. As a result, more life sciences companies are outsourcing many of their core business processes.

Over the past few years, this has given way to increasing popularity of virtual pharmaceutical models, where companies rely extensively on external capabilities, especially for manufacturing. In fact, virtual companies have become a major presence in the industry, developing many of the new drugs in the pipeline. These organizations are developing more treatments with minimal fixed assets and staff, which keep operational costs low and enable them to move with greater speed from development through commercialization.

Karyopharm Therapeutics, for instance, relies on the virtual manufacturing model and partners with a sizable team of contract manufacturing organizations (CMOs). It focuses on the discovery, development, and subsequent commercialization of novel first-in-class drugs for nuclear transport and related targets for the treatment of cancer and other major diseases. While Karyopharm has thrived with a purposefully limited staff and more than a dozen partners since its founding eight years ago, it experienced challengesto maintain singular, authoritative oversight of all the different documents exchanged with CMOs.

Without continuous and transparent content management, sponsor companies may not be aware of issues until near the end of the manufacturing process – potentially increasing the negative impact. Reviewing information earlier means issues can be detected sooner in the process, mitigating risks and enabling companies to be more proactive. Sponsors typically send large quantities of documentation and detailed information between them and their CMOs to maintain control, often via non-secure document sharing. This can cause versioning confusion and makes it difficult for sponsors to establish a reliable audit trail, all of which introduces compliance and product quality risks plus impacts process efficiency.

To overcome these challenges, and to create a single, always up-to-date source of information with detailed audit trail that both its internal team and contract partners can rely upon, Karyopharm adopted a cloud-based quality solution. The company recently shared its story at the 2016 Veeva R&D Summit in Philadelphia.

“We used to work across five or more different channels to share documents with our CMOs, making it difficult to find information, maintain visibility on the status of processes, and determine which exchanged documents were the most current. In addition, it was crucial for our organization to ensure a clear chain-of-custody not only for compliance purposes, but also to help assure data integrity,” explained Craig Gassman, associate director of regulatory operations at Karyopharm. “Collaboration and access among global stakeholders are critical to compliance and in driving operational alignment.

Almost immediately upon implementation, Karyopharm provided Canada-based CMO, Piramal Healthcare, with access to its quality system.Karyopharm first began working with Piramal in 2011, contracting with the company for preclinical services and sample preparation through toxicology, as well as Phase I material supply. The company also provides Phase III and commercial support. According to Piramal, intensifying regulatory requirements for oversight of partners brought additional challenges.

“Sponsors assume additional regulatory demands because they must take full responsibility for the work being done at CMO facilities. This has led to an increase in the exchange of information. Karyopharm is no exception,” explained Leslie Aucoin, program manager at Piramal. “With Karyopharm’s new cloud solution, we can stay fully aligned on projects at all times and have information at our collective fingertips for regulatory needs and project planning. Best of all, Karyopharm won’t have to come back to us years later to request documents.”

According to Karyopharm, the cloud has significantly improved its ability to work efficiently with external partners and enabled the organization to successfully implement a virtual model. Some of the cited benefits include:

· **Quality Control** – with a single source of information, Karyopharm no longer must do time-consuming manual checks to ensure the CMO is following guidelines and testing to the right levels.

· **Increased Visibility** – the cloud enables approved vendors to view documents at all times, ensuring that both Karyopharm and its partners are in sync.

· **Time Savings** – in the past, Karyopharm estimates it may have spent 20 minutes to hunt for one document. Now it takes less than two. "We don't have to retrace our steps – or a ghost's steps, if a staff person leaves – to find documents," added Gassman. In addition, Karyopharm's new solution has sped regulatory filing. With the cloud, all relevant documents and related information are easily found and linked directly into submissions.

· **Improved Compliance** – Karyopharm now has a clear chain of custody so it can see who reviewed and accepted information to support the batch release process. It's proof for authorities that all issues have been resolved before release.

Overall for Karyopharm, the most substantial advantage of moving to the cloud has been more streamlined collaboration with its partners, roughly estimated to result in a 30% increase in operational efficiency.

"Modern cloud technology enables our organization to seamlessly incorporate vital manufacturing partners into our quality processes, and link processes to relevant documentation for improved compliance," said Maria Conklin, quality control manager at Karyopharm. "If we investigate a nonconformance, for instance, we can now just link the testing reports to the change control document and close out the investigation confidently. We have a complete package to demonstrate to regulatory authorities that nothing was skipped and that the situation was resolved. And all of this is accomplished faster and more efficiently we ever could in the past."

Mike Jovanis is vice president of the Vault Quality Suite of products responsible for product strategy, custom and business development. He has more than 15 years of experience in life sciences, developing and design solutions for organizations. Before Veeva, Jovanis served as vice president of product management and strat Systems. While at Sparta, he was instrumental in the company's growth, driving product, vertical market stra strategic partner alliances. Jovanis received his bachelor's degree in marketing from Rutgers Business Scho in Strategy and Global Business from Rutgers Graduate School of Management.

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