



Virtual manufacturing models and the power of the cloud

How a cloud-based quality solution is transforming relationships with CMOs for Karyopharm Therapeutics

With ever-increasing pressure among life science companies to develop treatments and medicines faster, more and more are outsourcing many of their core business processes. During the past few years, this has given way to the growing popularity of virtual pharmaceutical models wherein companies rely extensively on external capabilities, especially for manufacturing.

In fact, virtual companies have become a major presence in the industry, developing more of the new drugs in the pipeline than many former blockbuster drug companies.¹

These organisations 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 to commercialisation.

Karyopharm Therapeutics, for instance, relies on the virtual manufacturing model and partners with a sizable team of contract manufacturing organisations (CMOs). It focuses on the discovery, development and subsequent commercialisation of novel first-in-class drugs for nuclear transport and related targets for the treatment of cancer and other major diseases.

Although Karyopharm has thrived with a purposefully limited staff and more than a dozen partners since its founding 8 years ago, it experienced challenges to 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, as well as impacting process efficiency.

To overcome these challenges, and to create a single, always up-to-date source of truth with a 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 Veeva R&D Summit in Philadelphia (PA, USA).

Compliance and data integrity

Craig Gassman, Associate Director of Regulatory Operations at Karyopharm, explained: “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 organisation to ensure a clear chain-of-custody — not only for compliance purposes, but also to help ensure data integrity. Collaboration and access among global stakeholders is critical to compliance and driving operational alignment,” he added.

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 clinical trial material supply. The company also provides Phase III and commercial support. According to Piramal, intensifying regulatory requirements regarding the 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, Programme Manager at Piramal.

“Thanks to Karyopharm’s new cloud solution, we can stay fully aligned on projects at all times

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Virtual companies have become a major presence in the pharmaceutical industry

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-based solution has significantly improved its ability to work efficiently with external partners and enabled the organisation to successfully implement a virtual model. Some of the benefits include the following:

Quality control: With a single source of truth, Karyopharm no longer needs to 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 member leaves — to find documents," added Gassman. In addition, Karyopharm's new solution has accelerated regulatory filing. With the cloud, all relevant documents and related information are easily found and linked directly into submissions.

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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.

Conclusion

For Karyopharm, the most substantial advantage of moving to the cloud has been more streamlined collaboration with its partners, resulting in a 30% increase in operational efficiency. "Modern cloud technology enables our organisation 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 non-conformance, for instance, we can now just link the testing reports to the change control document and confidently close out the investigation. 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 than we ever could in the past," she adds.

REFERENCE

1. A. Shanley, "New Business Models Attract Virtual Pharma," *Pharmaceutical Technology*, www.pharmtech.com/new-business-models-attract-virtual-pharma (2016).