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How Oxford Biomedica Streamlined Viral Vector Development and Manufacturing with LabVantage

Oxford Biomedica

Oxford Biomedica, headquartered in the United Kingdom, is a Contract Development and Manufacturing Organization (CDMO) that specializes in lentiviral, adeno-associated viral (AAV), and adenoviral vectors. With demand for cell and gene therapies growing, and viral vectors being pivotal delivery tools for these potentially life-saving treatments, the company recognized the need for a Laboratory Information Management System (LIMS) to enhance its operational efficiency.

"Until now, we have managed all of our data using paper, which is both cumbersome and requires significant resources to both maintain and mine for information," says David Park, Senior QC Specialist at Oxford Biomedica. "As we scale to take on more projects, having a LIMS will be fundamental to help streamline our processes."

The QC team began investigating available options in 2021 and quickly identified LabVantage as its preferred partner, signing a contract in October 2021 for implementation at its 96,000-square-foot US-based cell and gene therapy manufacturing facility. Oxford Biomedica began a Software-as-a-Service (SaaS) implementation of LabVantage Pharmaceutical LIMS, which is pre-configured and pre-validated for biopharmaceutical workflows, in early 2022. The LIMS platform includes a Scientific Data Management System (SDMS) for Instrument Integrations, with end users reporting a highly positive experience. It is anticipated that the system will go live by the end of Q2 2024.

Reasons for automating with LIMS

Several key factors led Oxford Biomedica to consider implementing a LIMS, not least the need to **simplify sample storage and tracking**. With viral vector capabilities spanning everything from laboratory concept

through to clinical-grade manufacturing or commercial production, the company routinely handles high numbers of samples that demanded automation.

"Besides unprocessed material, intermediate samples, drug substance, and drug product, we generate samples for analyses including stability testing, batch testing, and environmental monitoring," explains David. "All of these must be assigned a name and status, as well as be linked with relevant metadata. When you have just one product, sample handling is relatively easy to manage, but when you have multiple products, things can get more complicated. Add to that the fact that we often get *ad hoc* samples coming in, and the chain of custody can become quite overwhelming."

Another reason for implementing a LIMS was to **make running metrics easier**. Within the viral vector development and manufacturing industry, metrics are essential to safeguard product quality and guide continuous process improvement. Depending on the parameters that are measured, it is possible to perform batch-to-batch comparisons, monitor turnaround times, and identify potential bottlenecks, as well as confirm that assays are working as expected.

"With a paper-based system, running metrics to compare, for example, viral titers from batch-to-batch could take someone a whole week using Smartsheets and Excel system tools," says David. "In contrast, automating the process with a LIMS promises a greater breadth of information within a much shorter timeframe, for a more accurate, up-to-date picture."

Further support for a LIMS came from Oxford Biomedica's personnel, many of whom had a **pro-LIMS mentality** due to having previously worked in companies using such systems. These factors, in combination with a noted push from the US Food and Drug Administration (FDA) encouraging LIMS adoption for better traceability of samples and data integrity, led Oxford Biomedica to initiate the search for a suitable partner.

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>
> — David Park

Critical LIMS capabilities

To streamline the identification of a compatible LIMS partner, the QC team established a list of requirements and capabilities for their chosen platform. These included the following:

- **Sample management** – including a built-in labeling system, as well as the capacity to automatically assign each sample a name and status, and link to relevant metadata in a standardized fashion to increase reproducibility and decrease re-experimentation
- **Consumables management** – tracking and monitoring consumables and reagents inventory and use, encompassing details such as product codes, lot numbers, and expiration dates, to reduce waste and overspending
- **Instrument integration** – LIMS interface with the Scientific Data Management System (SDMS), to reduce one-off integrations for instrument proprietary APIs and various data formats
- **Data capture** – sample tracking from initial status through to test completion, that allows for running metrics as well as ensuring data integrity and a view of data from instruments, test results, analytics, R&D initiatives – all within the LIMS environment
- **CofA generation** – automated generation of Certificates of Analysis for all analyses performed in the LIMS
- **Chain of custody** – robust recording of sample activity – handling, analyses done, results, location, etc. – to simplify running metrics and perform audits
- **Built-in audit system** – with SDMS embedded in the LIMS, essential issues like audit trails, notifications, and logs are seamlessly addressed within the integrated platform; every entry or change to any part of the application is tracked and verifiable
- **Incubation component** – reusable functionality that is easily installed and deployed based on client need
- **Regular software updates** – in selecting a SaaS version of LabVantage Pharma LIMS, Oxford Biomedica reduced its initial capital outlay, paying an annual subscription fee that transfers responsibility for managing and hosting the LIMS environment to LabVantage, including delivering regular, pre-validated updates
- **Consumables management** – tracking and monitoring consumables inventory and use reduces waste and overspending
- **Pre-validation** – the software as delivered includes pre-validation with IQ, OQ, PQ, and executed Test Scripts
- **Professional services** – ongoing support throughout the requirements-setting and implementation phase, and post-sale
- **Scientific domain expertise** – LIMS provider knowledge and understanding of the biopharmaceutical QC environment and activities, and application of that expertise in the LIMS

Why LabVantage?

One of the main reasons that Oxford Biomedica chose to partner with LabVantage was its ability to accelerate the implementation of the LIMS. "When looking at the range of options available to us, we found that other potential partners were very configuration-heavy," reports David. "Few, if any, offered an **out-of-the-box system** with everything included like a pre-validated package. Being a relatively small company, with a lean validation team, it was important for us to have a system that didn't require extensive configuration. By partnering with LabVantage, we were able to leverage a baseline template that provided most of the functionality we needed. The only additional work was to write, verify, and execute a few additional scripts, beginning with one of our highest throughput assays to fully test the system's capabilities and ensure we gained maximum value where we needed it most."

Cost-effectiveness was another high-priority consideration, encompassing not only the system itself, but also the cost of hosting the cloud service. "When we looked at the overall cost package, we found the LabVantage system to be a really good value," says David. "Then, when we delved further into the cloud hosting options, we learned that there were additional benefits to be gained by having LabVantage host the cloud service for us as a SaaS deployment, rather than using our own IT department. Specifically, while the cost of hosting the cloud service was comparable across both scenarios, having LabVantage host meant they could access our system and help us troubleshoot any issues. Choosing to go down this route certainly paid off when it came to interfacing our instruments with LabVantage's SDMS, which would otherwise have involved liaising between multiple groups and might quickly have become very complicated."

A further factor that attracted Oxford Biomedica to the LabVantage LIMS platform was its **modern user interface**, which David describes as feeling fresh and intuitive. He also highlights the overall **professional service experience,** which he says left a really positive impression. LabVantage's professional services organization helped solve any workflow issues and provided a range of options. "It never felt like we were shoehorned into a decision," he says. "They're really good at solving problems and made my job easier."

CONFIGURING THE LABVANTAGE LIMS FOR A HIGH THROUGHPUT ASSAY

Droplet digital polymerase chain reaction (ddPCR) is one of Oxford Biomedica's highest throughput assays. It represents a critical step in viral vector production, where it serves to confirm that the vector contains the correct gene sequence.

Oxford Biomedica generates its ddPCR data using instrumentation from Bio-Rad Laboratories. However, these systems do not have an application programming interface (API) connection with the LabVantage LIMS.

To circumvent this issue, Oxford Biomedica and LabVantage worked together to produce a script that would parse out the data from the Excel files generated by the ddPCR instrumentation and transfer it through the LIMS to the SDMS for analysis.

As well as saving significant time spent on manual data processing, this approach mitigates against the risk of operator errors.

Key learning points

When implementing the LabVantage Pharma LIMS platform, Oxford Biomedica underwent several organizational changes that caused the scope of the project to deviate from the original plan. David notes that LabVantage's flexibility made adapting to these changes straightforward, although he advises a LIMS project should have strong visibility throughout the organization to ensure that internal personnel are kept up to speed. "If people are not aware that there is a LIMS project going on, they might make changes without considering the possible impact on LIMS deployment," he says. "Having a strong line of communication cross-functionally is key to avoid unnecessary delays."

David also recommends leveraging the services of LabVantage's professional services team to tailor the LIMS for specific needs. "With so many different industries using a LIMS, there is no one-size-fits-all solution available," he says. "One of my biggest concerns when embarking on this project was how to translate our workflows to LabVantage without getting bogged down in the weeds. The professional services team knew how to ask the right questions to get the relevant information, as well as provided a clear range of options for each challenge we encountered, so it was easy for us to make progress."

"Because the LabVantage LIMS is a database first and foremost, it has all of the metrics results in one place, which enables our QC team to track more, faster, with less people."

— David Park

The result

Having performed a trial run of LabVantage LIMS, David is confident that the system works as intended. The QC micro-environmental monitoring team have recently been trained, reporting the system to be highly intuitive, and the analytics and chemistry teams are next in line. The platform is scheduled to go live at the end of Q2 2024.

ABOUT LABVANTAGE PHARMA LIMS

LabVantage Pharma, the first pre-configured and pre-validated pharmaceutical LIMS in the market, is trusted by the pharmaceutical and biotech companies large and small to run their labs. Run your lab more efficiently by automating tasks and integrating with instruments and systems. With a flexible system along with an experienced global professional services team, you minimize the risk of project delays or failures. Once live, the system can easily adapt to evolving business requirements. LabVantage Pharma LIMS, with its pre-configured intuitive workflows, reduces your total cost of ownership by speeding deployment and training.

TO LEARN MORE about LabVantage for Pharma & Biotech, visit https://www.labvantage.com/industries/pharma-biotech/

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ABOUT LABVANTAGE SOLUTIONS

A recognized leader in enterprise laboratory software solutions, LabVantage Solutions dedicates itself to improving customer outcomes by transforming data into knowledge. The LabVantage informatics platform is highly configurable, integrated across a common architecture, and 100% browser-based to support hundreds of concurrent users. Deployed on-premise, via the cloud, or SaaS, it seamlessly interfaces with instruments and other enterprise systems – enabling true digital transformation. The platform consists of the most modern laboratory information management system (LIMS) available, integrated electronic laboratory notebook (ELN), laboratory execution system (LES), and scientific data management system (SDMS); and, for healthcare settings, a laboratory information system (LIS). We support more than 1500 global customer sites in the life sciences, pharmaceutical, medical device, biobank, food & beverage, consumer packaged goods, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, NJ., with global offices, LabVantage has, for four decades, offered its comprehensive portfolio of products and services to enable customers to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements.

For more information, visit www.labvantage.com.