VERITAS™

Global Biopharma CDMO Improves Protection of Business-Critical Data

A Chinese contract development and manufacturing organization (CDMO) for biopharmaceutical services deployed Veritas NetBackup™ to improve compliance with customer requirements while reducing the cost and manpower for data backup and recovery.

Challenge

For Chinese CDMO Zencore Biologics, data is business-critical. The firm develops and manufactures pharmaceuticals for companies around the world. And clients require Zencore to safely store data from development, testing, and manufacturing processes for many years.

Solution

Zencore Biologics' legacy data protection solution struggled to meet these customer requirements during the company's rapid growth. Zencore engaged Veritas Professional Services to deploy NetBackup-powered Appliances for company-wide data protection with monthly transfer to tape for long-term storage.

Outcome

The NetBackup-powered storage system has proven to be highly reliable. Every time a customer, the U.S. Food and Drug Administration (FDA), or another regulatory body has requested an audit of backups or test of data restoration, it has completed successfully. Moreover, the NetBackup compression rate of more than 90% is reducing hardware, bandwidth, and staffing costs for Zencore.

臻格生物
Zencore Biologics

INDUSTRY

Biotech/Pharmaceuticals

EMPLOYEES

700

HEADQUARTERS

Shanghai, China

WEBSITE

zencorebio.com

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CDMO Supports Evolving Pharma and Biopharma Industries

In the pharmaceutical sector, speed to market is critical, but developing and manufacturing drugs requires a complex web of expensive equipment and staff with highly specialized expertise. Frequently scaling production up and down to accommodate the innovation, introduction, and eventual retirement of a product can be challenging. This creates a business opportunity for contract development and manufacturing organizations (CDMOs).

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Many pharma and biopharma companies choose to outsource the development, production, and quality-control testing of pharmaceutical products. Through working with a CDMO, they bring new products to market without investing in additional infrastructure or dramatically expanding staffing. The rapid growth of Shanghai-based Zencore Biologics demonstrates the appeal of this approach.

"We started in 2017 with one lab and a couple of scientists doing cell line development," explains Mr. Sam Sun, IT Senior Director at Zencore Biologics. Very quickly, biotech and pharma companies around the world recognized the benefits of outsourcing to Zencore because of its expertise in big-molecule antibody development. "A year later, by 2018, we had expanded to two buildings, and we were able to provide full-service process and analytical development."

Today, the firm employs approximately 700 people in its research and development (R&D) lab and Good Manufacturing Practice (GMP) facilities, developing and producing pharmaceuticals for client companies from China, the United States, and Europe. Zencore has passed multiple audits and inspections performed by clients and regulatory authorities.

"That is a good achievement and proof of our capabilities as a CDMO," Mr. Sun says. "Since our founding, we have spent a lot of resources on building leading quality-control systems and on digitalization of all our processes."

In Biologics, Data Is King

For the customers that utilize Zencore Biologics' services, data is business-critical. It provides insight into the efficacy—and prospective risks—of new drugs. It also supports client companies' application for regulatory approval for their medications. As a result, Zencore accumulates huge volumes of customer-owned data for each drug it develops and produces.

"For example, we may need to constantly check the growth and health of a cell line in a test tube," Mr. Sun explains. "We have an instrument that takes pictures of the cells and stores them on a server." Each image is about 1 MB in size, and Zencore Biologics may take 50 images per test tube per day. There may be six clones, and six culture conditions for each clone, all of which require about two weeks of cultures.

"That is for just one project, in one stage of the procedure," Mr. Sun adds. "We have automated many of our monitoring and analytics processes, in both research and manufacturing, which means we have a lot of other instruments that do things like measuring the physical and chemical attributes of a culture. Every one of our hundreds of instruments is collecting data. In fact, we generate one data point every five milliseconds on average."

The company's data volume has ballooned as fast as its business. "We need to store customer data for a long time," Mr. Sun says. "GMP principles require us to retain all the raw data around development and manufacturing of a product throughout its lifecycle, up until several years after the drug is no longer on the market. And even after a medication has been retired, the client may request the data for use in the development of new drugs or for other purposes.

"Most of our contracts with our customers specify extreme penalties if we lose their data," Mr. Sun continues. "If our customer is a small biotech company, a data loss incident could potentially kill their business, so it is impossible to overstate how serious data protection is for both of us. Our customers frequently audit our data management processes. We also must be prepared for an inspection, at any time, from government regulatory authorities."

In addition to following GMP best practices, Mr. Sun says, Zencore Biologics must comply with the "very strict and detailed requirements for data integrity" from the U.S. Food and Drug Administration (FDA) and other government entities. "Data protection is top-of-mind for our CEO and management team and is one of the primary responsibilities of my IT department. Our management team relies on us to build and maintain a very robust data protection platform."

Veritas Professional Services Streamlines NetBackup™ Deployment

A couple of years ago, Zencore Biologics needed to improve its efficiency in data protection. Its legacy backup and recovery platform was not GMP-compliant and could not be adequately scaled to support a manufacturing plant under construction. The company needed its backups to be complete and trustworthy enough to meet customers' service-level agreements (SLAs), while not requiring exorbitant resources to maintain.

"A few of our customers are concerned about the security of cloud storage, so we currently store all data locally," Mr. Sun explains. GMP compliance requires that backed up documents and records be unabridged. Zencore Biologics also required its new data protection platform to pass an internal computerized system validation (CSV) audit.

Mr. Sun and his colleagues evaluated their options for backup and recovery and selected Veritas NetBackup-powered Appliances. "Our internal CSV team must validate every system before we start using it," he says. "These CSV audits are required by the FDA, and not all vendors in the market can provide validation expertise and service. We were pleased to discover Veritas knows how to do a GMP validation."

Zencore Biologics engaged Veritas Professional Services to assist in the rollout of its NetBackup data protection infrastructure. "The deployment went smoothly," Mr. Sun says. "Validation was the most challenging part of the deployment, and the Veritas Professional Services team provided us with a lot of help. Our internal quality department is comfortable with the implementation and with the validation, and using Veritas Professional Services saved our IT team a lot of time."

Reliable, Immutable, and Highly Efficient Backups

Now, data backups are automatically run from most of the company's systems to NetBackup-powered Appliances on a daily basis. Once a month, secondary backups are transferred to tape and moved offsite for long-term retention.

"We are monitoring the backup jobs, and they are almost always successful," Mr. Sun says. "Occasionally, a backup job will fail because a user turns off the computer, but otherwise we have had no issues. And if there is some kind of failure, we can handle it easily because the interface is quite user-friendly compared with our legacy solution."

In addition, he adds, the data immutability capability within NetBackup ensures the high level of data integrity (DI) that Zencore Biologics requires. "Once the data is backed up, no one can change it," Mr. Sun says. "This strengthens our case in audits because there is no risk of data manipulation."

Better yet, NetBackup's reputation has streamlined conversations with regulators and customers. "When the FDA or a client comes to inspect our facility, their confidence in Veritas means they usually do not require us to explain how we back up and restore data, and manage data storage," Mr. Sun reports. "If the FDA comes to us with DI questions, they are usually focused on permissions and training of whoever generated the data. They may also ask us to restore some data for comparison purposes, and NetBackup has performed well in all those requests."

NetBackup improved data protection and made backup processes more efficient. "Veritas gives us a compression rate of 91% to 92%, which is much higher than our legacy solution," Mr. Sun says. "The platform recognizes when data is redundant or duplicative, and instead of storing another copy, it links to the data backed up previously. That saves a lot of space," which, in turn, reduces Zencore Biologics' need for bandwidth and storage hardware, "saving a lot of money for us and for our clients.

"We can use each server for longer," he adds, "and the data can be backed up more quickly. We can schedule more work, and back up more instruments, every night of the week. That is the advantage of Veritas NetBackup compared with other products."

Another crucial efficiency comes in staffing. As the company's data volume grows rapidly, Zencore Biologics continuously needs its IT team to do more. The difference that NetBackup makes is clear when Mr. Sun compares backing up most of the company's data, via the automated NetBackup processes, with the small proportion of equipment that requires manual backup.

"We still have some instruments that are not connected to the network because of FDA and GMP compliance policies," he says. "Backing up these offline instruments takes my IT team about one person-day every week. Someone must go to each instrument with a portable drive to run the backup and copy it to the server, which is tedious and time-consuming. Then our quality department must review the backups from the offline instruments to ensure they are complete and accurate.

"Compared with the offline backups, NetBackup automation is saving our team a great deal of resources," he continues. "If all our backups were manual, my team would need three more people who were 100% focused on data protection, just running backups without doing anything else. The quality team would have to add staff as well. NetBackup has eliminated a lot of trouble and effort for every team involved in backups, not just IT."

Expanding an Already Strong Relationship

For Zencore Biologics, Veritas is a strategic partner that supports a critical business process. Mr. Sun is now working with Veritas Professional Services to streamline the task of searching for and recovering information in response to customer requests.

"If a client reaches out and says, for example, 'We reached milestone X; please send a package of all the data you have so far for this project,' it might be difficult to pull everything together from the various source systems," Mr. Sun says. "The project management team might find themselves collecting data from SharePoint, from documents in local storage, and sometimes from emails.

"But since we back up all these systems every day in the Veritas database, we figured it would be easier to use tagging and keyword searches to extract the data related to a particular project from NetBackup," he concludes. "I am now working with Veritas on a priority project to make this happen. We already have a prototype that works well. This initiative is extremely exciting and demonstrates the strength of our relationship with Veritas."

For More Information

Please contact your local Veritas Sales Representative or Business Partner, or visit Veritas NetBackup Appliances

About Veritas

Veritas Technologies is the leader in secure multi-cloud data management. Over 80,000 customers—including 91% of the Fortune 100—rely on Veritas to help ensure the protection, recoverability and compliance of their data. Veritas has a reputation for reliability at scale, which delivers the resilience its customers need against the disruptions threatened by cyberattacks, like ransomware. No other vendor is able to match the ability of Veritas to execute, with support for 800+ data sources, 100+ operating systems and 1,400+ storage targets through a single, unified approach. Powered by Cloud Scale Technology, Veritas is delivering today on its strategy for Autonomous Data Management that reduces operational overhead while delivering greater value. Learn more at veritas.com. Follow us on X at @veritastechllc.

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