

CASE STUDY
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BIOPHARMACEUTICAL COMPANY SPEEDS TOWARDS COMMERCIALIZATION WITH NETSUITE



ROUNDTABLE DISCUSSION ON PHARMA-ORIENTED NETSUITE ERP IMPLEMENTATION

As pharmaceutical and biotechnology companies push toward approval and commercialization of their pipeline, an essential consideration for finance teams is the time required to implement an ERP solution. As the organization and its vendor interactions grow, spreadsheets quickly become untenable ways to manage the complex financial tracking and reporting necessary to remain efficient and compliant.

Lisa Henderson, Editorial Director of Pharmaceutical Executive, sat down with James Neal, Principal at BDO Digital, and a BDO Digital client to talk about these issues. During the discussion, one biopharmaceutical company shared its experience working with BDO Digital to adopt NetSuite ERP and the factors driving decisions and timelines.

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GET TO KNOW THE CLIENT

The client is a clinical-stage biopharmaceutical company focused on developing and commercializing a pipeline of novel, proprietary therapeutic candidates that have the potential to transform radiotherapy in cancer. The lead product candidate is being developed for radiation-induced toxicities.

A New Drug Application for the product is currently under priority review by the U.S. Food and Drug Administration with a Prescription Drug User Fee date of August 9, 2023, for radiotherapy-induced severe oral mucositis in patients with head and neck cancer undergoing standard-of-care treatment. The company's second product candidate is in clinical-stage development to augment the anti-cancer efficacy of high-dose radiation therapy in patients with non-small cell lung cancer and locally advanced pancreatic cancer.

BEFORE NETSUITE

With headquarters in the U.S and an Australian subsidiary, the biopharmaceutical organization was heavily reliant on Excel spreadsheets to run its financial operations. Trial balances and financial statements for each organization were maintained in its financial system of record, the general ledger, which was also the source of accounting transactions and journal entries.

Consolidations and eliminations were handled in Excel from downloaded statements. Budgeting and accruals were also conducted in Excel, with business partners and vendors' providing input for calculating accruals. Outsourced manufacturing was also a consideration for the company, so billing and reporting required timely collection to support financial flow processes.

"As a newly public company with a growing clinical pipeline, we needed a more robust system that could scale with our business," said one employee who realized that a software upgrade was in order.

The company wanted a system to increase efficiencies while providing support for critical functions like accounts payable, contract management reporting, budgeting, forecasting and SOX compliance. With commercialization looming, supply chain and inventory management, revenue processes and transactions, and gross to net accounting would need to be incorporated into the system. Because of this, flexibility and scalability were crucial considerations.

The biopharmaceutical firm's SOX 404 compliance program provided additional business requirements. Its finance team works with an outside advisory firm to document critical controls, test them and report on the controls' effectiveness. The ERP system selected would need to automate those controls for additional efficiency.

A NEED FOR AN ERP

BDO Digital has focused on taking the agile and mature NetSuite technology and tailoring it to the pharmaceutical industry's unique needs. Its team has guided dozens of pharmaceutical companies to discern the most advantageous moment for transitioning to a fit-for-purpose and scalable ERP solution.

Neal is frequently confronted with questions about timing when meeting with potential clients. "The first thing they say is 'We're probably too early for this,'" he states. "It's generally never too early to ask the question 'Is it too early for this?' It's very difficult to do both the implementation and commercialization." In his experience, the below signs point to a need for an ERP.

TRIAL PHASE AND QUANTITY

Although it can vary by the company's complexity, Phase II is generally the time frame in which companies implement an ERP. Some companies may be able to wait until Phase IIb or III, but the closer to commercialization, the more difficult it may be to complete an adoption.

As a drug gets closer to commercialization, the number of vendors, contracts and resources being managed have typically grown considerably. Neal's team works with organizations to implement "as late as practical and as early as possible." It's best to acquire a system before massive growth happens, but not before the finance team is large enough to manage the software.

COMPANY PROFILE

A public company with a need for auditable systems is a complexity level best supported by an ERP. Global companies that spend significant time performing consolidation and eliminations, or handling intercompany service agreements, may benefit from the centralized data and functions provided by an ERP.

TIME INVESTED

As complexity increases, so does the amount of time required to manage it. QuickBooks and Excel may begin to impact quality and introduce risk due to decreased reliability and auditability.

WHY NETSUITE?

Currently, BDO Digital is the largest single-vertical NetSuite dealer globally. Before then, when Neal's team took on their first customer, they evaluated all available ERP software providers, finally settling on NetSuite as the most mature and capable cloud-computing ERP system.

This decision allowed them to partner with pre-revenue, pharmaceutical, biotechnology and medical device companies to leverage NetSuite's functionality to deliver complete white-glove ERP/MRP deployments exclusively to the pharmaceutical industry.

One of NetSuite's most useful features is its out-of-the-box ability to handle reporting in different countries. Its standard statutory reporting

in different countries. Its standard statutory reporting is dealt with seamlessly, and consolidations can occur in Euros or US Dollars, as applicable.

NetSuite is also a fully cloud-based model, providing enterprise-class computing power, security and accessibility for distributed workforces. Oracle's acquisition of the software took a mature, intuitive product and added functionality through significant investment.

BDO DIGITAL'S NETSUITE IMPLEMENTATIONS

This biopharmaceutical company implemented NetSuite in a single phase. The evaluation took place among the core team and included finance and IT teams, with input from the management team and audit committee. Because the process overlapped with quarter-end activities, the team planned for six months to adopt the system.

The company focused on including financials and budget functionality in the initial phase to help improve reporting, comparisons, forecasting consolidations, accounts payable and contract management. The initial stage included purchase order workflows and SOX compliance, automating delegation authority and the segregation of duties. With its NDA under priority review, the company plans to scale the system to include supply chain modules to manage inventory, revenue and gross to net accounting.

According to Neal, four to six months is a typical NetSuite implementation timeframe. A three-month implementation can be accomplished but is typically disruptive to the finance team's other responsibilities. For organizations seeking to include supply chain and GMP functionality, clients should plan for six- to nine-month deliveries.

NEXT STEPS

BDO Digital's roadmap seeks to build additional value into the company's deployments. Sarbanes-Oxley reporting and GMP are critical business operations for clients, and updates to the Approvals module can help extend NetSuite's functionality in these areas. The GMP functionality makes BDO Digital the fastest route to a GMP validated manufacturing system that easily scales across geographies.

Client feedback around auditor interactions has identified several areas where audit functionality can be improved. These updates will be included within the standard reporting bundle and accessible within the interface, giving users easy access to records needed to support auditing activities.

The biopharmaceutical client sees BDO Digital as a valued resource in the process: "BDO Digital understands the nuances of the pharmaceutical industry and our business model. They help design and tailor the system to address our current needs with an eye towards what the company will need in the future as we approach commercialization. That experience and guidance is invaluable in an ERP implementation."



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