

# A Tale of Two Pharmas: Case Studies on ERP Implementation

*A 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 departments 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*, recently sat down with James Neal, Managing Partner of AdaptaLogix, and two AdaptaLogix clients to talk about these issues. During the discussion, Chris Degnan of Galera Therapeutics and Lauren Piunti of Nabriva Therapeutics shared their experiences working with AdaptaLogix to adopt NetSuite ERP and the factors driving decisions and timelines.

## CASE STUDY: NABRIVA THERAPEUTICS

Nabriva Therapeutics is a biopharmaceutical company engaged in developing and commercializing anti-infective agents to treat serious infections. Its first commercial product, Xenleta, has been approved in the United States, Canada, and Europe to treat community-acquired bacterial pneumonia (CABP). Nabriva also recently licensed the US distribution rights for Sivextro from Merck and has another product in development, Contepo, for treating urinary tract infections. They are currently operating two Phase I clinical trials for lefamulin and Phase IV for fosfomycin.

Pre-NetSuite ERP Context

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Before implementing NetSuite, Nabriva used Microsoft Excel spreadsheets to manage consolidations and eliminations due to having different accounting systems in its European and United States divisions. Accounting was done separately and outside of the system, using Excel to combine all accounting activities, budgeting, and accruals quarterly. The team coordinated with external contract manufacturing organizations to ensure timely data capture and tracking of inventory movement.

As Xenleta entered the clinical trial phase, it became clear Nabriva would need an upgraded ERP system that would allow their finance team to work more efficiently. They wanted to implement a global solution to handle all entities' accounting activities and simplify the reporting process before commercialization, yet avoiding a more complex or robust system than their needs required. States Piunti, "Now with the brand NetSuite, our processes are automated, so we're able to use NetSuite to do consolidations and eliminations, for instance."

#### **CASE STUDY: GALERA THERAPEUTICS**

Galera Therapeutics is a clinical-stage biopharmaceutical company focused on developing products to work on both sides of the therapeutic index, reducing normal tissue toxicity from radiotherapy and increasing its anticancer efficacy. It is working to create a portfolio of small molecule dismutase mimetics that convert superoxide into hydrogen peroxide, which has demonstrated an ability to increase the anticancer efficacy of high-dose radiation.

Galera currently has seven trials in its clinical-stage pipeline. Its lead product candidate, Avasopasem, is presently in a 450-patient Phase III registrational trial for its lead indication. The trial seeks to reduce the onset of severe oral mucositis in patients with head and neck cancer, a side effect that creates mouth ulcers and pain that prevents eating and drinking, which is suffered by 70% of patients on radiation therapy. Avasopasem is also being developed to reduce normal tissue toxicity from radiotherapy and increase radiation therapy efficacy for patients with locally advanced pancreatic cancer and non-small cell lung cancer.

#### **PRE-NETSUITE ERP CONTEXT**

Galera has an American headquarters and an Australian subsidiary; the financial operations between the two are heavily Excel-based. Trial balances and financial statements for each organization are maintained in its financial system of record, the general ledger, which is also the source of accounting transactions and journal entries. Consolidations and eliminations are handled in Excel from downloaded statements. Budgeting and accruals are also conducted in Excel, with business partners and vendors' providing input for calculating accruals. Outsourced manufacturing is also a consideration for Galera, so billing and reporting require timely collection to support financial flow processes.

When Degnan joined Galera, he knew from previous experience they would need to upgrade their ERP system. "As a newly public company with a growing clinical pipeline, we needed a more robust system that could scale with our business," Degnan said.

Galera 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, so flexibility and scalability were crucial considerations.

Galera's SOX 404 compliance program provided additional business requirements. The finance department 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.

### **INDICATORS OF A NEED FOR AN ERP**

AdaptaLogix 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 following 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 counsels 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, will also 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 stretching resources' ability to maintain quality, introducing risk due to decreased reliability and auditability.

### **WHY NETSUITE**

Currently, AdaptaLogix is the largest single-vertical NetSuite dealer globally, but when Nabriva partnered with Neal's team, they

were its first customer. As part of that process, AdaptaLogix 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 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.

### **ADAPTALOGIX'S NETSUITE IMPLEMENTATIONS**

To assist in their search, Nabriva reached out to James to find a right-sized solution. Their team of five opted for a phased approach, implementing NetSuite in their US entity a year before deploying it to the Europe division. Each implementation took between four to six months.

Since the initial implementation of financials, Nabriva has worked with AdaptaLogix to add additional modules to the system. The

system has scaled to include supply chain, budgeting, expense reporting, and other system upgrades, capturing and recording all inventory movements. NetSuite has grown with Nabriva by accommodating evolving needs encountered in the drug development and commercialization journey.

Galera is currently implementing NetSuite in a single phase. The evaluation took place among the core team and included finance and IT teams, with additional input from the management team and audit committee. Because the process will overlap with quarter-end activities, the team plans for six months to adopt the system.

Like Nabriva, Galera has focused on including financials and budget functionality in the initial phase to improve reporting, comparisons, forecasting consolidations, accounts payable, and contract management. The current stage includes purchase order workflows and SOX compliance, automating delegation authority and the segregation of duties. Pending positive Phase III data, Galera 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 typical. 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**

AdaptaLogix's roadmap seeks to build additional value into their deployments.

Sarbanes-Oxley reporting and GMP are critical business operations for clients, and updates to the Approvals module will extend NetSuite's functionality in these areas. The GMP functionality will make AdaptaLogix 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.

Piunti sees AdaptaLogix as a valued partner in the process. "We really value their consulting advice, and they always have solutions to any problems we encounter," she says. "They're extremely helpful when we're deciding on system enhancements or upgrades. Because AdaptaLogix works with clients similar to us, they're able to provide us with input on what has worked well for companies in a similar position."

Degnan agrees: "AdaptaLogix understands the nuances of the pharmaceutical industry and our business model. They help design and tailor the system to meet 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."

