



THE PATH FROM R&D TO COMMERCIALIZATION

Developing Seamless Supply Chains for the
Pharmaceutical Industry

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Developing Seamless Supply Chains for the Pharmaceutical Industry

With NetSuite as its foundation, AdaptaLogix's SuiteSuccess for Pharma gives pharmaceutical companies everything they need to build out successful, end-to-end supply chains for their promising new drugs.

Once the FDA provides positive feedback on Phase 2 trials, the path from Phase 2b/Phase 3 clinical trials to commercialization is fast and furious. Within months, the same entity that once had tens of employees researching and developing life-changing drugs can suddenly experience a 300% increase in headcount, while needing to comply with federal regulations, adhere to SOX accounting standards and meet the complexities of global operations.

It's a lot to think about, and a lot to manage via the Excel spreadsheets and basic software

systems that these nascent pharmaceutical firms cut their teeth on. Also missing is the supply chain infrastructure needed to start and sustain product manufacture and distribution.

In this white paper, we explore the key challenges that these enterprising companies encounter on the path to commercialization and show how the AdaptaLogix supply chain models built on NetSuite enables a streamlined, end-to-end supply chain that starts at the point of production and ends at the patient.

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Chapter 1

THE PATH FROM R&D TO COMMERCIALIZATION

“One of the most important decisions that a pharmaceutical company will make involves picking the right tools to guide the business through monumental, high-velocity change. These companies need technology partners that intimately understand the unique needs of their business models, and that understand how to extend far beyond process efficiencies and ensure compliance.”

— James Neal, Managing Partner, AdaptaLogix

During the startup phase, most pharmaceutical companies spend anywhere from \$150 million to \$300 million per year to lay the groundwork for getting their new drugs to market. Relying on 40-50 employees, these firms are sharply focused on developing new cures.

The industry-specific supply chain challenges that surface once a pharmaceutical company begins its journey down the path to commercialization include:

- **Managing contract models and transfer pricing.**

Pharma companies that don't have their own production facilities typically outsource the manufacturing process to third parties. “They never even touch the product,” said Neal, “and they make up about 90% of the pre-revenue pharma market.” This creates

interesting challenges for the company that has to track expenses across various entities and processes. A company that purchases active pharmaceutical ingredients (APIs) from a producer in Bermuda, for example, may send the drug to Belgium to be packaged before having it finally shipped to the U.S. Capturing costs across and eliminating inter-company profit—a process known as transfer pricing—requires a robust software system that enables arms-length sales between subsidiaries and the orchestration of the “whole chain of events that occur with the build-out of the product,” Neal said.

- **Inventory management challenges.** The same companies that allocated so much effort and investment to developing new, life-changing drugs must now figure out how to make, stock

and record the distribution of those products. This process isn't easy for any company to master, and it's particularly difficult for those that are grappling with a host of new regulatory, compliance, financial management and HR issues. AdaptaLogix's Supply Chain 1 provides the demand planning and inventory management functionality that helps emerging pharma companies answer the question: If we're going to launch in January of next year and sell \$40 million in products the first year, when must we have our supply chain infrastructure live and ready to support the launch?

- **Packaging and labeling complexities.** In the pharmaceutical supply chain, every product has to be packaged and labeled in a way that ensures compliance. Whether the product in question is a liquid that gets injected or a tablet that gets ingested, the item that's not packaged and labeled correctly can quickly throw the end-to-end supply chain into a tailspin. With AdaptaLogix's Supply Chain 1 and Supply Chain 2 functionalities, companies can efficiently build out their distribution processes and networks while remaining compliant.
- **Regulatory requirements.** Under continual FDA scrutiny, pharma companies have to play by the rules or risk having their promising new

products pulled from the market (or never make it there in the first place). For example, products have to be traceable from the point of raw materials right out to the end user. These traceability requirements get tougher every year and keeping up with them is next to impossible for firms that don't have an industry-specific software suite in place. Just one incident of non-compliance can shut down an entire pharma supply chain and cost the manufacturer millions in lost sales as the company works to mitigate the problem.

- **Unique go-to-market strategy.** Different than most any other industry, the pharmaceutical sector rarely sells directly to its end customer. Instead, it relies on intermediaries—wholesalers, distributors and third-party logistics companies (3PLs)—that manage the product distribution, sales, A/R, and even the cash receipts. “Basically, the pharma company receives a check in the bank at the end of every month or quarter and must reconcile those against reports provided by the 3PL,” Neal said. This presents a unique problem in that the pharma company's data is virtually useless from a sales and revenue perspective. AdaptaLogix's Supply Chain 2 closes that data gap by establishing the software integrations needed to track real revenues and sales (i.e., gross-to-net and trace data) as they happen.

Chapter 2

AN INDUSTRY-CENTRIC SOLUTION THAT WORKS

Based on years of experience working for and supporting the pharmaceutical industry, the AdaptaLogix team has taken the NetSuite platform and built functionality and workflows into it that meet the unique requirements of pre-revenue pharmaceutical companies. Called NetSuite SuiteSuccess for Pharma, the solution includes:

- **Financials for Pharmaceuticals** is robust financial functionality that will scale as the business grows. Financials for Pharmaceuticals automates month-end close, puts in place the reporting and controls needed to ensure SOX compliance, supplier management, contract management, financial consolidation and planning functionality.
- **Supply Chain 1**, which handles the entire manufacturing process up to the point of finished product. The solution provides robust inventory management functionality tailored for the pharma client including raw materials, active pharmaceutical ingredients

(APIs), intermediate product, final product and secondary packaging. It also includes functionality to handle lot control, demand planning, receipts management and transfer pricing.

- **Supply Chain 2**, which enables the commercialization process and provides integration to the major 3PLs that warehouse, ship and handle accounts receivable for the pharmaceutical firm's customers. Supply Chain 2 functionality also includes automating the calculation of gross to net adjustments and supports standardized integrations for the 3PLs.

Financials for pharma is the base functionality provided to all clients, providing financial automation and controls. Supply Chain 1 and Supply 2 represent the logical progression of new pharmaceutical firms as they make their way down the path from trials to commercialization and beyond.

“Supply Chain 1 is largely focused on deploying inventory management capabilities, adding additional functionality to purchasing, and tracking physical inventory. It also manages the transfer pricing process by helping pharma companies move their product from country to country managing inventory, costs and profits accurately.”

— **James Neal**, Managing Partner, AdaptaLogix

With Supply Chain 1, companies can also effectively manage their worldwide partners, issue purchase orders, coordinate with raw material and API suppliers, work with packaging suppliers and build out the work orders to capture costs. This lifecycle gets the pharma company right to the door of the 3PL that will subsequently get the product to market—a process that’s handled by Supply Chain 2. It manages the inventory, storage, sales, returns and “everything to do with finished goods,” Neal said.

Supply Chain 2 also manages regulatory requirements and AdaptaLogix is currently working with one pharmaceutical company whose PDUFA date was approaching and they decided to implement Supply Chain 1 & 2 concurrently. Working with Austin, Texas-based ICS, AdaptaLogix determined which data and transaction sets would be housed in the pharma company’s system, and then worked with the company to build out its inventory model to match that process. There were roughly six supply chain links between the company and

its 3PL, with raw materials coming from various sources in Europe. For example, the API and raw materials were sourced from 2 different countries, API produced in a third, shipped to a fourth and fifth country for manufacturing and, finally, packaging/labeling was completed by a sixth vendor in the US.

“They basically had six different countries involved in the process,” said Neal, whose team used Supply Chain 1 to develop a logical process for the flow of goods. “There were seven different steps to get each product from raw materials to an ICS warehouse. At each step, we also created formula-based assemblies that brought those disparate pieces together for costing and lot-tracking purposes.”

In most cases, Supply Chain 1 takes about four months to implement while Supply Chain 2 requires between four to six months. The longer implementation time of the latter is due to the fact that it’s implemented alongside a 3PL which generally dictates the duration of the project.

Chapter 3

SUPPORTING EFFICIENT DEPLOYMENTS

“Pharma firms have to be able to prove their accounting from a statutory standpoint, and across multiple countries. That’s no easy task, and it’s definitely something that you don’t want to be doing manually in Excel.”

— **James Neal**, Managing Partner, AdaptaLogix

Once in place, the AdaptaLogix Supply Chain 1 & 2 solutions provide a host of benefits for growing pharmaceutical companies. For example, when one commercial pharmaceutical company required a replacement for its homegrown inventory system and manual processes used in manufacturing, it turned to AdaptaLogix for help. The company’s digital transformation to a cloud-based solution had to include quality approvals, lot tracking, and track and trace requirements unique to the pharmaceutical industry.

“The solution had to be FDA-validated and fit within the company’s budget,” Neal said, noting that the company chose AdaptaLogix and implemented its NetSuite SuiteSuccess for Pharma solution. “Our pharma-specific implementation model enabled the efficient deployment of the inventory and manufacturing solutions,” he explained, “while our FDA validation expert was able to prepare the testing protocols required for the FDA validation.”

Along with streamlining of the end-to-supply chain, Supply Chain 1 & 2 also enable accurate cost tracking in an environment where many different entities play a role in bringing the products to market. A company that outsources manufacturing and has multiple collaborations within its own industry, for example, may work with a larger pharmaceutical company that pays a portion of its costs (in return for a portion of future revenues).

“Knowing this level of detail across the entire supply chain, and without the help of a large accounting firm or IT department, is a big plus for growing pharmaceutical firms,” Neal pointed out. Another major benefit is the ability to track costs from country to country on a global operational scale—something that no spreadsheet or basic business software can achieve.

Chapter 4

TIMING IS EVERYTHING

Having worked on dozens of SuiteSuccess for Pharma implementations over the years, Neal tells the leaders of emerging pharma companies to get their systems and IT professionals involved in the supply chain development process early. Don't assume that just because your PDUFA date is two years out that you have ample time to put the product manufacture, distribution and logistics end together; start thinking about it now before the suppliers are in place.

For example, you'll want to make sure that the contracts you're signing with your 3PLs and other business partners will scale up as your drug is approved and brought to market. Ignore this step and you could find yourself scrambling to get these important elements in place at the 11th hour.

“Now is the time to start thinking about how you're going to implement your supply chain and track everything across it. When your company is in the middle of launching a product is not the time to be thinking about your systems.”

— **James Neal**, Managing Partner, AdaptaLogix

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