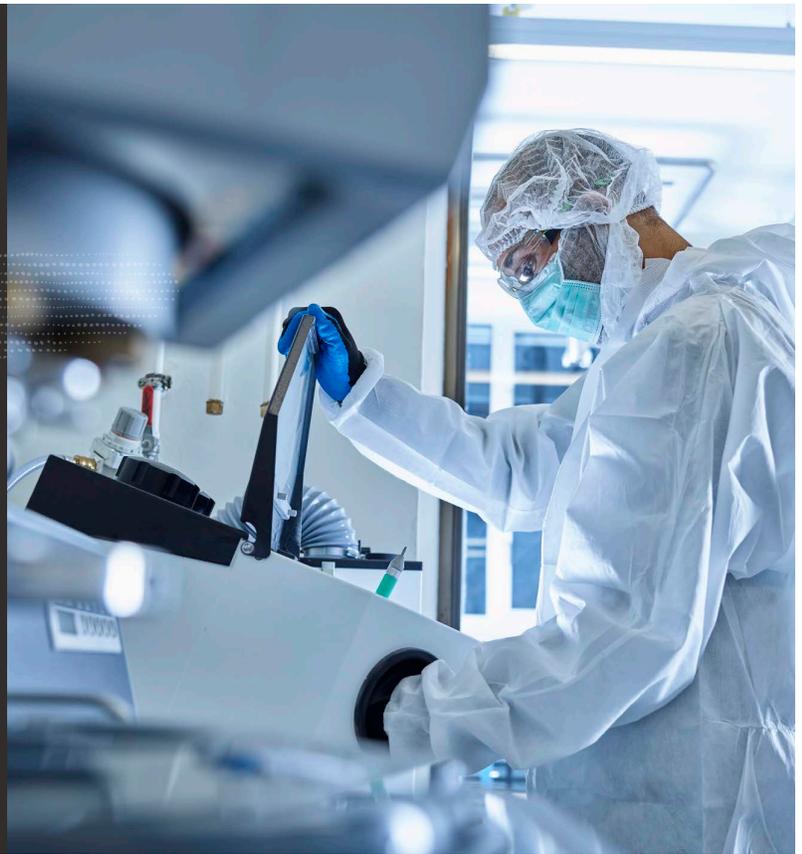




## NetSuite Cloud ERP for Gene Therapy Companies



In their quest to find groundbreaking cures for rare conditions and diseases that have limited treatment options, pharmaceutical companies are increasingly turning to gene therapy to explore and treat a multitude of different medical conditions.

Approved by the U.S. Food and Drug Administration in 2017, gene therapy concentrates on treatments that replace faulty genes with healthy ones, with an emphasis on diseases like cancer, hemophilia and muscular dystrophy.

Because the path from innovation to commercialization in gene therapy is still being developed—to date, the FDA has approved just 17 products for sale in the U.S.—pharmaceutical companies that are bringing these new products to market face significant challenges. There are a myriad of regulatory hoops to jump through, manufacturing sites to set up and supply chains to establish before gene therapy products can be placed in the hands of the patients that need them.

“Our supply chain model is largely focused on deploying inventory management capabilities, adding additional functionality to purchasing and tracking physical inventory. Our in-house manufacturing clients leverage our GMP Bundles in conjunction with the base manufacturing functionality inherent with NetSuite.”

James Neal, Founding Partner, AdaptaLogix



## Here's How it Works

AdaptaLogix offers industry experience and proven implementation methodologies to elevate companies toward commercialization and beyond. For the gene therapy sector, it offers a NetSuite-based GMP Pharma Bundle that takes about nine months to implement, depending on the company's individual requirements.

Here's a snapshot of the typical deployment model that begins with global financials through supply chain including GMP manufacturing capabilities and ending with integration to 3PLs and other commercialization entities:

These three models represent the logical progression of new gene therapy firms as they make their way down the path from trials to commercialization and beyond.

**ADAPTALOGIX**

**Partner Snapshot**

**Company:** AdaptaLogix

**Industry:** ERP implementation and consulting firm devoted exclusively to clinical stage, pre-revenue to commercial pharmaceutical companies.

**Offices:** Philadelphia, Pa., Columbus, Ohio, and New York, N.Y.

**Solutions:** SuiteSuccess for Pharma Financials, GMP Pharma Bundle, Supply Chain 1 (CMO and In-house Manufacturing), Supply Chain 2 (Sales), Contract Expense Accrual Management, and Approval Workflow and DOA.



## Financials

### Leverage the NetSuite SuiteSuccess for Pharma Financial Deployment

Global Financials	Purchasing to Pay	Contract Expense Accrual Management	Approvals	SOX Compliance and Documentation
Multiple Entity/ Multiple Currency	Dispersed PO and Requisition Entry	Automation of the Clinical Trial Expense Accrual Process	Easily configure and manage approvals for multiple transactions	Role-based user access and segregation of duties
Statutory Reporting	Routing and Approval	Integration to CLMS	Maintain auditability for SOX compliance	All entries are time stamped and traceable to person/IP address
Elimination/ Consolidations	Receipts Management	Increase visibility and effectiveness for contract managers	Delegation of Authority	Easily manage user access and controls
Intercompany Processing	Cost classification by indication, clinical trial and drug etc.	Maintaining auditability of all accruals	Easily reference approval stage and history	SOX reporting is standard with every implementation





# Supply Chain 1 (CMO and/or In-House Manufacturing)

**CMO Model – Leverage NetSuite to track all costs of drug development**

Inventory Management	
Raw Material/API	Arms-Length Transaction/ Intercompany
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Intermediate Product	Automatic Eliminations of IC Sale
-----	-----
Final Product	Serialization
-----	-----
Secondary Packaging	Demand Planning
-----	-----
Transfer Pricing	Lot Traceability

**In-House Manufacturing Model – Leverage AdaptaLogix’s GMP Manufacturing Bundle for NetSuite**

GMP Manufacturing	
GxP Vendor Onboarding	GxP Manufacturing Process
-----	-----
GxP Material Onboarding	GxP Samples Management
-----	-----
Approved Suppliers/ Materials Lists	GxP Final Product Release
-----	-----
GxP Purchasing Process	Barcoding/WMS
-----	-----
GxP Inventory Process	Security Configuration/ 21 CFR Part 11



# Supply Chain 2 (Sales)

3PL Integration to NetSuite
Inventory Movements
-----
Revenue
-----
Gross-to-Net
-----
Cash Receipts
-----
Sunshine Act Reporting

Forecasting and Planning
Inventory Forecasting
-----
Personnel Forecasting
-----
Gross-to-Net Forecasting
-----
Facilitating Coordination
-----
Revenue Forecasting

