



# CLOUD ERP HELPS GENE THERAPY COMPANIES COMMERCIALIZE INNOVATIVE DRUGS

ORACLE NETSUITE  
Solution Provider

**BDO** DIGITAL

## Table of Contents

- [3 Introduction](#)
- [4 500+ Gene Therapy Companies, and Growing](#)
- [4 The GMP Pharma Bundle Checks all the Boxes](#)
- [7 Getting Out from Behind the Eight Ball](#)
- [8 Saving Gene Therapy Companies Time and Money](#)



## WITH NETSUITE AS A FOUNDATION, BDO DIGITAL SAVES EMERGING AND ESTABLISHED GENE THERAPY COMPANIES TIME AND MONEY AS THEY PROGRESS DOWN THE PATH TO SUCCESSFUL COMMERCIALIZATION AND INTRODUCE THEIR INNOVATIVE THERAPIES TO THE MARKET.

A promising new medical field that could potentially treat and cure various diseases, gene therapy is still in the early stages of development and growing quickly. There are [more than 500 U.S. organizations](#) currently operating in the field focus on modifying or replacing specific genes—effectively addressing the root cause of disease versus just treating symptoms.

On the path to revolutionizing disease treatment, gene therapy companies face numerous technological challenges. To develop therapies that are both accessible and affordable for patients, gene therapy organizations must be able to operate at scale as they work towards product commercialization. Along the way, these firms will also have to manage regulatory hurdles and financial constraints while preparing for long-term success in their nascent market.

As the gene therapy sector continues to mature, companies operating in it are forming partnerships and selling capacity on a “contract development and manufacturing organization” (CDMO) basis. Doing so creates new operational challenges for the companies, which are building multimillion dollar facilities not only to build out their own intellectual property (IP) but also offering any extra plant capacity to other companies. This helps companies add new revenue streams, but it can also complicate their business models.



In other cases, gene therapy companies will run their operations on basic accounting systems and spreadsheets right up until the point of commercialization—or, when they can start selling their drugs on the market. Other companies invest in on-premises ERPs that serve a purpose during the startup phase, but that quickly become expensive and impractical as their organizations mature.

For example, gene therapy organizations not only have to scale up, hire new employees and establish their physical infrastructures, but they also need to get good manufacturing practice (GMP) systems in place very quickly. A set of practices that are designed to ensure the quality of manufactured products, GMPs are used by the food, beverage, pharmaceutical, medical device and cosmetic manufacturing industries, among others.

“Trying to put GMP systems in place while gearing up for commercialization can quickly turn into the classic ‘painting the plane and installing the seats while it’s inflight scenario,” said James Neal, Principal and NetSuite Practice Lead at BDO Digital, a NetSuite Solutions Provider and Developer.

“As soon as that firm hits any kind of scale—phase three clinical trials, for example—those manual processes become extremely inefficient,” Neal continued. “At that point, companies need an automated system like NetSuite.”



## 500+ GENE THERAPY COMPANIES, AND GROWING

Pharmaceutical companies are increasingly turning to gene therapy to explore and treat a plethora of different medical conditions. Approved by the U.S. Food and Drug Administration in 2017, gene therapy centers on treatments that replace faulty genes with healthy ones, with a particular emphasis on diseases like cancer, hemophilia and muscular dystrophy.

Since the FDA first approved the use of gene therapy in 2017, the market for these treatments has expanded rapidly. Today, [more than 500 companies](#) develop cell and gene therapies in the United States. To date, the Office of Tissues and Advanced Therapies division of the U.S. FDA has approved [27 cell and gene therapies](#) for use within the United States

As gene therapy firms move closer to drug commercialization, they have to track and invoice sponsors—drug manufacturers of record who hold the IP for the therapies—and any third parties that are using the company's facilities on a CDMO arrangement. Onboarding those "customers," managing project costs and running fulfillment infrastructures are not always in the early-stage gene therapy firm's wheelhouse.

Take the small gene therapy company that's using a 24,000-square-foot facility primarily for research and development (R&D), for example. Reliant on paper, spreadsheets and basic software solutions, employees handle a lot of processes manually during the startup phase. As the company grows, uploading scanned copies of every document quickly becomes unscalable, expensive and error prone.

## THE GMP PHARMA BUNDLE CHECKS ALL THE BOXES

On track to reach [\\$8.7 billion in revenue this year—up from \\$7.5 billion in 2022](#)—the global gene therapy market is experiencing exceptional growth. A direct result of the unprecedented growth is a multi-year backlog for outsourced manufacturing which is driving the need for these companies to develop and manufacture their therapies in-house. A unified cloud ERP like NetSuite can help gene therapy companies at all stages meet the unique demands of their nascent industry.

Through its 2022 acquisition of AdaptaLogix, LLC, the only Oracle NetSuite Solutions Provider and Developer with IP designed for the pharmaceutical industry, helps gene therapy companies extract more value from their ERP investments. BDO Digital 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 includes the GMP Pharma Bundle in the supply chain deployment:

Leverage the NetSuite SuiteSuccess for Pharma Financial Deployment	CMO Model – Leverage NetSuite to Track All Costs of Drug Development	
<p><b>Global Financials</b></p> <ul style="list-style-type: none"> <li>▶ Multiple Entity/Multiple Currency</li> <li>▶ Statutory Reporting</li> <li>▶ Elimination/Consolidations</li> <li>▶ Intercompany Processing</li> </ul> <p><b>Purchasing to Pay</b></p> <ul style="list-style-type: none"> <li>▶ Dispersed PO and Requisition Entry</li> <li>▶ Routing and Approval</li> <li>▶ Receipts Management</li> </ul> <p><b>Contract Expense Accrual Management</b></p> <ul style="list-style-type: none"> <li>▶ Automation of the Clinical Trial</li> <li>▶ Expense Accrual Process</li> </ul> <p><b>Approvals</b></p> <ul style="list-style-type: none"> <li>▶ Delegation of Authority</li> <li>▶ Employee Portal</li> </ul> <p><b>SOX Compliance and Documentation</b></p> <ul style="list-style-type: none"> <li>▶ Segregation of Duties</li> <li>▶ Audit Support</li> </ul>	<p><b>Inventory Management</b></p> <ul style="list-style-type: none"> <li>▶ Raw Material/API</li> <li>▶ Intermediate Product</li> <li>▶ Final Product</li> <li>▶ Secondary Packaging</li> <li>▶ Lot Control</li> <li>▶ Demand Planning</li> </ul> <p><b>Transfer Pricing</b></p> <ul style="list-style-type: none"> <li>▶ Arms-Length Transaction/ Intercompany</li> <li>▶ Automatic Eliminations of IC Sale</li> </ul> <p><b>In-House Manufacturing Model – Leverage NetSuite's GMP Manufacturing Capabilities</b></p> <ul style="list-style-type: none"> <li>▶ GxP Vendor Onboarding</li> <li>▶ GxP Material Onboarding</li> <li>▶ ApprovedSuppliers/MaterialsLists</li> <li>▶ GxP Purchasing Process</li> <li>▶ GxP Inventory Process</li> <li>▶ Barcoding/WMS</li> <li>▶ GxP Manufacturing Process</li> <li>▶ GxP Samples Management</li> <li>▶ GxP Final Product Release</li> <li>▶ Security Configuration/21 CFR Part 11</li> </ul>	<p><b>3PL Integration to NetSuite</b></p> <ul style="list-style-type: none"> <li>▶ Inventory Movements</li> <li>▶ Revenue</li> <li>▶ Gross-to-Net</li> <li>▶ Cash Receipts</li> </ul> <p><b>Trace Data</b></p> <ul style="list-style-type: none"> <li>▶ 867/852 Data</li> <li>▶ Ready for Export to CRM/ Reporting</li> </ul> <p><b>Forecasting and Planning</b></p> <ul style="list-style-type: none"> <li>▶ Revenue Forecasting</li> <li>▶ Inventory Forecasting</li> <li>▶ Gross-to-Net Forecast</li> </ul>

Knowing that the supply chain can present big challenges for gene therapy companies, BDO Digital enhances NetSuite's functionality and workflows in a way that meets the unique requirements of gene therapy companies, including:

**Supply Chain 1** handles the entire manufacturing process whether leveraging a CMO or manufacturing in-house. The solution provides robust inventory management functionality tailored for the gene therapy client including raw materials, plasmids, intermediate product, final product and secondary packaging. It also includes functionality to handle lot control, demand planning, receipts management and transfer pricing. The in-house manufacturing functionality of the solution provides GMP compliance for the MRP and Manufacturing. Approved suppliers and materials lists, inventory and sample management, manufacturing, supply and demand planning as well as 21 CFR Part 11 compliance are a subset of the GMP bundle's robust functionality.

**Supply Chain 2** supports the commercialization process and provides integration to the major third-party logistics companies (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.

These two models plus Financials represent the logical progression of new gene therapy firms as they make their way down the path from trials to commercialization and beyond—starting with the Financials deployment and moving on to Supply Chain 1 and Supply Chain 2.

With Supply Chain 1, gene therapy companies can also effectively manage their worldwide partners, issue purchase orders, coordinate with raw material, plasmid and API suppliers, work with packaging suppliers and build out the work orders to capture costs. This lifecycle gets the 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 all activities related to finished goods.

Supply Chain 2 also manages regulatory requirements. In most cases, Supply Chain 1 takes about four months when using a CMO and nine months to deploy the GMP Bundles and in-house manufacturing functionality. Supply Chain 2 requires between four to six months, the longer implementation time is due to the fact that it's implemented alongside a 3PL that generally dictates the duration of the project.

*“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 companies move their processes from country-to-country, managing IP protection and so forth for those leveraging a CMO. Our in-house manufacturing clients leverage our GMP Bundles in conjunction with the base manufacturing functionality inherent with NetSuite”*

- James Neal, Principal and NetSuite Practice Lead at BDO Digital



## GETTING OUT FROM BEHIND THE EIGHT BALL

Designed for startup pharmaceutical operations, BDO Digital's GMP Pharma Bundle infuses the right level of automation into their growing operations at an affordable price. For companies that may have initially invested in an on-premises ERP like SAP, the bundle offers a more financially-viable way to manage scale and growth. "We're working with a gene therapy company right now that's transitioning away from spending \$1.5 million a year just to host SAP," said Neal. "That's a pretty typical scenario in this sector."

With NetSuite and GMP Pharma Bundle, companies also get a right-sized solution that's tailored for their industry. For example, BDO Digital is currently working with another customer that's building on the world's largest CDMO facilities for gene therapy companies. With a small subset of its operations already up and running, the company is developing a "very large box" that will eventually be filled with manufacturing sites, each of which will be run by a different customer. "They're about 20% built out and already running GMP processes," Neal explained.

Because the gene therapy company embarked on this expansion while still using basic systems and spreadsheets, it ran into challenges as soon as it started to scale up. "It can't keep up with the growth, which has already outpaced the company's ability to track things manually and there's no other systems in place," said Neal, whose team is currently implementing NetSuite and the GMP Pharma Bundle for the customer.

With that combined solution in place, the company will be able to handle its current production load and also scale up as it moves toward 100% completion of its new facility. It will also have the automated processes that it needs to be able to take on new customers as part of its CDMO operations.

"This is just one of many examples of how companies that 'went manual' to get their operations up and running quickly find themselves in need of a solution like NetSuite plus our industry-specific bundle," Neal said. "As with many gene therapy firms, the tipping usually comes when their current systems just can't keep up anymore."



## SAVING GENE THERAPY COMPANIES TIME AND MONEY

When it begins working with a new gene therapy customer, BDO Digital takes a holistic approach that factors in the customer's R&D, manufacturing, distribution, GMP, fulfillment, transactional, CDMO and other requirements. Then, BDO Digital offers up a solution that hits all of those points by asking very specific questions like: How will you stop quarantined materials from making their way into the GMP warehouse?

"This is the kind of question that many software providers wouldn't think to ask during the sales process," said Neal. "Then, the customers wind up coming to us to help them 'patch' their systems up and replace any solutions that aren't working for them."

Through its holistic approach, BDO Digital assesses all the requirements related to GMP deployment—right down to the individual barcodes that are placed on products and then read on handheld devices. The company also provides a full GMP validation model that automates all of the documentation related to the NetSuite implementation.

"Completing an ERP implementation is one thing, but if you don't have the documentation on how NetSuite was implemented and how you're making sure that certain processes work, then you're going to have to put an incredible amount of effort into retrofitting," said Neal. "With BDO Digital's implementation and validation services, we're saving customers tons of time and energy."

### LEARN MORE ABOUT BDO DIGITAL'S NETSUITE SOLUTIONS

BDO Digital is the only NetSuite Solutions Partner dedicated to providing ERP systems tailored to the pharmaceutical and biotech industries' distinctive financial, supply chain, manufacturing and commercial requirements. We create services that scale with your business — so when you grow, your ERP grows with you. [Learn more about our capabilities.](#)

**HAVE QUESTIONS OR WANT TO LEARN MORE? CONTACT US!**

BDO Digital, LLC is a Delaware limited liability company, and a wholly-owned subsidiary of BDO USA, P.A.

BDO USA, P.A., a Delaware professional service corporation, is the U.S. member of BDO International Limited, a UK company limited by guarantee, and forms part of the international BDO network of independent member firms. BDO is the brand name for the BDO network and for each of the BDO Member Firms. For more information on BDO Digital, LLC please visit: [www.bdodigital.com](http://www.bdodigital.com).

Material discussed is meant to provide general information and should not be acted on without professional advice tailored to your needs.

© 2023 BDO USA, P.A. All rights reserved. [www.bdo.com](http://www.bdo.com)

