Cloud ERP Fine-Tuned For Pre-Revenue Pharma & Biotech Companies

BDO DIGITAL

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CLOUD ERP FINE-TUNED FOR PRE-REVENUE PHARMA & BIOTECH COMPANIES

WELCOME TO THE FUTURE OF BIOTECH AND PHARMACEUTICAL ENTERPRISE RESOURCE PLANNING

Pre-revenue pharmaceutical organizations play a high-stakes game with little room for error and no second chances given to companies that don't hit the mark on their first time out. Once a promising new drug or therapy is ready for clinical trials, these organizations must quickly shift from research and development (R&D) over to testing and commercialization—a pivot that's difficult to make using basic software systems and spreadsheets.

Having the right business process in place from the start is crucial for pharma, bioscience, gene and cell therapy developers, and that includes an enterprise resource planning (ERP) solution that's been fine-tuned for the industry and battle-tested by dozens of pre-revenue pharma companies.

In this white paper, we explore the typical issues that pre-revenue pharma, biotech, gene therapy, and cell therapy companies face when implementing ERP. We show how a solution that's prebuilt for the industry—and implementation professionals that know the industry inside and out—provides fast-growing companies.

A LASER-FOCUS ON PRE-REVENUE PHARMA

Startup companies generally take on any new customer that crosses their threshold, knowing that over time they'll be able to hone their market approaches and work only with clients who truly need their products or services (and who are willing to pay for those offerings). The team at BDO Digital took a different tack, instead putting a laser-like focus on the technology needs of pre-revenue pharmaceutical, biotech, gene therapy and cell therapy organizations.

Responsible for the research, development, production and distribution of medications, the pharmaceutical industry has experienced significant growth over the past two decades, with pharma revenues worldwide totaling over **$1.48 trillion in 2022**. Much of this growth can be attributed to small, enterprising startup companies that discover and develop new therapies and drugs. Focusing all its efforts on the pre- revenue pharma space—those companies that are receiving R&D funding but not yet generating revenues for their products—BDO Digital designed a software solution that specifically addresses the distinct needs of those target customers. Knowing that traditional ERP's implementations leave behind critical gaps for these types of clients, it boosted NetSuite Cloud ERP in a way that provides financial and data solutions for pre-revenue pharma organizations' unmet needs.

OFFERING EXTREME BUSINESS VALUE

The plan to create business solution to address the needs of pre- revenue pharma and bioscience companies, began in 2016. After exploring their options, the team selected NetSuite Cloud ERP and began using it as a centralized, enterprise system for its early

customers. It also built a team with deep vertical industry knowledge, knowing that it can serve as a strong foundation for both existing and prospective customers.

So rather than trying to be "all things to all people" the team built an application with functionality designed exclusively for the pre-revenue life sciences sector. Over the years, it's gotten to know that sector very well, so much so that its team members can often spot gaps and fulfill needs even before the customers ask about them. It can also provide a smooth ERP implementation, having previously encountered and addressed virtually any issue that may arise during this process.

> *We knew that if we could focus on a very narrow target market, we'd be able to serve it exceptionally well and provide the most successful ERP implementation possible...The strategy worked, and our successful track record attests to the extreme business value that we provide before, during, and after implementation.*
>
> **JAMES NEAL**
> Enterprise Business Applications, BDO Digital, Principal

REPLACING BASIC, MANUAL SYSTEMS

Starting out as small organizations of 10-20 employees operating primarily on partnerships or royalties, pre-revenue companies focus on developing drugs for clinical trials and potential commercialization. They outsource most of their business operations and are usually public companies, which means they have to comply with Sarbanes- Oxley (SOX) audit controls and other regulations.

Once clinical trials start, and roughly one year before drug commercialization, these pre-revenue organizations start hiring salespeople, building out their supply chains and signing contracts with 3PLs—all in the name of getting the groundwork in place for FDA approval and subsequent commercialization.

At this point, basic systems (e.g., QuickBooks, Xero, and Excel spreadsheets) put in place during startup no longer work. Sharing data across these highly-manual systems is cumbersome (or in some cases, impossible) and these solutions can't handle the reporting, audit controls and other regulatory requirements of a growing pharmaceutical firm.
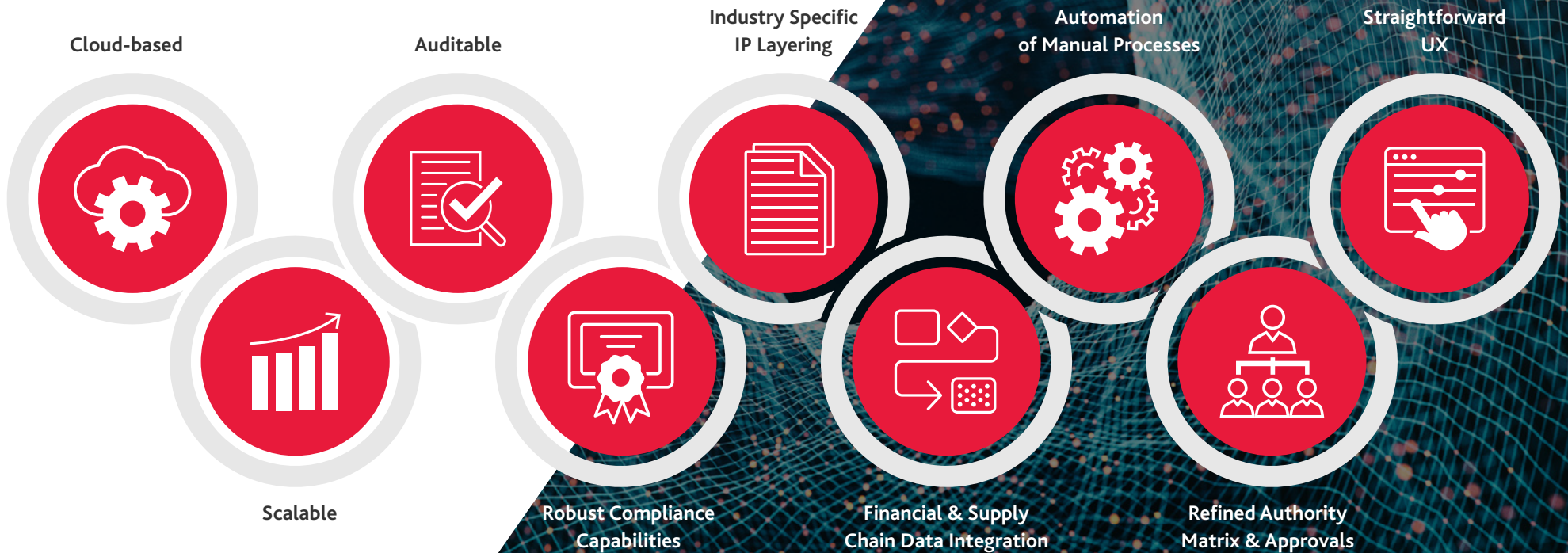
WORKING TO MEET 100% OF OUR CLIENT'S NEEDS

Taking their decades of experience in pharma & system development, BDO Digital's partners sought out an ERP that met roughly 90% of those customers' needs out of the box, and then finetune that enterprise system to help meet 100% of their needs. The company then developed software modules and enhancements customized specifically for pre-revenue pharma companies. As a result, BDO Digital can now deliver an ERP that consistently works to meet 100% of its clients' needs, while continually honing that offering to accommodate those customers' changing requirements.

By developing a platform that was designed with pre-revenue companies in mind, BDO Digital removes the complexities and guesswork from the ERP selection and implementation processes. For example, where another integration team may need a primer on contract accruals before being able to help a company address this issue—often by developing a solution from scratch or just using Excel spreadsheets to manage them—BDO Digital is well versed in contract accruals and their related requirements.

We fill the gaps because we know exactly where those gaps exist.

Cloud-based

Scalable

Auditable

Robust Compliance Capabilities

Industry Specific IP Layering

Financial & Supply Chain Data Integration

Automation of Manual Processes

Refined Authority Matrix & Approvals
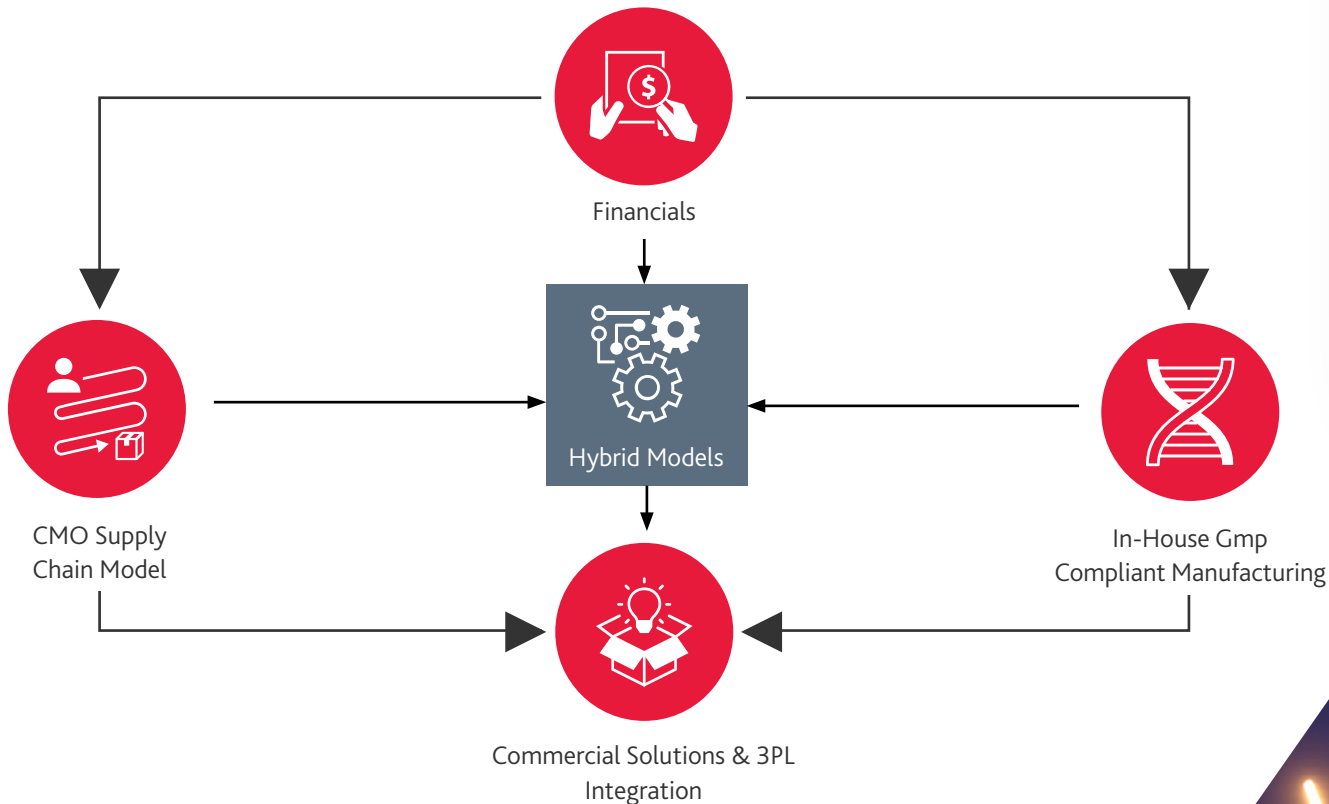
Straightforward UX

THE BDO DIGITAL DIFFERENCE

BDO Digital also offers a standardized deployment model that saves pre-revenue companies significant time, money and hassle during the implementation process. Where another team may request one or more "getting to know you" meetings on the front end, and then have to figure out its new clients' operational model (e.g., how does it collect revenue? Who are its vendors? How does it pay those vendors?), BDO Digital comes to the table equipped to answer these and other relevant questions.

Armed with this insider intelligence, the BDO Digital team presents a pre-built, predefined system that works to meet all of its pre-revenue pharma, biotech, gene therapy and cell therapy customers' needs right out of the gate. *"Where other teams start from ground zero,"* Neal says, *"we start from 'nearly complete' and then tweak to accommodate every company's individual differences."*

Templatized Implementations that Anticipate Pharma's Growth

Financials

CMO Supply
Chain Model

Hybrid Models

In-House Gmp
Compliant Manufacturing

Commercial Solutions & 3PL
Integration

> *We know that our customers don't collect revenue, don't know who their vendors are, and who handles their sales function. In most cases, it's third party logistics companies [3PLs]... We also know their business models are heavily contract-oriented (versus purchase order), at least until they reach commercial status. So, in essence, we aren't so much collecting your system requirements as we are confirming them*

JAMES NEAL
Enterprise Business Applications,
BDO Digital, Principal

MEASURING THE PROGRESS

With firsthand knowledge of the struggles that these companies are enduring during this stage, BDO Digital serves as a true business resource before, during and after ERP implementation. Companies get a system which can be validated for Good

Manufacturing Practices, Good Clinical Practices, Good Lab Practices, etc., (GxP). Pre- revenue pharma, biotech, gene therapy and cell therapy companies also get:

▶ A contract accrual module that automates the contract and invoice management process and a paperless approval module that provides an audit trail and the ability to quickly retrieve and review vendor bills (and view the complete approval flow for those bills).

▶ Mobile capabilities that allow employees to approve orders and release payments via laptop, tablet or another mobile device via the web.

▶ High levels of traceability and auditability. For example, a GMP lot inspection records and maintains all data captured via receipts and on specific movements of product within the system. *"If the FDA comes in and says, 'Show me this batch, how did you release this, and where is documentation for it?'"* Neal explains, "*it's all documented right in the system.*"

▶ Proof of system dependability. BDO Digital provides a complete audit trail for pharma companies that need to know how the ERP was installed, how it was tested, any changes that were made (and who made them), and the related change controls.

▶ Automated sample management. Tracking samples is a big job for pharma companies, which must maintain all of their product samples (or, "retains") for access at a later date. BDO Digital replaces paper records and automates the process of capturing, inventorying and tracking those samples.

PERPETUAL REFINEMENTS & ENHANCEMENTS

Developed and honed over time, these and other capabilities provide the best compatibility with the modern, pre-revenue pharma company. Because it works closely with every one of its customers, BDO Digital continues to build out its offering in a way that complements the best features of NetSuite Cloud ERP. In many cases, those customers get to test out the platform's latest capabilities and functionalities before BDO Digital introduces them to its broader client base.

"Our modules have been battle-tested across many implementations, which means that they're not only made bulletproof over time," Neal says *"but we're also continually adding new capabilities and offering them to our existing customers."*

For example, with its latest release, BDO Digital included the ability to add approval comments to contracts, invoices, and other documents. This is just one example

of how BDO Digital continues to add value for its pre-revenue clients through the process of repetition, and because it focuses on a single industry.
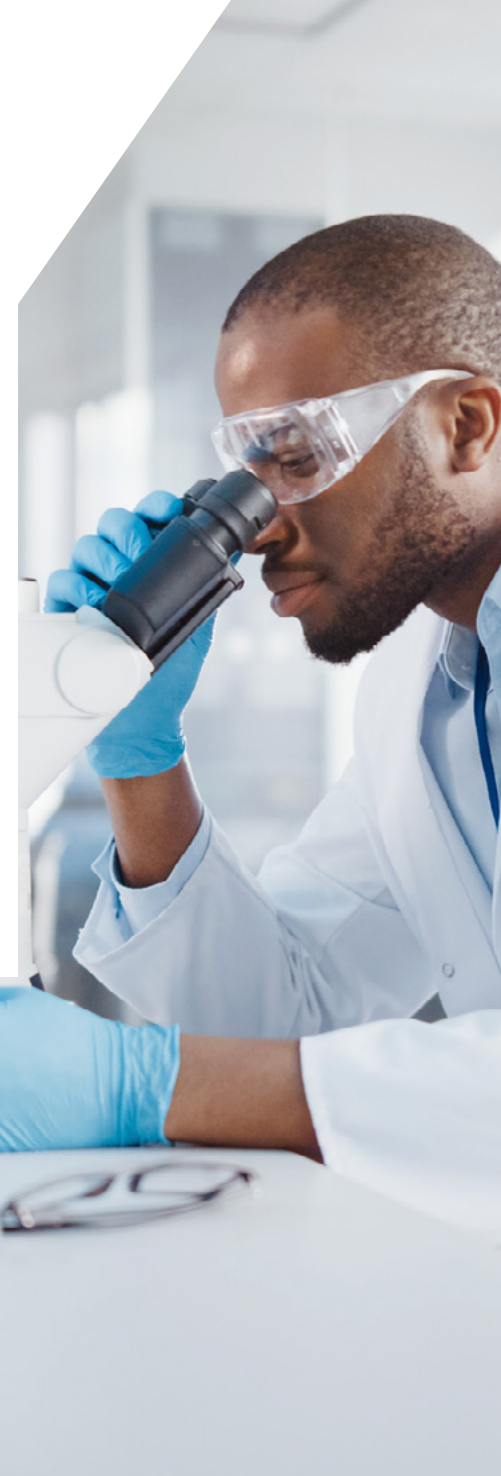
AS EARLY AS POSSIBLE, AS LATE AS PRACTICAL

"Knowing that the typical pre-revenue pharma organization operates with a handful of accounting employees, a basic financial system, and a lot of spreadsheets," Neal says "The best time for that company to make the move to a cloud-based ERP is as early as possible, and as late as practical."

A company that's in Phase 1 clinical trials, for example, may want to wait to implement an enterprise system. However, the one that's in Phase 2 and still working with a small accounting team and no commercial salespeople, should make the move before its operations move into a hyper-growth phase.

"Companies that implement ERP before they hit the complexity that require it usually find that the process is cheaper and also easier on their staff," says Neal, "versus trying to change the whole structure of a company that's working at 100% steam during commercialization."

"Regardless of which stage a pre-revenue pharma, biotech, gene therapy, or cell therapy company is at when that decision is made," Neal says "BDO Digital greatly reduces the risk associated with major technology implementations."

"The customers we work with don't have a chance to 'get it wrong,'" he adds. *"If they pick another implementation team who doesn't work out, they'll be grappling with that system for years until they get a chance to fix or replace it. At BDO Digital, our team has perfected the roadmap for successfully launching a drug or product, for whatever phase our customer is in."*

"Our modules have been battle-tested across many implementations, which means that they're not only made bulletproof over time," Neal says, "but we're also continually adding new capabilities and offering them to our existing customers." For example, with its latest release, BDO DIgital included the ability to add approval comments to contracts, invoices, and other documents. This is just one example of how BDO DIgital continues to add value for its pre-revenue clients through the process of repetition, and because it focuses on a single industry.

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Solution Provider

YOUR ERP SOLUTIONS ARE WAITING!

Contact us to learn more about our vision to help customers realize real business results from their ERP investments and capture their full power by providing ERP solutions across cloud applications.

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