SUPPORTING LIFE SCIENCES COMPANIES
FROM STARTUP TO COMMERCIALIZATION

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Sikich's SuiteSuccess for Life Sciences, built on NetSuite, helps companies grow from pre-revenue to commercialization in a fast, painless manner that ensures compliance and allows users to focus on what they do best: developing new medicines for patients who need them.

The road from startup to revenue-generating entity is pretty short for most life sciences companies—so short, in fact, that after just a few years in the industry, most of these organizations' initial, fragmented technology systems can no longer keep up.

All too often, these companies wind up with technology infrastructures that lag behind their company goals—a reality that becomes obvious as life sciences firms move from Phase I clinical trials to Phases II and III. Because business software was never a core focus, compromises and bottlenecks start to interfere with the organization's mission.

"As digitization continues to shape the corners of pharma, a new generation of startups and tech giants have emerged, disrupting the status quo and threatening pharma's legacy culture," Deloitte reports. "While pharma giants are investing in gene-based therapeutic solutions, more than 250 startups are already developing these therapies and building them around the patient."

Using the right software platform, these pre-revenue organizations can design, configure and manage the roles, controls and workflows the business needs—all without having to onboard more finance professionals or IT managers.

This white paper explores the critical steps that all life sciences companies take on the road to commercialization and tell how Sikich's SuiteSuccess for Life Sciences enables these enterprises' success, supports Sarbanes-Oxley (SOX) compliance and helps life science companies run their businesses more efficiently.

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DEVELOPING THE FORMULAS THAT ENHANCE LIVES

Most life sciences companies start out with scientists and researchers exploring promising approaches to new medication or other vital pursuits. These activities consume most of the organization's energy, time and resources, and rightly so. For without the intellect, persistence and curiosity of these knowledge workers, there would be no new drug breakthroughs in the first place.

While these scientists are putting their heads together and developing new formulas and drugs, a core group of finance, IT and business managers are managing the associated business processes and infrastructures. This core group is usually in place through the Phase I trials, with some life sciences companies going public with just a handful of people on their finance teams. Even with demanding system workloads and stringent regulatory requirements for managing data and intellectual property, the IT team often remains small and typically outsourced as companies grow and evolve.

This can quickly turn into a real issue for the company that finds itself hurtling toward clinical trials and potential commercialization of its drugs. For many smaller life sciences companies, the tipping point comes on the path to a public offering and while they're still running the business on the shoulders of a small team. This presents real challenges when it comes time to navigate financial and approval controls and workflows that keep companies compliant with regulatory frameworks such as Sarbanes-Oxley, and non-negotiable requirements (i.e., the need to realize a proper segregation of duties).

In most cases, these companies spend most of their money on research and development (R&D), and work with contract research organizations (CRO) to handle some or all of that R&D work.

"They hit a certain stage in the drug development process," said Mike Kean, a Partner with Sikich's Technology Practice, "start adding finance professionals to their teams, and then say, 'Oh boy, we may go public soon.'"

When that realization hits, the life sciences company must start thinking about issuing stock options, going public and/or setting themselves up for a successful acquisition by another firm. "That's the point where they have to get off of QuickBooks or another financial program and start looking at options like NetSuite," said Kean, who has seen more than one life sciences firm actually go public while still relying on QuickBooks for financials.

A viable choice for a small, uncomplicated enterprise, this program simply can't handle the financial intricacies of a growing life sciences firm.

The problem is that most life sciences firms don't realize the problem with QuickBooks until a year or two in the industry. By that time, their systems aren't robust and scalable enough or they lack the financial reporting capabilities needed to keep up with a growing life science company's needs. At that point, creating a robust and scalable technology approach has been complicated by fragmented software environments comprising simple accounting software systems, the use of common business productivity tools, and the addition of specialty software systems.

LOOKING FOR SOLUTIONS

In an attempt to keep their organizations on the path to success, life science leaders turn to standard ERP and CRM software products, most of which require significant customization to fit the unique operation model and working conditions of their enterprises. However, Oracle NetSuite has the power and flexibility to become a platform upon which life sciences organizations can manage their programs and processes, along with their contributors and resources.

Most life sciences companies want to keep close tabs on their cash flow and spending, especially when they are not yet generating revenue. While their IT departments are often lean in terms of staffing, their software systems are overly complex and create high management workloads. When life sciences businesses use specialized, separate procurement and contract management tools—which may not integrate with their financial software—that complexity can become overwhelming.

With years of experience and numerous successful deployments to its credit, Sikich helps life sciences companies overcome these and other hurdles.

"During the last few years, we've deployed NetSuite in several dozen life sciences companies," said Kean. "While every organization is unique, some of their challenges and the best ways to address them are very much the same."

A 5-Star Oracle NetSuite partner, the Sikich Life Sciences Practice builds upon successful projects to deliver a version of NetSuite that comes with commonly needed workflows, reporting, functional roles and compliance enablement features.

"Because timeliness and speed are often essential in this industry, we can implement the solution rapidly," said Kean.

Designed to help rapidly-growing companies manage all aspects of their businesses on a single system, for example, Sikich's SuiteSuccess for Life Sciences enables 120-day implementations, with most core capabilities in place and running within just 30 days. "Within that 30 days," he added, "we give life sciences firms everything they need to get through the next two years. They just need to turn on the features we have already included in our bundle."

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With NetSuite in place, growing life sciences firms can overcome these and other challenges:

- Tracking and easily adding and consolidating additional legal entities.

- Multiple sources of company information (different systems, Excel spreadsheets, etc.).

- Manual processes that cannot scale.

- Implementing financial controls.

- Preparing for equity events/SOX controls.

- Efficient and controlled purchasing processes.

- Generating accurate reporting for multinational, multi-company, SEC reporting.

- Program/project management.

Sikich SuiteSuccess for Life Sciences also helps:

- Deploy a single, integrated solution.

- Leverage a true cloud application with real-time access to data.

- Automatically pull systems and processes together to manage financials and operations.

- Connect seamlessly with third-party applications like payroll, banking, CRM or industry-specific systems.

Using Sikich and NetSuite, companies can alleviate these issues and focus on what they do best: bringing revolutionary new drugs to market.

THE LONG ROAD TO COMMERCIALIZATION

Life sciences customers progressing through clinical trials, evaluating or planning an IPO, while also undergoing rapid growth, have unique financial, contract, compliance and reporting needs. For example, about 63% of life sciences companies engage CROs or CMOs for Phase II studies, the former of which can help reduce review time by up to 30%. Leveraging CRO expertise makes good business sense, but managing both CROs and CMOs is a real challenge for life sciences firms.

Compliance is another area that tends to catch new life sciences companies by surprise as they scale up and grow. SOX, for example, requires that the management of public companies assess the effectiveness of the internal control of issuers for financial reporting, with Section 404(b) requiring that publicly-held company's auditor attest to, and report on, management's assessment of its internal controls, according to the AICPA.

Even during the pre-revenue stage, life sciences firms will have to comply with these and other requirements that will lay the groundwork for transformation into a full-blown, profit-generating entity.

"The first step on that path is usually the 404 audit, which essentially allows a life sciences firm to go public," Kean said. "Before that audit, companies need to have the software and controls in place to build out journal entry approvals, do AP approvals, and other basic steps you can't do in a QuickBooks or Excel spreadsheet world."

THE VALUE OF THE CLOUD

Early-stage life science companies must make the transition from spreadsheets to full-blown technology systems as quickly as possible.

"They need to be up and running fast," said Kean, "because they're operating in an industry where it's all about being lean and mean—and without having to add a lot of resources or make a lot of changes."

For this and other reasons, outsourcing technology implementation and management to Sikich is a very exciting proposition for enterprises that want to fully leverage the cloud, where there is no version lock and no IT infrastructure to manage.

The value of cloud computing is becoming more evident for life sciences companies that are on the fast track. "The pharmaceutical industry has a long history of leveraging cutting-edge technologies to improve human health, yet unlike other industries, only recently has life sciences begun to realize the benefits of the cloud," Information Age reports.

"Today, companies focused on drug development are harnessing the cloud to create a central location for all data spanning the entirety of the drug development continuum," it continues, "allowing researchers and patients to access data no matter where they are geographically located and sharing information faster than ever before."

Consider, for example, the cost and length of time it takes to bring a therapy from discovery to commercialization, which Information Age currently estimates at 12 years and $1.25 billion. "Unlike other industries where the gains from the cloud are simply efficiencies," it states, "in health care, the cloud could have a life-changing impact on the speed at which patients can get the medicines they need."

EVERYTHING LIFE SCIENCES COMPANIES NEED TO SUCCEED

By creating and implementing standardized integrations between NetSuite and many popular procurement tools including Prendio, Coupa, Jaggaer, Lab Cloud and PunchOut2Go, Sikich literally gives life sciences companies everything they need to succeed. Perhaps more importantly, it provides these services in a very fast, affordable manner that requires little or no additional infrastructure or IT investment on the company's part.

"Companies get everything they need from Sikich SuiteSuccess for Life Sciences built on NetSuite," said Kean, "plus another host of capabilities that they probably didn't even know they needed—standing by, ready to turn on."

This is possible because NetSuite cloud ERP adds functionality as life science firms mature and require new software capabilities:

- Early stage/startup: Segmented reporting, G/L and AP plus integrated purchasing, procurement, electronic payments and multi-entity management

- Grow stage: Fixed Assets, Payroll, Advanced Reporting and System Auditing for IPO

- Production phase: Vendor Contract Management, Forecasting and Planning

- Commercialization: Track revenue, AR and capture costs

Although each life sciences organization is different, they do have many similarities. In most cases, these organizations need a financial system which will allow them to scale quickly and be prepared for any potential path the organization may take.

"Key areas of functionality can be deployed quickly during the initial engagement," Kean explained, "or in phases over time as the organization matures."

Jim Hickey, a Partner with Sikich's technology practice, works with a lot of customers in the life sciences space and says most are tightly focused on getting their digital strategies into place and running quickly. They also want tools that will scale up along with them as they move through the various maturation stages—something that NetSuite is well known for.

"These folks want to be able to just do their jobs and not worry about what's going on behind the scenes, and how their companies are being run on the back-end." said Hickey. "We know that implementing ERP can be disrupting for a business, and we reduce that disruption with NetSuite, the de facto solution for the life sciences industry."

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