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How the right technology can streamline the back office and support drug development

Enhancing efficiency for biopharma companies

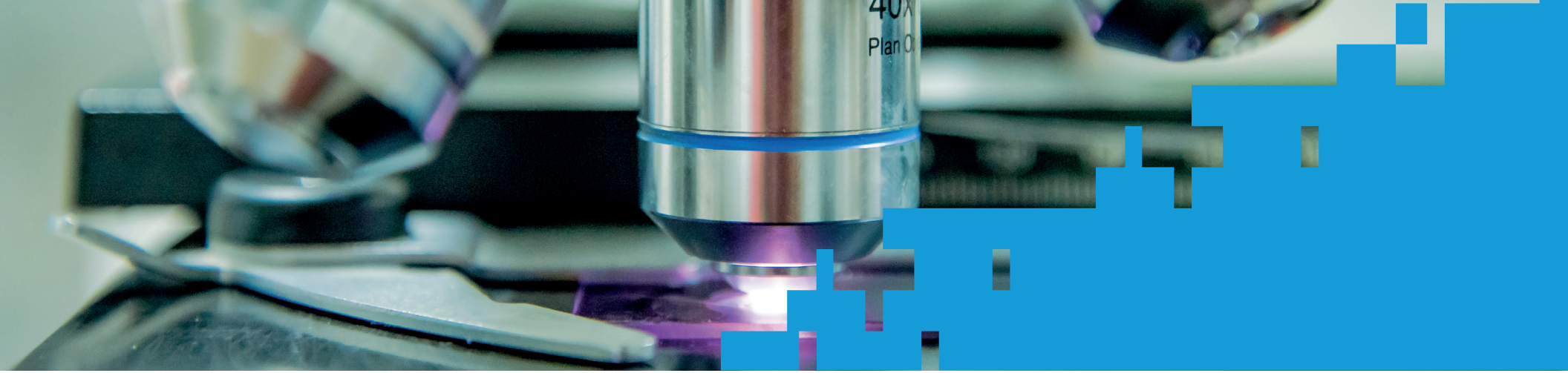
Life sciences companies face a myriad of challenges during drug development. The right back-office technology is essential to replace outdated manual processes and allow teams to stay focused on moving new therapeutics from discovery and development through approval and commercialization with as little overhead as possible.

In fact, integrating technology innovations can reduce costs and bring medicines to market 500 days faster, creating a distinct competitive advantage.

"A lot of the struggles come down to data," said Kyle Mandala, consulting director for RSM. "Without a unified system, there is no real-time visibility into the status of clinical trials, project progress and financial performance; it hampers decision-making and holds up the science."

Implementing a technology solution such as NetSuite can streamline data capture, track spending, break down silos, enhance cross-functional communication, address bottlenecks, and mitigate risks. This approach is crafted to hasten drug development by enhancing overall business operations, ensuring efficient support for research without disrupting scientific processes.

Replacing legacy processes with the right technology at all stages of drug development — from grant tracking and clinical research to FDA review and commercialization — can ensure life sciences companies adhere to timelines and budgets, improving speed to market.



Managing Business Complexities During Discovery and Development

Drug development may start in the lab, but researchers depend on funding to support their work. The National Institutes of Health provided $8.1 billion in grant funding to support the development of new drugs between 2010 and 2019, according to the most recent data.

Grants help support research to better understand diseases but grant management can be arduous. Life sciences companies often use manual or semiautomated tools that are less efficient and more error-prone, making it difficult to track grant requirements.

NetSuite offers grant management, including converting awarded grants into billing transactions, generating invoices for cost reimbursable grants and producing grant milestone reports. Without this kind of enterprise resource planning (ERP) solution, it's challenging for life sciences companies to provide funders with financial statements, track spending, and manage expense reports, reimbursements and other business processes that are pivotal for securing funding, said Steve Kemler, life sciences senior analyst at RSM.

Besides providing a single source of truth to stakeholders, implementing a cloud-based solution during the earlier phases of drug development makes it easier to manage the complexities of business operations as products move through clinical research and commercialization.

Kemler said there was a risk in waiting until further on in the product life cycle to implement the technology solutions required to scale.

Investing in the right technology early can make it easier to navigate the entire drug-development life cycle, including the clinical research phase.

"Even relatively simple organizations have a lot of different data sources and different data-processing tools, and making sure that you've got appropriate controls over them as you grow becomes a bigger and bigger task. The back office needs support as life sciences companies grow and become more sophisticated."

STEVE KEMLER, Life Sciences Senior Analyst at RSM

Technology Reduces Risk

In the lab, there are a wide range of risks during drug development, from the lack of suitable bioassays or insufficient potency to toxicity; there are risks on the business side, too. The right technology can help manage them.

Financial risks: Once a life sciences company goes public, federal legislation regulates the financial auditing and reporting.

"When you go from one capital raise to the next, as the size of investments keep going up," Kemler said, "the expectations of your investors also goes up. You need to have the right systems and the right controls and delegations of authority to ensure that their money is spent wisely."

Third-party risks: Life sciences companies outsourcing many tasks and may contract with clinical research organizations, manufacturers or other external providers. Implementing tools and processes to monitor and manage those external processes and external risks is essential.

Regulatory risks: Regulators, including the FDA, require pharmaceutical manufacturers to provide documentation that appropriate assessments are conducted and vendors are audited. A quality management system can provide and maintain validation, Kemler noted.

Investing in Technology During the Clinical Research Phase Counts

On average, it takes more than 10 years to progress from clinical trials to regulatory approval. Along the way, the FDA has strict guidelines for Phase 1, 2 and 3 clinical trials, including operating procedures, written protocols and reports.

NetSuite makes information available across functional areas and streamlines the process of sharing data in real time to turn it into actionable insights. During the clinical research phase, life sciences companies can oversee project tasks and resource allocations, track time and expenses, and manage project budgets and reports in a single ERP.

As the clinical research phase draws to a close and manufacturers begin to anticipate FDA approval, the focus shifts to launch planning. This phase, which could start 18 to 24 months before approval, involves scaling operations, supply chain and order management and increasing staffing in preparation for commercial launch; all these tasks can be managed with NetSuite.

Working in disparate software systems can hinder the process, said Robbie Weatherwax, manager of business applications for RSM.

"A lot of biopharma companies bring in a lot more third parties like logistics companies or outsourced manufacturers as they prepare for commercialization," he explained. "Having all the data from those different vendors in one place can keep the entire team on the same page."

The right combination of tools allows for seamless crossover between clinical operations and the finance department. Without them, Kemler said, it becomes more difficult to manage processes that span the organization and could make the already difficult road to commercialization even more difficult.

"It's all about coming up with a road map for these types of inflections and making the investments at the right time. You don't want to get to an inflection point and realize you need to make these changes."

STEVE KEMLER, Life Sciences Senior Analyst at RSM

Helping Biopharma Companies Navigate their Digital Transformation

Review and approval for a new drug takes between six and 10 months — but few companies ever make it this far.

Investing in effective technology is essential for scaling effectively and preparing for the regulatory requirements of being a commercial company.

Once a drug is approved, scaling operations and supply chain to get a drug to market is a key operational challenge. Life sciences companies must deal with potential shortages of raw materials, resource-intensive management of laboratories and other facilities, and a host of other potential supply chain concerns that affect their ability to bring a drug to market.

"Traceability is very important," Mandala said. "Precise and timely data is required to know where lots originated, where they went and who has them."

Technology needs change, too. Although an ERP that captures data for operational decision-making becomes an essential tool to navigate the transition from drug development to launch, few platforms can manage the complexities of the drug-development life cycle.

"Most of the roadblocks are around operational inefficiencies, data management and limited visibility into the silos within the organization," Mandala added. "You need real-time data and scalability in the platform to allow you to make timely decisions."

FDA approval is not the last hurdle for life sciences companies. Managing the post-commercialization phase requires continued monitoring of data and metrics to ensure commercial success.

"You need real-time data and scalability in the platform to allow you to make timely decisions."

KYLE MANDALA, Consulting Director for RSM

Underscoring the Need for Technology After Commercialization

Besides maintaining compliance with FDA postmarket drug-safety monitoring, life sciences companies need order management and procurement, raw materials tracking, and product valuation throughout the manufacturing process.

The departments that track vendor costs, purchase raw materials and manage supply chain often operate in isolation and store data in silos. An ERP creates a central point for product costing, which can help life sciences companies move toward commercial readiness.

SuiteApps can be implemented to meet specialized requirements from order management and taxation to manufacturing and account reconciliation; and NetSuite's integration interface allows it to connect to systems you have already invested in.

Once a drug hits the market, life sciences companies continue scaling operations, hiring staff for commercial operations and sales. Software needs to grow with head count, but expanding from 50 to 500 staff is not the time to implement an ERP system.

Integrating procurement and quality management tools can also help with an audit, turning a stressful process into one that is easier to navigate. It encourages staff to follow processes, reduces the likelihood of purchasing supplies from unapproved vendors and prevents inventory that should go to quality assurance from going to sales.

An ERP system also eases the transition during an acquisition. Manufacturers need technology with multiple-subsidiary functionality that allows access to their existing ERP system to manage internal reporting and the flow of information to the acquiring entity without major investments in operational changes—and finding the right technology partner is essential.

" When you haven't laid the groundwork, it becomes really hard to add the types of tools that you'll need to manage commercial sales into your existing environment. You need a good game plan, and you need to start early so you're able to give your organization the tools they need to then execute on a drug launch."

STEVE KEMLER, Life Sciences Senior Analyst at RSM

Embracing the RSM Solution

RSM is a leading NetSuite solution provider. The cloud-based ERP combined with RSM's industry-leading implementation solutions help life sciences companies manage business operations, optimize operational efficiencies, improve financial visibility, enhance customer service and expand global capabilities.

Life sciences companies rely on RSM for NetSuite solutions that allow data visibility and tracking required in the highly regulated pharmaceutical industry in a system that is accurate and efficient.

A global pharmaceutical services company selected NetSuite as its ERP after experiencing a compound annual growth rate of 67% and recognizing the need for support with its ERP implementation.

A biopharma company that manufactures medicines in-house partnered with RSM to implement NetSuite, and the Pennsylvania-based company noticed an immediate benefit from the custom reports for department spend, dashboard views of profits and losses, and data analysis, calling NetSuite the right tool to expand its business.

RSM can tailor NetSuite solutions and perform optimizations to meet your implementation needs in the earliest stages of drug development and prove invaluable throughout the product life cycle, Weatherwax said.

"Everyone is working from the same data because it's all connected within one ERP system, which means that someone can make a change in the lab and it flows through to accounting," he explained. "In one unified system, there is inherent trust that what the NetSuite ERP is producing is going to be correct because everyone's playing on the same field."

As the global consumer retail market continues to push toward the $40 trillion mark,more middle-market retailers will shed their basic, legacy systems in favor of a cloud ERP that can scale up as they grow, automate many of their processes and better meet their customers' ever-changing expectations. By working with a reliable, experienced partner like RSM before, during and after ERP implementation, retailers can effectively tackle the "now" while also preparing for future success.

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