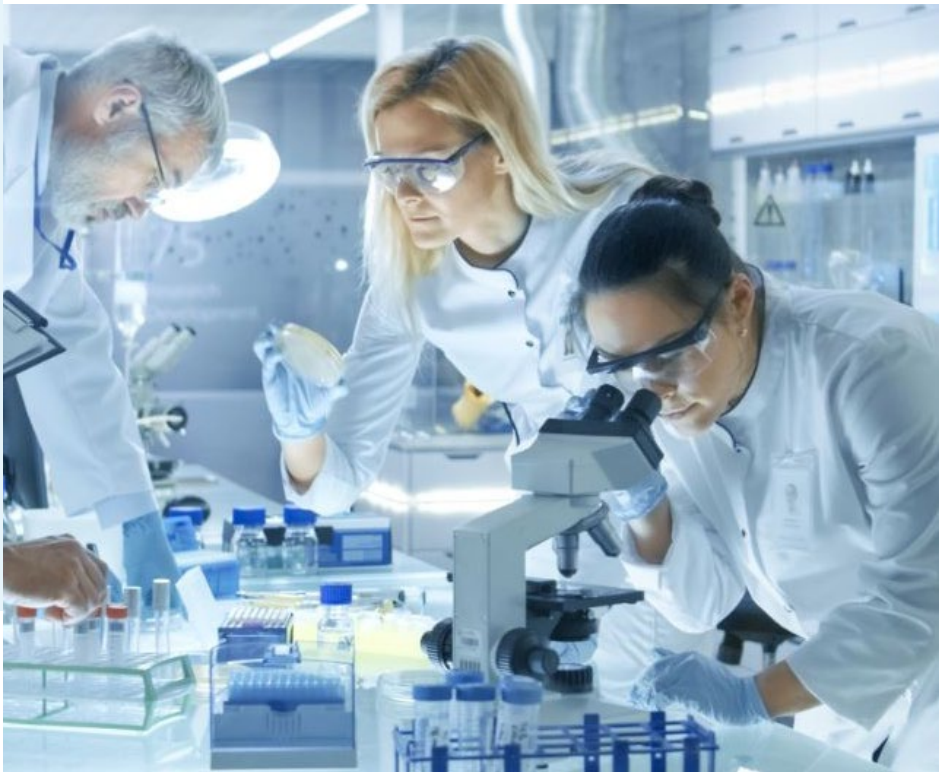
The Copley Consulting Group

ERP System Selection, Implementation and Beyond: A Playbook for SMB Manufacturers in FDA-Regulated Industries

Benefits of Modern Enterprise Resource Planning

Learn how ERP can set your business up for success in an evolving industry.

CONTENTS



ERP System Selection, Implementation and Beyond: A Playbook for SMB Manufacturers in FDA-Regulated Industries

This e-book is a comprehensive guide for small and midsize manufacturers in FDA-regulated industries who are considering ERP system adoption. We will walk through what growing companies should be looking for in an ERP solution as well as key considerations for hosting your system on the cloud. From there, we'll help you sidestep common mistakes in the implementation process, learn more about validating your system and discuss how ERP can set your business up for success in an evolving industry.

1 Choosing Your ERP Solution: What to Look For

How to select an ERP system that will help you safely scale-up in an FDA-regulated industry.

Startups in any industry must master the skill of achieving short-term scale-ups without losing sight of their ultimate goal. For small and midsize businesses (SMBs) in the life sciences industry, the long-term target might be FDA approval, sustained profitability or acquisition. Because documented processes and organized recordkeeping help demonstrate the integrity of your operations to auditors and investors alike, an ERP system is a worthwhile asset for any life sciences startup looking to earnestly invest in their growth.

Here are some key considerations when selecting an ERP system for an early-stage life sciences company.

Compliance

As your organization grows and your operations expand, so too will your responsibility to maintain regulatory compliance. It's important that your ERP system is validated to meet the expectations of regulatory bodies; however, don't stop there.

Examine the functionality of the software and consider how it will support your ability to meet regulations long-term. Does it offer e-signature approvals, simple documentation management, full lot and serial tracking and other features that will make it easier to do your job in a compliant fashion? Then, look beyond the product, and consider the ERP vendor. Do they have industry experts on staff who will ensure the software remains in lockstep with shifting regulations? Choose a partner who is committed to anticipating regulatory changes, so you don't need to worry about gaps in compliance following system adoption.

Capabilities

There are plenty of lightweight ERP solutions on the market today. However, just because a software meets your company's needs today doesn't mean it will continue to do so in the years ahead.

Your ERP system requirements list should be a reflection of your long-term business plan. If your goal is to grow your organization to introduce new products or offer additional services, then you need a system with the broad capabilities to support those needs. Increased functionality doesn't necessarily mean a higher price tag. You can consider a modular ERP system with a lean architecture that allows you to add on features as they become relevant to your business. Or you can minimize the expense of IT infrastructure by hosting your ERP system in a private cloud. Work with your vendor to find a software package that will accommodate growth without busting your budget.

There are plenty of lightweight ERP solutions on the market today. However, just because a software meets your company's needs today doesn't mean it will continue to do so in the years ahead.

Stability

The development of pharmaceuticals and medical devices can take years, and once a product has been introduced to the market, its supply chain and life cycle must also be managed. You don't want to adopt an ERP solution only to have it become unsupported a couple of years down the road.

Life sciences SMBs would be wise to work with an established and financially stable ERP vendor. For one thing, you'll be confident that your software partner has the expertise to shoulder the burden of technical troubleshooting should it be needed. It also means that you minimize the risk of needing a system reboot – and the downtime that comes with it – should your vendor suddenly close up shop.

As a life sciences SMB, your business is inherently risky. You're balancing regulations, high costs and competitive pressures in a race to market. The ERP system you select can add to or mitigate that risk, so choose wisely.

2 Hosting Your ERP System: Is It Safe on the Cloud?

How to confidently meet your regulatory obligations in a cloud-based environment.

Over the last few years, cloud-based ERP has become an increasingly popular option for manufacturers across industries. In contrast to an on-premise ERP solution, cloud ERP offers distinct advantages – most notably, easy online accessibility for employees who are away from the office. Deployment options for cloud ERP range from public, multi-tenant options to private, single-tenant clouds to hybrid models that lie somewhere in between. There is no one-size-fits-all solution, but as a life sciences company, you have regulations and compliance concerns to take into consideration. Below are some decisions you will need to make as you consider adopting a cloud-based ERP solution.

A Cloud of Your Own?

There has been lingering distrust surrounding the use of public clouds for ERP. Some believe they aren't secure, they aren't reliable, or they cost too much to maintain. Most of these misgivings are rooted in misconception, but it is true that there are unique challenges involved in operating on a traditional public cloud in an FDA-regulated industry.

Companies that utilize public clouds, which are multi-tenant, often share servers with other companies. If you go this route, it's important to understand how data is siloed and access is managed by your cloud provider. Do their security measures allow you to meet your compliance requirements?

Many life sciences companies prefer to operate on a single-tenant cloud. This can be achieved by hosting a private cloud yourself or using a third-party option. In either case, you will have more control over your infrastructure and can design an environment tailored to your unique security and data management FDA compliance needs.

The Upside of a Private Cloud

ERP system implementation requires a considerable investment – of both money and time. Your budget and timeline can help determine whether a private, company-owned cloud or third-party, single-tenant cloud is right for you.

Hosting your ERP system on a private cloud may increase the time and capital involved in implementation and will require ongoing in-house resources for upkeep and maintenance. It may also mean purchasing server space you won't utilize in anticipation of your long-term needs. Working with a reputable implementation and hosting partner allows you to benefit from their technological equipment and expertise as well as packaged operational validation scripts, which can significantly speed the deployment process. Utilizing a third-party cloud may also offer more flexibility to quickly augment server bandwidth in times of peak demand or company growth – especially if you are working from a subscription model.

Whether you are hosting yourself or using a hosting partner, private clouds offer more transparency into system upgrades, which can be critical for compliance.

Whether you are hosting yourself or using a hosting partner, private clouds offer more transparency into system upgrades, which can be critical for compliance. For companies whose ERP systems operate on a public, multi-tenant cloud, system updates are often frequent and automatic. When these changes are rolled out to tenants of the cloud, they can affect established processes or the logic of rule-based workflows. This opens the door to minor inconvenience in other industries, but for those whose operations align with FDA regulations, compliance could be at stake. As the single tenant in your private cloud or third-party server, you have control over the timing of your updates, making it easier to plan and validate system upgrades.

Rent or Own?

When choosing between hosting your own private cloud and using a third-party partner, you can weigh your options as you might in deciding to own or rent a home. If you are prepared to manage all of the upkeep involved in hosting your own cloud-based environment, then investing the upfront capital may pay off in the long run. If not, a subscription-based private cloud with a trustworthy third-party host might be a better fit. With a hosting partner, you benefit from the expertise of an organization focused on cloud management, not to mention the often extensive backup systems in place, which offer a high level of security and uptime. Still not sure? Ask your implementation partner to review hybrid options to find a cloud environment that's right for you.

3 Avoiding Common ERP Implementation Blunders

With resources, capital and compliance on the line, how can you effectively manage risk during ERP deployment?

When you're a small or midsize business in an FDA-regulated industry, implementing a new software can introduce a significant amount of risk. You're dedicating a substantial portion of your annual budget to a system that will transform how you do business. This transformation is where the return on your investment lies, but to make it happen, you'll need to manage your time, your resources and your budget – all while maintaining your compliance obligations. What could go wrong? Here are three scenarios to look out for during your ERP implementation – and how to get ahead of them.

1. Your system is not truly validated.

Manufacturers who work in FDA-regulated industries know that regulatory compliance is dependent upon successful business process validation – including the functions managed by your ERP system. The process of validating a new ERP system can consume valuable resources and material costs, and expose a company to the risk of FDA audit non-compliance if not correctly executed. "Pre-validated" ERP software packages can be an attractive option, but beware that out-of-the-box solutions don't always deliver on their promise. There is no true one-size-fits-all answer, but vendor-supplied validation scripts and best practice templates can help reduce the effort, resources, and risk it takes meeting stringent regulatory requirements. To cover your bases, select a software partner who offers not only the tools but also the expertise to advise you as you complete the validation activities required for your company's unique use case.

Factor in the time you need to introduce the system properly so you can maintain productivity – and compliance – before, during and after deployment.

2. Your company isn't ready for deployment.

It's a common mistake to think of ERP implementation as an operation of IT when, in actuality, its effects will be felt throughout your entire organization. Agreeing to a rigid deployment methodology and unrealistic timeline can spell disaster down the road. Rather than automatically agreeing to a first-draft deployment calendar, think hard about potential sources of delay or difficulty and work with your software partner to plan accordingly. Have you adequately accounted for the time it will take to train your workforce? Maybe certain departments will need to drastically rethink their SOPs in light of the rollout, or you foresee possible supply chain complications that will need to be worked out. Factor in the time you need to introduce the system properly so you can maintain productivity – and compliance – before, during and after deployment.

3. You blow your budget.

As an early-stage life sciences company, the decision to invest in an ERP system is not one made lightly. The efficiencies achieved through your new software will be a boon to your business, but until those benefits can be realized, the focus will be on the price tag. To stay on budget, you need to expect the unexpected – and then account for it. Work with an implementation partner who will conduct a complete gap analysis and plot out exactly what's needed to get you from where you are to where you want to be. Then, ask yourself about other scenarios or services that are not covered in your vendor's proposal. For example, will you need temporary staff to help manage deployment tasks or your day-to-day work throughout implementation? What if another module needs to be added prior to your go-live date? Remember your total budget is something determined by you, not your software partner. Your leadership team and/or investors will be most focused on the total not the line items, so factor in a cushion where you can. Whether you need it or not, you'll be glad you did.

4 Validating Your ERP System: A Critical Step for Life Sciences SMBs

What are the consequences of a faulty software validation, and what do manufacturers stand to gain in verifying their ERP system?

For a manufacturer in a regulated industry, such as a medical device or pharmaceutical firm, compliance is a responsibility that permeates through all facets of your business, including the software you use in your manufacturing processes. A critical step in implementing your ERP system is validating that the software meets business requirements in accordance with FDA regulations. Many of these specifications are detailed in the US Code of Federal Regulations (CFR) Title 21, including GMPs and Quality System Management principles that must be followed. However, compliance is more than just "ticking boxes." Early attention to software validation can benefit your company in the long run. Here's how.

Software Implications

FDA regulations do not dictate the exact validation process as requirements can differ between organizations and software types; however, auditors generally expect to see certain evidence of your validation. This includes documentation such as risk analysis, test specifications and test cases, and a final validation report. Often your ERP system implementation partner can equip you with templates, test scripts and best practices to streamline the validation process. The resulting documentation will guide your software compliance throughout the life of the system, so it is worth putting your best foot forward.

Validating your system out of the gate is also important to the ongoing functionality of your software. Systems that are reliably validated upon deployment are easier to modify and revalidate. Validation documentation should be designed with upgrades in mind, with an easy-to-follow change control process for upgrades and module additions.

If you're making updates to your system within a year of your original validation, you may be able to revise documents by integrating new functionality into the software requirements, updating other validation documents and adding new module test cases. If more than a year has passed, you'll want to follow your change control process and assess whether a full revalidation is required.

Operational Integrity

The goal of validation is to not only ensure the quality of your software but also the operations that rely upon your software. Compliance is enforced through the review and approval of document submissions as well as periodic site inspections by

regulatory authorities. The consequences of non-compliance include criminal and civil penalties – but more than that, non-compliance can increase your odds of recall and corrective action and put patients' and end users' lives at risk. For this reason, a comprehensive validation effort is critical to consumer safety. Were all your files transferred from system A to system B? Are all of your workflows functioning as expected in the new environment? Thoroughly testing your configuration will ensure that mission-critical activities are being performed as they should.

The consequences of non-compliance include criminal and civil penalties – but more than that, non-compliance can increase your odds of recall and corrective action and put patients' and end users' lives at risk.

Conclusion

System validation may seem like a time-consuming step in the ERP implementation process; however, an early investment in a thorough and successful validation can save manufacturers time and money in the long run. No matter the system or your circumstances, it is imperative that you verify that your system's installation and configuration align with your intended use. Your auditors – and your consumers – are counting on it.

5 Leveraging ERP for Traceability

As new technologies are introduced, how will expectations for tracking change for FDA-regulated manufacturers?

A shift is happening among manufacturers in FDA-regulated industries. The popularity of generics, direct-to-consumer business models and the recent explosion of SKUs has brought new pressures to biotech developers, laying out new expectations for manufacturers. What was once a transactional relationship is becoming a more collaborative one, as developers and manufacturers partner together to obtain an edge in an increasingly competitive and complex supply chain.

How can manufacturers leverage enhanced tracking capabilities to become more agile in the face of shifting market conditions?

Ensure Product Quality

While the Internet of Things (IoT) in the healthcare industry is often focused on wearables that can collect data on patients' vitals such as heart rate and physical activity, IoT presents opportunities for manufacturers to track the health of products as well. When used together with technologies like RFID, your ERP system can help you collect feedback on the working condition of manufactured devices. For example, if an RFID-tagged medical device were to malfunction, a corresponding IoT-enabled ERP system could notify the product technician. The technician could then investigate the issues at hand based on the data that have been recorded and transmitted, identify the specific device based on its machine ID, and take appropriate action. This level of proactive monitoring can not only improve customer service and product quality but also help prevent recalls and limit the revenue lost through counterfeiting.

Maintain Compliance

Heightened compliance requirements not only in the United States but in Europe have biotech developers and manufacturers investing in methods that bring them closer to comprehensive, end-to-end product tracking. The ability to know of units

about to expire and their exact location is both a competitive advantage and a valuable compliance tool. However, to make this a reality, partners along every step of the supply chain need to meet the same standards of transparency. The rising adoption of IoT technologies and potential for tighter regulations will help determine whether complete supply chain visibility becomes the norm. In the meantime, ERP system functions like e-signatures, approved vendor management and integrated quality control can provide a solid foundation for a comprehensive tracking system and ensure your organization is prepared for audits and product recalls.

The ability to know of units about to expire and their exact location is both a competitive advantage and a valuable compliance tool.

Right-size Your Inventory

Demand within FDA-regulated industries can be difficult to forecast; however, the ability to track product beyond the warehouse could facilitate more optimized inventories. Such visibility would allow manufacturers to collect supply levels down to the SKU and to anticipate the needs of downstream partners. In an ideal system – and in what perhaps will become the standard in future years – partners up and down the supply chain would share real-time inventory information through a shared database, such as a common ERP system. With a single source of truth among a collaborative network, supply could get ahead of demand, manufacturers could forecast customer orders, and biotech developers could anticipate the needs of patients who need their products most.

About The Copley Consulting Group

For nearly 30 years The Copley Consulting Group has delivered Infor CloudSuite™ Industrial implementation success to more than 400 enterprises. From Fortune 1000 companies to start-up operations, Copley has provided education, training and technical services melded with a focus on Best Practices. As one of Infor's premier Gold Level Channel Partners, Copley has assembled a team of dedicated professionals committed to increasing the productivity and profitability of our customers.

For more information about our Infor Cloudsuite Industrial (SyteLine) system implementations in FDA regulated environments, contact a Copley Consultant at 855.884.5305 or sales@copleycg.com.

Follow us on social media, click on the icon below

facebook.com/copleycg/

twitter.com/CopleyCG

linkedin.com/company/copley-consulting-group/

COPLEY
CONSULTING GROUP