



IMPROVING ERP IN THE LIFE SCIENCES INDUSTRY: HOW VALIDATED SAAS SUCCEEDS

Software as a Service (SaaS) reaches into the ERP space

Over the last two decades, Enterprise Resource Planning (ERP) solutions have enabled thousands of manufacturers to reduce risk, improve financial management, reduce operating costs and increase corporate governance. But for small and medium-sized biotechnology and pharmaceutical manufacturers, ERP system implementations can be time-consuming and costly.

For one, most generic ERP systems today lack the industry-specific functionality so essential in today's regulatory climate, forcing manufacturers to pay for expensive customizations or bolt-on functionality.

Furthermore, ongoing system maintenance is extremely resource-intensive when validation issues are brought into the fray. Once an ERP system is implemented and validated, even the smallest configuration change or enhancement involves a tremendous amount of work and supporting documentation.

For instance, every change must be researched against system documentation, applicable predicate rules, and data-entity diagrams to make sure that the impact to the system is fully understood. Test scripts must be developed and executed to ensure that the system is operating as designed. And the entire process must be fully documented.

Trying to manage this effort without a full-time, specialized resource is nearly impossible. Yet such a resource can be a costly proposition for life sciences companies facing cost pressures. As a result, most companies opt to forgo the expense and instead try to manage this process with existing IT resources.

But in too many cases, system changes—even critical changes essential to meeting evolving business requirements—are simply not performed. And eventually, without these changes and updates, the ERP system stops meeting the company's business requirements. It becomes obsolete. And before long, the manufacturer is back in the market for a new ERP system.



From old to new

For emerging and mid-sized life sciences manufacturers, the Software as a Service (SaaS) approach offers a viable alternative. The SaaS delivery model has grown in popularity over the last few years for its rapid deployments and cost benefits. For companies with limited resources and aggressive timetables, the concept seems attractive on the surface. But when it comes to applications such as ERP, the problem has been traditionally finding an industry-specific solution and a provider that can offer and maintain a fully-validated system.

The typical SaaS model works by having multiple companies working from a multi-tenant database on shared servers. This approach spreads hardware, software and maintenance costs across companies, making it more cost-effective for the service provider to deliver the solution and for its clients to buy the service.

But when you enter the life sciences industry, this model begins to break down. First, generic ERP systems often fail to meet the unique requirements of biotechnology and pharmaceutical manufacturers. They force companies into generic processes, impractical workarounds, and costly customizations.

Furthermore, validation becomes an issue in traditional SaaS scenarios. The requirements around GMP and validation require a manufacturer to have its own dedicated server so it can have a documented Installation Qualification (IQ). In a multi-tenant environment, where multiple companies are hosted on a single server, an IQ is impractical. As well, when an update is released, a life sciences company running a validated system can't simply be told, "Your platform will be upgraded on Saturday night."

Fortunately, managed service providers are now filling this void by offering a set of benefits not found in traditional SaaS ERP offerings: validated SaaS solutions tailored for the life sciences industry—an approach that marries the convenience of SaaS with the industry-specific, GMP-validated ERP solutions that have found exceptional success in the life sciences industry.

The unique combination of industry fit, rapid deployment, and low cost makes this approach to software delivery well-suited to a broad array of emerging and mid-sized biotechnology and pharmaceutical manufacturers. Some providers even give their clients the option to choose an off-site hosted solution or an on-site managed deployment.

Many emerging pharmaceutical and biopharma manufacturers and research organizations simply cannot afford the license fees for a GMP-validated system, the long implementation cycles or the costly maintenance of typical enterprise software systems, so as a result, managed service providers are stepping up. These managed services providers help by minimizing the high costs of maintaining an IT infrastructure and the industry-specific challenges of GMP assessments, validation, and change control.

Benefits of validated SaaS solutions

For companies that can't afford massive up-front license fees, the risk of long implementations or the burden of maintaining a validated enterprise software system, managed SaaS solutions offer a number of key benefits, including the following:

¶Life sciences business fit: The validated solutions offered by managed service providers are specifically tailored to pharmaceutical and biotechnology manufacturing and rarely require further customizations. They are process manufacturing-based, and they enable the monitoring, tracking, control, validation, and auditing of critical resources and activities across the manufacturing and distribution processes, according to the stringent guidelines set by regulatory agencies.

¶Enabled SOX compliance: When it comes to Sarbanes-Oxley (SOX) and other regulatory mandates, the role of ERP systems in enabling compliance can't be overstated. To address these and other issues, industry-focused SaaS companies provide life sciences manufacturers with the financial-systems foundation and best practices necessary to create the secure, auditable and controlled environment needed to achieve SOX compliance.

¶Chargebacks management and project accounting: Beyond core ERP functionality, some managed systems also include chargeback management, contracts management, and project accounting as part of their standard package—capabilities that have become critical for life sciences manufacturers.

Chargeback claims between wholesale distributors and a manufacturer may reach as high as 5% of gross sales. As a result, systems that automate processes, ensure data quality, confirm the validity of the chargeback, decrease overpayments and provide the audit trails mandated by regulatory requirements can have a significant impact on the manufacturer's bottom line.

Considering that a stand-alone chargeback and contracts management system can easily run \$500,000 once implementation costs are factored in, having this functionality built in to a managed ERP solution can be a tremendous benefit for cost-conscious manufacturers and those on a timetable.

¶Operating in a continually validated environment: Studies have shown that the standard ERP system validation takes approximately 120 days to complete. Considering the cost of having an experienced full-time IT resource heading this effort—and considering the time-sensitive nature of an ERP deployment—manufacturers are often

best served by a SaaS provider that can shorten the time to validation by at least 50 to 75%. At the same time, the right vendor must be able to systematically assist clients with validation of their own systems as updates and upgrades are released.

Beyond providing essential industry-specific functionality, life sciences-focused SaaS companies also provide their clients with dedicated hardware and a validated environment, as well as all of the necessary validation documentation protocols and test scripts, saving the manufacturer an enormous amount of money and headaches.

And this value-added service goes beyond the original implementation. As the SaaS company releases upgrades, fixes and patches for the ERP software, it automatically provides clients with all of the documentation showing where and how those changes affect the system. Typically included in this documentation are all of the data-entity diagrams showing where the system was affected, as well as all of the test scripts clients need to ensure that all changes are in compliance with industry and governmental regulations, such as the FDA's 21 CFR Part 11 and its impact on the GxP environment.

One particular validation strategy for SaaS deployed by managed service provider, Vantage Systems, is based on Good Automated Manufacturing Practice (GAMP4) methodology mapping ERP transactions to the applicable FDA predicate rules. The validation of the cGMP-critical functions of the ERP system and the utilization of an Electronic Batch Record (EBR) represents a significant improvement in the process manufacturing functionality. The benefits of this approach are:

- Multiple-regulation predicate rule mapping to the common business process model identifies any ERES compliance requirements.
- Use of a common software set-up across all sites ensures cost-effective and ease of validation.

Cost structure

The inherent cost benefits of a SaaS solution are well-known such as minimal upfront capital required with a subscription pricing model and cost avoidance of IT infrastructure and resources with managed hosting. The typical investment analysis for small-to-medium size companies shows that cumulative subscription costs do not reach perpetual license costs until close to three years. Some managed service providers allow you to convert to perpetual licensing, after a period, so you can maximize your software investment.

As expected, there is a premium seat price for a validated SaaS solution over a generic offering; however, the value proposition is clear to companies that understand the internal costs of doing business in a regulated environment. For example, one of the areas that is a major concern for life sciences companies are validation costs. A validated SaaS solution can cut up to 80% of the effort required, yielding substantial cost savings.

IT operational expertise in life sciences

Manufacturers should look for service providers that have more than just a working knowledge of the life sciences industry. The right partner should have a solid track record of IT operational expertise in biotechnology and pharmaceutical companies. It must have a firm grasp on the challenges of the life sciences industry from an IT, financial, manufacturing, and regulatory standpoint. And it must demonstrate a solid commitment to helping its clients achieve operational excellence in a highly regulated environment.

In a climate that increasingly calls for tighter cost controls and faster time to results, small and mid-sized life sciences companies would do well to consider industry-focused SaaS providers that can deliver fully functional, validated ERP solutions quickly and reliably while removing the cost burden and headaches of a traditional installed deployment.

It's important for emerging pharma and biotech companies to focus on their core competencies while considering the challenges of commercialization as it relates to IT infrastructure and technical resources to support their operation. Big or small alike, these companies need to operate in a secure, reliable and controlled environment to maintain their validation. Finding a partner with extensive expertise in areas such as change control and regulatory compliance is important to feeling confident in a provider's ability to manage a SaaS approach for life sciences. PC



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