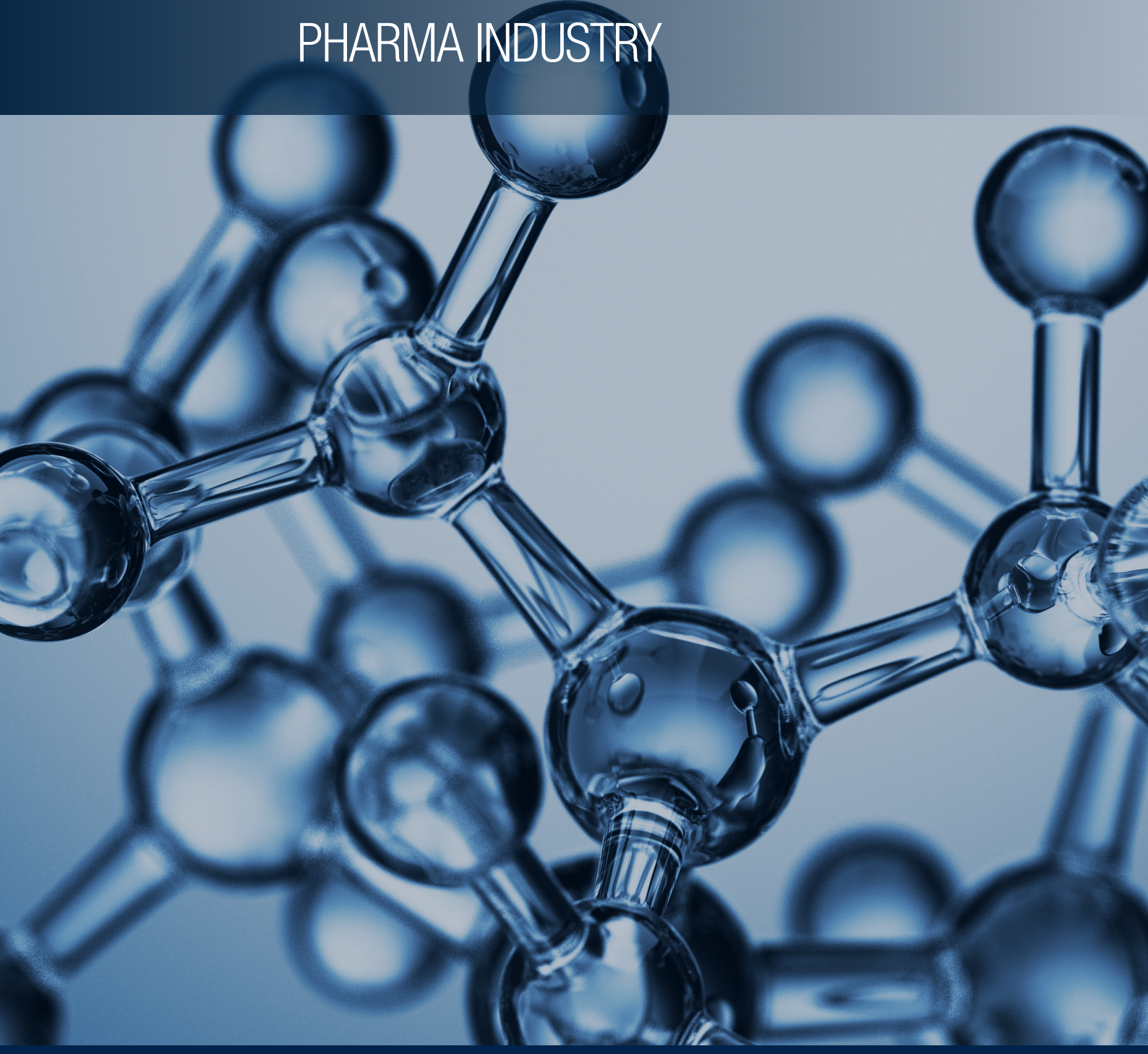
GETTING IT RIGHT: TOP STRATEGIES FOR SUCCESSFUL ERP IMPLEMENTATION IN THE HIGHLY REGULATED PHARMA INDUSTRY



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INTRODUCTION

Imagine a leading pharmaceutical company on the brink of launching a groundbreaking new drug. The stakes are high, with millions of dollars invested and the potential to save countless lives.

However, as the company is undergoing the transition to a new SAP system to streamline operations and ensure compliance with stringent regulatory standards, unforeseen challenges arise. The integration process is fraught with issues: data inconsistencies lead to incorrect batch records, compliance documentation is incomplete, and critical supply chain disruptions occur. As a result, the company faces a regulatory audit failure, leading to a halt in production and a delay in the drug's market release. This not only results in significant financial losses but also damages the company's reputation and delays access to life-saving medication for patients in need.

This scenario highlights the critical importance of meticulous planning, robust data management, and comprehensive compliance checks in ERP implementations as well as system updates, release changes or any other significant change of processes within the pharmaceutical industry. It underscores the potential risks and consequences of inadequate preparation and execution in such a highly regulated environment.

This is of course an extreme scenario, but the scary part is, that this is a viable scenario after all. Therefore, we will layout the necessary success factors for a successful implementation and the cost impact of not doing it right.

ERP AND REGULATORY CONSIDERATIONS

Let's take a step back to understand the importance of ERP. Standardized ERP systems are vital for all types of companies due to their ability to

- enhance operational efficiency
- ensure regulatory compliance
- provide real-time data insights and
- support growth strategies such as mergers and acquisitions.

These systems also help optimize cost structures, boosting value in the investment lifecycle.

While operational efficiency, regulatory compliance and reporting are essential in pharma companies, timely go-live planning and execution matter even more.

The industry is heavily regulated by agencies like the Food and Drug Administration (FDA) in the U.S. and the European Medicines Agency (EMA) in Europe. A standardized ERP system helps ensure compliance with good manufacturing practices (GMP), good clinical practices (GCP) and other regulatory standards (in summary, GxP) by providing accurate, real-time data for reporting and audits.

Pharma companies need to maintain detailed records of product batches, clinical data and quality control measures. An ERP system facilitates documentation, audit trails and traceability, which are critical for regulatory inspections and reducing compliance risks.

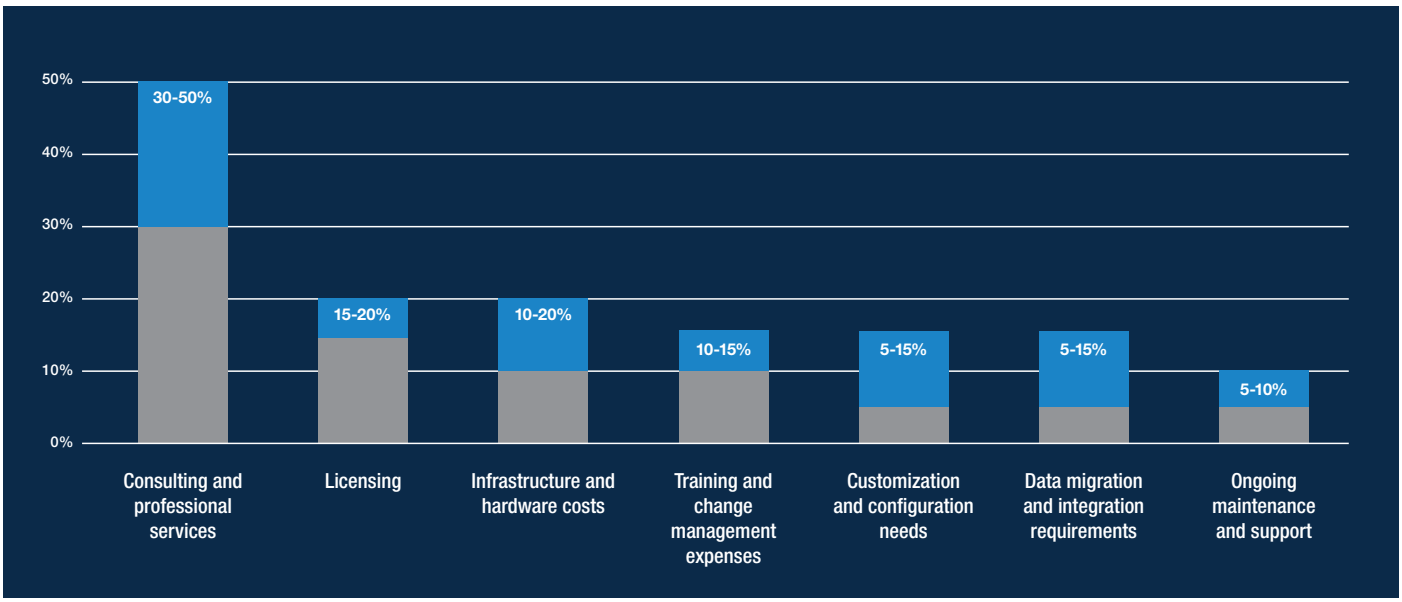
COSTS AND PHASING OF A TYPICAL ERP IMPLEMENTATION

The typical duration of an ERP implementation can vary significantly depending on factors including the complexity of the project, the size of the organization and the number of modules being implemented. On average, the implementation of a new ERP system for one entity takes about 12-18 months, split into the different phases Prepare, Explore (incl. fit-gap analysis), Realize, Deploy and finally Run (incl. Hypercare).

In each phase, all the necessary topics must be completed adequately and on time from a computer system validation perspective. This includes all approved documents needed to ultimately have a validated ERP system. System validation helps to safeguard both business operations and regulatory adherence.

“Go-live” refers to the point at which the ERP system is officially put into operation within an organization at the end of the Deploy-phase. In this phase, the system transitions from the development and testing stages to being fully functional and used in the day-to-day operations of the business. Successful go-live is crucial for the overall success of the ERP implementation, as it directly impacts the organization’s ability to leverage the new system for improved efficiency and productivity.

Below is a typical breakdown of the total project costs for ERP implementation based on A&M’s experience with clients:



THE COST OF DELAYS TO GO-LIVE

About 60% of the costs (consulting, professional services, training, change management expenses, data migration and integration requirements) are directly influenced by the implementation plan and the addressing of regulatory requirements.

Repeating individual phases or repeating the entire implementation project due to missing validation steps or a failed audit easily increases these costs by 50-100%. The worst-case scenario in the pharma industry is that after the go-live of the new ERP system, the authorities shut down the system due to errors in the validation of the system during implementation.

A postponement of the go-live is the most common cause of increased costs. According to A&M's analysis, only about 25-30% of ERP go-lives occur on time. Delays can have a negative impact on the following cost types:

Direct financial costs
Higher project costs, re-training of employees, licensing and penalties

Operational costs
Reduced productivity, inefficiency in production and supply chain disruptions

Compliance and regulatory costs
Legal penalties, non-compliance and delays in product approvals, potentially even the loss of manufacturing license

Opportunity costs
Delayed return on investment and missed market opportunities

Employee costs
Lower morale and increased frustration

These costs can be significant, especially in the pharma industry, where both operational efficiency and regulatory compliance are critical to success. The following levers can help avoid additional costs:

- Ensure **realistic planning**, including all relevant phases and tracking milestones for critical deliverables as well as establishing the basis with a **realistic business case**
- Select **experienced service providers**, paying careful consideration to relevant industry knowledge, track record as well as expertise
- Ensure sufficient know-how to sufficiently cover all the **GxP-relevant topics** in the project and include all relevant deliverables in the project plan
- Set up honest, transparent, short-cycle **reporting** as part of the **solid project governance** to identify any deviations from the project plan and expected timelines
- Enable **direct communication** to decision-makers concerning status updates and definition of countermeasures in case of any deviation - no time-consuming communication cascade

Ensure that there is sufficient **internal capacity** in the areas concerned, that the **relevant people** are involved and that the **necessary knowledge of the ERP-relevant processes** is available. ERP roll-outs are usually handled by system integrators (SI), who are responsible for ensuring a smooth go-live by managing the technical, functional and organizational aspects of the ERP system implementation, mitigating risks and making sure the system delivers value as intended. The SI may be supported by an additional Project Management Office (PMO) that focuses on project management, risk management and change management. In the absence of a PMO, these tasks will also fall to the SI.

In our experience, an SI is often selected by a procurement stakeholder in a cost-driven decision, is frequently an afterthought or the choice is based on existing relationships. What we see missing is a thorough check of whether the SI has actual experience in a regulatory context in the past, as well as a proven track record of executing tasks within budget and on time.

Extending the implementation timeframe due to SI's planning errors or lack of experience is a costly proposition. In almost all cases, the costs incurred outweigh the anticipated cost savings by using the cheapest proposal. It is even worse if the SI then needs to be replaced during the implementation by another firm, as it could lead not just to an increase in costs but to legal issues.

BALANCING COST AND REGULATORY REQUIREMENTS

When implementing ERP in the pharma environment, it is important to validate GxP-relevant areas and to document the evidence of validation – the latter is especially important as documentation is checked by auditors at regular intervals. The necessary validation places additional demands on an already tight schedule. It is advisable to involve external experts in the validation process to obtain an independent assessment of the validation-critical issues and to have additional capacity for time-critical validation. Moreover, it is essential to integrate these activities into the overall project plan.

Regardless of the use of external validation experts, it is important that the system integrators have experience in the regulatory environment of the pharma industry. The execution of the project is significantly influenced by validation-critical activities and the SIs must regularly provide evidence that flows into the documentation.

The following aspects are essential for systems validation:

- **Regulatory compliance:** Validation ensures that the ERP system meets regulatory requirements, providing documented evidence that it performs as intended. Documents such as the evidence required (e.g. comparison of data from source to destination via a test system using pre-defined acceptance criteria) need to be prepared, approved and signed by the SI, key user and the quality representative.
- **Data integrity:** System validation verifies that the ERP can accurately process, store and retrieve data without errors. Defined test scenarios are run through for validation and the results are documented and approved in each case.
- **Risk mitigation:** By ensuring the ERP functions correctly before go-live, potential risks related to system bugs, integration issues or security vulnerabilities are mitigated. Deviations in validation-critical topics can lead to all implementation topics being stopped at any time.
- **Process consistency:** ERP validation ensures that automated processes like supply chain management, production planning and quality control operate uniformly, aligning with good manufacturing practices. All processes must be defined end-to-end and must be linked to business incl. organisational structure.
- **Business continuity:** Validation helps identify and resolve issues before the ERP goes live, reducing the risk of disruptions in key business processes such as inventory management, production scheduling and distribution.
- **Audit readiness:** Auditors expect to see a clear, traceable validation trail, including system requirements, test cases and performance results, demonstrating that the ERP meets industry standards.

Balancing cost and compliance in a regulatory environment during an SAP implementation requires a strategic approach to ensure that compliance needs are met without incurring unnecessary expenses. Here are some strategies to help achieve that balance:

- **Early identification of regulatory requirements:** Identifying all relevant regulatory requirements early in the project will help avoid costly changes later on.
- **Focus on essential compliance features:** Prioritize the implementation of features that are critical for compliance.
- **Regular compliance audits:** Conduct regular audits during the implementation process to ensure compliance measures are being met. This proactive approach can identify potential issues early, reducing the risk of costly rework.
- **Engage regulatory experts:** Involve experts who understand both the ERP-system and the regulatory landscape. Their insights can help in designing a system that meets compliance needs efficiently, potentially reducing the need for extensive customizations.
- **Optimize resource allocation:** Allocate resources efficiently by focusing on areas that have the greatest impact on compliance, dedicating more experienced personnel to compliance-related tasks to ensure they are completed correctly and efficiently

It is important that all phases relevant to ERP implementation are completed. While there is a tendency for companies to skip or shorten phases when there are timing issues, this can lead to a delay in the go-live date as critical issues need to be reworked or additional capacity is required for rework before the date. It is also advisable to report regularly on the status of the project, as well as on the results of individual phases, so that deviations can be identified and countermeasures taken in a short cycle.

CLEAR FULFILMENT CRITERIA FOR SUCCESSFUL GO-LIVE

Before the go-live, it is important to ensure that all critical issues are under control. We have summarized the key issues into the following six categories. The status of each category must be regularly reported to the decision-making body prior to go-live.

Category	Description
1 **Program Management**	• Program risks - no major risk open that can case a business to failure
2 **Solution Delivery**	• UAT successfully executed w/o pending critical issues • Master and transactional data successfuly migrated
3 **Validation Quality**	• Migration reports approved • IQ-/OQ-/PQ-report approved (incl. data quality check)
4 **Change Management**	• All impacted stakeholders are aware of Go-Live • User Roles understood • Necessary user training performed
5 **Technical Architecture & Infrafstracture**	• All interfaces set-up • Access is granted to ERP users • Technical Monitoring is set up for all applications
6 **Production Support / Hypercare Readiness**	• IT Organization & Business is properly staffed to support Q&A scheduled for all ERP-users • Hypercare phase prepared Key user 1st level support • System Integrator 2nd level support

UAT = User Acceptance Tests | **IQ** = Installation Qualification | **OQ** = Operation Qualification | **PQ** = Performance

CALL TO ACTION

Based on our extensive experience working with businesses, the following six factors contribute the most towards a successful ERP rollout in highly regulated industries:

1. **Setup, governance and communication**
   Check that the project setup and governance are well-managed, risks are minimized and goals are met, while communication guarantees that all stakeholders are informed, engaged and ready for the changes ahead.

2. **System integrator selection**
   Ensure that the SI for your ERP go-live has the right technical and regulatory expertise, project management capabilities and cultural fit with your organization. A successful SI selection leads to a smoother ERP implementation, reducing risks and ensuring timely project delivery. Don't let your procurement drive the selection based on cost alone.

3. **Business user involvement**
   Business user involvement in the ERP go-live process is vital at every stage, from planning and testing to go-live and post-go-live support. By engaging business users, organizations ensure that the ERP system is aligned with actual operational needs, minimizing disruption, enhancing user adoption and ensuring long-term success.

4. **Focus on execution & challenge timelines**
   Are timelines clear and do you have gates (e.g. post-simulation readiness assessments) that will force decisions regarding risk and go-live readiness? Focus on execution and don't be afraid to challenge timelines if regulatory issues arise. During ERP implementation, many interdependent workstreams need to be managed. However, if regulatory issues get on the critical path or even cause deviations, these should be taken seriously. Regulatory issues build on each other throughout an ERP implementation. This means that deviations in the regulatory framework cannot be easily compensated for.

5. **Keep the ERP in a validated state after go-live**
   Systems validation is NOT a one-time achievement. After the successful introduction of a new ERP system, it is essential to keep the system in a valid status. Any change in process or the ERP system needs to be documented, validated and approved to be compliant with the audit trail. Validation should not be disregarded even in the event of necessary short-term changes that are critical for the operational business. Even the smallest changes to the system can jeopardize this status and destroy the entire roll-out process.

6. **Evaluate the initially calculated potentials and costs**
   After the successful implementation of an ERP system, it is necessary to compare the actual costs with the budgeted costs. It is equally important, however, to track and report the originally calculated and budgeted savings potential associated with the roll-out of the ERP system in the P&L.

HOW A&M CAN HELP

A&M can help businesses achieve successful ERP rollouts, especially when the go-live situation is complex and time-critical. We have experts in ERP, pharmaceuticals and software validation to provide targeted support. Experienced interim managers can facilitate the implementation of the ERP go-live on the desired date.

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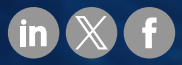

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