ARMANINO'S **LIFE SCIENCES**

IT PLAYBOOK

A guide to ERP system infrastructure to support regulatory compliance, FDA validation and supply chain excellence – for fledgling startups to global enterprises.

armanino

INTRODUCTION

As they innovate and expand, life sciences companies must navigate a growing maze of stringent regulations related to how they manufacture and distribute their products. **pg 6**

1 UNDERSTANDING BUSINESS VALUE ACROSS THE PRODUCT LIFECYCLE

Whether your product is in development or past the approval stage, be sure you are realizing the value of ERP to streamline business processes, overcome compliance challenges and position your firm for scalability. **pg 8**

2 MERGERS & ACQUISITIONS

Life sciences companies often buy or merge with other firms in order to acquire new technologies, expand their existing product lines or take advantage of tax strategies. Learn how the right technology can make these transactions easier for both sides, from organizational, reporting and operational standpoints. **pg 12**

3 FULLY INTEGRATED ERP VS. BOLT-ON SOLUTIONS

As life sciences companies develop their products, they must make key decisions about what business systems strategy is right for their organization. **pg 16**

4 THE IMPORTANCE OF SYSTEM AND VENDOR VALIDATION

Life sciences companies have an added factor to consider when choosing an ERP solution. Ensuring that your system complies with the FDA validation requirements is critical. **pg 20**

5 TOP 15 LIFE SCIENCES SYSTEM CHALLENGES

See how medical device, biotech, pharmaceutical and nutraceutical companies like yours address these top 15 regulatory, operational and strategic industry challenges. **pg 24**

6 BUILDING THE BUSINESS CASE FOR A NEW ERP

Here are three straightforward, effective ways to build your business case for instituting a best-in-class IT infrastructure. By laying this foundation, your company will be better able to manage all aspects of its day-to-day business, from quality and sales to operations and finance. **pg 34**

ABOUT ARMANINO

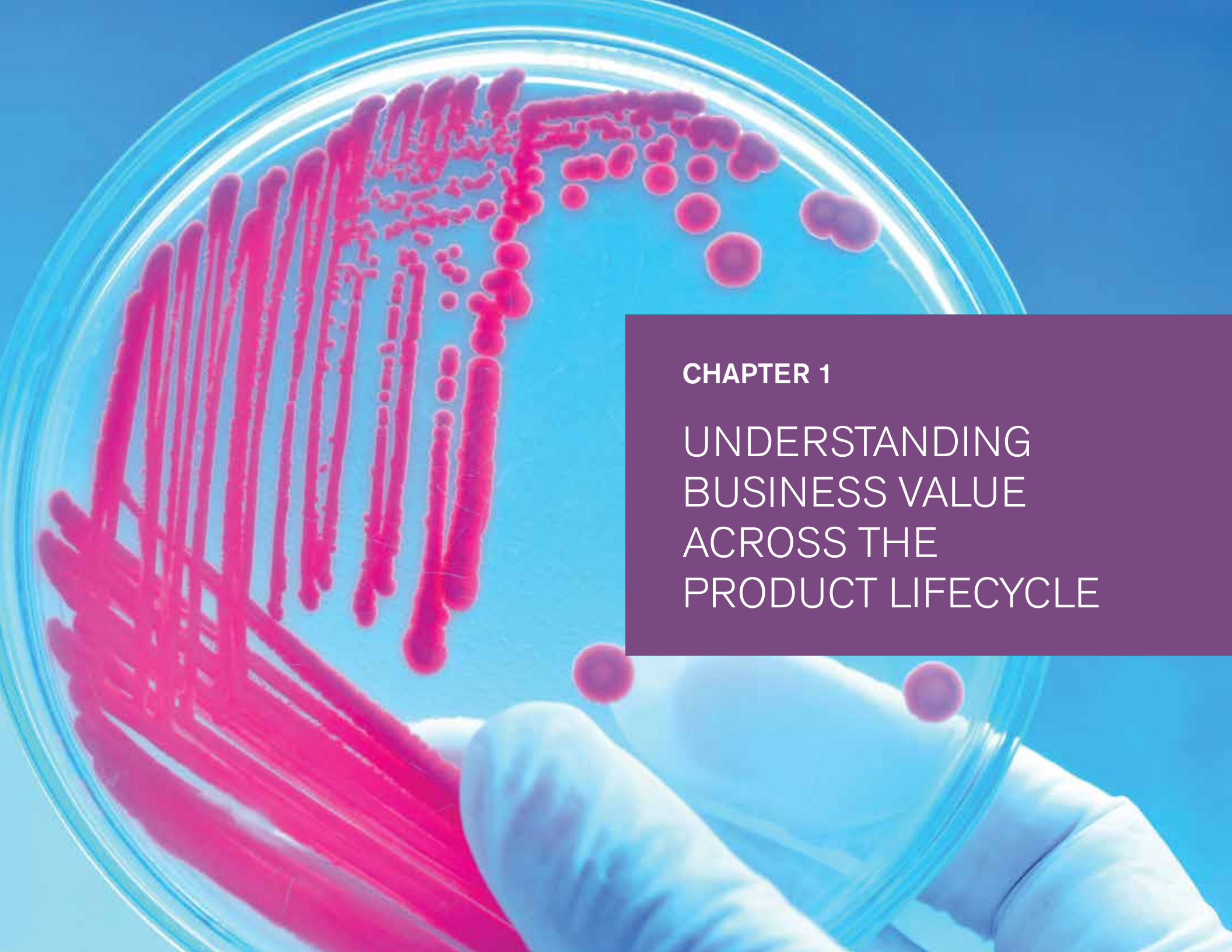
We deliver the tools you need to focus on your customers and grow. **pg 40**

Life sciences companies must navigate a growing maze of stringent regulations related to how they manufacture and distribute their products.

Although the Food and Drug Administration (FDA) has been working to streamline its requirements, new rules such as the Sunshine Act, the Drug Quality and Security Act and unique device identifier (UDI) regulations continue to hit the books, as regulators strive to improve transparency and patient safety.

These compliance challenges will only increase as medical device, biotech, pharmaceutical and nutraceutical firms enter new global markets, where they must pass additional regulatory scrutiny. As firms innovate in rapidly evolving areas, such as wearable devices, they must also be ready for the added regulatory requirements that inevitably follow new product launches.

To succeed in this highly controlled environment, life sciences companies need to comply as efficiently as possible with existing regulatory guidelines and be prepared for new ones. The right enterprise resource planning (ERP) system has the flexibility and industry-specific functionality to address these challenges and support growth, by allowing firms to easily consolidate and leverage data and change their business processes to meet evolving compliance needs.



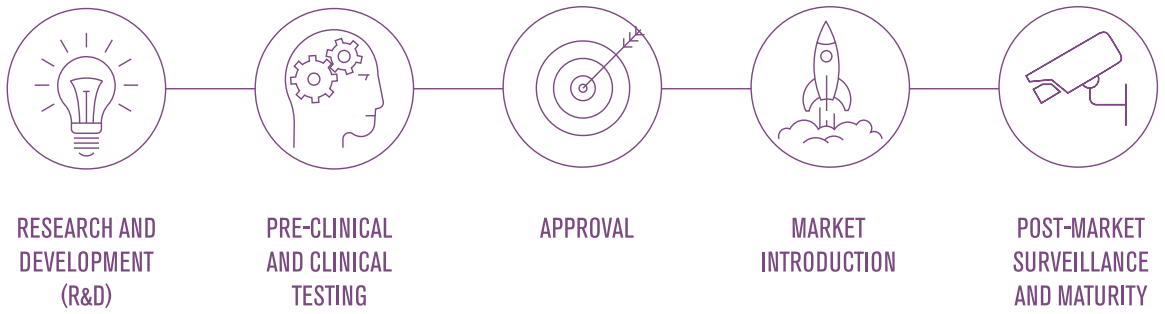
CHAPTER 1

UNDERSTANDING BUSINESS VALUE ACROSS THE PRODUCT LIFECYCLE

No industry is more heavily regulated than the life sciences sector.

Life sciences companies face scrutiny at every step of their product life cycle, and their success depends on their ability to meet these regulatory requirements. To grow their business, these firms need an ERP system that addresses their unique compliance needs, in addition to streamlining their business processes.

Although the length of their life cycles differ, life sciences companies share the same general product path:



They must meet a succession of compliance challenges throughout this journey, both before and after their products are approved.

ERP value during development

Whether you're a startup or an established manufacturer, your focus during the pre-approval phase is on getting your product to market as quickly as possible. To do so, you need an ERP solution that streamlines your operations and gives you the tools to meet regulations such as unique device identifier (UDI) guidelines and electronic signature requirements (21 CFR Part 11).

Although you can't control the length of FDA review periods, you can leverage ERP system data to navigate the review process more quickly. By pulling information like supplier, item, quality, yield, manufacturing and UDI attributes, you can build the robust reports and analytics the FDA requires, and submit more accurate documentation in less time.

As you work to win product approval, you must also ensure that your supply chain, manufacturing and other processes are compliant and efficient. The right ERP system can help you electronically manage and document everything from materials evaluation and potency to equipment calibration and device/batch history records, across multiple modes of manufacturing. By automating key functions such as order entry and UDI compliance, you can streamline your crucial business processes.

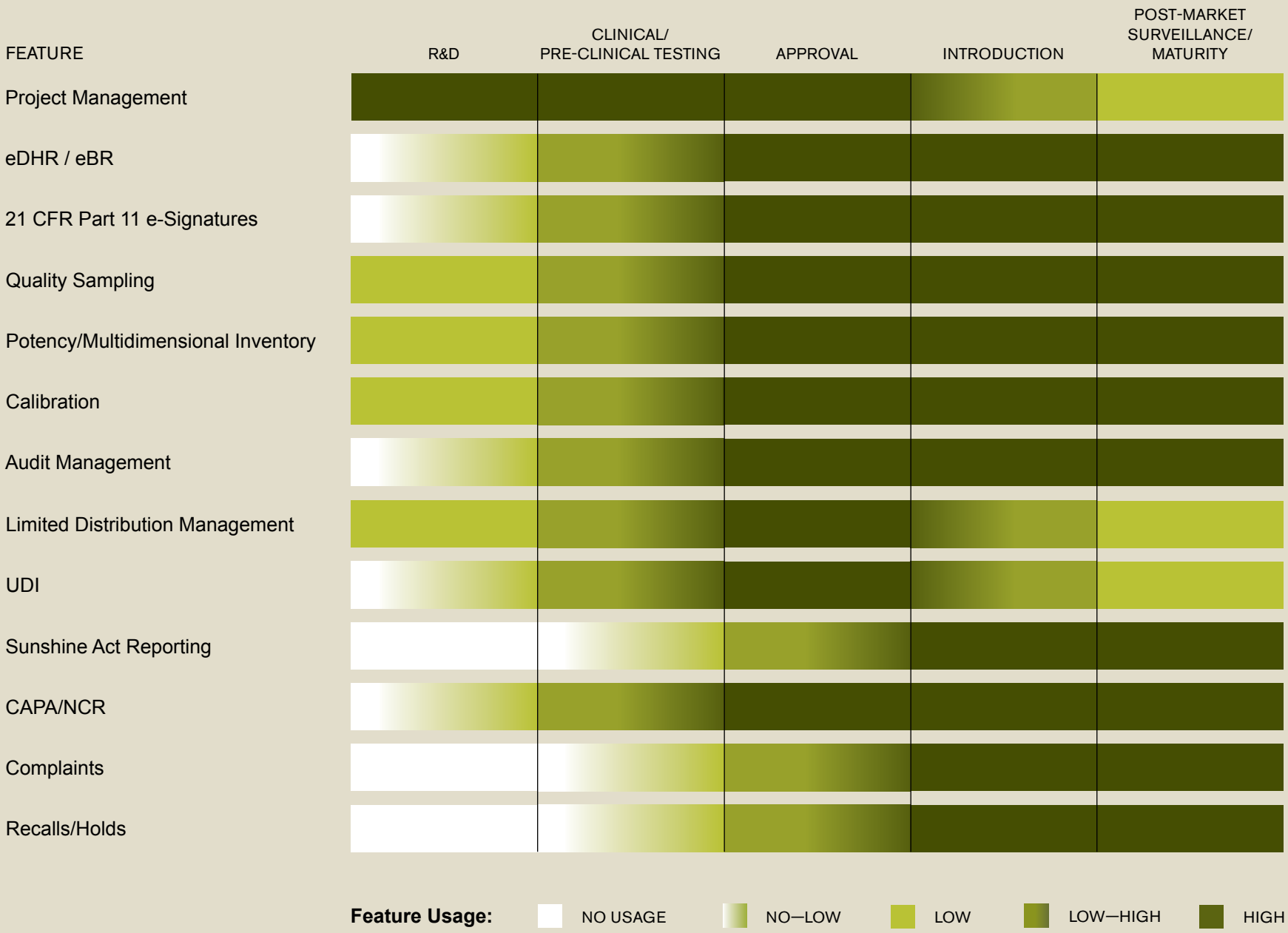
Value after product approval.

After your product is on the market, you need to focus on risk management, compliance and expanding your distribution. You must identify potential safety issues early and respond quickly to complaints and failures, so the ability to track and manage products throughout the supply chain is critical to your success. This capability is important even if you're a young company with no commercialized products, because you have to be ready to handle the inevitable regulatory and operational challenges that lie ahead.

An industry-specific ERP solution can help you protect product end users and minimize potential business disruptions. For example, it will allow you to set product holds and trigger non-conformance reports (NCRs), investigations, and corrective and preventive actions (CAPAs), based on your own risk categories. In case of a recall, you can identify affected products and quickly pull them from the market. The system will record your actions throughout, giving you the documentation regulators require.

The regulatory landscape changes often, so as the FDA and other agencies update existing rules and introduce new ones, you must be able to adjust your system and processes accordingly. As your business expands to new markets, you will also have to comply with new rules in these jurisdictions. You need an ERP system that gives you the flexibility to adapt to these changes—by enabling you to gather data to meet Sunshine Act reporting rules, for example, or allowing you to automatically limit where you distribute your products.

PRODUCT LIFECYCLE INFLUENCE ON BUSINESS NEEDS



CHAPTER 2

MERGERS & ACQUISITIONS

Whether you are a buyer or a seller, your system should include some key capabilities.

Life sciences companies often buy or merge with other firms in order to acquire new technologies, expand their existing product lines or take advantage of tax strategies. The right integrated technology platform can make these transactions easier—for both sides—from organizational, reporting and operational standpoints.

Having critical compliance practices built into your ERP system will make you a more attractive target if you're readying your business for a sale. If you're making an acquisition, it will simplify integration. Whether you're a buyer or a seller, your system should include key capabilities such as:

- Product registration and UDI compliance
- Vendor and distribution models
- Data collection and manufacturing execution systems
- Compliant quality screening via recognized sampling plans
- Process controls with non-conformance, corrective and preventive action (CAPA) and complaint management reporting

What sellers need to consider

Buyers look for companies with mature processes and technology, because they present fewer uncertainties and require less due diligence. If you are positioning yourself to be acquired, you need an infrastructure that minimizes your risks, and allows you to operate efficiently and in a compliant manner. ERP capabilities such as non-conformance tracking and reporting, complaint management, traceability and CAPA management are particularly important to have.

If your strategy involves selling part of your business, you will also benefit from a system that enables you to create additional entities. This capability allows you to do reporting and analytics by business segment or practice area, and to segregate information for a particular entity. Having this focused data makes it easier to position a unit for sale.

From an execution standpoint, the sale of a business unit requires you to roll the entity out of your corporate structure. So you need a system that allows you to segregate the unit and remove it from any elimination or consolidation framework that you have in place.

What's important for buyers

If you're the purchaser, you need to assess whether your ERP application can handle legacy business requirements that come with the new addition. What you don't want is a solution that is so inflexible it requires a re-implementation to support the acquisition. Compliance is a critical part of any life sciences transaction, so your ERP system should have specific 21 CFR Part 820 quality management system capabilities, such as quality sampling tables, calibration tables, electronic device history records (eDHR) and controls to enforce distribution limitations. Having this built-in functionality will allow you to integrate the new entity as efficiently as possible.

You also need to be able to quickly change your corporate reporting hierarchy. An integrated platform provides the necessary organizational flexibility and makes it easy to either fold the acquisition into an existing entity or adjust the corporate reporting structure. It allows you to add a new entity or series of entities—including consolidations and elimination entities—at any point in time.

On a day-to-day level, your finance team needs reporting that enables them to manage regulatory compliance and that supports a higher-level analysis of the overall business. You don't want to compromise your monitoring of existing reports and metrics because of the acquisition.

Your business intelligence (BI) structure also must be capable of supporting multiple entities and adjusting to changes in corporate structure. Agility is key, and your BI strategy and framework need to support inorganic growth and allow you to fold in new business units, entities and markets for reporting, charting, trending and key performance indicator (KPI) analysis.

From a supply chain and operational standpoint, you need a robust ERP solution that allows you to handle intercompany buy-sell activity, royalties and pricing markups. Life sciences companies often make acquisitions in order to vertically or horizontally integrate their business, so having the ability to manage intercompany trade and planning is critical for your operations.

CHAPTER 3

FULLY INTEGRATED ERP VS. BOLT-ON SOLUTIONS

As life sciences companies develop their products, they must make key decisions about what business systems strategy is right for their organization.

In the early clinical and startup phases, prior to FDA approval, firms can often get by using a small business accounting package and Excel to manage their operations. But as their product nears commercialization, they must meet additional regulatory requirements and more complex operational needs, such as product traceability and process audits.

At this point, life sciences companies face a choice: Invest in a fully integrated ERP solution, or continue using a small business accounting system while deploying bolt-on solutions to help govern and manage operations. There are pros and cons to each path, both initially and in the long run.

A fully integrated ERP solution for the life sciences industry represents the best-in-class option. It fully supports global financial management and real-time regulatory and compliance operations tracking throughout the supply chain, in a single database solution. This option can best support the company in its early growth stages and on through global expansion—with no need to implement a new solution at a later date.

You can phase in the deployment of a fully integrated ERP solution's capabilities, or you can take the "big bang" approach and implement everything at once. In either scenario, you can typically achieve full implementation in 6 to 12 months, depending on the complexity and size of your organization.

A bolt-on solution approach is a relatively short-term option that helps companies quickly deploy operational management capabilities outside of their small business accounting package. By using this model, companies can meet many of their initial business requirements at a relatively low up-front cost and on a rapid deployment timeline.

The core accounting package is still designed for small business operations, however, so there remain natural limitations that may make it difficult to maintain compliance with federal and global regulations. Eventually, a growing life sciences company will have to explore a fully integrated solution. Bolt-on solutions also often require duplication of effort and entry to manage activities and keep alignment between systems.

With a best-in-class industry solution, you also get the benefit of a peer-tested system that can be easily scaled to address global business requirements such as localized financials, regulatory controls or export compliance. Small business accounting systems aren't equipped to manage an international organization's needs, and bolt-on solutions can't make up for these limitations. You must either heavily customize the system—which isn't always possible—or live without these crucial capabilities.

FULLY INTEGRATED ERP SOLUTION *VERSUS* BOLT-ON INDUSTRY SOLUTION

Fully Integrated (Tier 1) Industry Solution

PROS

- FULL SYNCHRONIZATION BETWEEN OPERATIONS, ACCOUNTING AND COMPLIANCE
- SCALABILITY TO SUPPORT ALL STAGES OF GROWTH
- GREATER ELASTICITY IN PARTNER-SUPPORT SELECTION
- GLOBAL DEPLOYMENT SUPPORT
- VALIDATION, CONTROLS AND SINGLE SOURCE OF TRUTH
- CROSS-DEPARTMENTAL WORKFLOWS AND ELECTRONIC SIGNATURES WITHIN A SINGLE SYSTEM OF RECORD
- ADDRESSES CRITICAL SPECIALIZED NEEDS (LOCALIZED REGULATORY CONTROLS AND EXPORT COMPLIANCE)

CONS

- REQUIRES GREATER FINANCIAL COMMITMENT UP FRONT

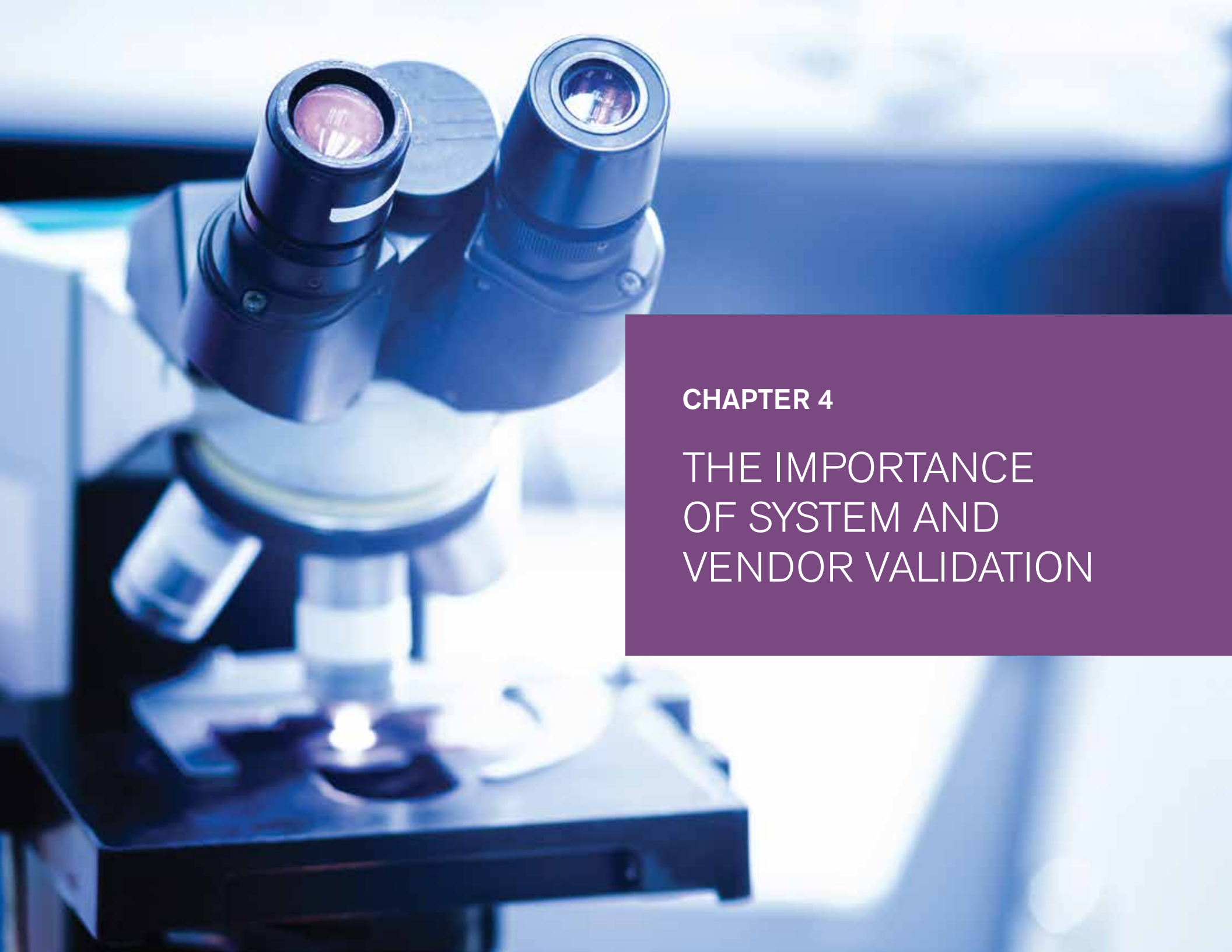
Bolt-On (Tier 2) Industry Solution

PROS

- LESS EXPENSIVE TO DEPLOY
- FASTER DEPLOYMENT

CONS

- NEEDS TO BE REPLACED WITH A TIER 1 SOLUTION EVENTUALLY (DOUBLE WORK)
- REPORTING DEFICIENCIES FROM MULTIPLE DATABASE SILOS BETWEEN ERP, OPERATIONS AND COMPLIANCE
- INTEGRATIONS ARE PRONE TO FAILURE
- DOES NOT ADDRESS REGULATORY CONTROLS AND EXPORT COMPLIANCE
- MAINTAINING COMPLIANCE ACROSS DISPARATE SYSTEMS IS DIFFICULT AND INEFFICIENT
- CROSS-SYSTEM PROCESSES OFTEN REQUIRE PAPER-BASED SIGNOFFS FOR CONTROLS



CHAPTER 4

THE IMPORTANCE OF SYSTEM AND VENDOR VALIDATION

Your ERP solution must meet your validation needs.

Life sciences companies have an added factor to consider when selecting an ERP system, because the FDA requires them to validate, for its intended use, any software used in the device or drug production process. When choosing an ERP solution, it is critical that you consider your business requirements, your validation needs and the vendor's experience, so you can ensure that your system complies with the FDA rules.

What's required

The FDA validation guidelines apply to software used in areas that could introduce a risk to the end user. This includes any software used to automate any business processes related to the device design, bill of materials/formula control, testing, component or ingredient acceptance, manufacturing, labeling, packaging, distribution, complaint handling or other aspects of the quality management system, according to CFR 21 Part 820. This also includes any software used to create, modify or maintain electronic records or manage electronic signatures. The guidelines don't apply to software used for areas like payroll, which involve no risk to the end user.

Key Advantages of Software Validation:

- ✓ Ensures repeatability & consistency
- ✓ Ensures software quality & production readiness
- ✓ Ensures software performs according to its INTENDED USE
- ✓ Decreases risk of data compatibility issues
- ✓ Decreases risk of system performance issues
- ✓ Decreases risk of non-compliance with cGMP guidelines

To comply, companies must validate the process flow, document it, test it, then validate that the process works as intended, and that it follows their compliance procedures for specific FDA requirements, such as the CFR 21 Part 11 electronic signature rules. In practice, this typically means that you perform a process and record all the steps, then repeat it, with an observer watching to validate that each step is done exactly as documented.

In addition to validating processes, firms are also required to validate their ERP implementation. This means you must have a written historical record of every action, from design through installation, with screen captures and signatures. If there is a change to the software, you also need to validate the code promotion, as well as any affected business processes—something that will add extra steps and oversight to any system customizations you may make.

Have a validation plan

When you're purchasing a commercial, off-the-shelf software application such as ERP from a vendor, it is important to qualify both the vendor and the solution. Vendors with experience working in validated industries should be able to provide documentation, including validation templates that can serve as a starting point for your company's validation project. Note that these templates will not replace the need to perform your own validation, which has to be specifically tailored to your intended use.

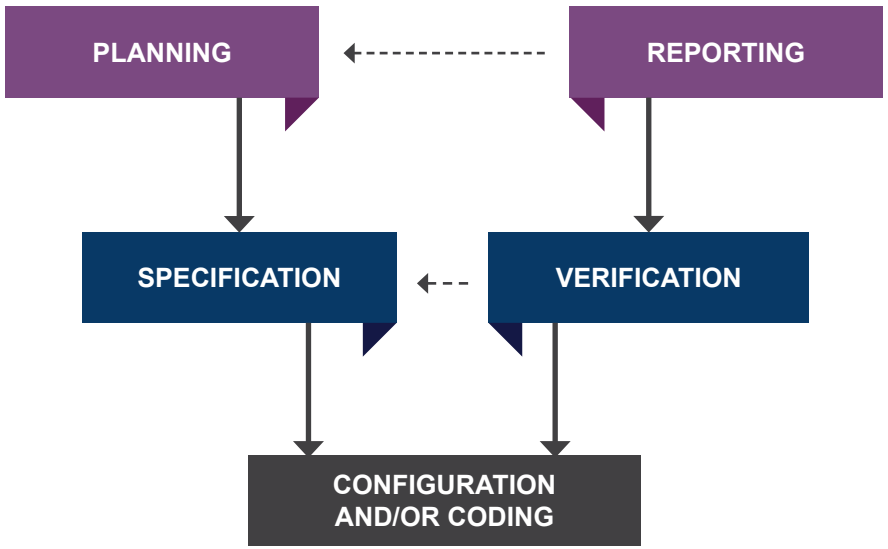
Although actual validation doesn't start until the installation of a production environment, you should have a plan in place for it before implementation begins. You'll need to select a manager for the overall validation project, then ensure the system is validated according to a written procedure for the particular intended use, and will perform as intended in the chosen application.

The validation will need to document everything, including the defined user requirements, validation protocols used, acceptance criteria, test cases and results, and validation summary. You also have to look past the go-live date and decide who will manage and perform ongoing validation duties, such as maintaining the procedures throughout the software development life cycle for any future changes, and performing periodic testing over the life of the system.

Your internal quality assurance (QA) team plays a key role in this planning process, because they will be heavily involved in activities like observing and signing off on processes. At the end of the go-live period, QA usually takes over the overall validation responsibilities from the validation team.

Some life sciences firms have an internal validation team. If you do not, your ERP vendor can provide the resources to help you manage your validation needs. This can range from simple templates, if you already have a validation process in place, to a project manager for the validation side of the implementation. On complex implementations, you may use one or two outside people full-time for the duration of the project. In any case, the manufacturer retains the ultimate responsibility for ensuring that the production and quality system software are validated.

As you select your software package, it's important to think about these needs and look for a vendor who has experience in validation, and who can provide templates or other tools to help you through the process. Whatever ERP solution you choose, you must make sure that the system conforms to key FDA guidelines, the project goes through validation with an internal team or a third party, and there is a plan in place to keep the system validated on an ongoing basis.



SUPPORTING PROCESS INCLUDING RISK MANAGEMENT

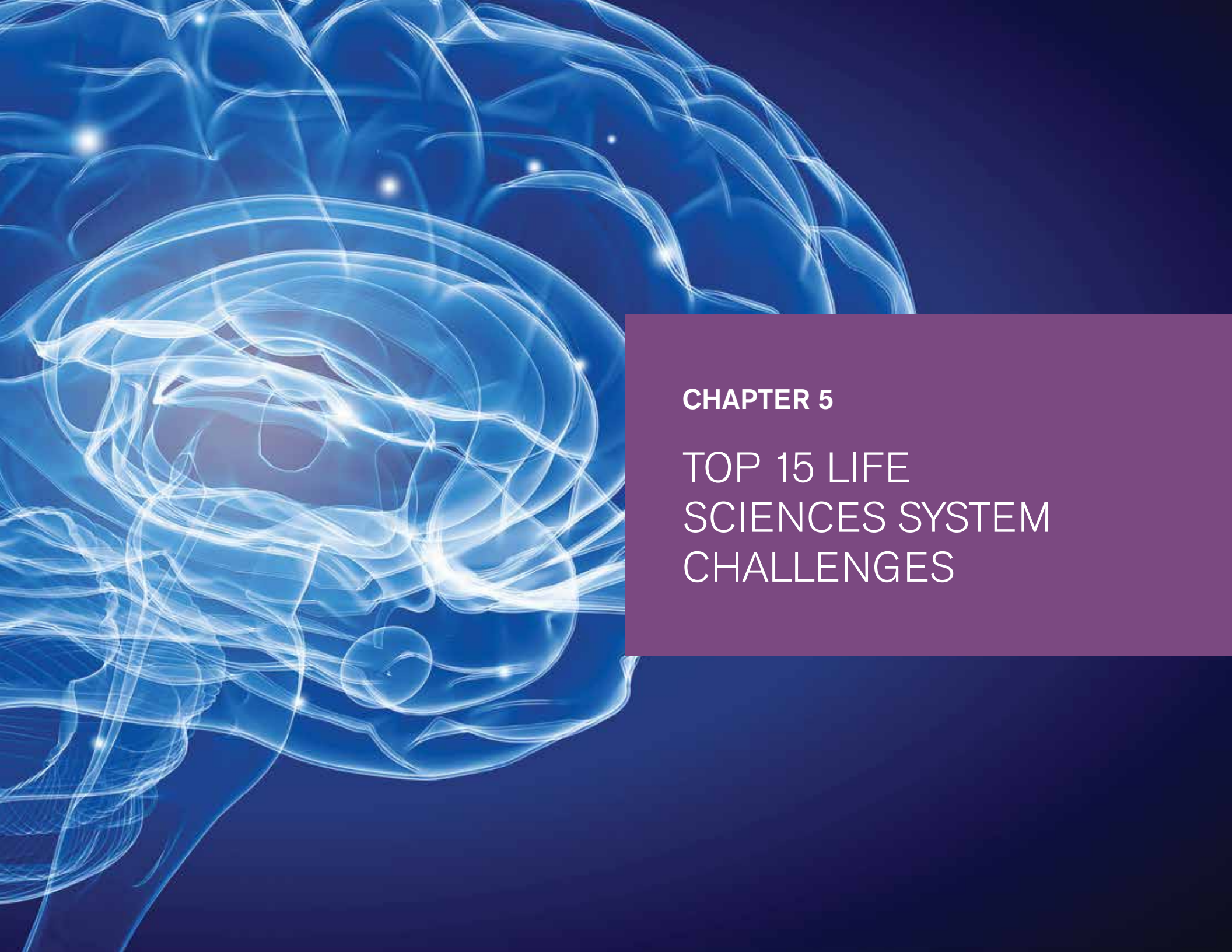
Source: Figure 3.3, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.IPSE.org.

Use GAMP 5 as a Guide

The current good automated manufacturing practice (GAMP 5) industry guidelines are a useful reference point for reviewing your validation methodologies.

These are some GAMP-related questions to consider:

- Is your validation method built on a science-based quality management of risks?
- Is the focus on patient safety, product quality and data integrity?
- What are your critical quality attributes?
- Do you have the effective governance needed to achieve and maintain GxP compliance?



CHAPTER 5

TOP 15 LIFE SCIENCES SYSTEM CHALLENGES

Life sciences companies have unique regulatory, operational and strategic challenges.

To meet the highly specialized needs of medical device, biotech, pharmaceutical and nutraceutical companies, Armanino's Life Sciences for Microsoft Dynamics 365 for Operations ERP solution provides a complete range of industry-specific functionalities.

- eDHR/eBR
- Limited Distribution Matrix
- UDI
- Reports/Metrics
- CAPA, NCR & Complaints
- Quality Sampling Tables
- Calibration
- Multidimensional Inventory
- Audit Management
- Electronic Signatures
- Mixed Mode Manufacturing
- Clinical and Commercialization Project Management
- Product Holds/Recalls
- Field Service/Asset Management
- Revenue Management

1 eDHR/eBR

Challenge

The FDA requires life sciences companies to maintain device or batch history records that provide cradle-to-grave traceability and document everything from raw material testing to post-sale servicing. Traditional paper documentation is not an efficient way to compile, record and update this critical product data.

Solution

Armanino's Life Sciences Solution for Dynamics 365 compiles a current electronic device history record (eDHR) or electronic batch record (eBR) for each product, using manufacturing execution system data collection to capture information such as the material batch/serial numbers, equipment used, work instructions and revisions, pass/fail criteria and results, quantity released, acceptance records and primary identification label.

CHALLENGES ADDRESSED

TRACEABILITY | DOCUMENTATION

2 LIMITED DISTRIBUTION MATRIX

Challenge

Life sciences firms need a way to manage the rules and exceptions around where their products can be sold. If they ship to a location where they don't have regulatory approval/pre-approval, they may be fined, the products may be blocked, and the regulatory body may launch an investigation.

Solution

The system enables you to capture any limitations, restrict distribution to approved locations only, and add distribution confidence for sites where pre-market clinical trials have been approved. It also enforces the limitations—for example, by preventing sales representatives from placing orders for a non-approved site.

CHALLENGES ADDRESSED

MANAGEMENT | COMPLIANCE

3 UDI

Challenge

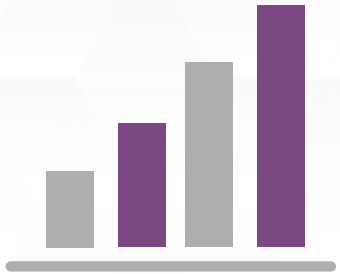
The FDA's unique device identifier (UDI) regulations require companies to gather detailed product data and print it on each product label, so the item can be tracked in case of a recall or other event. Manufacturers must also be able to prove their control over the number and destination of labels printed.

Solution

A pre-defined table within the system contains the 62 fields that make up the FDA global UDI database (GUDID). This single source of truth encompasses data from operations, quality and other relevant business functions, allowing you to generate FDA-compliant labels that contain the required UDI information.

CHALLENGES ADDRESSED TRACEABILITY COMPLIANCE

4 REPORTS/METRICS



Challenge

Business leaders need robust business intelligence reporting that enables them to pinpoint quality issues and trends early on, and quickly adjust their operations as needed.

Solution

Armanino's Life Sciences Solution for Dynamics 365 generates quality reports that provide actionable insights on manufacturing processes and vendor performance. This feedback creates an environment of continuous improvement and monitoring, and allows you to quickly adjust your operations.

CHALLENGES ADDRESSED MANAGEMENT REPORTING

5 CAPA, NCR & COMPLAINTS

Challenge

Life sciences firms must be able to identify and respond swiftly to any current or potential product quality risks, failures or customer complaints.

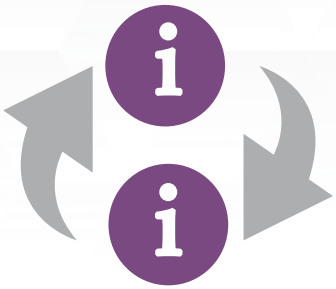
Solution

The system enables you to quickly identify, address and record risks, events and complaints, via a configurable workflow for user actions and approvals. You can launch non-conformance reports (NCRs), trigger investigations, and for severe problems, based on your business risk categories, initiate a corrective and preventive action (CAPA). The system also documents your steps throughout, simplifying your regulatory compliance.

CHALLENGES ADDRESSED

MANAGEMENT COMPLIANCE

6 QUALITY SAMPLING TABLES



Challenge

Life sciences manufacturers use standardized quality tables to determine the recommended number of items to sample when they're testing a product or process. They need to be able to customize the parameters and obtain the information without going offline.

Solution

Industry standard sampling tables such as ANSI, ISO and NIST are embedded in the system, so you can easily access sampling plans, set customized pass/fail rates and dictate the actions to take if a failure occurs.

CHALLENGES ADDRESSED

MANAGEMENT CUSTOMIZATION

7 CALIBRATION

Challenge

The FDA requires manufacturers to ensure and document that all instruments used in their facilities are properly calibrated and maintained.

Solution

Calibration and preventive maintenance tables are integrated into Armanino's Life Sciences Solution for Dynamics 365. You can establish the periodic activities required to keep your equipment compliant, such as inspections and maintenance, and document the results. The system also notifies you when an instrument is due for an inspection or servicing.

CHALLENGES ADDRESSED

COMPLIANCE | MANAGEMENT

8 MULTIDIMENSIONAL INVENTORY

Challenge

Ingredient purity varies, so life sciences manufacturers need to calculate and manage the potency of the components used in each batch, to keep formulation consistent.

Solution

Armanino's Life Sciences Solution for Dynamics 365 enables you to track and store inventory in multiple units of measure, and identify the amount of active ingredient each unit contains.

CHALLENGES ADDRESSED

MANAGEMENT | TRACEABILITY

9 AUDIT MANAGEMENT

Challenge

To meet internal standards as well as FDA requirements, life sciences firms must perform regular audits of their design, manufacturing and quality processes.

Solution

The system allows you to manage your audit schedule to meet internal requirements and provide an audit trail for regulators. You can define and trigger audits, record the results, and if need be, launch an NCR or CAPA.

CHALLENGES ADDRESSED

COMPLIANCE MANAGEMENT

10 ELECTRONIC SIGNATURES

Challenge

As life sciences companies shift to electronic records, they must also adopt electronic signatures, per the 21 CFR Part 11 federal regulations for electronic data.

Solution

You can generate FDA-compliant electronic signatures for functions performed within the system, such as signing off on an inspection or creating a new bill of materials.

CHALLENGES ADDRESSED

COMPLIANCE DOCUMENTATION

11 MIXED MODE MANUFACTURING

Challenge

Life sciences companies often use several modes of manufacturing. If their ERP system can only handle one of these, firms have to work outside the system for the remaining mode(s) or limit themselves to one type of manufacturing.

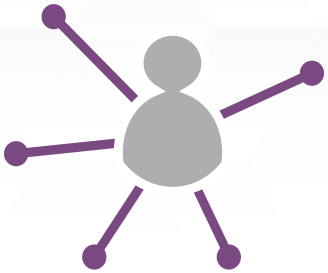
Solution

Armanino's Life Sciences Solution for Dynamics 365 enables you to use all three manufacturing modes—process, discrete and lean—in one environment and within a single product structure.

CHALLENGES ADDRESSED

MANAGEMENT | MAINTENANCE

12 CLINICAL AND COMMERCIALIZATION PROJECT MANAGEMENT



Challenge

The clinical approval process is long and complicated, and often involves multiple locations and third-party vendors. Life sciences companies need a way to manage these complex projects before and after they are approved.

Solution

The system allows you to track and manage expenses, activities, milestones and regulatory requirements as projects move through the clinical trial process and undergo post-approval research and monitoring.

CHALLENGES ADDRESSED

MANAGEMENT | TRACEABILITY

13 PRODUCT HOLDS/ RECALLS

Challenge

When life sciences firms see an anomaly in areas like production or equipment calibration, they need to put potentially impacted products on hold, so they can investigate the issue and determine what action to take. If the problem is severe, firms must be able to identify the affected items and recall them from the field as quickly as possible.

Solution

The system can trigger a hold on products throughout the supply chain, giving you time to investigate potential problems. If a recall is needed, you can quickly trace products and determine what inventory is affected and where it resides. This critical capability helps you prevent harm to patients and avoid extensive costs.

CHALLENGES ADDRESSED

TRACEABILITY | MANAGEMENT

14 FIELD SERVICE/ ASSET MANAGEMENT

Challenge

Medical device firms must keep their field equipment up-to-date and performing properly. They have to upgrade equipment promptly when they roll out new hardware or software, and when there is a problem with a product, they need to service it in a timely manner, to minimize customer down-time and prevent potential misuse. They must also maintain records of asset management status, for future upgrades and in case of potential service exposure issues.

Solution

Armanino's Life Sciences Solution for Dynamics 365 allows you to schedule routine service or field corrective actions, and append original manufacturing records with the service record.

CHALLENGES ADDRESSED

MANAGEMENT | DOCUMENTATION

15 REVENUE MANAGEMENT

Challenge

Life sciences firms must meet industry- and business-specific requirements around revenue management in order to comply with general accepted accounting principles (GAAP). These include the deferral and recognition of revenue from distributor sell-through arrangements, and the recognition of revenue from bundled products, which may include hardware, software, services, warranties and maintenance agreements.

Solution

The system streamlines complicated revenue recognition scenarios, including point-of-sale reconciliation for distributor sell-through arrangements. It also supports the reallocation, deferral and recognition of revenue by automatically allocating the relative value of the total agreement across the individual elements, according to their vendor-specific objective evidence (VSOE) or best estimated selling price, and scheduling the recognition, so you can recognize the appropriate revenue as various components are delivered to the customer.

CHALLENGES ADDRESSED

COMPLIANCE | TRACEABILITY

CHAPTER 6

BUILDING THE BUSINESS CASE FOR A NEW ERP

Win over your executive suite and board of directors with a 3-step best practice process.

Here are three straightforward, effective ways to build your business case for instituting a best-in-class IT infrastructure. By laying this foundation, your company will be better able to manage all aspects of its day-to-day business, from compliance and operations to sales and finance.

STEP 1

Link your application initiative to the company plan

Armanino's annual CFO Evolution® Survey revealed that while companies' top priorities are market expansion, more efficient operations and new product launches, the average CFO spends less than 40% of their time on these priorities. All three of these major business initiatives are supported by prevailing ERP systems and optimized business processes, so link your recommendation to invest in ERP to your organization's mission and goals. This will demonstrate your grasp of, and focus on, strategic priorities.

A new ERP implementation is an opportunity for operational change and process improvement. The prospect of improved financial and operational functionality is enormously valuable to any organization preparing for an IPO or merger/acquisition, poised for rapid growth or geographic expansion, or looking to save money through greater efficiencies. That said, in order to secure the investment necessary for this major undertaking, expect your CEO and board of directors to hold the new ERP implementation project leadership accountable for its realization.

Anticipate that bonus compensation for the key project leaders will be tied to the bottom line impact the new ERP initiative has on the entire organization. In turn, align finance and operational staff compensation and incentives around the successful implementation and adoption of the new ERP solution in support of your company's priorities.

STEP 2

Include improved internal controls in your ERP initiative scope

Life sciences companies must manage an ever-growing list of regulatory compliance issues, such as unique device identifier (UDI) requirements, e-pedigree rules and the Sunshine Act. Therefore, you need to see and control where and how your products are being manufactured and distributed. An industry solution with built-in functionality that enables your organization to institute compliance controls around regulated products, jurisdiction exclusion or inclusion lists, and ever-evolving regulatory reporting requirements is essential to the continued success of your business.

Perhaps most important to public companies or those preparing for IPO, a modern ERP system's automated controls (e.g., segregation of duties in the system, standardized processes and workflows) provide management and investors an increased level of confidence and assurance around the reliability of their financial reporting.

Adding an integration component will also be invaluable for achieving a centralized system. Ensure your team realizes that by integrating ERP with CRM, your sales force can create quotes that are then pushed into ERP for fulfillment—reducing errors and creating an end-to-end system.

STEP 3

Establish well-defined, measurable business objectives for the new application initiative

To set a clear expectation of what a successful ERP implementation will look like, define SMART (specific, measurable, achievable, realistic, time-related) objectives for each of the key solution elements. By providing the desired and needed accountability to the CEO and board, you've created a shared vision for the project team to work toward.

At Armanino, we begin our ERP implementations with a mutual understanding of our clients' critical business objectives. In order for the ERP project objectives to support the strategic plan of the business, they have to be defined at a level of detail that is actionable. Here are some examples of project objectives that are too vague and others that are quantitative.

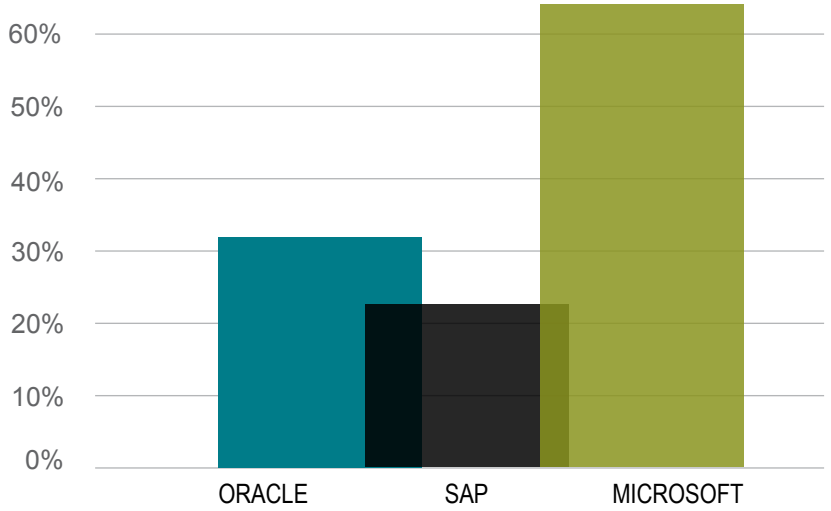
Vague Project Objectives	Actionable, Measurable Project Objectives
Improve system controls to support FDA compliance.	Incorporate all GxP business processes within unified ERP while also ensuring that security, segregation of duties and e-signatures are present throughout.
Improve productivity.	Automate processes prone to human errors, eliminate redundant steps, refine roles, and realign resources to perform higher value work.
Retire old software systems.	Consolidate 10 software applications, establish a BI strategy, and integrate applications to the Cloud.

The key business objectives for your project will always be specific to your circumstances but usually fall into some common categories.

New skill development is one common example of people-related project objectives. Also keep in mind that a new ERP system implementation provides the opportunity for organizational culture change. It forces a cross-functional redefinition of core business processes and brings finance and operations teams out of their silos to develop joint approaches. As the project leader, you have the opportunity to hand pick team members to participate in the ERP implementation. They will become your change agents and champions for collaboration throughout the entire organization.

Using technology to automate new and improved “best practice” business processes is another category of relevant ERP initiative objectives. When proposing a new ERP system, it’s easy to point to modern software and say that it will make your organization more efficient and productive. You might also suggest that a new ERP software solution will provide the data to help executives speed their decision making and take advantage of market opportunities. There are any number of studies to back you up. For instance, Forrester Research completed a detailed analysis of the costs and benefits of implementing Dynamics 365 for a composite organization. The three-year risk-adjusted ROI was 92% over a payback period of 21 months. Furthermore, a recent Ovum Research study revealed Microsoft as the preferred ERP vendor for enterprise organizations.

MICROSOFT PREFERRED VENDOR FOR NEXT INVESTMENT IN ERP FOR GLOBAL ENTERPRISE ORGANIZATIONS (>$1B)



Excerpt from Ovum Research: ICT Enterprise Insights study of 6700 companies across geography & segment

Governance objectives are your internal controls objectives (as described above). These include ERP-related, implementation and operations, best practice and regulatory compliance, financial, operations and IT controls. Objectives specific to the ERP implementation project itself (like on time, on budget) fall under the IT project objectives sub-category.

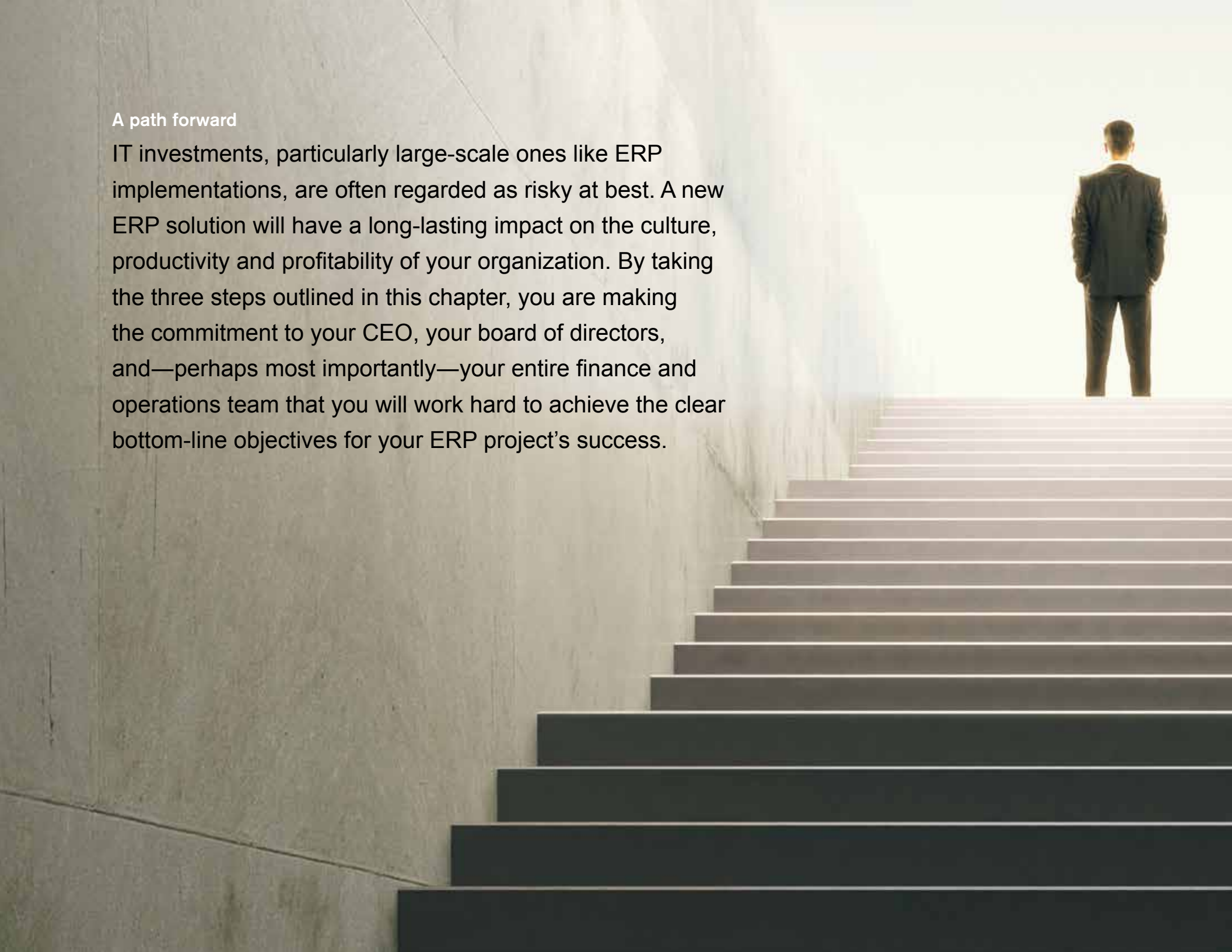
> **“Successful ERP strategies can truly transform manufacturing organizations. Manufacturers today are pressured with rising costs, shorter decision windows, growth aspirations, and demanding customers. ERP provides that ability to discover potential efficiencies, increase visibility, and perform as a more cohesive organization.”**
>
> *Aberdeen Group Research*

Investing in a platform

By investing in Microsoft technology, companies are better positioned to take advantage of a wide array of business applications that work alongside each other to build unparalleled value for life sciences firms.

Because Microsoft uses the same framework for core applications, IT can eliminate the need for specialized skillsets often required to support a wide variety of disparate technologies. This also enables faster user acceptance throughout different Windows applications by centralizing authentication and security across the network, using single sign on and user profiles for BI, ERP, CRM, SharePoint, Office and more.

Benefits can also be realized at the user level. With a familiar look and feel throughout applications, you can reduce training time and increase adoption rates while providing a seamless user experience.



A path forward

IT investments, particularly large-scale ones like ERP implementations, are often regarded as risky at best. A new ERP solution will have a long-lasting impact on the culture, productivity and profitability of your organization. By taking the three steps outlined in this chapter, you are making the commitment to your CEO, your board of directors, and—perhaps most importantly—your entire finance and operations team that you will work hard to achieve the clear bottom-line objectives for your ERP project's success.

Did you enjoy the read?

At Armanino, we deliver the tools you need to ***focus on your customers and grow.*** For further information visit:

http://learn.armaninollp.com/life-sciences-erp-for-dynamics-ax

armanino

ABOUT ARMANINO^{LLP}

Armanino is a Gold Certified Microsoft Dynamics 365 ERP and CRM Partner with a reputation for developing innovative solutions for life sciences companies. As part of the Microsoft Industry Partner Program, we work hand-in-hand with Microsoft to develop comprehensive solutions; we also work continuously with Microsoft and independent testers to certify the quality and consistency of our design and code.

Based on our experience working with leading life sciences firms, we've developed core functionalities that address critical life sciences needs. Let us bring our industry knowledge, strategic insight and Dynamics 365 expertise to your next project.

For further information contact:

Tom Mescall
Consulting Partner-in-Charge
Armanino^{LLP}
Tom.Mescall@armaninoLLP.com
925 790 2812

Jeff Russell
Consulting Director
Armanino^{LLP}
Jeff.Russell@armaninoLLP.com
925 790 2600 x7084

Armanino's Life Sciences Solution delivers the robust enterprise resource planning (ERP) capabilities of Microsoft Dynamics 365 for Operations, plus extended functionality to help medical device, biotech, pharmaceutical and nutraceutical manufacturers overcome critical regulatory, quality and business challenges.