Life Sciences: 6 Ways to Thrive in a Digital Future

Simplified compliance, operations and data management from start-up through high-growth

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Digital technologies designed for pharmaceutical, biotech and medical device organizations

The unique nature of life sciences organizations, with years of up-front investment followed by potentially explosive growth—all under intense regulatory scrutiny—requires a higher level of control over processes and data. Digital transformation allows companies to use data to deliver life-changing value to customers and build a foundation for profitable growth and expansion.

In this eBook, we'll explain how an integrated business platform for ERP, CRM, and BI designed for your industry can optimize operations and accelerate your path to growth. Whether your organization is pre-clinical, preparing for FDA clearance or coping with the challenges of more employees, new locations and new lines of business, we'll help you chart a better course forward in an increasingly digital world.

Contents

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Process automation to improve efficiency and profits

One of the most valuable benefits that digital transformation delivers to organizations is process automation. Automation can free workers from manual tasks, allowing them to focus on profit-producing activities. For life sciences organizations, automation drives procedural consistency and simplifies compliance.

Maximize the value of digital business

To achieve the highest return from automation, you'll need to reevaluate current business processes objectively. As you identify areas that are holding back productivity, digital platforms designed specifically for life sciences will allow you to streamline and simplify processes like:

- Integration with supply chain partners, 3PLs, CMOs, and other systems to reduce manual data entry and potential errors.

- Document management control to ensure compliance with FDA, ISO and other requirements.

- Using advanced workflow and tracking to ensure product testing protocols are followed with full audit trails and electronic signatures.

- Ensuring consistent procedures across departments, business units and regional locations as the business grows.

Benefits for Early-Stage Companies

- Establish consistent processes from the start.

- Demonstrate modern business processes and accountability to investors.

- Attract millennial workers to a modern, digital workplace.

Benefits for In-Market Companies

- Support new users, new locations and new lines of business.

- Ensure consistent processes across business units and locations.

- Improve productivity to increase profitability.

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Agility to support phases of growth and expansion

The growth model of life science companies—years of research followed by potentially meteoric growth after product approval—requires a different mindset in business management from the start. While cost control and compliance are fundamental in all phases of the business, life sciences organizations must be prepared to connect global resources and dispersed teams to support continued innovation and growth.

The foundation for growth

When evaluating business management systems, your organization needs to consider how the solution will simplify operations, compliance and reporting at each phase of the business. As the business scales, systems need to:

- Connect a diverse set of users, driving more efficient workflows and fostering collaboration.
- Enable fast introduction of new products with analytics to understand markets and collaboration between employees.
- Streamline day-to-day operations activities by leveraging automation to support higher productivity as the volume of transactions increases.
- Integrate data across the organization to provide centralized information across operations and throughout product lifecycles.

Benefits for Early-Stage Companies

- Cloud ERP can grow with the business, unlike niche systems like QuickBooks.
- A single system that will support the R&D phase as well as orchestrate your supply chain.
- Establish quality assurance and CAPA processes from the start.

Benefits for In-Market Companies

- Cloud ERP can provide enterprise level functionality without the high price tags of Oracle or SAP.
- Break down cultural and geographic barriers as the company expands.
- Eliminate the "workarounds" that take valuable data out of the system.

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Cost-effective, adaptable compliance management

A fundamental challenge in the life sciences industry is ever-changing and geographically specific compliance requirements. To respond, companies need business management systems that can meet regulatory requirements without compromising or complicating quality and safety practices.

Unified, digital platform reduces risk

To manage all of the aspects of development, manufacture and distribution, your business needs a digital platform designed specifically for life sciences. A single source of information across operations and across the product lifecycle. A digital platform that can effectively support compliance will:

- Track testing, certifications and approvals of products to minimize the risk of non-compliance and simplify managing recalls and audits.

- Manage quality documentation from cradle to grave.

- Record serial or lot numbers for all components manufactured internally and received from suppliers and be able to link those to finished units in use by customers.

- Provide robust ECN (Engineering Change Notice) capabilities that help identify and track affected units, regardless of their location.

- Identify specific quality issues by item, serial number and lot to take corrective action on any identified quality problems.

Benefits for Early-Stage Companies

- Establish standardized operating procedures to ensure consistent quality assurance processes.

- Demonstrate reliable quality and compliance processes to investors.

- Operate in a qualified technology environment from the start.

Benefits for In-Market Companies

- Support compliance with regional regulations across the globe.

- Reduce organizational risk with integrated quality and compliance management capabilities.

- Be prepared to react quickly in the event of a recall.

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Easy access to business data and intelligence

In the life sciences business, nothing stays the same for long. Decision makers need a continuous flow of real-time data—not periodic reporting that doesn't support immediate response to threats and opportunities. With immediate, enterprise-wide visibility into accurate operational data from R&D, the production line and the supply chain, employees can respond to continuous change, capitalizing on opportunities and mitigating risk.

Real-time data in users hands

To build your competitive edge, you must have centralized information that allows managers to make the best use of resources and manage risk. Increasingly strict traceability and transparency requirements require instant data access and business intelligence that provide visibility plus deeper insights through analysis. A unified, digital platform allows you to empower your people with information at all levels to help them plan more effectively and make faster, well-founded decisions. The system should:

- Monitor performance of strategic drivers and operational outcomes to minimize growing pains.

- Provide insight into market conditions, research and development costs and supply chain activity.

- Capture and track data as it flows across the organization, parsing out the specific information that each person needs to do their best work.

Benefits for Early-Stage Companies

- Provide a single source of the truth.

- Increase ability to forecast, plan and make informed decisions.

- Support validation-ready ERP for less risk and a faster ROI.

Benefits for In-Market Companies

- Provide a single source of the truth.

- Reduce exposure to risks by increasing visibility into changes, delays or unexpected events.

- Increase ability to forecast, plan and make informed decisions.

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End-to-end supply chain visibility

When it comes to saving lives, minutes matter. That's why fast, accurate track and trace capabilities are crucial for life sciences companies. To respond to audits or even more importantly, a recall, organizations need to identify the location of every component with a potential quality issue, whether it's in stock, in finished goods or in use at a customer site.

Tacking every product at every stage

Traceability requires that data tracking one up, one down in the supply chain plus maintaining continuous history and documentation on every product. Evolving regulations will continue to impact safety, purity and traceability requirements for your organization. A digital business management platform designed for life sciences companies will:

- Support industry regulations like 21 CFR and others with Serial and Lot Number Traceability through the entire value chain.

- Track As Built / As Maintained Configurations to know exactly what product configurations exist at each customer.

- Track ECN through rapid product changes while maintaining audit trails and traceability.

- Identify inventory stored in stockrooms and warehouses by serial and/or lot number.

Benefits for Early-Stage Companies

- Processes to handle the complexities of commercialization.

- Ensure the highest standards for quality consistently.

- Support validation-ready ERP for less risk and a faster ROI.

Benefits for In-Market Companies

- Improve inventory management to prevent expirations and obsolescence.

- Support a distributed supply chain, including contract manufacturers, 3PLs and more.

- Reduce risk by enforcing consistent and harmonized change control procedures.

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Lower cost of ownership

To conform to regulations that prevent tampering with electronic systems and results, life sciences companies need to develop and adhere to procedures showing that their IT systems are secure. For startups and growth companies alike, staffing and training an IT department that can maintain a qualified environment and stay ahead of technology regulations is expensive and takes focus off the business of product development.

Industry-specific cloud support

To take advantage of the savings that cloud business management systems can deliver, organizations must be careful to select a partner with industry knowledge, able to support a qualified environment. As your organization evaluates cloud options, it's critical to select the right partner with deep knowledge of the life sciences industry. Questions to ask include:

- Can they demonstrate strict procedures for access and operation of the data center where business management systems reside?

- Has an FDA-certified auditor validated the procedures to ensure that they are delivering the necessary qualified environment?

- Is the cloud-based business management system validation ready?

- Does the system provide easy-to-use tools with a familiar user interface?

- Will the digital platform scale as the business grows?

Benefits for Early-Stage Companies

- Industry-experienced partners provide best practices for more efficient processes.

- Focus on the business, not on technology.

- Assure a qualified environment that prevents tampering with electronic systems and results.

Benefits for In-Market Companies

- Conserve capital for R&D while still supporting growth with enterprise ERP.

- Connect employees across the globe through a single, unified business management system.

- Assure a qualified environment that prevents tampering with electronic systems and results.

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A Unified Digital Platform Without the Disruption and Costs of Big ERP

At Merit Solutions, we help biotech, pharmaceutical and medical products companies improve efficiency and use data to work faster and smarter than ever before. We enable you to focus on the research, development and distribution of products that improve the lives of people around the globe.

Built specifically for life sciences companies, MAXLife extends the core functionality of the Microsoft Dynamics 365 platform and has been a leading ERP solution for FDA-regulated companies since its launch in 2009. MAXLife is different than traditional Life Sciences ERP systems because it is:

- A true enterprise ERP solution without the high price tags of Oracle and SAP.
- More robust and integrated than smaller scale, startup or niche ERP systems.
- Extensible and scalable—accommodating the complexities of commercialization, high growth, M&As and global expansion.
- Built to consistently meet the highest standards for quality.
- Validation-ready and able to be rapidly deployed with less risk and a higher ROI.

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www.meritsolutions.com

Let's talk about the growth of your life sciences company. Contact us to schedule an initial assessment and exploratory discussion at **info@meritsolutions.com** or **(630) 614-7133**.

Hundreds of companies like yours have chosen to work with Merit Solutions for good reason:

- We have been implementing, integrating and customizing Life Sciences ERP and mobile applications for more than 10 years.
- We understand the rigors of designing and deploying validation-ready systems.
- Our MeritCare team has been providing clients with issue resolution, ongoing support, systems optimization and management services for years.
- We have a proven implementation methodology—both for enterprise transformations and rapid, pre-configured and best practices deployments.

Take a deeper look

Download the *ERP in Life Sciences* White Paper for a deeper discussion of common requirements including Track and Trace, Electronic Signatures, Effectivity Dates, Quality Management Systems, Document Management and ERP Validation.

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