Scaling Success in Life Sciences

How to build a future-ready current Good Manufacturing Practices (cGMP) facility

Today's life sciences manufacturers face an uncertain landscape.

And they're responding by seizing the moment.

Evolving regulations. Impending tariffs. Persistent supply chain delays. With no sign of relief from ongoing global disruptions, manufactures have begun reshoring production to the US as they aim to adapt to international changes.

The news of reshoring is promising for industry growth—but building a ground-up facility is no small task, often taking years of planning and upfront investments.

The manufacturers who manage to build new facilities on time and on budget and keep pace with industry change are **those acting now to infuse resilience into the fabric of their business.** As they move to open and operationalize new facilities, they're leaning on critical partnerships while focusing on strategic priorities that enable flexibility and growth.

In short, they're **seizing the moment for the foreseeable future.**

In this eBook, we'll highlight **five of those strategic priority areas for new capacity.** We'll provide insights on how they contribute to the operational readiness needed to stay on target, deploy capital faster than competitors, and achieve the earliest possible revenue recognition—even in times of disruption.

With major investments on the line, getting it right matters

The end-to-end process of building a current Good Manufacturing Practices (cGMP) facility can be an exacting test in discipline and timing. From site selection and facility design to equipment validation, inspections, employee training, and more, the journey can take 2-3 years and cost hundreds of millions of dollars.

More importantly, financial losses from disjointed planning, incomplete design, or siloed workflows can be equally costly.

*Source: McKinsey & Company, The speed-to-market imperative for life sciences capital delivery, August 2025

A recent survey of capital projects across industries shows **95%** of life sciences projects **did not meet their authorized cost and schedule***

Planning for the future starts with today's decisions

Given the complexities of building a cGMP facility, every decision you make impacts the success of your launch. Being intentional and framing your decision-making around five key priority areas can help combat the challenges of building a new facility and contribute to your overall operational readiness.

Strategic priorities for building a life sciences facility for today and beyond

Speed time to market	Improve operational efficiency	Empower your workforce	Consider sustainability objectives	Maintain regulatory compliance
What can you do to ensure that you open ahead of schedule?	How can you work efficiently to recoup investments?	Which solutions will help people to have a smooth transition?	How can you seek added sustainability benefits?	How can you keep up with evolving regulations?

There's another opportunity here not to be missed: The technology solutions that you implement across these five priority areas will not only streamline your initial planning and building processes, but also improve overall productivity and flexibility for the foreseeable future. This will help to safeguard against the disruptions of tomorrow, even without the full picture of what those might be.

Let's take a closer look at each of these priority areas and consider some of the technology solutions that can streamline your new capacity build and position your business for future growth.

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Speed time to market

In a hyper-competitive industry, your opening timeline is directly connected to several make-or-break opportunities. These include first-mover advantage, brand loyalty, patent exclusivity, better ROI on R&D, and stakeholder confidence.

New capacity projects can amount to years of planning and meticulous execution. From conceptual design to start up—and everything in between—the risk of inadvertent slowdowns is real.

So what can you do to build strategic efficiencies into your planning stage so you can ensure timeliness throughout execution?

The answer lies in smart technology solutions and services that **reduce risk, complexity, effort, and validation across system lifecycles**, ultimately helping to shorten the entire project timeline by accelerating some of the lengthiest phases.

Open the doors faster through technology partner engagement

We believe that early engagement is key for a successful timeline. A best practice that we've seen proven successful is to **work with strategic partners early in the planning process**. This collaboration helps to develop and implement a **technology roadmap** that enables standardization, virtual design and testing, and digital collaboration, all before breaking ground.

Formulating a plan for the right technology solutions can help you:

- Quickly and accurately **scale from a pilot plant to an efficient facility** using simulation capabilities in solutions like **Emulate3D™** digital twin software

- Empower your design and engineering teams to **collaborate more efficiently** using centralized file storage plus version and access control capabilities in **FactoryTalk® Vault™**

- **Maximize design productivity and accelerate timelines** with the integrated design environment in **FactoryTalk® Design Hub™** and **Studio 5000®**

- **Reduce engineering and integration time** with standardized libraries and architectures in **PlantPAx®**, rather than costly custom implementations

Improve operational efficiency

Opening doors to a new facility requires significant upfront commitments in time and financial resources. Ensuring continued operational efficiency becomes even more critical for recouping those investments and meeting market demand.

One of the biggest challenges in this realm is that operational efficiency can be impacted by countless variables every day—some of which you can't always control.

This already-challenging scenario becomes even more complex with disconnected systems that don't talk to each other. Trying to gain visibility across these disparate systems can quickly become time-consuming, leading to needless churn and loss of productivity. And when you're just getting up and running, that's the last thing you need.

What's needed instead is a modern approach to tackling siloed systems—an approach that not only creates a connected plant, but also a predictive and adaptive one via improved data availability. You might start by considering an **integrated approach to plant-wide control**, which can help by establishing a backbone for flexibility, as well as a connected and secure automation architecture that adapts and scales without constraint.

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Bring all your industrial systems onto a single, streamlined platform

From level 1 to enterprise, Rockwell Automation is **uniquely positioned to deliver IT/OT integration and cybersecurity across operational layers**. Our standardized **Integrated Architecture®** approach helps unify critical systems like process, power, safety, and motion control and makes it easier to harmonize site-wide systems such as distributed control, building automation, and environmental monitoring.

The seamless integration of cybersecurity, building management, robotics, and more under the same centralized design framework results in:

- **Enhanced enterprise risk management** with a safe and secure operating environment

- **Faster retrieval of data** for system-wide intelligence and informed decision-making

- **Improved asset utilization and optimization** through predictive maintenance

- **Faster integration** of validation-ready OEM equipment through plug-and-produce capabilities

- **Reduced time and expenses** associated with training

- **Lower total cost of ownership** through efficient lifecycle management, energy consumption, and technology migration

Integrated Architecture® works seamlessly with cornerstone solutions like **FactoryTalk® PharmaSuite® and PlantPAx®**, which act as information and control layers while providing real-time visibility into production. As needs evolve, Integrated Architecture® can scale accordingly, helping protect investments and enabling new capabilities.

Integrated Architecture® can set you up to leverage Rockwell Automation's **vast partner ecosystem for smart machines that feature DataReady™ solutions**. These machines yield data that's accessible, organized, and can be seamlessly shared across applications—unlocking new potential to **boost productivity and flexibility** beyond the equipment level.

Learn more about DataReady™ solutions for your new capacity project.

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Empower your workforce

From those that design and build the footprint to those that operate the environment, highly prepared and skilled teams are among your greatest assets for opening and maintaining a new facility.

Skilled labor shortages continue to plague the manufacturing industry, with a recent survey indicating that workforce issues remain among the top five greatest obstacles to growth this year*.

Life sciences manufacturers, in particular, face mounting pressure to attract, train, and retain talent with the requisite skill sets. This can be an exceptional challenge when building new capacity, as **slowdowns across hiring and training can significantly impact launch timelines.**

If this sounds familiar, you might be looking for ways to amplify training and make sure that everyone is prepared and productive when they set foot on site. A helpful approach is to **integrate more digitized workforce enablement solutions** to ensure sustained operations.

By 2030, it's estimated that the industry will have **7.9 million fewer workers** than what's needed*

*Source: Rockwell Automation, 10th Annual State of Smart Manufacturing Report: Life Sciences Edition, 2025

Prioritize technology that gives workers on-demand access to critical information

Equipping your workers with digital tools that help them gain fast, reliable access to critical information—when and where they need it—can be a game changer when it comes to worker productivity, safety, and engagement.

For example, you can empower workers with technology solutions that:

- **Deliver secure mobility while keeping critical information at their fingertips**. With solutions like **ThinManager®**, floor workers don't need to be tethered to a particular terminal or workstation. Instead, they can sign in using thin client devices and **access the data they need instantly**, no matter where they are, enabling consistent, streamlined workflows.

- **Replace paper-based SOPs with interactive, digital work instructions**. For example, **FactoryTalk® PharmaSuite®** helps ensure consistent execution of tasks across operators and shifts with digital instructions tailored to each step of the production process. This not only helps reduce errors in real time, but also contributes to improved safety, quality, and compliance.

- **Enable fast, informed decision-making through powerful data visualization**. With solutions like **FactoryTalk® Optix™** operators can leverage real-time visualization that transforms complex machine data into intuitive dashboards and graphical insights, enabling faster, more informed responses to operational conditions.

*Source: McKinsey & Company, The speed-to-market imperative for life sciences capital delivery, August 2025

Companies that build strong internal delivery teams through **structured training, digital tools, standardized processes, and centralized support** report fewer delays, faster ramp-up of new sites, and a **15–30% increase** in capital project throughput across the portfolio*

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Consider sustainability objectives

Life sciences manufacturing can be resource-intensive, requiring large amounts of natural resources and chemicals. As ESG regulations tighten and investors seek sustainable initiatives, manufacturers are looking for ways to reduce their carbon footprint.

Fortunately, new capacity planning offers ample opportunities to implement selective technology solutions and strategies that both **optimize operations** *and* **help mitigate common sustainability challenges** through data management and analysis.

What's more, being intentional about the usage of water, air, gas, electricity, and steam (WAGES) and the reduction of Scope 1 and Scope 2 emissions can have lasting positive impact on your own bottom line by reducing utility costs and material consumption.

Combined with the internal sustainability initiatives that you likely already have underway, this approach can enable far greater sustainability value for the long term.

Take advantage of innovative technology for a sustainable new capacity footprint

You're constructing a new facility designed to operate for years, if not generations. By prioritizing sustainability goals from the outset, you can help ensure that your plant consistently operates at peak efficiency.

Some of the sustainability objectives to consider might include:

- **Improved accuracy for compliance reporting** with energy data aggregation and contextualization in solutions like **FactoryTalk® Energy Manager™**

- **Lowered energy costs** through unified, scalable building management systems

- **Reduced consumption of power and utilities** via the unified process and power control capabilities of **Integrated Architecture®**, which uses intelligent and integrated devices to provide context to production and power systems

- **Improved HVAC optimization** with pre-engineered and pre-tested HVAC control modules delivered via LifecycleIQ™ Services

It's also worth noting that some of the building management solutions that track waste production, water usage, and emission outputs can also yield capabilities that help teams work more efficiently and ultimately get to market faster. **Success is all about getting the most mileage from the technology solutions** that you put in place as you open and operate your new facility.

Maintain regulatory compliance

Today's life sciences landscape is quickly changing, making way for the modern technologies needed to accelerate time to market, improve operational efficiency, empower the workforce, and achieve sustainability goals. As technology and processes change, so do regulations—and it's crucial for long-term business viability to keep up with the regulatory requirements as they evolve alongside the landscape.

From facility design and construction permits to operational licensing, SOP and quality management documentation, clinical and product safety oversight, and much more—the need to maintain compliance **throughout new capacity building and beyond is nothing new**.

But as we discussed early in this narrative, regulatory twists and turns are **unfolding at a new pace**—and are likely to do so for the foreseeable future, complicating what's already a massive undertaking.

Despite its uncertain nature, this reality doesn't have to set you back. Instead, a key element of **being successful is *being agile***.

A strategic technology partner can help. In the final part of this book, we'll explore how.

Integrate agility into the fabric of your business

An intentional approach to strategic planning and technology implementation can help you maintain compliance by remaining agile when it matters most.

Here are some of the solutions, services, and resources you might consider to build agility and tackle the regulatory landscape with confidence:

- Innovative IT and OT solutions that are **designed to work together**, enabling a highly connected and flexible facility that quickly scales and adapts

- Virtual design and testing technology that **streamlines collaboration and accelerates timelines**

- Consulting services that help identify compliance-related goals and create a tailored technology plan that accounts for changing regulations

- Ongoing support capabilities from **Kalypso technology experts with deep life sciences industry expertise**

- **FactoryTalk® PharmaSuite®**, purpose-built with out-of-the-box functionalities for the life sciences industry that help you **achieve Title 21 CFR Part 11 compliance**

As the industry progresses, regulatory compliance is an area that's bound to hold just some of the many changes in store. But as we've learned in recent years, **disruption is the only real constant in the manufacturing world**—and agility is among the best weapons to tackle it.

With the right planning, solution implementation, and ongoing support services, you can reduce risk, minimize complexity, and infuse flexibility across production processes and employee workflows, ultimately enabling better preparation to respond to whatever the changing landscape holds.

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Dong-A ST builds new cGMP-compliant smart factory

CHALLENGE

Dong-A ST needed to meet excess production capacity by building a new GMP-compliant facility, which required managing data for different regulations while minimizing system downtime.

SOLUTION

Leveraging insights from the implementation of smart factory solutions at a different plant location, the company integrated a series of Rockwell Automation hardware and software solutions for visualization and operations management, including FactoryTalk® PharmaSuite®.

RESULTS

The integration has resulted in improved system automation, product quality management, and business intelligence throughout the plant. The successful establishment of GMP global regulation in the production environment and system also enabled Dong-A ST to break into global markets.

North American biotechnology company cuts commission time in half

CHALLENGE

A leading biotechnology company faced an aggressive timeline to build a new state-of-the-art facility with four process areas, 3 x 12,000l bioreactors, and full upstream/downstream capabilities.

SOLUTION

The company used a skid-based approach with pre-assembled units, complete with ControlLogix® controllers, I/O, PanelView™ HMIs, and other required equipment that met regulatory requirements.

RESULTS

The company reduced commission time by 50% and can now install, commission, qualify, and license a process area in 2 years rather than 4 or 5 years, which was typical in the past.

Cytiva increases production throughput while reducing energy use

CHALLENGE

Given the small window of time before patents expire, Cytiva wanted to reduce the time from product inception to market release by streamlining system deployment and data management.

SOLUTION

Standardized digital libraries of tested code, improved data analytics, and streamlined testing environments all contributed to time saved. By automating processes and diving into deeper data analysis with Rockwell Automation solutions, the company was able to help customers realize economies of scale with flexibility, efficiency, and confidence.

RESULTS

Cytiva achieved 10-20% increases in production throughput, as well as 5-30% decreases in energy use, scrap material, batch release time, maintenance, and downtime investigations.

What sets us apart: Our deep understanding of life sciences combined with expertise in end-to-end new capacity planning and execution
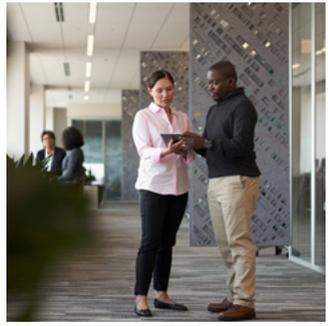
New capacity services

Whether you're building a ground-up facility or expanding your current footprint, we help ensure a smooth execution from planning through commissioning and continued support.
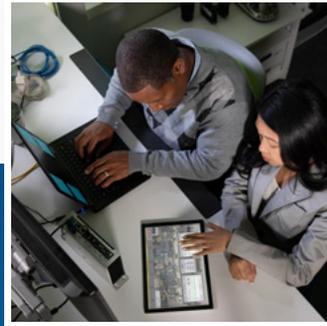
Technology and ongoing innovation

We've built a portfolio of integrated hardware, software, and services that help streamline your new capacity projects, all guided by our commitment to digital transformation.

Robust customer & partner ecosystem

Our network of key global end users, OEMs, technology partners, and system integrators deliver key results for you with industry-specific solutions that help you get to market faster.
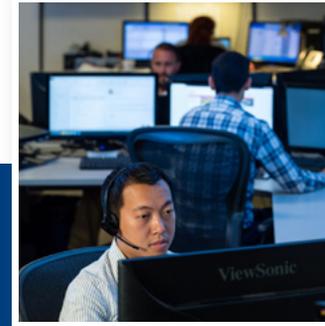
Commitment to cybersecurity

Our connection with leading experts and our extensive cybersecurity investments help mitigate security risks and enhance protection across your new capacity efforts.

World-class customer support

We are a global company providing in-region support, so you benefit from global resources plus local market insights that help you open the doors to your new facility faster.

Our commitment is to walk alongside you from the earliest stages through execution and continuous improvement.

Connect with us.

ControlLogix, DataReady, Emulate3D, expanding human possibility, FactoryTalk Design Hub, FactoryTalk Energy Manager, FactoryTalk Optix, FactoryTalk PharmaSuite, FactoryTalk Vault, Integrated Architecture system, LifecycleIQ, PanelView terminal, PlantPAx, Studio 5000, and ThinManager are trademarks of Rockwell Automation, Inc.

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