Chrysalis

Your manufacturing, **your way**

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Speed, flexibility and control without the complexity

Every therapeutic manufacturer faces a critical challenge: how to achieve good manufacturing practice (GMP) compliance quickly and affordably, without sacrificing all of their control. This challenge goes beyond an upfront facility buildout. Idle capacity can become a sustained financial burden, as companies must keep a validated facility operational and retain specialized staff during gaps between campaigns or while awaiting clinical trial results. This not only represents a logistical hurdle, but a critical decision about manufacturing capacity and supportive infrastructure with profound implications for a company's cash flow, ability to raise investment and overall survival. A misstep at any stage can lead to millions of dollars wasted, jeopardize regulatory approvals and even derail promising therapies.

This eBook serves as a practical decision-making tool, designed to help you navigate complex dilemmas with confidence. It unpacks the hidden costs of traditional manufacturing capacity options, highlights the benefits of flexible, GMP-ready solutions and provides a clear framework for assessing the best path forward for your unique needs. By the end of this guide, you'll be better equipped to make informed choices that accelerate your therapeutic's journey from discovery to the patients who need it.

Complex therapies, compressed timelines

Today's therapeutic manufacturers, particularly those developing complex modalities, face immense pressure to accelerate their journey from concept to clinic and ultimately to commercialization. This urgency often clashes with the inherent slowness and rigidity of traditional infrastructure models, creating a significant bottleneck in the path to patient access.

Several macro and micro trends are driving this imperative for rapid progress:

Shorter development cycles and faster IND timelines

The industry is witnessing a dramatic compression of development timelines. Regulatory agencies are increasingly open to expedited pathways for groundbreaking therapies, and competitive pressures demand that companies reach Investigational New Drug (IND) application status and initiate clinical trials at an unprecedented pace. Traditional facility builds, with their lengthy design, construction and validation phases, simply cannot keep up with these accelerated schedules. Every month spent on infrastructure development is a month lost in patient impact and market opportunity.

Growth in complex therapies requiring specialized, compliant environments

The therapeutic pipeline is increasingly dominated by advanced modalities, including cell and gene therapies, mRNA vaccines and highly potent biologics. These innovative treatments demand highly specialized, precisely controlled, and rigorously compliant manufacturing environments. Building such bespoke facilities from the ground up requires in-depth expertise and a significant amount of time. It is often a steep learning curve in navigating the unique regulatory requirements for these complex products. The one-size-fits-all approach to infrastructure is no longer viable.

Investment volatility and milestone-based funding

The financial realities for many biotechs have shifted. Investment is often milestone-driven and subject to market fluctuations. This makes large, upfront capital expenditures (CapEx) for facility construction a difficult proposition to justify. Investors are increasingly wary of committing significant capital to fixed assets that don't immediately contribute to clinical progress or revenue generation. Companies need cleanroom infrastructure solutions that align with their funding cycles, enabling them to preserve capital for research, development and clinical trials, rather than investing it in real estate.

In this demanding environment, the need for infrastructure that offers flexibility, speed and de-risked pathways has become vital. Companies can no longer afford to wait years for a facility to be built, nor can they risk massive capital outlays on infrastructure that might become obsolete or underutilized if their programs evolve. The ability to rapidly access compliant, specialized space and scale it as needed is a fundamental requirement for success in the evolving therapeutic landscape.

What you lose while you wait: **The hidden costs of building**

While the idea of owning your own GMP manufacturing facility might seem appealing, the reality often comes with a host of hidden costs and unforeseen burdens that can significantly impede progress and drain valuable resources. These include monetary costs, time, critical talent and strategic agility. When a therapeutic manufacturer opts to "go it alone" without a strategic GMP cleanroom infrastructure partner, they often find themselves sacrificing more than they anticipated. Here are the often-unseen burdens of working without a partner:

Timeline delays from construction, validation and regulatory readiness

Building a GMP-compliant facility is an incredibly complex undertaking. It involves navigating intricate architectural designs, securing specialized construction expertise, managing equipment procurement and undergoing rigorous validation protocols (IQ, OQ, PQ). Following construction and validation, the facility must then be deemed fully regulatory ready, often involving pre-approval inspections and extensive documentation. Each of these phases is fraught with potential for delays, from supply chain disruptions to unexpected regulatory hurdles or construction setbacks. These delays can easily push back IND filings, clinical trial initiations and market entry by months or even years.

Talent drain: The need to recruit specialized roles early

A GMP facility is a highly regulated operational ecosystem. To design, build, validate and operate such a facility, you require a highly specialized team from the outset. This includes senior-level hires in Quality Assurance (QA), Validation, Facilities Management and GMP Operations. Recruiting these experienced professionals is a challenging, time-consuming and expensive process. Furthermore, they need to be brought on board well in advance of manufacturing, as this represents significant expenditures on salary and benefits that do not immediately contribute to product development. This early recruitment diverts critical resources and management attention away from core research and development (R&D) activities.

Possible compliance risk due to a lack of internal expertise

GMP facility design and regulatory expectations are highly specific and constantly evolving. Without deep, in-house expertise in these areas, companies face a significant risk of non-compliance. Errors in facility layout, HVAC systems, water systems or documentation protocols can lead to costly remediation or regulatory citations. Relying on external consultants can be helpful, but ultimately, the responsibility and associated risk lie squarely with the building owner.

Lack of flexibility if trial designs or product profiles shift post-build

The therapeutic development journey is rarely a linear process. Clinical trial designs may evolve, patient populations might shift or the product profile itself could be refined based on new data. A custom-built, fixed-footprint facility can become an expensive white elephant if your program's needs change significantly post-construction. Retrofitting or re-purposing a specialized GMP space is incredibly costly, time-consuming and often impractical, leading to either underutilized assets or the need for entirely new infrastructure.

Sunk cost risk: What happens if a trial fails or is deprioritized mid-construction?

This is perhaps one of the most significant hidden costs. Imagine investing millions in a facility, only to have a critical clinical trial fail or for the program is deprioritized due to new scientific data or a shift in corporate strategy. The capital sunk into construction, design and early staffing becomes a massive write-off, severely impacting financial runway and investor confidence.

Did you account for this?

- ☐ **Development delays:** How many months or years could construction, validation and regulatory approval add to your critical path?
- ☐ **Talent acquisition costs:** Have you budgeted for early, high-salary hires for specialized QA, Validation and GMP Operations roles, even before manufacturing begins?
- ☐ **Compliance headaches:** Do you have the internal expertise to design and maintain a facility that will pass rigorous FDA/EMA inspections from day one?
- ☐ **Rigidity and adaptation:** What's your plan if your product's needs or clinical trial design shift after the facility is built? Can your fixed asset adapt?
- ☐ **Program failure protection:** What is the financial impact if your lead program fails or is deprioritized mid-construction? Is your capital protected?
- ☐ **Ongoing maintenance:** Have you factored in the long-term operational costs of facility maintenance, utilities and continuous validation beyond the initial build?
- ☐ **Opportunity cost:** What R&D or clinical milestones are you not able to pursue because capital is tied up in real estate?

Build versus partner: **How the models stack up**

When therapeutic developers are ready to take control of their own GMP manufacturing, the decision often comes down to two primary paths: undertaking the monumental task of building their own dedicated facility from the ground up, or strategically partnering with a specialized, GMP-ready cleanroom facility provider. Each model presents a distinct set of implications for a company's financial health, operational burden and speed to market.

Option 1: Build your own facility

This traditional approach involves designing, constructing, validating and staffing a manufacturing facility entirely in-house.

- You own the physical asset and have complete control over its design and long-term use.
- This model requires significant capital expenditure (CapEx), often ranging from $5 million to $25 million or more, before any manufacturing can commence. This capital is tied up in real estate and fixed assets.
- Expect timelines of 12–24 months (or even longer) for design, permitting, construction, equipment installation, facility validation and the recruitment of a full operational team.
- The entire burden of ensuring the facility meets all current GMP regulations, establishing robust QA systems and preparing for regulatory inspections falls solely on your internal teams.
- If your clinical programs evolve, shrink or fail, you may find yourself with an expensive, underutilized asset that is difficult to adapt or divest.
- You must recruit and retain a large, specialized workforce covering everything from facilities management and engineering to QA, validation and manufacturing operations.

Option 2: Partner with a GMP-ready cleanroom facility provider

This model involves leveraging an existing, compliant facility and associated services offered by a specialized partner.

- Access to GMP-ready space can be achieved incredibly quickly, often in as little as 4–6 weeks, enabling immediate initiation of manufacturing activities.
- The financial structure typically shifts from CapEx to operational expenditure (OpEx), aligning costs with funding cycles and clinical milestones, preserving your capital for R&D.
- Many providers offer a suite of integrated services, including QA, validation support, tech transfer assistance, supply chain management and even facility operations support, allowing you to focus on your core science.
- These facilities are designed from the ground up to meet stringent regulatory requirements and often undergo pre-audits or have a proven track record of successful inspections, significantly reducing the risk to your compliance pathway.
- Partners typically offer modular or scalable solutions, allowing you to expand or contract your footprint and service needs as your programs evolve without the burden of physical renovation.
- By leveraging the partner's cleanroom and support services infrastructure, you retain full control and ownership of your intellectual property, manufacturing process and critical decision-making. The partner handles the facility's operational complexities.

You don't have to build it to own it

A common misconception is that partnering with a GMP-ready cleanroom facility provider means relinquishing control over your product, process or intellectual property. This couldn't be further from the truth. A strategic partnership empowers you to maintain complete ownership of your science, your process and your critical decisions, while offloading the immense operational and financial burden of facility ownership. You gain the benefits of a compliant, state-of-the-art manufacturing environment without the associated capital risk or lengthy timelines, allowing you to focus on what you do best: developing life-changing therapies.

Criteria	Build	Partner
Timeline to GMP readiness	12–24 months (design, construction, validation)	4–6 weeks (GMP-ready space)
Upfront cost (CapEx)	High, often $5M–$25M+	Low, OPEX-based model
Operational ownership	Full responsibility for staffing, compliance, QA	Optional shared services, partner-led setup
Regulatory readiness	Internal teams must build from scratch	Inspection-ready infrastructure and SOPs in place
Scalability	Fixed footprint, risk of over/underbuild	Modular, scalable by program needs
Tech transfer	Likely needed for the commercial phase	Co-located clinical commercial support possible
Internal expertise needed	High (validation, QA, facilities, regulatory, GMP ops)	Reduced (provider offers built-in experience)
Control over process	Full control	Full control retained (operational collaboration only)

Table 1. Build versus partner: Simplifying the decision-making process.

The financial benefits of renting expertise, **not just space**

Traditionally, building your own facility was considered the ultimate sign of growth and stability. However, a closer look reveals that partnering with a GMP-ready cleanroom provider is a capital-efficient growth strategy, enhancing a biotech's financial health and long-term viability. It's about renting expertise and infrastructure rather than just space.

The shift to an OpEx-based "partner" model presents significant financial benefits. Unlike massive upfront capital for construction, OpEx aligns costs with your clinical milestones and funding rounds. You pay only for what you need, when you need it, preserving vital capital for R&D, clinical trials and team expansion. This transforms unpredictable expenses into predictable operational costs.

An OpEx model keeps your capital liquid, avoiding its diversion into real estate. This maximizes its impact on your company's valuation and scientific progress, enhancing financial agility. Partnering also offers predictable costs, free from construction overruns, without compromising quality or control. You retain full control over your IP and processes while leveraging your partner's compliant infrastructure and expertise for faster, more sustainable growth.

Making the right choice crystal clear

Below is a diagnostic checklist to help you assess your priorities:

Criteria	Checklist
Speed to GMP readiness	☐ Do you have 12–24 months available to design, build, validate and staff a GMP facility? ☐ Will delays in cleanroom setup not impact your clinical or commercial timeline? ☐ Can your investors or partners absorb schedule shifts caused by construction setbacks?
Internal expertise	☐ Do you have in-house QA, validation and GMP manufacturing leads? ☐ Have you previously built or managed a GMP-compliant facility? ☐ Do you have regulatory personnel experienced in facility audits and inspection readiness?
Financial readiness and runway alignment	☐ Do you have sufficient capital available for upfront infrastructure investment (CapEx)? ☐ Is a long-term facility build aligned with your current fundraising stage or milestones? ☐ Would investing in infrastructure now not constrain your product development budget?
Program stability and scale	☐ Are your development programs mature enough to justify a fixed facility footprint? ☐ Are your space, scale and personnel needs unlikely to change within 12–18 months? ☐ Are you confident that your facility will be fully utilized during both the clinical and commercial phases?
Risk and regulatory burden	☐ Are you comfortable assuming regulatory responsibility for facility design and SOPs? ☐ Do you have systems in place for maintaining GMP compliance during scale-up? ☐ Can your team navigate an FDA or EMA inspection of a newly built site without external support?

- ✓ **10–15 "Yes" answers:** You may be well-positioned to build if timelines, capital and programs are firmly aligned.
- ✓ **5–10 "Yes" answers:** Consider a hybrid approach or phased infrastructure strategy.
- ✓ **Fewer than 5 "Yes" answers:** A strategic partnership model will likely reduce risk, accelerate readiness and preserve resources.

Where therapeutic innovations have space to transform: **The Chrysalis Way**

Navigating the complexities of GMP manufacturing infrastructure doesn't have to be a bottleneck for innovation. At Chrysalis, we don't just offer space; we provide a strategic partnership built by people who genuinely understand the intricate challenges and urgent demands of therapeutic development.

We've lived with the pressures of compressed timelines, the anxiety of capital expenditure and the critical need for compliance. This deep understanding is precisely why Chrysalis was created: to provide therapeutic developers with a better, faster and more capital-efficient way to access GMP manufacturing, enabling them to focus on their science, not facility management.

The Chrysalis Way is defined by key differentiators designed to accelerate your journey from bench to bedside:

→ Unmatched speed to deployment

We eliminate the long lead times of traditional builds. Our GMP-ready environments are designed for rapid access, allowing you to transition into a compliant manufacturing space in as little as 4–6 weeks, shaving critical months or even years off your development timeline.

→ Modular cleanroom design for true agility

Our innovative modular cleanroom architecture provides unparalleled flexibility. This design allows you to right-size your space from the outset and easily scale up or down as your program evolves, ensuring optimal utilization and avoiding the sunk costs of fixed, oversized facilities.

→ Optional wraparound services for de-risked operations

Beyond the physical space, Chrysalis offers a comprehensive suite of optional support services. From QA and validation oversight to facility-fit and operational support, we help de-risk your manufacturing journey, allowing your internal teams to concentrate on their core scientific expertise.

→ Co-located commercialization support to avoid tech transfer disruptions

Our innovative modular cleanroom architecture provides The journey from clinical development to commercial manufacturing often involves a complex and risky technical transfer. Chrysalis is designed to offer co-located support from early clinical stages through to commercial scale, minimizing the need for disruptive transfers and ensuring seamless operational continuity.

→ Strategically located US-based footprint

Our facilities are situated within the US, offering vital proximity to a deep pool of specialized talent and established clinical sites. This geographic advantage streamlines regulatory interactions and fosters collaborative opportunities within the vibrant US biotech ecosystem.

With Chrysalis, you gain a dedicated partner committed to transforming your therapeutic innovations into tangible realities, faster and with greater confidence.

This is your time: **Take control without slowing down**

The landscape of therapeutic development is more demanding than ever before. In this fast-paced, capital-constrained environment, agility is the decisive factor in achieving success. The traditional path of building a dedicated GMP facility, while seemingly offering ultimate control, often leads to significant delays, unforeseen costs and a dangerous drain on vital resources.

While the aspiration to own your manufacturing facility may resonate for the future, partnering today allows you to move faster, significantly reduce risk and, critically, preserve control over your science and strategic direction. You gain immediate access to compliant, state-of-the-art facilities and a wealth of embedded expertise, bypassing the lengthy and risky process of building from scratch. This strategic choice enables you to dedicate your capital and talent to what truly matters: advancing your innovative therapies through the clinic and to the patients who need them most.

This is your time to redefine how you approach manufacturing. With Chrysalis, you gain a true partner — one with the purpose-built infrastructure, deep expertise and a shared mindset focused on helping you grow efficiently and effectively. We're here to help you transform your therapeutic innovations into impact.

Ready to accelerate your path to GMP readiness and take control of your future?

Schedule a call with the Chrysalis team today to explore how a strategic partnership can unlock your potential.

Schedule a Call

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