

Flexibility in cell therapy manufacturing at scale

How modularity and adaptability enable industrialised production of therapies



Cell therapy developers operate in a world of complexity. Every process brings together multiple instruments, each with its own degree of automation, control logic and data structure. Today, these systems work side by side, but not always in harmony. As manufacturing expands, these disconnections become points of friction; physical and digital gaps that slow progress and threaten consistency.

One route to scale is to rebuild manufacturing around closed, end-to-end 'boxed' systems. However, this approach carries a heavy cost: redevelopment delays, high capital investment and, most critically, biological compromise. When proven routes are sacrificed for scalability, it's not only the cells that suffer, but the patients who depend on them. Each unnecessary process change, or delay in comparability studies slows access to potentially life-saving therapies.

The only sustainable route to industrial-scale cell therapy manufacturing is to automate what already works. Rather than rebuilding proven processes around closed systems, or introducing new equipment, materials and processes at such a late stage, developers can integrate existing technologies into a flexible manufacturing ecosystem that

scales from clinical development to commercial production without process redevelopment.

This flexibility gives developers manufacturing freedom. Freedom to use the technologies they trust. Freedom to automate at the right time. Freedom to expand capacity without redesigning their process. And, freedom to move from clinical manufacture to commercial production with confidence. It enables systems to adapt as science evolves, allowing each therapy to progress from clinical to commercial manufacture at the right time, with cost efficiencies and minimal process development or tech transfer delay. It gives organisations the freedom to invest when ready, preserving both capital efficiency and biological integrity.

At Cellular Origins, collaboration underpins this approach. We work extremely closely with leading technology providers across the cell therapy ecosystem to automate proven instruments and integrate them into a connected manufacturing environment. This partnership-led approach enables developers to scale with confidence while preserving the biology at the heart of every therapy.

Why flexibility matters for scale

Cell therapy developers face continual evolution across their portfolios: new cell types, emerging analytical tools, changing regulatory requirements, and advancing supply chain models. While individual therapies must remain tightly controlled once approved, the broader manufacturing landscape is far from static. Flexibility enables developers to share effort, infrastructure and insight across multiple therapies; enabling them to scale efficiently without re-engineering every process from the ground up. Fixed, hard-wired systems make this impossible.

Automation designed for a single process soon becomes a constraint. To achieve true scalability, manufacturers must be able to:

- **Preserve proven biology whilst increasing throughput**
- **Integrate best-in-class technologies without redevelopment**
- **Expand capacity easily without duplicating infrastructure**
- **Move from clinical to commercial manufacture without process change**
- **Invest in automation at the pace the business demands**

Flexibility is not simply the ability to change. It is the ability to scale without compromise. Flexible manufacturing allows developers to preserve proven processes, adopt new technologies when appropriate, optimise facility utilisation, and expand capacity in line with demand. The result is faster scale-up, lower risk, improved capital efficiency and a manufacturing operation that remains aligned with both the biology and the pace of innovation.

The modular foundation: designing for change



Constellation®, Cellular Origins' automated manufacturing platform, combines mobile robotics, proven bioprocess technologies and intelligent orchestration to create a flexible manufacturing ecosystem. Workstations automate individual process steps while remaining connected across the facility, enabling expansion without disrupting validated processes. By sharing capacity, balancing workloads and coordinating activities in real time, Constellation delivers true factory-scale manufacturing rather than isolated automation islands.

Modular workstations give manufacturers the power to adapt timing, process steps and layouts, while dynamically balancing workloads and maintaining uptime, all without compromising quality, safety or regulatory confidence. They also provide the flexibility to fit within existing facilities of any shape or size, or to support new-build layouts, maximising available space, capacity and output.

Modularity in practice:

- **Plug-and-play workstations:** Each manufacturing step (e.g. from isolation to fill-finish) can be automated independently, then orchestrated as part of a fully connected, adaptive ecosystem in the right ratios for maximum utilisation and efficiency.
- **Integration of best-in-class tools:** Constellation integrates tools from leading technology providers, allowing developers to use the instruments they already trust. Each integration is the result of significant joint engineering effort, built through deep relationships with manufacturers and supported by development, co-supply and co-marketing agreements. This close, hands-on collaboration ensures every tool is automated with full technical alignment and manufacturer confidence, giving developers a level of assurance and interoperability unmatched elsewhere in the industry.
- **Dynamic scalability and resilience:** Through intelligent orchestration, Constellation balances workloads across multiple modules, allowing shared contingency, live replacement and repair without halting production. Unlike traditional automation approaches that require duplication of infrastructure, Constellation increases capacity through intelligent orchestration and shared resources. As systems expand, throughput increases while maintaining operational efficiency and providing efficient redundancy, enabling manufacturers to scale without proportionally increasing complexity, labour or facility footprint.

Orchestrating every process with precision

Timing defines success in cell therapy manufacturing. Cells are living entities and output quality depends on precise synchronisation between culture, media exchange, sampling and downstream operations.

Orchestration is what transforms individual automated workstations into a scalable manufacturing system. Rather than automating isolated process steps, Constellation coordinates people, instruments, materials and robotics across the entire facility, ensuring every activity occurs at exactly the right time.

Constellation's robotic ecosystem ensures every transfer, incubation and handover happens at the exact right moment. Industrialised mobile robots (IMRs) perform tasks on multiple production lines in parallel, transporting materials between instruments, robotically operating those instruments, and dynamically coordinating timing to maintain continuous operation 24/7. Designed for resilience, Constellation continuously monitors process performance and equipment availability, adjusting schedules and pathways in real time to keep production on track, even when conditions change or maintenance is required.

Key advantages

- **Optimised scheduling:** Intelligent orchestration adjusts automatically to process demands and resource availability.
- **Reduced downtime:** Robots move efficiently between workstations, eliminating bottlenecks and idle time.
- **Process synchronisation:** Real-time digital control safeguards consistency and quality across every batch.
- **Operational resilience:** Continuous monitoring and adaptive routing ensure uninterrupted production, even when adjustments or interventions are needed.

This orchestration delivers the flexibility required for growth and the reliability required for commercial manufacture. By coordinating every activity across the manufacturing process, Constellation enables developers to scale production while maintaining consistency, control and product quality.

Designing future-flexible factories now

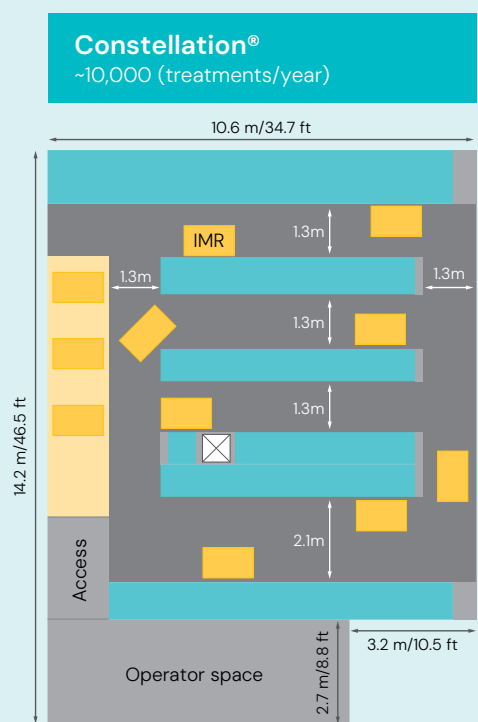
As cell therapies move towards commercial adoption, facility design becomes a strategic advantage. The most successful manufacturers will not simply build larger facilities; they will build smarter factories capable of adapting as therapies, pipelines, technologies and demand evolve.

Constellation enables facilities to be designed around manufacturing requirements rather than automation constraints. Mobile robotics connect instruments wherever they are located, eliminating the need for rigid production lines and enabling layouts that maximise throughput, flexibility and space utilisation. Capacity can be expanded incrementally by adding workstations where needed, without redesigning the entire facility.

This spatial flexibility is not just about engineering. It's about enabling the biology to thrive within environments designed for precision, safety, and continuous adaptation. It empowers therapy developers to make the most of their space, resources and science, building truly future-proof facilities that evolve as their pipelines do.

Modular automation advantages:

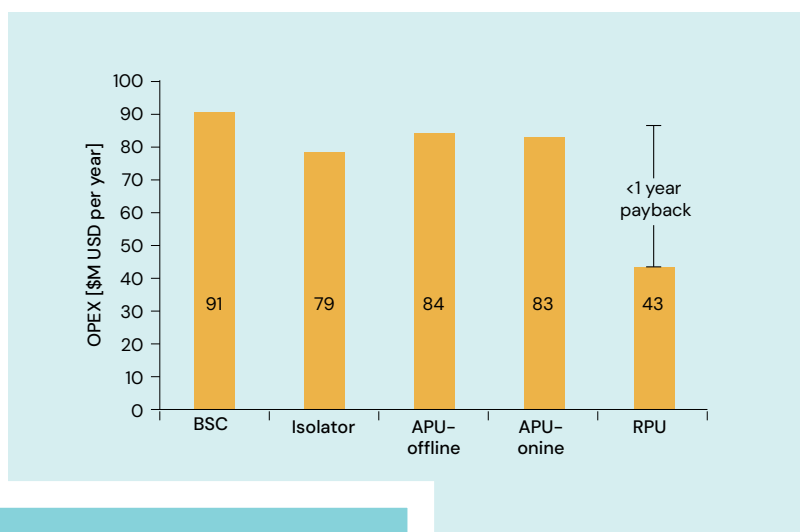
- **Facility-scale flexibility:** Constellation's mobile robotics navigate efficiently through a variety of layouts, in existing facilities, or new, connecting instruments wherever they are positioned.
- **Optimised space utilisation:** By removing the need for rigid, linear automation, manufacturers can reduce footprint while maintaining throughput.
- **Scalable growth:** Expansion is simple - replicate modules and add workstations in the most efficient ratios, and extend the digital orchestration layer to scale seamlessly.
- **Capital efficiency:** Facilities grow with demand, minimising upfront investment while ensuring readiness for commercial scale.



True scale comes from redesigning flow, not duplicating infrastructure.

Addressing common objections

Concern	Response
"Automation removes control from operators."	Constellation enhances operator oversight through digital monitoring, full traceability, comprehensive quality control and simple manual intervention points. Human expertise remains central.
"Our process is too variable or requires too much human intervention to automate."	Constellation is designed for processes with high variability and biological sensitivity and standardises them to the full extent possible. Developers can automate the steps that are ready, expanding automation gradually as the process matures without disruption or risk to the biology. Human oversight is maintained wherever it adds value.
"Automation limits future adaptability."	Constellation's modular design allows individual tools or modules to be swapped, updated or expanded as technology advances.
"It's too early to invest in automation."	Building flexible automation at the right time avoids high-risk early manufacturing investments and avoids costly redevelopment later. Constellation scales with you, from early-stage manufacture to global commercial deployment.
"Automation is too expensive or risky; the return on investment doesn't make sense."	In practice, the strongest ROI comes from flexibility. Constellation pays for itself quickly by using the tools developers already trust, while increasing throughput, reducing downtime and maximising facility space. As the platform scales, the financial return accelerates significantly. Independent modelling by PM Group, presented at Interphex 2025, shows that Constellation delivers packback in around 11 months and illustrates exactly what developers are seeing: flexible automation delivers value sooner and outperforms fixed systems by a wide margin.



PM Group, 2025 (presented at Interphex 2025).

Conclusion

Cell therapy manufacturing should not require a choice between flexibility and scale. The future belongs to manufacturing systems that preserve proven biology, integrate best-in-class technologies and expand capacity without forcing process redevelopment. Success will come from connecting technologies, orchestrating workflows and enabling continuous evolution as therapies move from clinical development to commercial production.

Constellation delivers this future today. Combining mobile robotics, intelligent orchestration and deep partnerships across the cell therapy ecosystem, Constellation enables developers to scale manufacturing with confidence while preserving the processes and technologies they trust.

Automate without risk. Scale without redevelopment. Expand capacity without duplicating infrastructure. Move from clinical to commercial manufacture with confidence. That is the power of flexibility.