

Beyond Off-the-Shelf: Rethinking Manufacturing for the Next Generation of Cell and Gene Therapies

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Andrew Stratton of TTP Advanced Therapies explores why bespoke engineering, multidisciplinary collaboration and manufacturing-by-design will be critical to turning increasingly complex advanced therapies into commercially scalable treatments.



The next generation of cell and gene therapies is pushing manufacturing beyond the limits of conventional platforms. As pipelines expand into engineered tissues, organoids, stem cell-derived therapies and complex combination products, developers must increasingly design manufacturing strategies around the biology rather than force emerging therapies into existing workflows.

In this interview with **BioSpectrum Asia**, **Andrew Stratton, Project Leader and Mechanical Engineering Consultant at TTP Advanced Therapies**, discusses the shift towards purpose-built manufacturing, the evolving role of CDMOs and the importance of integrating engineering much earlier in therapy development. He also examines how AI, digital twins, process analytical technologies and modular automation could help accelerate commercialisation over the next five years, while making advanced therapies more scalable, robust and economically viable.

Why are conventional manual and automated "off-the-shelf" manufacturing platforms no longer sufficient for the next generation of cell and gene therapies?

The first generation of commercial cell and gene therapies established manufacturing approaches around a relatively small number of therapy types, providing the industry with valuable experience and proven manufacturing platforms. However, the next wave of advanced therapies is becoming far more biologically diverse, spanning engineered immune cells for solid tumours, stem cell-derived therapies, organoids, tissue-engineered constructs and increasingly sophisticated combination

products. These emerging modalities often present manufacturing challenges that conventional manual processes or standardised automation were never designed to address.

As therapies move from early development towards clinical and commercial manufacture, developers are increasingly finding that forcing their process onto an existing platform requires compromises in throughput, operator intervention, facility utilisation, process consistency or cost of goods. These compromises may be acceptable during early research but become significant barriers to commercialisation.

Rather than adapting biology to fit existing equipment, we're seeing a shift towards designing manufacturing around the biology itself. This doesn't mean every therapy requires entirely bespoke equipment. Instead, it means identifying where proven technologies remain appropriate and where purpose-built consumables, automated unit operations or specialist process equipment can remove the bottlenecks that ultimately limit scalability and commercial viability.

Importantly, this engineering should happen alongside process development rather than afterwards. By considering manufacturability from the outset, developers gain confidence that their process can evolve successfully through clinical manufacture and into commercial supply, reducing technical risk while protecting future commercial viability.

What scientific and manufacturing trends are driving the growing proportion of CGTs that require bespoke manufacturing processes rather than standardised workflows?

The scientific landscape of advanced therapies is evolving rapidly. While early commercial successes were largely centred on a relatively small number of cell therapy modalities, today's pipeline is becoming far more diverse, encompassing stem cell-derived therapies, organoids, engineered tissues and increasingly sophisticated combination products. This growing biological diversity is driving the first major trend: therapies with fundamentally different manufacturing requirements.

Many of these next-generation therapies possess biological characteristics that conventional manufacturing workflows were never designed to accommodate. Adherent cells require fundamentally different expansion and harvest strategies to suspension cultures. Fragile cell aggregates, such as islet organoids, require manufacturing processes that preserve viability, architecture and function throughout production. Engineered tissues, such as cardiac patches, present additional manufacturing challenges because their therapeutic function depends on maintaining tissue structure as well as cell viability. Similarly, combination products rely on the interaction between the biological drug substance and the engineered product to deliver therapeutic benefit. Product performance therefore depends not only on the biology or the device individually, but on how those two elements interact. As complexity increases, understanding and controlling these coupled interactions becomes increasingly important, making it essential to develop the biological process, product design and manufacturing strategy together from an early stage.

Alongside these scientific advances, manufacturing expectations are also evolving. Developers are under increasing pressure to reduce cost of goods, improve process robustness and accelerate technology transfer, while maintaining the flexibility to support evolving clinical programmes. At the same time, there is growing interest in decentralised manufacturing for selected advanced therapies, placing greater emphasis on manufacturing systems with smaller footprints, simplified operation, reduced dependence on highly skilled operators and consistent performance across multiple manufacturing sites. These trends demand manufacturing solutions that are designed around the specific requirements of the therapy rather than constrained by existing platforms.

Importantly, bespoke manufacturing does not mean every process starts from first principles. Although therapies are becoming more diverse, many share common engineering challenges, creating opportunities to combine proven manufacturing technologies with targeted innovation. The objective is not customisation for its own sake, but to develop manufacturing solutions that maximise product quality, minimise variability and provide a robust foundation for commercial manufacture.

How should developers balance flexibility, scalability, regulatory compliance, and commercial viability when designing customised manufacturing strategies?

Flexibility, scalability, regulatory compliance and commercial viability are often presented as competing priorities. In reality, decisions made early in process development influence all four simultaneously, shaping not only technical performance, but also manufacturing cost, regulatory strategy and future scalability. Rather than optimising each independently, developers

should consider manufacturability as a fundamental design input from the outset.

The starting point is understanding which aspects of the biology genuinely require bespoke solutions. Every additional layer of complexity introduces cost and regulatory burden, so standard technologies should be used wherever they adequately meet the product requirements. Bespoke engineering should be reserved for the steps that critically influence throughput, product quality, process robustness or economic viability. This targeted approach avoids unnecessary customisation while ensuring the manufacturing process is built around the therapy's critical needs.

Integrating engineering with biological process development enables manufacturing decisions to evolve alongside increasing biological understanding. This is particularly important for next-generation therapies and combination products, where interactions between the biological material, the manufacturing process and the final product can all influence therapeutic performance. Considering these elements together reduces the risk of progressing with suboptimal product designs or manufacturing strategies that become increasingly difficult and expensive to modify later in development.

Even during early development, developers should maintain a clear understanding of what a commercially viable manufacturing strategy could look like. Manufacturing systems need to be robust, reproducible and economically sustainable while remaining sufficiently flexible to accommodate process evolution. Achieving this balance requires close collaboration between biologists, engineers, regulatory & quality specialists, and manufacturing teams from the earliest stages of development. Organisations that adopt this integrated approach are better positioned to accelerate development, simplify technology transfer and establish manufacturing processes that can support successful commercialisation.

In what ways must the traditional CDMO model evolve to support increasingly complex and personalised advanced therapies?

The traditional CDMO model has played a critical role in translating established manufacturing processes into GMP production and remains effective where manufacturing platforms are well understood. However, many advanced therapies are reaching the clinic before a commercially viable manufacturing process has fully matured. Scientific understanding, process development and manufacturing strategy continue to evolve together, making it increasingly difficult to separate development from industrialisation.

This creates new demands on the manufacturing ecosystem. Therapy developers must balance speed to the clinic with long-term manufacturability, while making decisions under significant technical and commercial uncertainty. At the same time, the landscape has become more fragmented. Large CDMOs offer extensive manufacturing capacity, regulatory expertise and established platforms, while smaller specialist organisations often provide the flexibility needed to develop novel processes and technologies. Both play important roles, but neither is optimised for every stage of development.

As a result, I expect the future to rely less on a linear handover between organisations and more on integrated partnerships established much earlier in development. Rather than waiting until a process is ready for technology transfer, developers, CDMOs, specialist engineering organisations and technology providers will increasingly need to work together to shape manufacturing strategies from the outset. This not only improves technical decision-making but also reduces downstream risk by creating clearer, more resilient pathways to commercial manufacture.

Ultimately, success will depend less on any one organisation expanding its remit and more on combining complementary capabilities. The organisations that create the greatest value will be those that help developers make confident manufacturing decisions while preserving flexibility as therapies, technologies and commercial requirements continue to evolve.

TTP describes its Advanced Therapies division as the "special forces" of CGT manufacturing. What does this operating model look like in practice, and how has it enabled you to solve manufacturing challenges that others could not?

Advanced therapy manufacturing challenges rarely fit neatly into a single discipline. A manufacturing bottleneck may appear to be a biological problem, but the solution could involve fluid handling, automation, process control, materials science or systems engineering. Equally, a technically elegant solution is of little value if it cannot be translated into a robust, GMP-compatible manufacturing process. Solving these challenges requires expertise across multiple disciplines from the outset.

Our "special forces" model reflects this. Rather than relying on large functional teams working sequentially, we bring together multidisciplinary teams comprising biologists, engineers, physicists, software developers and product designers to rapidly understand the underlying problem and identify the constraints that are genuinely limiting manufacturing performance. This allows us to evaluate the biological, engineering and commercial implications of different approaches simultaneously, rather than optimising each in isolation.

Importantly, success is not measured by developing bespoke technology. In many cases, the best outcome is identifying that an existing manufacturing platform is entirely appropriate. Where conventional approaches become the limiting factor, however, multidisciplinary teams can rapidly develop and evaluate novel manufacturing technologies, allowing developers to make informed decisions before committing significant time and investment.

Ultimately, our role is to help developers escape manufacturing dead ends. By integrating engineering with process development from the earliest stages, we can de-risk manufacturing strategies, accelerate development and establish practical routes to commercial manufacture. In a field where every programme presents unique scientific challenges, bringing together the right expertise at the right time can make the difference between an innovative therapy that remains confined to the laboratory and one that successfully reaches patients.

Looking ahead over the next five years, what manufacturing innovations do you believe will have the greatest impact on accelerating the commercialisation of advanced cell and gene therapies?

The greatest advances won't come from a single technology, but from a more integrated approach to therapy and manufacturing development. Historically, manufacturing has often been treated as a downstream activity, with engineering challenges addressed once biological feasibility has been demonstrated. Over the next five years, I expect this to shift significantly, with manufacturability becoming a core consideration from the earliest stages of product development.

That said, we'll undoubtedly see continued advances in enabling technologies. Artificial intelligence will help accelerate process optimisation and experimental design, while digital twins and increasingly sophisticated process analytical technologies (PAT) will improve process understanding and enable more robust manufacturing. Modular automation and flexible manufacturing platforms will also continue to mature, allowing developers to deploy proven technologies while tailoring critical process steps to the needs of individual therapies.

However, the biggest opportunity lies in how these technologies are applied. Rather than asking how to automate an existing laboratory process, developers will increasingly design therapies with commercial manufacture in mind from the outset. This requires closer collaboration between biologists, engineers and manufacturing specialists, ensuring that process performance, product quality and commercial viability are considered together rather than sequentially.

Ultimately, successful commercialisation will depend on building manufacturing strategies that are robust enough for routine clinical production while remaining adaptable as therapies continue to evolve. Organisations that embrace this integrated approach will be better positioned to reduce development risk, accelerate technology transfer and deliver advanced therapies to patients at a scale and cost that supports widespread adoption.