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Building Cell & Gene Therapies for Commercial Reality Starts Long Before Commercialisation

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Drew Hope, Senior Bio Manufacturing & Compliance Consultant and UK Qualified Person (QP), explains why early manufacturing decisions determine long-term success, how automation and closed systems are reshaping advanced therapy production, and why scalability has become as important as scientific innovation.

As cell and gene therapies progress from promising research to commercial reality, manufacturing has emerged as one of the industry's greatest differentiators. Success now depends not only on scientific innovation but also on designing scalable, robust and economically viable processes from the earliest stages of development. **In this exclusive Q&A with BioSpectrum Asia, Drew Hope, Senior Bio Manufacturing & Compliance Consultant and UK Qualified Person (QP) at eXmoor Pharma**, shares his perspectives on avoiding common scale-up mistakes, embedding commercial thinking into process development, and the technologies—from automation to synthetic biology—that are redefining the future of advanced therapy manufacturing.

What are the most common manufacturing and process development mistakes companies make when preparing for clinical scale-up?

One of the most common mistakes is focusing on getting a product into the clinic without thinking about what happens afterwards.

Many developers transfer a research or preclinical process into a GMP environment to generate clinical data as quickly as possible. While that can help achieve an early milestone, it can also result in a process that is difficult to scale, control or commercialise.

For cell therapies, a good example is a product developed around a very short shelf life without considering cryopreservation early enough. That approach may be workable for a limited clinical study, but it can become a significant challenge as programmes expand to multiple sites or larger patient populations.

From a Qualified Person (QP) perspective, another issue is that manufacturability, process robustness and quality requirements are sometimes considered too late. Decisions around raw materials, analytical methods and process controls

can have long-term consequences that only become apparent as development progresses.

Generating a GMP batch and developing a GMP-ready process are not necessarily the same thing. A process may be capable of producing clinical material today, but the real question is whether it can consistently deliver a product that remains suitable for future clinical development and eventual commercialisation.

How early should biotechs begin planning their commercial manufacturing strategy?

The starting point should be a Target Product Profile that defines what the eventual commercial product is intended to look like. That does not mean every manufacturing decision needs to be fixed before clinical development begins, but it does provide a framework for making better decisions throughout development.

In reality, programmes evolve and assumptions change as clinical data emerges. However, having a clear view of the intended end product helps avoid development choices that later become obstacles to scale-up, regulatory approval or commercial supply.

I often see organisations treat commercial manufacturing as a later-stage problem. By that point, some important decisions have already been made. Thinking about the commercial pathway before entering the clinic allows developers to identify potential risks earlier, when they are usually easier and less expensive to address.

What trends are you seeing in facility design and manufacturing models for advanced therapies?

Automation remains one of the most significant trends across the sector. Developers are increasingly looking for ways to reduce operator dependency, improve consistency, and lower manufacturing costs. As a result, there is growing interest in automated platforms that can support more reproducible manufacturing processes.

We are also continuing to see a move towards closed processing systems and isolator-based approaches. In many facilities this is reducing reliance on traditional Biological Safety Cabinets operating within higher-grade cleanroom environments.

The attraction is not only contamination control. Closed systems can also improve operational efficiency, simplify facility design and support more scalable manufacturing models. As therapies move closer to commercial reality, these considerations are becoming increasingly important.

How can developers balance speed, cost and quality during process development?

There is no single formula because the balance changes throughout a product's lifecycle. One of the most useful tools is early Cost of Goods analysis. Even at an early stage, it can help identify which parts of a process are likely to become major cost drivers and where development effort is likely to have the greatest impact.

Equally important is taking a risk-based approach to process development. Not every aspect of a process needs to be fully optimised before entering the clinic. Trying to solve every challenge at once can consume valuable time and resources without necessarily reducing the most important risks.

The key is understanding where investment will deliver the greatest benefit at a particular stage of development. Developers need to be clear about which activities are essential for clinical progress and which can be addressed later as more data and funding become available.

Programmes are most successful when speed, quality and cost are treated as interconnected considerations rather than competing priorities.

What manufacturing innovations do you expect to shape the next generation of CGT products?

The next phase of innovation will be driven as much by manufacturability as by biology. Automation, advanced process monitoring and improved analytical technologies will help developers produce therapies more consistently and efficiently. These tools can reduce variability, improve process control and support scale-up.

I also expect to see growing interest in approaches that reduce reliance on highly variable biological systems. Developments in synthetic biology may help create more standardised manufacturing platforms that are easier to scale and control, while improving affordability.

Investors are increasingly focused on these factors. Scientific promise remains important, but therapies that can demonstrate a clear path to reliable, scalable and economically viable manufacturing are likely to be best positioned for long-term success.