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ASIA EDITION

Cell Collection Must Evolve From Operational Step To Strategic Infrastructure For CGT Scale Up

June 1, 2026 | Opinion | By Ankit Kankar | ankit.kankar@mmactiv.com

Liza Loidolt of Terumo Blood and Cell Technologies explains why starting material quality, standardised collection practices, and stronger ecosystem alignment are becoming critical to achieving consistent and scalable cell and gene therapy manufacturing.

As cell and gene therapies transition from clinical development to commercial reality, the industry's attention is increasingly turning toward the foundations that enable scalable delivery. While scientific innovation continues to drive therapeutic breakthroughs, variability in cell collection remains a significant challenge affecting manufacturing consistency, operational efficiency, and patient access. **In this interview, Liza Loidolt, General Manager, Cell and Gene Therapy at Terumo Blood and Cell Technologies,** discusses why cell collection is emerging as a critical component of CGT infrastructure and outlines the steps needed to build more standardised, connected, and globally scalable therapy pathways.

Why is cell collection increasingly emerging as a bottleneck in CGT scale up efforts?

Given our role in supporting apheresis and cell collection globally, we see this across a wide range of programs and geographies. As cell and gene therapies move from clinical trials into broader clinical use, the challenge is delivering them consistently and reliably to more patients. **Cell collection is increasingly being recognised as a critical piece of CGT infrastructure, because it determines how reliably therapies can scale across patients, sites, and regions.** In autologous therapies the starting material comes directly from the patient, so every collection is different.

That makes collection both variable and operationally complex. It requires experienced teams, coordination across clinical and manufacturing settings, and careful execution to achieve target yields.

As more therapies move into late-stage development and commercialization, we hear from teams that variability becomes harder to manage at scale. **Many CGT workflows were originally built around individual programs or centers of excellence. The challenge now is building systems that can operate consistently across networks, regions, and larger patient populations.**

For that reason, the industry is increasingly viewing cell collection not just as a starting step, but as part of the manufacturing system itself. And one that needs to be designed for consistency, not just success in individual cases.

How does variability in starting material affect downstream manufacturing consistency and clinical outcomes?

In cell therapy, the starting material is not just an input, it defines what is possible downstream.

We see this every day with our customers. The cellular composition of a collection can vary significantly from patient to patient, and that affects yield, purity, viability, and how well cells expand during manufacturing. The source of this variability is a patient's own disease and treatment history as well as how the collection procedure is conducted at each site.

In practice, manufacturers often need to compensate downstream by adjusting processes or timelines or managing inconsistency from batch to batch.

In some cases, this can contribute to delays or failed manufacturing runs. It also makes it harder to build workflows that are truly repeatable and scalable.

That is why there is growing alignment across the field around the importance of starting-material quality. If we want more predictable manufacturing outcomes, we need more predictable inputs. Improving consistency at the point of collection is one of the most practical and impactful ways to achieve that.

Are current industry standards sufficient to support commercial scale CGT manufacturing globally?

There is a strong foundation in place, and frameworks like FACT and FACT-JACIE have helped establish high standards across collection, processing, and clinical practice. But as more programs move toward commercial scale and expand across regions, standards alone are not enough.

The challenge is not defining quality but making it work consistently in practice. Practices still vary across institutions and geographies, particularly in collection workflows, training, data capture, and operational readiness.

What we often hear from our customers is: "We understand the standards; how do we apply them consistently in real-world settings?" That is where shared metrics, consistent data, and workforce readiness become essential.

The standards are necessary, but they are not the end point. The opportunity now is to make them work reliably at global commercial scale.

What infrastructure or process changes are most urgently needed to standardise cell collection practices?

If we want to standardize cell collection, we first need to make it more visible and measurable, so teams can see what's actually driving outcomes.

One important step is broader adoption of practical quality indicators across the full collection process, from patient readiness through post-collection handling. Efforts led by organizations such as ASFA are helping define these parameters, but wider adoption would help create a more consistent language across the field.

One of the biggest infrastructure gaps today is end-to-end visibility. Many organizations still struggle to connect collection data, manufacturing outcomes, and operational performance in a way that enables true standardization. Many teams still have limited visibility into how collection variables affect downstream outcomes. When organizations connect data across patients, procedures, and manufacturing results, patterns begin to emerge, and that is where standardization becomes possible.

We also need to scale training and support, so expertise isn't limited to a small number of highly experienced sites. Apheresis still depends heavily on operator expertise, so there is a real opportunity to make that expertise more accessible.

Finally, stronger alignment between collection and downstream manufacturing requirements is essential. When collection centers, manufacturers, clinical teams, and technology partners are connected through shared expectations and data, it becomes much easier to reduce variability.

Do you believe the industry is now shifting from a therapy-centric mindset toward a broader infrastructure-centric approach?

Yes, I do, and I think it’s a necessary shift. As the field matures, the focus is naturally expanding beyond the therapy itself. **The industry is moving toward a more connected understanding of the therapy pathway, where collection, manufacturing, logistics, clinical operations, and data systems all influence one another.**

In the early stages of CGT, the priority was to show safety, efficacy, and the potential to improve patient outcomes. But as the conversation shifts toward broader access and commercialization, **the question becomes whether the infrastructure exists to deliver these therapies consistently and equitably across patients, sites, and regions**.

That is where infrastructure becomes critical — from cell collection and manufacturing to workforce readiness, digital systems, logistics, and coordination across the treatment pathway. Scalability depends not only on scientific innovation, but also on operational readiness and ecosystem alignment.

At Terumo Blood and Cell Technologies, we see this as a full pathway challenge, from collection through clinical deliver, and one that no single organization can solve alone. The goal is not just to optimize individual steps, but to create processes that are repeatable, connected, and scalable.

Ultimately, this shift is about making sure more patients can benefit from these therapies in a predictable and timely way.

Just as importantly, it’s about making sure developers don’t have to navigate these challenges alone; we need to solve them together.