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Why Donor Supply Chains May Decide the Future of Cell Therapy Commercialisation

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From ethical sourcing to decentralized manufacturing, OrganaBio's Justin Irizarry outlines the operational challenges and opportunities shaping the next era of advanced therapies.



As cell and gene therapies advance toward commercial reality, the industry's focus is rapidly shifting beyond manufacturing technologies to the operational foundations that underpin successful scale-up. **In an exclusive conversation with BioSpectrum Asia, Justin Irizarry, CEO of OrganaBio,** discusses the hidden complexities of donor sourcing, supply chain resilience, analytical readiness, and the evolving role of integrated CTDMOs. He shares why starting material variability remains the greatest risk to cell therapy development and how next-generation manufacturing models could reshape global access to advanced therapies.

Q1. As cell therapy pipelines continue to mature globally, where do you believe the industry still underestimates the operational complexity of scaling autologous and allogeneic manufacturing?

The industry has spent the last few years building extraordinary process technology such as closed systems, automation, and advanced analytics. What we still underestimate is everything upstream of the cleanroom. Starting material variability, reliability, and scalability are the single largest source of cost, schedule, and yield risk in cell therapy manufacturing, and they remain the least controlled.

For autologous programs, every patient is effectively a new lot. The process has to absorb biological variability that bench-scale development was never designed to accommodate. Apheresis slot timing, chain-of-custody handoffs between collection sites and manufacturing, cold chain windows, and manufacturing slot availability are scheduling problems that compound. They are typically analyzed in isolation instead of as a group.

For allogeneic programs, the assumption that a few qualified donors ensure adequate supply dramatically underestimates the complexity of managing donors who need to be routinely recalled. There is significant regulatory and operational work involved in providing sustained commercial supply. I believe cell therapy developers should view their suppliers as real partners: qualifying donors under 21 CFR 1271 for commercial use, maintaining recallability over multi-year programs, managing donor health and consent over time, and demonstrating comparability when a master donor must be replaced constitute a program – and not just a procurement transaction – that is mission critical to the success of the developer's drug.

A second area where the industry underestimates complexity is analytical readiness. Potency assays, comparability protocols, and method bridging from development to commercial are routinely the schedule-defining items in BLA timelines, not the bioreactor or fill finish. Sponsors who treat analytical development as a parallel workstream rather than a gating one tend to discover the cost of that decision late.

Q2. OrganaBio operates across ethical cell sourcing, GMP processing, and manufacturing under a unified framework. How important is vertical integration becoming for reducing variability and accelerating clinical timelines in cell therapy development?

Vertical integration is not new in pharmaceutical manufacturing, but it is comparatively underdeveloped in cell therapy because the industry grew up around specialized vendors. There were separate collection, processing, and manufacturing relationships, each with its own quality system. That structure created speed in the early years, but it now decreases speed and increases supply chain risk.

The core problem with disaggregated supply chains in cell therapy is that variability accumulates at every handoff. Each transfer is a sample, a temperature excursion risk, a documentation reconciliation, and a release decision under different quality management systems. This is to say nothing about the transportation and logistics risk associated with each hand off. Each link has its own deviation rate. When you stack them, the joint probability of a deviation in the chain becomes the determinant of timeline reliability.

Integration compresses that chain and benefits developers with increased speed, decreased risk, and simplified relationship management. When donor recruitment, collection, isolation, and manufacturing operate under one quality framework, one management team, and one culture, deviations are visible in real time and investigations cross functional teams without friction. The result for developers is a more predictable supply chain, less risk of losing valuable downstream resources (like clean room time), and a substantially shorter investigation cycle when something does go wrong.

That said, integration is not a universal good. Forcing every program through a single vendor's stack creates concentration risk if that vendor underperforms. The model works when each capability in the supplier's stack is independently credible. Sponsors should consolidate when their sourcing partner has a track record of success, speed, and quality, and disaggregate when optionality is maximally important.

Where we have seen the most acceleration is in early clinical programs that previously coordinated three or four vendors. Bringing that under one roof can compress timelines by months simply by removing the schedule slack that historically sat between handoffs.

Q3. Ethical sourcing and supply chain transparency are increasingly under scrutiny across advanced therapies. How is OrganaBio approaching long-term donor sourcing sustainability while maintaining GMP consistency at scale?

Ethical sourcing likely means different things to different suppliers. For us, it means three concrete things: (i) documented informed consent at the point of collection under IRB-approved protocols, (ii) traceability from donor to manufactured product, and (iii) donor health and safety.

We don't allow our donors to give more than once every eight weeks (otherwise known as the deferral period). This also allows for maximum recovery of their cells. A minimum deferral period is not specified in the regulations, so we adhere to the most conservative ones, which is for whole blood donation.

The structural risk in the current ecosystem is broker-mediated donor material. A material can be marketed as "ethically sourced" with paperwork that satisfies a customer audit, but the underlying donor relationship often sits two or three layers removed from the entity selling the cells. When that material enters a commercial cell therapy program, the gap between what the regulator expects and what the supply chain can demonstrate becomes a real risk.

Our approach is to own the donor relationship directly. Our FDA-registered blood and tissue subsidiaries, HemaCenter for adult leukapheresis and GaiaGift for birth tissue and cord blood, recruit, screen, and collect from a donor pool we maintain ourselves.. With our recent acquisition of Excellos, we have extended our donor footprint and network to the West Coast, as Excellos and San Diego Blood Bank have a longstanding sourcing relationship. San Diego Blood Bank is one of the largest blood banks in the United States with a registered donor base in the tens of thousands. Combined with our proprietary pool and additional blood bank partnerships, our total accessible donor network is larger still.

We are often asked how “large” our donor network is by prospective customers. This question is often motivated by the assumption that a specified donor is more likely to be found in a large donor pool. Size, alone, is not what matters. This is because size doesn’t account for (i) what percentage of the donor pool is active (i.e. how many donors routinely give, and the recency of those donations), and (ii) the supplier's ability to recruit new donors per the developer’s specifications. Over time, developers’ donor specifications have become more complicated, meaning the frequency of the specified donor appearing in the general population has become proportionally lower. Successfully finding those donors means having the operational agility to find the areas where the donor is disproportionately represented, recruit within those communities under IRB-approved protocols, and then recall the same donors reliably over the life of the program.

That custom-sourcing capability, combined with speed and quality assurance, is what differentiates us.

Sustainability over time depends on relationships, not transactions. Donors are contacted on a regular basis to maintain eligibility and recallability, and we make project-specific reservations available to lock recallable donors for multi-year commercial supply. As cell therapy moves from clinical to commercial scale, that recallability is what allows comparability to be anchored to a real donor rather than re-established from scratch with every new lot.

Q4. Many emerging biotech companies struggle with the transition from early process development into clinical manufacturing readiness. What are the most common gaps you currently observe among early-stage cell therapy innovators?

The transition from process development to clinical manufacturing is where most early-stage programs lose time. Four gaps come up repeatedly.

First, analytical readiness lags the process. Developers usually say they are ready for GMP tech transfer with a process that performs reliably in their hands but with potency, identity, and purity assays still in development. Because regulators expect those assays to govern lot release, they become the rate-limiting factor and the critical path that few anticipated. We consistently recommend that sponsors invest in analytical method development at least as aggressively as process development, and treat the potency assay as a multi-year effort rather than a step inside tech transfer.

Second, starting material specifications are not locked early enough. Programs run process development on a small set of donor materials, then expand to clinical supply with the assumption that any donor in the broader pool will perform similarly. The biology rarely cooperates. When the assumption breaks, the program absorbs unplanned variability at a critical moment, specifically during IND-enabling toxicology batches or first-in-human supply. Donor specification, like analytical specification, deserves a deliberate design phase.

Third, tech transfer documentation tends to be optimized for the developer's own use rather than for transfer to another team operating under cGMP. Process records that captured what worked do not always capture why it worked, which is what an external manufacturing team needs to reproduce the result reliably. This gap could show up as investigations in early GMP batches.

Fourth, and most importantly, emerging biotechs often select a sourcing partner for their needs at the moment, rather than for the program's trajectory. The supplier who can deliver small volumes with attractive lead times and pricing at the IND-enabling stage is not necessarily the supplier who can scale through clinical and commercial supply, hold the same donor specifications across years, and maintain comparability over the life of the program. When the developer realizes this, the program is forced to change vendors mid-development. The real cost is not qualifying the new supplier, but rather redoing much of the upstream work. Process development, comparability data, and analytical method qualification all anchor to the starting material. Change the material source, and a meaningful portion of that work resets. Sponsors who select sourcing partners against a multi-year and multi-stage capability profile, not a short-term one, usually avoid that reset.

These four gaps betray a structural pattern. Early-stage teams often treat clinical manufacturing as a project they hand off rather than a capability they continue to own with their CDMO partner. Programs that maintain technical leadership through

GMP transfer consistently move faster.

Q5. The industry continues to discuss cost pressures surrounding cell and gene therapy commercialization. Which process innovations or manufacturing strategies do you believe will have the greatest impact on improving accessibility over the next five years?

A big driver of improved access and lower costs is an expanded geography of when and where manufacturing and cell processing can take place. There is a strong industry bias toward centralized manufacturing and service hubs (for economies of scale), however many programs now would benefit even more so from localized processing of tissue that doesn't have to leave where the tissue is sourced. There is also the question of where costs accumulate in the process. The largest unit cost drivers in cell therapy are open-system manual operations, release testing turnaround, and starting material yield. Closed system technologies, compressed turnaround times, and increased processing capabilities in more geographies will all reduce COGS more than any one factor alone.

The most impactful near-term innovation is the maturation of closed-system and automated manufacturing platforms. Closed systems reduce environmental control requirements, compress operator labor, and improve batch-to-batch consistency in ways that meaningfully shift the cost structure. They also hold the promise of decreasing the need for controlled air space in the industry, capabilities that are very costly and time-consuming to build. Their full impact requires sponsors to be willing to redesign processes around the platform rather than retrofit it.

The second is rational allogeneic strategy. For programs where the biology supports it, well-characterized allogeneic starting materials offer step-function reductions in cost per dose by amortizing donor qualification, raw material acquisition, and process development across many patients.

The third is analytical efficiency. A meaningful fraction of cell therapy COGS sits in release testing rather than manufacturing. Rapid sterility, faster identity panels, and platform potency assays that can be qualified once and bridged across programs all shorten release cycles and reduce per-batch cost.

Decentralized manufacturing will be part of the answer for autologous programs with logistics constraints, but it will not be the answer for every program. We expect better segmentation over the next five years, such as centralization where scale creates economies, and decentralized where processing or manufacturing proximity to tissue sourcing dominates, and a tighter analytical layer connecting both.

Q6. With increasing investment flowing into decentralized manufacturing, automation, and next-generation analytical platforms, how do you see the future CTDMO model evolving compared to traditional CDMO structures?

Decentralized manufacturing turns a single facility into a network. The traditional CDMO model was anchored to a specific site — the site was the asset. In a decentralized world, the asset is the quality framework that can run consistently across multiple sites, not the cleanrooms themselves. A CTDMO is built around that framework from the outset.

Automation collapses operator-dependent variability, but it also moves value from the people running the process to the people designing and validating it. That is process development work, which sits inside the CTDMO model and largely outside the traditional CDMO one.

Next-generation analytical platforms — multiparameter flow, mass cytometry, digital and CRISPR-based potency assays — are platform investments no individual developer can justify on their own. They are also where comparability across clinical phases gets won or lost. A partner who owns the analytics becomes structurally hard to replace; a partner who outsources them is exposed at every phase transition.

The result is that the future CTDMO is less a building and more a network with deep technical integration — donor sourcing, process development, manufacturing, analytics, and release, all under one quality system, with the geographic flexibility to manufacture wherever the patients are. Some of that infrastructure has to be built. Some, in our case, was acquired. The Excellos acquisition gives us bicoastal cGMP manufacturing under a single quality framework — a concrete step toward that network model, not an end state.

Q7. As advanced therapy manufacturing ecosystems expand across North America, Europe, and Asia, what differentiates OrganaBio's long-term vision within an increasingly competitive CTDMO landscape?

Three things differentiate OrganaBio in a crowded landscape.

The first is that we own the donor pipeline and raw material supply chain. Our FDA-registered subsidiaries, HemaCenter and GaiaGift, recruit, screen, and collect under our own quality system, with no third party layer between donor and drug product. That ownership is unusual among CTDMOs, and it directly addresses the comparability and traceability concerns that regulators increasingly bring to commercial cell therapy programs.

The second is geographic depth in the United States without dilution of capability. Following our acquisition of Excellos earlier this year, our Miami and San Diego sites both operate the full stack: leukapheresis, tissue sourcing, cell processing, cell isolation, commercial-scale cGMP manufacturing for autologous and allogeneic programs, process development, QC and analytical testing, and cryopreservation. That dual-coast configuration gives sponsors GMP redundancy without the program-level disruption of switching vendors mid-development.

The third is that we operate at commercial scale today. The combined platform supports leading pharmaceutical and biotechnology partners in cancer and autoimmune indications, with programs in both clinical and commercial supply. Capability is demonstrated, not asserted.

The longer-term vision is more ambitious. Cell therapy development is increasingly global, and the manufacturing infrastructure to support it must follow. We see meaningful opportunity to support Asia-Pacific developers whose therapies require U.S.-based manufacturing for U.S. clinical trials and commercial supply, and we are actively building those relationships.