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13 Ways Logistics Specialists are Transforming Cell & Gene Therapy Supply Chains

Therapy owners are increasingly partnering with specialists who offer logistics platforms for next gen supply chain management – but what are the real-world benefits?

The trend towards a partnered, collaborative approach to logistics is emerging within cell and gene therapy development. Many small, mid-sized—and even large—manufacturers face challenges when planning scalable cell or gene therapy supply chains, as the degree of interconnectivity between stakeholders is far greater than that required in traditional specialty pharmaceutical production.

From apheresis draw to the manufacturing process, through to the delivery and patient infusion and, inevitably, the billing for the cell or gene therapy product, detailed knowledge of the complete supply cycle is critical. There is currently no out-the-box single logistics solution available that brings all of these stages and processes together.

But forward-thinking therapy owners are now connecting and consolidating vendors to plan and execute scalable supply chains designed to their exacting specifications; ones that help them navigate the clinical trial process and scale through to commercialization process.

Patient-specific therapies require therapy-specific supply chains.

Meeting the supply chain challenge

To manage such a complex set of demands, therapy owners are turning to logistics partners to plan and execute unique supply chain strategies for them. Critically, such specialists are also able to connect patient services, market access and order-to-cash in a single logistics platform designed to address the owner's unique supply chain needs.

Supply chain transformation

By aligning with the right partner and connecting with a bespoke logistics platform, progressive therapy owners are benefiting in 13 key areas:

1. Global reach, local knowledge

Demand for cell and gene therapy products is global and as a result, the supply chain must be able to cross international boundaries, time zones and climatic regions. The right logistics partner should be able to help therapy owners navigate these challenges and minimize risk to the product, and in turn, the patient's treatment. Successful partners should offer access to global networks via a dedicated logistics platform to secure standardized quality processes. This includes ensuring employees are trained to the same standards and working to the same SOP worldwide, meaning as the supply chain extends into new countries, support is in place to meet the increased demand.

In addition, the right partner will have the global presence to offer enhanced flexibility and response times—for example, collecting an apheresis sample with pre-conditioned packaging—wherever in the world the patient is located.

> Local knowledge is equally critical in global reach to ensure successful outcomes.

Knowledge and experience of cross-border shipment regulations is also vital for the smooth transfer of novel cell and gene therapies, particularly in areas where the regulatory landscape is still evolving. The right logistics partner works proactively with customs and other agencies to ensure the quickest possible clearance.

To bring all these disparate elements and processes together, product-specific and detailed route-by-route planning is required. This should cover all aspects of the shipment, including packaging, airline choice and contingency options, all viewable via the logistics platform. Partners who use data to complement their knowledge and experience are also able to give therapy owners additional confidence in the safety of their product. For example, logistics providers can bring greater certainty to packaging choice decisions through route-specific temperature data (see Entry 3—Tested innovations).

2. Rolling back risk

By partnering with a specialist, owners benefit from risk-based contingency planning that saves valuable time when preferred routing is not available. For example, a pre-formulated plan to use ground option alternatives in case of an air traffic control strike could mean the difference between the patient receiving their treatment or not.

A trusted logistics partner is able to give therapy owners more flexibility in other aspects of their commercialization plans as well; for example, allowing a larger geographical area to be served from a single manufacturing site, thereby reducing the risk and investment required to serve high patient numbers.

3. Tested innovations

As momentum continues to build around cell and gene therapies, this is driving innovation in areas beyond the therapies themselves. For example, the specific combination of size and temperature requirements for these therapies are driving packaging innovations to be more efficient in meeting their needs. Logistics partners have a dual role to play in identifying these advances, and robustly testing them before introduction.

For instance, World Courier has partnered with SAVSU Technologies to offer fully-vetted smart precision shipping containers. These cloud-connected passive storage and transport containers are specifically designed for the cell and gene therapy supply chain. They allow the shipment of biological materials at cryogenic temperatures globally, while featuring enhanced visibility and shipment monitoring capabilities, all accessible via World Courier's logistics platform.

4. Distribution excellence

Therapy owners are expected to meet stringent standards, ensuring Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) are adhered to. These high standards should also be expected from logistics partners charged with transporting materials. Word Courier is the first logistics company to attain global Good Distribution Practice (GDP) certification against three major standards; EU GDP, USP 1079 and WHO GDP1. The GDP certification was achieved across the 140+ global office network, and underscores World Courier's commitment to and compliance with quality management standards and international requirements throughout the supply chain.

> ''The quality of pharmaceutical products can be affected by a lack of adequate control over the numerous activities which occur during the distribution process.''
>
> WHO Technical Report 937, Annex 5, 2006

5. Lean alliances

Within this sector, less is more—in other words, choose fewer partners who can deliver more via their logistics platform to strip away silos and create true connectivity between all relevant stakeholders. Such an advancement removes complexity in an already intricate process and purges potential points of failure.

With a reduced number of partners all managed via the logistics platform, therapy owners also benefit from more efficient logistics tracking and kit management. Most importantly, they are able to monitor the performance of all partners – including the logistics provider – more easily, while optimizing spend and minimizing co-dependent data exchange activities.

6. Patient-centric solutions

A dedicated logistics platform is able to capture the complete journey of the patient from initial pre-treatment consultation, to enrollment in the patient support program, to appointment scheduling, shipment coordination and more. Said integrated platforms are essential to offer fully coordinated patient-centric processes for each stage of the treatment journey.

7. Scalable processes

Unlike small molecules and biologics, there is no distinct hand-off between the clinical and commercial supply chains for cell and gene therapies. This means that decisions made in clinical environments will shape the commercial supply chain.

Supply chain strategies must focus on scalability; planning for future success should be emphasized from the very beginning (see page 6 – Make the Leap Early) with any initial processes able to grow into fully fledged commercial operations.

Such processes enable learning and optimization during the clinical trial stage and, critically, produce data viewable via the logistics platform to verify the effectiveness of the supply model for regulatory submissions.

8. Integrated data

The right partner's logistics platform solution will connect and provision data to the off-the-shelf or in-house cell orchestration platforms. This enables effective communications between all stakeholders involved in the process. At a minimum, this will allow the supply chain to be choreographed so that the arrival of starting material is coordinated with available manufacturing slots, and that pre-conditioned packaging is delivered as soon as the product is ready for delivery.

Beyond this, the logistics platform can be used to create a communications infrastructure for "navigators" to serve as a single point of contact for providers and patients, allowing for the coordination of all activity while streamlining communications. It can also enable teams to evaluate the patient journey holistically, identifying opportunities to continuously improve offerings that reduce barriers to access and increase speed to therapy.

For instance, data aggregated from various sources can provide transparency and visibility for patients' caregivers and providers, while informing what requirements are needed for the commercial supply chain. Critically, the analysis of the data via the logistics platform can act as a "single source of truth" for audit purposes and serious adverse events, as well as chain of custody and tracking. For instance, full end-to-end temperature monitoring of cell and gene therapies is a requirement to demonstrate that the cold chain was maintained throughout transit.

> Therapy owners are looking for real-time GPS tracking to supplement other shipment tracking data.

Another key question is how to make the most of GPS data; knowing that a shipment is almost out of range is not useful if the only available option is to return to the start of the supply chain. The value of temperature and GPS data is amplified within the logistics platform as it can be used to intervene in cases of temperature excursions or delay in transit, and potentially save a therapy that would otherwise be lost.

9. Invaluable volume

A logistics platform offers the ability to handle volume, enabling true "economics of scale" and genuine leverage. High-quality contingency planning can be undertaken while ensuring a high return on investment on packaging and transport costs, plus the effective rollout of an integrated systems strategy.

10. Tapped talent

Therapy owners are able to move to a robust system earlier with a suitable partner in place, ensuring large lifts later in the product cycle are avoided while safeguarding the supply chain (eg, moving from paper/Excel-based tracking to a digital solution). Designing the logistics platform with the right partner in place also enables the scaling out of the operation, becoming a vital training exercise in the process.

11. Parallel programs

The manufacturer, the supply chain and patient programs can connect to work in a matrix with one another to ensure the best possible outcomes for cell and gene therapy development and commercialization. To help deliver this strategy, robust patient programs are required with the "navigators" in that program playing a key role in directing the commercial supply chain.

Imagine the programs as hub models with case managers whose actions trigger supply chain activities. For instance, patient enrollment triggers the apheresis scheduling; this triggers a kit distribution and the need to arrange logistics for the sample to be delivered to the manufacturing site, which in turn, must have a slot reserved. Critically, such disparate elements can be organized, managed and monitored using the logistics platform.

12. Commercial logistics infrastructure

Accounting for commercial logistics infrastructure and process is a requirement for pre-market launch. Apheresis kit warehousing, customer service, returns, accounting, contract/chargeback administration and, most importantly, the front-end ordering system should be tailored to customized product requirements.

Looking at financial services, an integrated third-party logistics partner can provide proven methodologies and processes, and offer comprehensive accounts receivable management, including account setup, invoicing, collection and cash application efforts. Because the complexity of this therapeutic category is so immense, the financial services to support each product must be customizable based on business model, including credit procedures, payment terms, cash application, collection efforts and monthly reporting.

13. Transformed supply chains

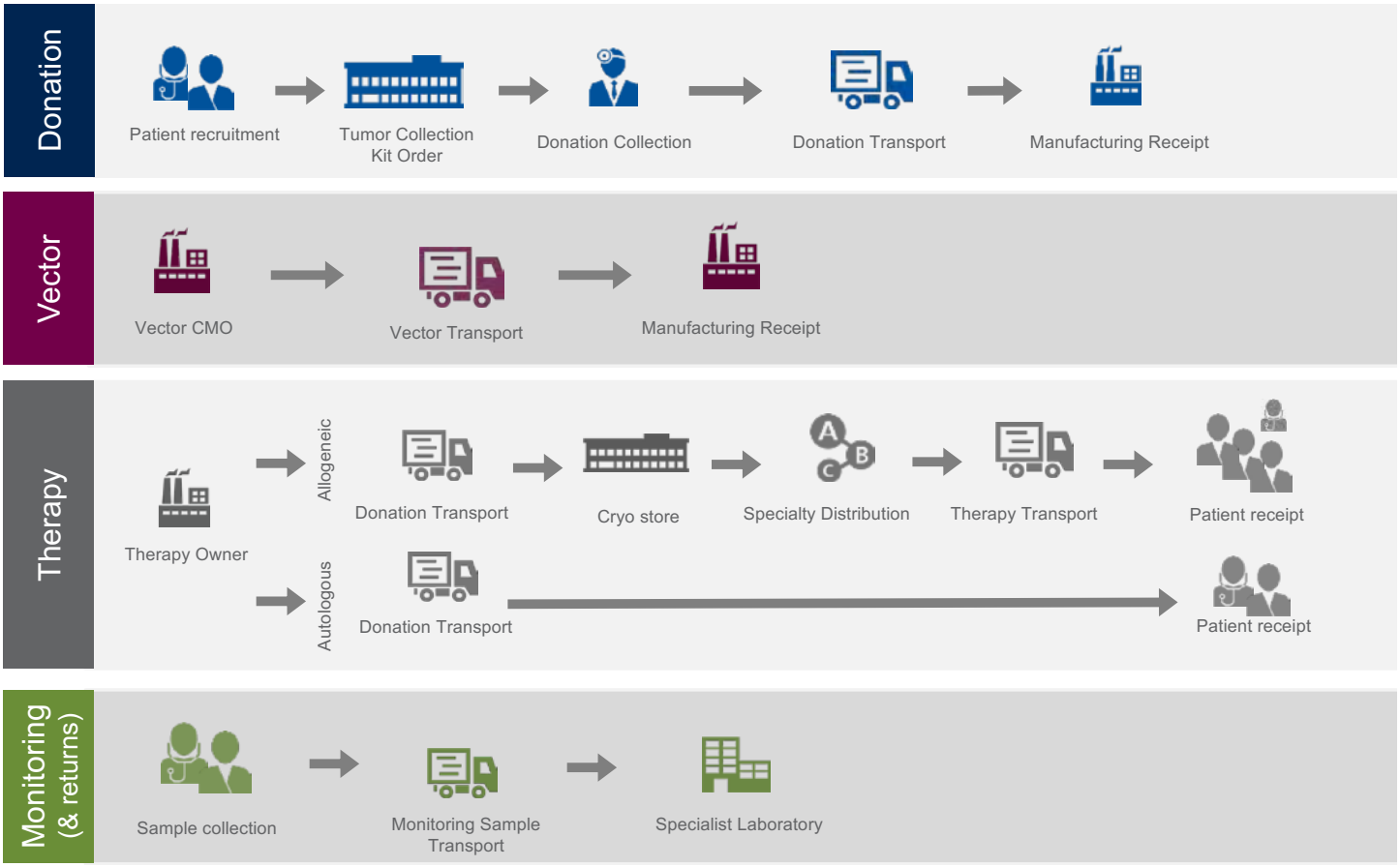
As the product moves into full commercialization, the existing visibility in the supply chain transforms into the need for visibility of the entire patient journey, including enrollment and access, as well as logistics events to trigger order-to-cash processes and payment collection. For example, phase 1 studies for a cell therapy may happen at a single location and move to multiple sites for phase 2 and 3 studies, before becoming international as the therapy commercializes globally.

The seamless management abilities offered by a logistics platform mean that apheresis scheduling in a patient hub program links to an available manufacturing slot. This triggers logistics preparations, such as the shipment with temperature-controlled packaging and a time-definite pickup, which should in turn initiate invoicing. The number of participants involved in the supply chain will grow over time—but the right partners and logistics platform will ensure that this transitional period is fully mapped, rather than being rolled out on an ad hoc, reactive basis.

Make the leap early

The key to the successful transition to a viable commercial operation is not only how—but when—the logistics platform is embedded to ensure effective future supply chain management.

World Courier's data shows a dramatic increase in the volume of shipments by therapy owners as well as a rise in clinical locations. This has created sizeable challenges for therapy owners due to the struggle to realize and understand the challenges represented by the number of shipments now typically required for successful patient treatment.



The above figure reveals that depending on therapy modality, there are four critical shipments for each patient; each of these must be controlled, monitored and managed to ensure successful therapy. The need to effectively manage these demands—and how they can be serviced by a logistics platform—illustrates the need for such a platform to be embedded in development processes as early as possible.

This ensures the operations can be scaled up from the more localized needs of a clinical trial to the global demands of full-blown commercial operations that must answer to investors, regulators and critically, patients. To achieve transitional success, three 'connecting' steps should be considered:

1. Connect manufacturing with logistics

The Issue

Fresh cells offer the best viability and function. However cryopreservation increases the shelf life/shipping window. Balancing these two opposing forces impacts on prioritization within process development; geographic spread of clinical sites; as well as the number and size of manufacturing centers.

The Solution

Understanding what can be delivered, where and when, helps define where on the continuum, between centralized and distributed manufacture, the therapy sits.

2. Connect clinical development with logistics development

The Issue

Waiting until the end of phase III to define commercial scale logistics systems.

The Solution

Such a delay is too late; instead owners and logistical specialists must work together throughout the clinical trials to optimize the logistics platform for each therapy so owners are able to clearly describe their delivery system to the board, regulators and investors.

3. Connect all via communication

The Issue

When critical shipments are in transit, there is a failure of communication between therapy developers and logistics technical experts.

The Solution

Enable therapy developers and logistics technical experts to clearly exchange information by starting the communication early in the therapy's development process. This will enable the impact of different shipping temperatures, expanding geographic locations, etc. to be taken into account, and a robust logistics platform created.

Logistics Platforms: Key Takeaways

Complex medicine requires a personalized and complex supply chain. The right partner navigates this complexity on behalf of the therapy developer with a dedicated logistics platform to support studies as they move rapidly through the clinical phases to market.

To effectively manage the inherent complexity of commercializing cell and gene therapies:

- Select a partner who can support the growing complexity; from increased production volumes to geographical reach and the creation of patient specific programs, all should be supported via a dedicated logistics platform that will grow with your operations.
- Ensure the logistics partner operates to an exceptionally high standard—from GDP certification to the deployment of the latest innovations in packaging and shipping, they must be able to demonstrate that they not only set the bar high to protect your business but crucially, will always prioritize the patient in the supply chain.
- Make clinical decisions early on that have the capacity to scale up and out as the product moves to market while focusing on logistics throughout – from time and temperature-shipping requirements to the financial processes required to support the commercial launch.
- Communicate with and between vendors to remove silos and enable seamless transition through the supply chain

To find out how to utilize World Courier's logistics platform to transform your cell and gene therapy supply chain please contact our specialist team today.