



5 Considerations to **LOWER YOUR RISK** When Selecting a Supply Chain Partner

Orchestrating cell and gene therapy logistics is complex and susceptible to variability at each point of the supply chain. When your shipments are life-critical, a delay or oversight has the potential to impact the progress of your therapy development, and most importantly, a patient's second chance at life.

As your therapy operations scale from early-phase clinical trials to larger populations in late-stage trials and commercialization, your supply chain complexity—and risk—increases. Anticipating common setbacks and actively planning for their solution requires a specialized and collaborative approach with your supply chain logistics partner.

Keep these key considerations top of mind as you evaluate whether potential partners have the experience, expertise and relationships required for the successful transport and delivery of your cell and gene therapy.

1

Cell and gene therapy shipment volume

Cell and gene therapy shipments have inherent challenges that are unlike traditional pharmaceutical drug shipments. But your cellular starting material or manufactured product must be delivered where it needs to go, when it is expected to get there, and in the required condition and temperature. A patient’s life depends on it.

That is why shipment volume—and the experience gained over time—is so important. Supply chain vendors who routinely coordinate logistics for time-critical cell therapies understand how to overcome cell and gene therapy shipment challenges.

When evaluating cell and gene therapy shipment volume, ask:

- How many cellular therapy product shipments a year does your organization manage?
- How many total cellular therapy product shipments has your organization managed?
- On average, how many cellular therapy product shipments a day is your organization tracking?
- What is your company’s annual volume of fresh product shipments? What is your company’s annual volume of cryopreserved products?
- What volume of cellular therapy product shipments managed by your company cross international borders?



We’ve learned to overcome challenges inherent to shipments for cell and gene therapies, and we’ve done so more than 108,000 times*. For almost any anomaly, we’ve seen something similar before and we’ve found a way to overcome it to save someone’s life.”

RAY HORNUNG, MBA, CEM, CBCP
Manager, Logistics and Emergency Preparedness Team, NMDP BioTherapiesSM

*NMDPSM “FY2021 Annual Numbers”. These figures are for our fiscal year 2021 (Oct. 1, 2020–Sept. 30, 2021)

2 Company experience overcoming logistics challenges

Every day, shipments go exactly as planned. But when issues arise and a person’s life relies on your product, your vendor’s systems, processes and relationships to reroute, problem-solve and deliver are critically important.

Those systems, processes and relationships are not developed overnight. For example, our more than 65-person Cell Therapy Supply Chain Management and Logistics team relies on the experience gained over 30 years of coordinating logistics for 108,000 time-critical cellular therapies—including more than 6,600 annually—to successfully overcome challenges*.

When evaluating a vendor’s experience, ask:

- How many years of experience does your organization have providing logistics to cell and gene therapy developers?
- What is your process for enacting your emergency preparedness or disaster recovery plan?
- How does your company handle changing a product itinerary mid-travel due to an unavoidable supply chain disruption?
- What experience does your company have managing logistics during a natural disaster or geopolitical event?



Experience is a big benefit for cell and gene therapy developers. Orchestrating cell therapy logistics is more complicated than most people realize. These shipments are life critical and they can’t be replaced. There is no room for error.”

RAY HORNUNG

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3 Cell therapy supply chain manager oversight

Even with a well-designed logistics plan and an experienced team, supply chain disruptions will happen. For example, a collection may take longer than expected causing a pick-up delay or a natural disaster may impact flights.

That makes a dedicated cell therapy supply chain manager an essential member of your vendor's supply chain team. Cell therapy supply chain managers work with their team and yours to build contingencies into itineraries and troubleshoot any issues that arise.

A cell therapy supply chain manager should be available 24/7 ready to take action and keep all stakeholders informed about revised plans.

When evaluating a vendor's supply chain management team, ask:

- How large is the team that will support the logistics activities for our product? Who are the team members?
- Does your company provide after-hours, weekend and holiday on-call support to manage unexpected changes and emergencies?
- What is your company's escalation process to manage and communicate delays or changes to schedule?
- How and when will your company communicate schedule changes to us?
- Is your team solely dedicated to managing the supply chain for cell and gene therapy products?



We have someone available 24/7 to ensure the people transporting our products have the knowledgeable support of the organization behind them.”

RAY HORNUNG

4

Established domestic and international relationships

Building key domestic and international relationships in advance of unavoidable challenges—such as severe weather, customs complexities and flight delays—is essential to lessening risk and variability within the supply chain.

Look for a partner that has relationships with people and organizations across the supply chain. For example, our team has relationships with customs brokers throughout the world to help us manage and resolve border crossing challenges and ensure the correct import and export documentation is in place.

A supply chain partner should also have strong relationships with emergency preparedness teams at all levels of government, connections to government agencies, access to chartered forms of transport and a robust business continuity team.

A case in point: The COVID-19 pandemic. Throughout the pandemic, our team members continued to successfully deliver life-saving cell therapies globally every day despite major travel challenges.

In fact, when international borders closed, our strong government relationships allowed us to obtain a CDC waiver. This meant foreign nationals could deliver cell therapy products into the United States. With nearly 60% of our products crossing international borders, the waiver was critical to our operations.

When evaluating a vendor's domestic and international relationships, ask:

- What processes and relationships do you have in place to overcome border-crossing issues for cell-based products?
- Can you provide me with specific examples of your company's relationships with domestic and international agencies?
- How has your company used your relationships with domestic and international agencies to manage logistics during a natural disaster or geopolitical event?
- Does your organization have an emergency response team in place to mobilize in the case of events that could negatively impact the transport of cellular products?

5 Expansive supply chain infrastructure

Building an expansive infrastructure to collect your starting material and move that starting material or your final therapy from one location to another is costly, labor intensive and requires specialized expertise.

A supply chain partner should have extensive partnerships with commercial couriers to move your starting material and manufactured product. For example, we work with multiple commercial couriers to accommodate pick-up needs and our volume of shipments allows for priority loading.

When evaluating a vendor's supply chain infrastructure, ask:

- Is your company courier agnostic (i.e., do you work with multiple commercial couriers)?
- How many courier companies does your organization use for moving cellular material both domestically and internationally?
- How does your company choose a courier for a given transport leg? What considerations go into that decision?
- Describe the relationship between your logistics staff and the couriers. What processes do you use to rectify issues when they arise?
- What experience does your company have providing a high-touch service, such as a hand-carried courier service?
- Do your shipping lanes allow for customized itineraries or do you only transport product through specific airports or hubs?



We have proven experience and extensive relationships that have continually evolved as the cell and gene therapy landscape has expanded. That's the biggest advantage cell and gene therapy companies have when they tap into our expertise."

RAY HORNUNG



A supply chain partnership **YOU CAN COUNT ON.**

Over the last 30 years, our team has developed a proven supply chain infrastructure to more efficiently deliver cell and gene therapies.

Since our inception, we've coordinated the collection of cells and delivered those cells to manufacturers and waiting patients around the world. And we've done so more than 108,000 times.*

Our organization is responsible for more than 36,000 time-sensitive cell and blood shipments a year, including more than 6,600 cell therapy shipments managed by our team of more than 65 Cell Therapy Supply Chain Managers and Logistics Specialists.*

We've developed the systems, processes and relationships needed to overcome unexpected challenges in the U.S. and abroad so you don't have to.

Connect with us to discover how you can rely on our team to minimize your risk so each cell therapy product is delivered where it needs to go, when it is expected to get there.

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*NMDPSM

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