INNOVATOR INSIGHT

The critical role of shipping & logistics in the commercialization of cord blood therapies

David Murphy is a 30 year veteran of The Quick Group of Companies, holding various leadership roles in Quick's Life Science division. Over the past 8 years, David has served as Executive Vice President of Quick Specialized Healthcare Logistics, and works closely with major health-care organizations to develop specialized logistics solutions to safely transport human organs, tissue, blood and blood products for transplant or research. He also works with biotech and pharmaceutical companies to plan and implement transportation strategies for personalized medicine; including cell, gene and immunotherapy treatments. He develops scalable transportation solutions that preserve the product integrity of these life-saving shipments, and most importantly, the overall safety of patients. He helps to ensure adherence to the strict regulations of the life science industry and the chain of custody at every shipment milestone. David was instrumental in the logistics planning of the first FDA approved cancer vaccine, and subsequent commercialization roll out.

Q Having worked in the cord blood sector for many years, which advances have stood out as the most significant to you?

Our organization has performed logistics services for the cord blood community for over 25 years. Back in the 1990s there were only a handful of private banks providing cord storage solutions to expecting families. Today there are numerous private banks competing for the same expectant family population. At the same time, we have seen more activity from the public side of the industry and we are collecting shipments from hospitals throughout the USA every day on their behalf. Inside each

package there could be multiple cords, or just one, so it's very difficult for us to make a true determination of the quantity; however, we are definitely seeing an upward trend in the public cord blood sector.

Overall, in recent years the cord blood banking industry has been maturing and consolidating, and with that we have seen advances and a growing focus on ways of maintaining the integrity of the shipments. Packaging improvements, temperature-monitoring solutions, tracking technologies, such as GPS, indicate that the cord blood industry is reaching new levels of logistics sophistication.

With the growing number of medical therapies being explored through the use of cord blood, I believe these technological efficiencies will continue to be the focus of the cord blood industry.

Q What are the critical risks and challenges associated with shipping cord blood?

Temperature control is certainly a key challenge. Most of our cord blood clients are based in North America and here we have a vast weather system, where we can have extreme highs and lows. In the heart of the summer in Phoenix, it may be 120°F whereas in Minneapolis in February it could be -40°F. Weather certainly poses a challenge in terms of the type of container we (each client) uses to maintain temperature control for the varying temperatures.

The other challenge is timing. There is of course no set 'schedule' for a mother giving birth so this means we are collecting cord blood 24/7, 365 days of the year, 7 days a week at any time of the day. Identifying Quick staff that can commit to making a collection in a very short timeframe in the middle of Montana or North Dakota can be difficult. We also have to gain access to restricted areas within universities or hospitals, such as Operating Rooms, blood banks, or maternity wards.

Unpredictable problems such as traffic and airline delay are always a challenge. Natural disasters, hurricanes, snowstorms, volcano eruptions that might affect where airplanes can or can't fly. While situations such as Hurricane Sandy are a tremendous challenge, we do have some ability to prepare for them. We did this for Hurricane Sandy, as we did for many of the snowstorms that affected the East Coast of the USA. We were able to manage that storm with a lot of ease because we were prepared and had discussed whether we were going to make collections or ask donors to hold collections until the following morning. As a solution to the problem, we chartered an aircraft that stopped in Illinois, Colorado and Phoenix, so within its path we had all the planned collection spots. This not only ensured that our customers could continue to provide their cord processing and storage services but by coordinating across our client base we were also able to minimize the impact on cost.

All these factors pose specific challenges to cord blood collection and transportation, but having been in the business for over 35 years, we have proven techniques to accomplish the task.

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Q What approaches have you developed to mitigate these risks?

Over the last 25 years we have transported three-quarters of a million cords. We're proud of the fact we're averaging close to 40,000 shipments of cord blood a year. This level of experience has enabled us to learn a great deal over the years and in turn continually improve our processes and procedures to meet the needs of our clients.

For example, to control for temperature variations, we will run quarterly packaging tests with each of our cord blood partners. Most of the packaging we work with is the proprietary packaging of the organizations that we represent, often specifically designed for summer and winter use. Therefore, in order to mitigate risks associated with temperature fluctuations we run temperature studies with their packaging that mimics real transport scenarios. The test shipments contain a temperature monitoring device and we analyze the data from each scenario to ensure the target temperatures are being maintained for each type of packaging.

We also make sure that the service partners who work with us are trained to the point that they understand how vital the deliveries are. They understand the time and temperature constraints and put in the extra effort to pick up the cord blood within the protocols we have established. That's also a very important factor in our success: the commitment and expertise of the people who are part of the Quick team.

We also ensure we have kit availability at a moments notice. We have kits for every one of our cord blood partners stored in strategic locations throughout the country. This allows cord blood organizations to recruit clients right to up to the last opportunity. For example, a mother might be considering whether to donate and all of a sudden goes into labor and says, "Yes I do want to do this". By strategically having kits available in different locations we can respond to these last minute decisions and ensure the timely collection and viability of the cord blood cells.

Cord blood organizations receive hundreds, if not thousands, of cord blood deliveries on a monthly basis so when a sample comes in, they need to have staff available to start processing those cells. Our QuickBoard technology allows our cord blood customers to have visibility over all the cord blood shipments coming into their facilities. QuickBoard technology is a live feed from Quick's system that tells our clients when the samples are due to arrive and how many they can expect. This allows them to staff appropriately and has proven to be a very valuable tool for them.

Q You work with stakeholders from public and private cord blood banks; what do you see as the key differences in these relationships and the support they require?

There are similarities but some very vast differences between the organizations. The tools we've built, the quality and standard operating procedures we've implemented, work for both sides of the banking

industry. Ultimately it's about the integrity of the cells, whether it's a private or public bank and we have standardization and quality matrixes that work well for both.

In terms of operation, the public and private banks work on different models. Most cord blood organizations are privately enrolling donors months in advance of their due date. Once they're enrolled, that information, along with the kit number is put into the cord blood organization's IT system which links automatically through an API to Quick's system. This record remains in our operational database until the donor mother calls months later and asks us to collect their kit. The information is crucial in making sure we maintain the chain of custody. As you can imagine, parents are often so excited and tired that they may provide wrong information. The data in our system ensures that we verify important information before collection.

On the opposite side is public banking, where the cord blood banks have relationships with hospitals, not individuals. We are asked by the public banks to go to each hospital every day at a pre-agreed time and make that collection and send it off to the public cord blood bank. We don't receive the patient information as we do for private industry; we don't even get the number of cords in that collection, it could be one, it could be 10.

Q Do you feel the cord blood industry is now starting to move towards the commercialization of cord-blood-based therapies?

There's so much research being conducted for diseases such as multiple sclerosis, cerebral palsy, arthritis, diabetes, ALS, that you can't help but feel the future is so unbelievably ripe for this industry to take off in the next 3–5 years. We find ourselves well positioned by virtue of our sector-specific experience and having supported this community for many years. This was highlighted by our involvement with organizations such as the Cord Blood Association, who recognize us as the top logistics provider for the industry. We were asked to participate in their *Annual Cord Blood Association Summit*, which is a Think Tank of key individuals associated with the Cord Blood Association. We represent the transportation side and are committed to supporting the industry and to continually providing new ideas to improve the safety of cord blood transportation.

Q You work with a number of cell and gene therapy companies at various stages of commercial development. What are the unique challenges for these types of therapies in terms of shipping?

For the companies we are engaged with on a pre-commercial basis it's all about data – they want to be able to publish data to be reviewed by the regulatory agencies to achieve commercialization of their product.

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Between 2007 and 2009 we were working with the first FDA-approved immunotherapy vaccine up to pre-commercial stage. This biotech company had ambitious goals in that at the time when they expected to get FDA approval, we were already working with them on their commercialization strategy and being able to scale-up to the volumes they were anticipating. We knew early on we were probably going to see upwards of 5–10 thousand shipments a year, which is fantastic. But in a very short period of time, we had to be ready to scale to the level of 90–100 thousand shipments per year. We had to demonstrate that we had the ability from a technological and staffing standpoint, as well as from a liquidity and solvency standpoint, to be able to be their partner in transportation.

Q Across the different stakeholder groups you work with, are you seeing any trends in terms of awareness of shipping and logistics as part of a commercialization strategy?

In my 30 years of working in this industry, I can honestly say there is now a community, the cell and gene therapy community, that puts an emphasis on logistics. They truly understand the importance of logistics.

Transportation is so critical when talking about personalized medicine. We're not talking about a pill bottle that if you lose your prescription you can go the pharmacy and get a new one. We're talking about a one-off medication that's often for very sick people. The patient base we are dealing with ranges from infants to older people but they are often critically ill and taking part in a clinical trial that potentially offers them a last option for treatment. That's a very serious responsibility for us as part of the supply chain. To maintain the cells from the time they are collected from the patient, brought to a manufacturing facility (where a therapy is made within 3 to 22 days), and returned to that patient where those cells are re-infused, hopefully to treat a condition that would otherwise be incurable.

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There is much more engagement and discussion surrounding logistics and how this will impact the cord blood, cell and gene therapy industries. This represents a big shift in the industry. Previously we were seeing clients realize far too late in the commercialization pathway, that their supply chain and transportation strategy were less than robust; but as with any new industry or technology, we often learn the most from the missteps of the trailblazers and now it's great to see the importance of logistics being recognized by the community.

We know that the sooner you can engage with companies in the preclinical phase the better – it's never too early. We are working with

organizations that will have an approved product on the market in 2 years. By engaging with us and working on their commercialization and scalability strategy at this stage, they will have all aspects of their plan in place and ready to go at the point of approval.

From a cell and gene therapy perspective, we are engaged with so many organizations that have late-stage products in their pipeline, with two organizations that fully expect to be FDA approved by the end of 2017. So for us it's a strategic priority to continue to invest in our network and facilities so that we can help these companies with commercialization. We are right at the threshold of a lot of incredible science and medical therapies that are truly going to change the landscape of human healthcare and it's fantastic that we will play a major role in supporting these companies with their logistics and supply chain.

AFFILIATION

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Click here to download an e-book on the Commercialization of Personalized Medicine – Supply Chain Solutions.

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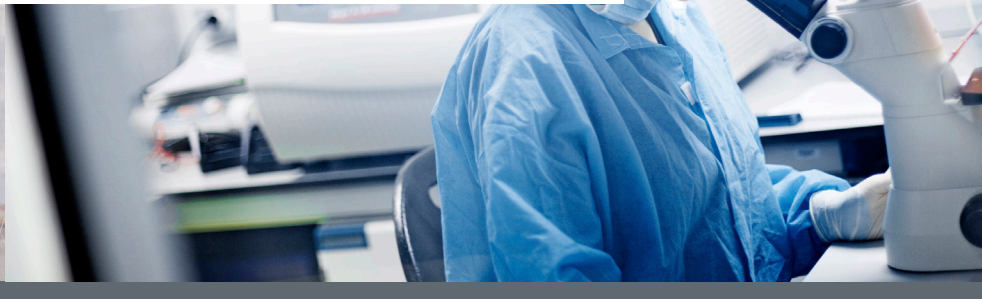
Quick *Specialized Healthcare Logistics*

Personalized Medicine Logistics

SOLUTIONS FOR GENE, CELL AND IMMUNOTHERAPIES

Quick, the trusted industry leader, delivers customized solutions for your personalized medicine supply chain, ensuring stability and integrity of your therapies throughout transit. Our logistics experts provide:

- **Expert temperature-controlled logistics solutions**
- **Robust chain of custody, security and integrity**
- **Pre qualified routing and real-time GPS tracking**
- **Advanced IT platform to manage your supply chain**
- **Next flight out, hand carry and air charters to meet critical deadlines**



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