

World Courier & TrakCel Q&A: How the Tendency Towards Decentralized Supply Chains has Changed in CGT

Exclusive interview with Jennifer Fenwick & Dr Matthew Lakelin.



Dr Matthew Lakelin

VP Scientific Affairs and TrakCel Co-Founder

TrakCel design, deploy and support digital cellular orchestration solutions to manage CGT value chains from clinical trial to commercialization, ensuring therapies reach patients quickly and safely and in line with quality and regulatory requirements. The OCELLOS cell orchestration platform can be configured to match specific CGT supply chains, tracking Chain of Identity, Chain of Custody and automating processes.

Dr Lakelin is a co-founder of TrakCel. Using his knowledge in handling and distribution of CGTs he has assisted with the development of the technology platform, he is passionate about democratising advanced therapies.



Jennifer Fenwick

Senior Manager Personalized Supply Chain,
World Courier, part of Cencora

Jennifer is part of World Courier's team leading the cell and gene therapy and direct-to-patient service lines, focusing on defining strategy, driving growth, and solving operational and process challenges arising from these shipments' complexity. With experience in roles on both the sponsor and vendor side for clinical and commercial pharmaceutical logistics, Jennifer has served in many leadership roles in the clinical trial supply chain, project management, vendor and alliance management before joining World Courier in 2022. Jennifer is helping the health tech sector integrate and grow within the continuously shifting landscape.

Can you give us an idea on the key differences between CGT and other health care sectors?



TrakCel was founded by a team with experience in cold chain logistics, specifically because there are some key differences that govern how CGT materials are handled. The primary reason relates to the often personalized nature of these therapies. Many advanced therapies are autologous in nature which means that a patient's own cells or tissue are used for the manufacture of the drug product, subsequently for the drug product to be safe and effective, full traceability is required ensure that the correct patient receives the correct drug product. Collecting, manufacturing and administering drug produces based on live cells exacerbates the complexity if these supply chains, introducing time and temperature constrains which are more stringent that standard pharmaceutical products.



Cell and gene therapies are at the forefront of innovation and bring much hope for the future of medicine, they could transform how we treat and potentially cure certain diseases, so the stakes are really high. But they come with new considerations for therapy owners as they are brought to the market. The nature of these treatments and their use of living cells or genetic material create new intricacies and dependencies that disrupt the traditional commercialization process. For the first time, the patient is now part of the supply chain. The supply chain starts with the patient. When it comes to cell and gene therapies we are talking about an interconnected and personalized model which requires a higher degree of integration between specialized logistics partners, patient programs, and the health outcomes evidence which is required to drive physician adoption.

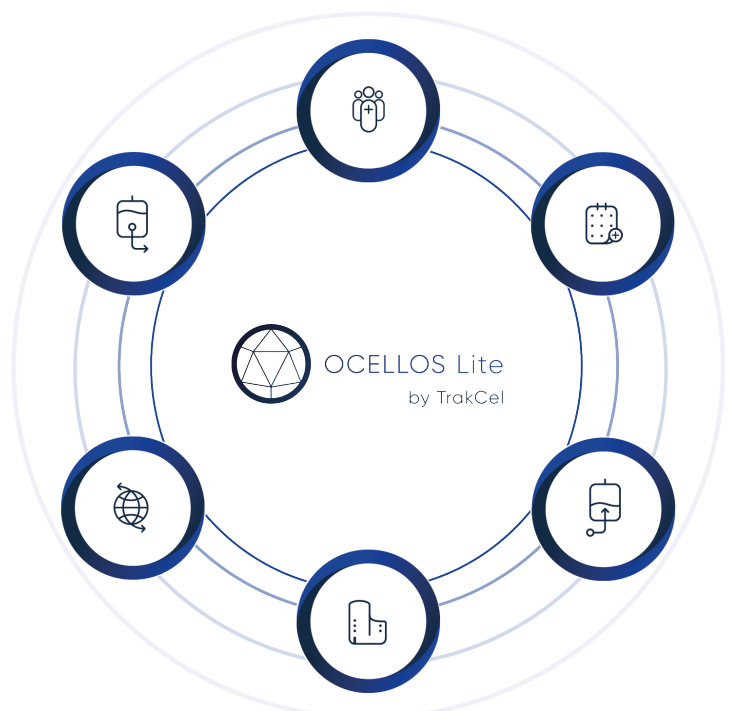
Can you give some examples of any industry challenges World Courier is looking to address/ focus on in the near future?



That is such a huge question as the industry moves so quickly it is a never-ending cycle of evolution and development, but an example related to the challenge I just mentioned would be to promote and improve cryogenic logistics. Cryo-preservation gives developers extra time in their supply chain. In 2021 we did some survey work with CGT sponsors and 59% of them were predicting that their need for partners to support global cryogenic logistics would grow. This needs to be considered in line with the growth in the industry, there are thousands of CGTs in development, and many of these will have need of a global cryogenic shipping infrastructure, so this is something we are working hard to support.



It is an excellent point and we are seeing signs that the logistics burden could increase even more than what those figures might indicate. We are seeing more and more therapy methodologies coming through, those with multiple dosing cycles, multiple cell collections, even multiple starting material types like tumor biopsies as well as apheresis samples. This expansion means that a patient treatment is no longer simply limited to a raw material and a finished product shipment, there could be many stages or parts to the process. We also must look at the indications that are being treated, yes rare disease and blood cancers remain a focus, but there are many promising treatments being researched for solid tumors and autoimmune diseases that if approved, the potential for scale-up would be unprecedented. In the interests of supporting accessibility to these life-saving treatments in future, it is vital that as an industry we invest in developing and facilitating robust infrastructure.



What are the top 3 reasons why CGT customers partner with World Courier?



I think it comes down to the fact that we have an unmatched global network made up of highly trained team members. We offer a wide range of shipping options to suit therapies and where needed, a bespoke and tailored service.

What has the partnership with World Courier added to OCELLOS?



OCELLOS delivers value in simplifying the supply chain and offering visibility of the right information to the right people at the right time. Having a network of integrated partners means that this information flows effortlessly, minimising the opportunity for errors as data is shared automatically. This saves time, reduces errors, and can trigger real time notifications of status changes as new information is collated. This essentially extends the scope of OCELLOS' orchestration capabilities.

What key piece of advice would you offer to companies considering investing in an integrated, digital supply chain for CGT?



There are a number of things that we have found are key to consider when looking at CGT supply chains specifically, and this is obviously a pre-cursor to building an integrated network of partners. In order to select the right partners and understand what information needs to be shared to facilitate the process there are some key decisions that need to shape this. For example, the pros and cons of using fresh vs frozen cells within the process and then the impact of cryopreservation within the supply chain.

As discussed before, the use of cryopreservation alters the supply chain significantly both in terms of the services and the suppliers that are used and the critical time-lines and the locations of the partner sites that are feasible. In many areas of CGT, cryopreservation has become more commonly used and as a result specialist logistic providers have been forced to update the technology that supports the tracking and monitoring of cryogenic shipments. The capabilities relating to the temperatures that a logistics partner is able to handle can be very influential when selecting logistics partners for each stage of a therapy journey.



The complexity of the supply chain process is what makes digitalization and integrating the supply chain so beneficial as it can significantly mitigate some of the potential risk areas.

Automating processes, reducing the chance of error or delay is vital when considering how time sensitive these therapies are and how much of a priority it is to handle them safely. But as Jennifer says, that makes the mapping of the process vital well ahead of the integration side of things.

Once this is done, the next thing we would advise is to prioritize the elements that you want in your scope. It is possible to build something really sophisticated with lots of integrations, but also something that is much simpler, which can be implemented sooner; the sophistication of your orchestration system should be commensurate to the complexity of the drug products supply and the development stage of your therapy. The important factor though is to look for systems and partners that can scale with you, that way you avoid wasting resource on something that needs to be replaced in the short term.



Can you give us an example of any challenges that World Courier faced that were specific to the CGT sector?



For autologous therapies, the patient is the source of the material that is used to manufacture the individual therapeutic. We've seen challenging cases when shipping the material fresh where, while the manufacturing was centralized in the U.S., the patient was based in Europe. With an apheresis and a finished product only stable for 48 hours at refrigerated temperature (+2°C to +8°C), securing and scaling logistics was not deemed feasible due to the distance and lack of available shipping lanes at the time, and to the need to set up an EU importer with a Qualified Person (QP).

Are there any complexities within CGT logistics that you would want the industry to understand more about?



I think it is easy to overlook that CGTs have development and manufacturing paradigms completely dependent on patients and logistics, so the logistics partners really are critical to the process. Within this, there are other complexities to CGT such as the requirements around biological and human cells, which vary between countries. Chain of Custody and Chain of Identity and labelling requirements that also need to be mindful of the geography and local language and regulations. Add to this that CGTs often have to

introduce whole new manufacturing and distribution models to support patient populations of one due to the unique nature of the therapies.



Yes and that aspect makes the challenge of scaling safely really complex and something that needs to be thought through in advance. This was one of the reasons why Dendreon's Provenge was delayed when it went through FDA approvals, Dendreon had to go to lengths to prove its supply chain fidelity. In traditional pharma, you are producing a drug product to treat thousands of patients at a time, but for CGT each of those administration or logistics tasks needs to be performed for each patient and tracked and audited

on a per patient basis.

What are the most compelling reasons a therapy developer should consider integrating partners to their digital infrastructure?



For simplicity and efficiency. OCELLOS was born because the supply chains and all their interdependent steps and stakeholders are incredibly complex and fragile. A breakdown or a delay could result in a therapy being unusable or even worse, could result in harm to a patient. Digitalizing and integrating allows CGT developers to leverage efficiencies of faster, more accurate information flow and reduced manual processing to make these supply chains safer, more manageable, and more scalable. Take just the

example of logistics, one patient's therapy is likely to involve at least two time and temperature sensitive logistics legs, in a manual system they would have to be booked, monitored and recorded via phone calls, emails or third-party web apps or similar. Every time that information is repeated or re-entered, resource is consumed and there is a risk of error; manual systems typically result in important documents such as labels, waybills or address books being split over multiple systems which is frustrating for users and inefficient to review or audit. OCELLOS can use direct integration with couriers and other partners to collate all the information into a single system in close to real-time automatically. This means that developers have far less risk in their processes and are able to scale up in a sustainable way.

About the OCELLOS Platform

The OCELLOS platform powers both OCELLOS and OCELLOS Lite, cellular orchestration solutions for both clinical and commercial therapies. The system modules are connected with leading third-party software and service providers (couriers, manufacturing systems, etc.) through our industry-leading "Integration Hub" built on the leading middleware solution from MuleSoft. From patient enrollment, scheduling, manufacture, right through to final product delivery and administration, OCELLOS gives complete visibility of the patient's journey. Implementing a cellular orchestration platform for your advanced therapy has never been easier.

www.trakcel.com

About World Courier

World Courier manages the logistics for your precious innovations. Across our global network, we pro-actively monitor the safety and integrity of your product, ensuring it reaches patients without delay. We plan for contingencies, so you don't have to, leveraging our global capabilities and local knowledge to navigate logistics complexities. Our innovative distribution services for medications, including rare, orphan, and gene therapies, are customized and scalable to fit your product's needs. We go the extra mile to ensure supply chain efficiency, maximum return on investment, and enhanced patient care.

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