

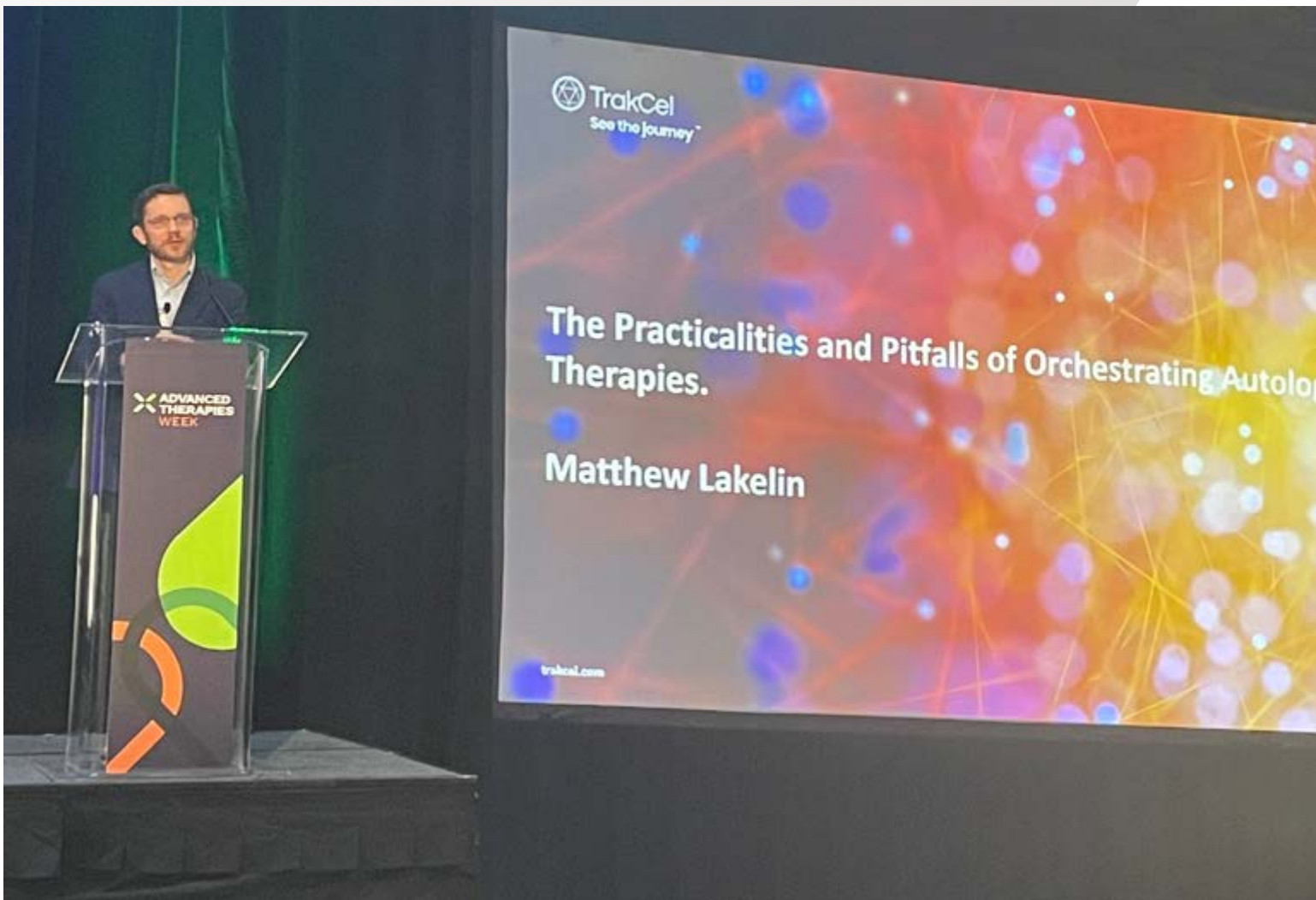
## Advanced Therapies Week, Miami - Key Takeaways

- **'The Practicalities and Pitfalls of Orchestrating Autologous Therapies'**

Dr Matthew Lakelin - TrakCel.

- **'Practical advice and logistical considerations'**

Jennifer Fenwick - World Courier.



○ **Dr Matthew Lakelin**

Dr Matthew Lakelin, VP Scientific Affairs & Product Development, Co-Founder. Using his knowledge in handling and distribution of CGTs, he has assisted with the development of the technology platform and is passionate about democratising advanced therapies. Matthew is one of TrakCel's industry experts who is tasked with insuring projects are delivered on time and in budget.



○ **Jennifer Fenwick**

Jennifer Fenwick, Senior Manager, Personalized Supply Chain of World Courier. 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.



## Introduction

Advanced Therapies Week, Miami, was a fantastic kick off to the year and it was great to catch up with colleagues, customers and partners. This year's theme was patient accessibility; as the industry focusses on growth and scale up, both TrakCel and our partners over at AmerisourceBergen's World Courier, ran presentations with a very practical flavour to try to assist therapy sponsors that are looking at moving to clinical trial, or scaling up to commercial supply in the near future.

Our Speakers, Dr Matthew Lakelin Co-Founder of TrakCel and Jennifer Fenwick, Senior Manager, Personalized Supply Chain of World Courier were kind enough to summarise their key points for those who missed the sessions, or just wanted a reminder.

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## Practicalities and Pitfalls of Orchestrating Autologous Therapies

*"One of the most challenging aspects of delivering an orchestration system is when partially defined requirements are shared with software vendors. Clarity is essential for the delivery of efficient and simple to use software and should be sought in the early stages of design." Matthew Lakelin*

### 1. Set a clear brief

Ensure you have your brief outlined prior to starting. This requires a detailed understanding of the type of system and the features and functions you need. It pays to take a multidisciplinary approach to designing, building, and configuring an orchestration system as this helps to prevent scope creep later on in the project.

### 2. Prioritize

Throughout the discovery process it is critical to understand the value of each feature and function so that you can prioritise activities in the software's delivery. E.g. you may want to delay the introduction of integrations to your orchestration system until you have experience using the system, and more insight into the value the integrations will bring to your supply chain, and where the greatest efficiencies are available.

### 3. Plan

When introducing an orchestration system for the first time, it is important to think beyond the project and have a vision for all the products in your development pipeline, and potentially commercial supply. This will allow you to collaborate with your vendor to develop a technology oad map for delivering a system that is suitable across the whole business, and a product that will suit your business vision for the future needs.

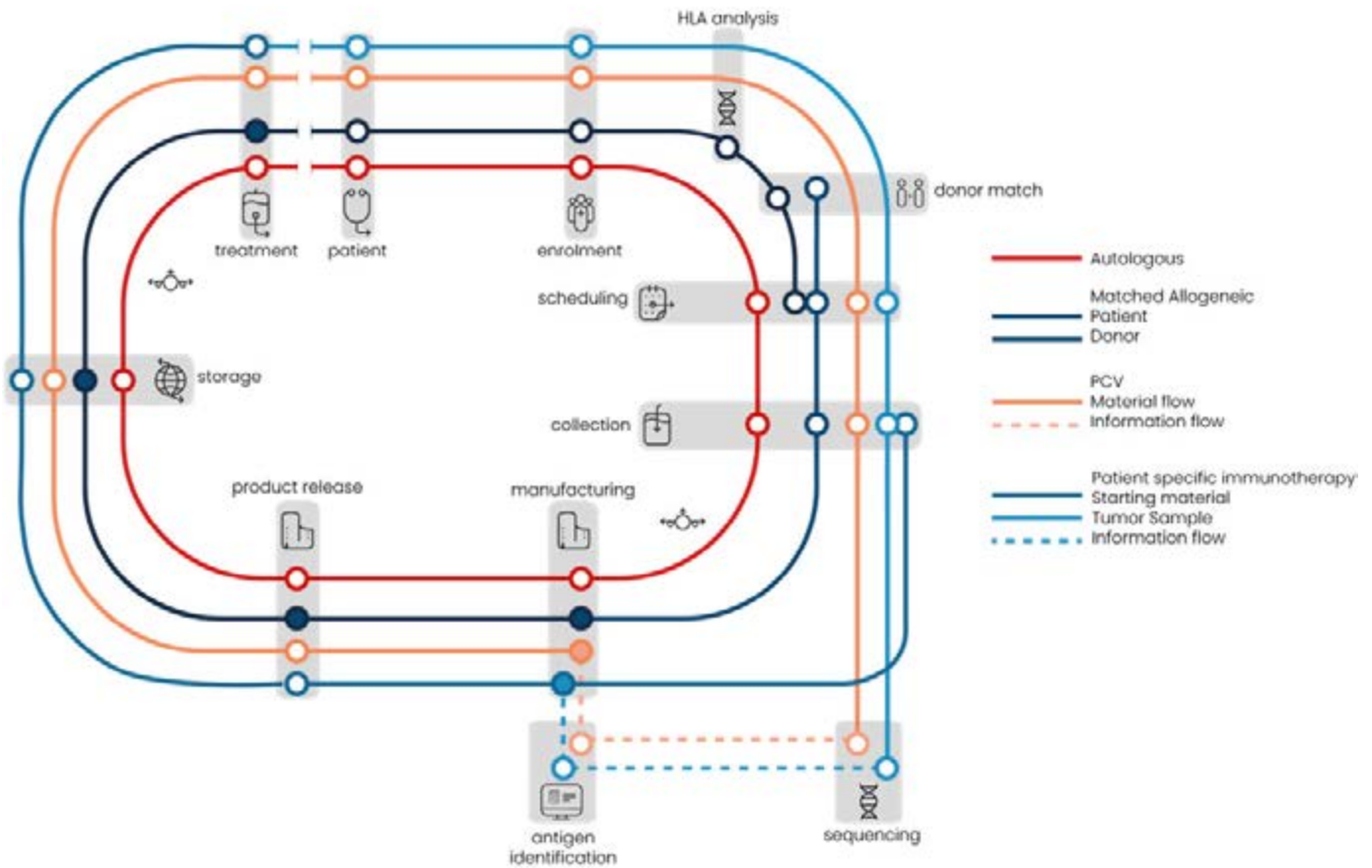
### 4. Make it Simple to Use

Increase user adoption, reduce training and make processes easier to follow by ensuring the software is not over engineered, overcomplicated, and over burdensome for its users. Recognise that the therapy may be administered relatively infrequently, thus hospital-based users might only access the orchestration systems occasionally, so the user interface must be uncluttered, providing simple visual cues on how to operate the software to manage the drug product during all aspects of its supply.

### 5. Consider Regulatory Requirements

When detailing features and functions used for orchestration systems, it is advisable to associate these features with the regulatory requirements with which the software is facilitates compliance. This is a useful way to demonstrate that the functionality of the software meets the needs of the supply chain and regulatory compliance can be assured and enforced.

To validate any compliant GMP software system, the correct documentation is necessary. TrakCel use a high-level business requirement specification to in turn, generate software configuration specifications. TrakCel's Process Analyst works with the process owner to write the configuration specification.



## How Can Partners Help?

The planning and scoping parts of a project can seem daunting as they appear drawn out and resource heavy. Many partner companies will have a discovery process that can help you through the briefing stages and help to clear up any ambiguity before delivery begins, but there are ways to keep your project on track beyond the initial planning stages and they can you save time, resources and money.

TrakCel follows agile methodology for the delivery of OCELLOS its orchestration system, this means our customers can review the configuration of the software as it's being produced. The configuration will be broken down into two week 'units' of activity called sprints, with each Sprint ending with a Sprint demonstration for the customer to see progress made. This gives first-hand experience of the system before it's available and allows our customers to give feedback on the build while it's in progress.

Another thing that can help you keep on track for an on-time, on-budget delivery is respecting the 'design freeze'. A design freeze is an agreed date, after which no further features or functions will be added. This helps to protect key deadlines. Even ahead of the design freeze the consequences of changing requirements, specifications, and product design should be fully understood to prevent scope creep and issues further down the line.

***"Great project governance and great project management leads to great project outcomes. An essential part of project governance is to have regular meetings with key stakeholders to nurture collaboration."* Matthew Lakelin**

## After Deployment

The bulk of the project may be in the deployment but a strong orchestration system will be running for the lifetime of the therapies that it supports. As such it is critical to plan for in-life support from the beginning of your project.

***“Define the performance criteria of your orchestration system prior to use. Agree service level agreements and support options so you can be confident that safety, security, and accessibility is documented and agreed.” Matthew Lakelin***

### 6. Plan in Management Time

A large part of selecting a platform is to ensure that it will continue to serve your requirements as they change but this takes an ongoing commitment to collaboration with your service provider. Utilize your long-term project technology roadmap and build time in to review as your processes or therapies evolve.

### 7. Collaborate on User Support

Most of the support requests to TrakCel’s Customer Support team are process-related rather than software-related. The support team have developed a robust understanding of each customer’s supply paradigm to allow them to assist where possible with requests not directly related to the application of the software. However, we also have contact details of key personnel at trial sponsors and therapy owners to escalate any challenges that are not associated with software operation.

## How Can Partners Help?

There are all sorts of ways that your partners can help moving forward - working together to bring new products, solutions and collaborations to the market place to help support new therapies and processes or facilitate the growth of the integrated supply chain ecosystem. There are also lots of things that can be done to help to leverage the maximum amount of benefit from your existing systems.

TrakCel’s Customer Support Team can help to implement new features or process changes, and support user management when staff or partners change. Some of our customers will undertake user management themselves but others will rely on TrakCel to provide this service. I would wholeheartedly recommend finding an orchestration vendor who can provide a flexible approach to supporting live systems and the types of services that you may need once your software is being used. The support team can also assist with generating custom reports to help users access the information they need, setting up new sites, or configurations or other simple system changes that help to keep the platform up to date and easy to use.

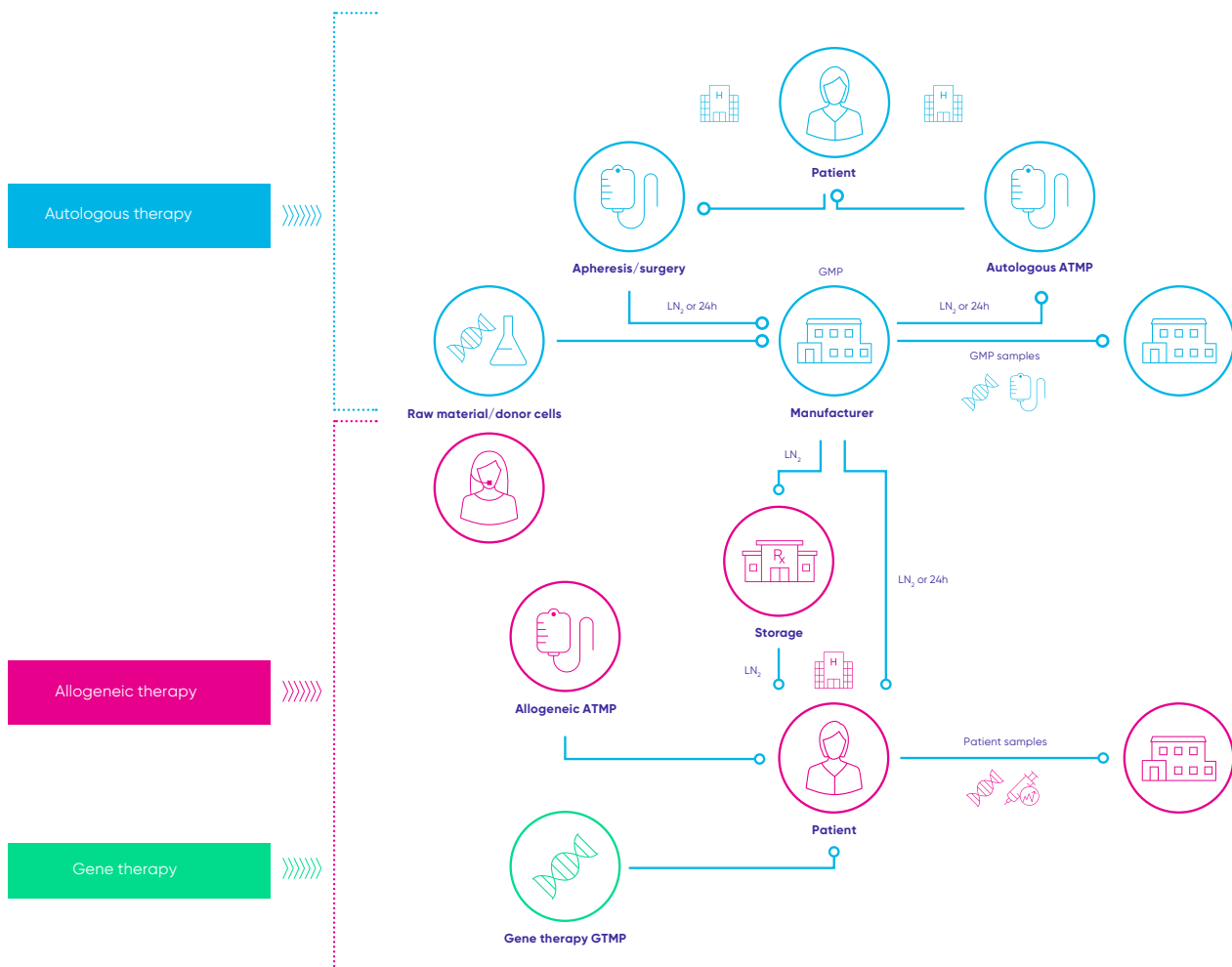


## Ensuring patient access to innovative cell and gene therapies: Practical advice and logistical considerations

The last decade of cell and gene therapy development have seen a vast array of changes in clinical methodologies and the types of cells and shipments that need to take place to support these therapies. Initially, one of the key challenges was around the shipping time lines and parameters that moving fresh cells entailed and then as the industry matured there was more reliance on cryo-preservation to alleviate some of the challenges associated with moving fresh cells over huge distances quickly.

However, changes to the methodologies, cell types and clinical techniques as well as the technology that is available to support the logistics and supply chain has created a rapidly changing landscape that is starting to see specialists in CGT logistics emerge to support the industry and the unique challenges it brings.

The three new requirements of pharmaceutical logistics for cell and gene therapies are time criticality, chain of custody and cryogenic logistics. In order to assess what the end-to-end supply chain will look like, the decision must be made to use either fresh cells or frozen cells. Both options have benefits and disadvantages.



World Courier has been managing cryogenic shipments for more than 10 years, and its existing global quality systems in place, supported by established standard operating procedures (SOPs) ensure operational excellence and proactive quality assurance. With TrakCel's cloud-based software, we deliver personalized processes and workflows for every participant in the supply chain, allowing cell and gene therapy owners to safely manage and scale with confidence through clinical trials to a global commercial success.

## Methodologies

In order to assess what the end-to-end supply chain will look like, the decision must be made to use either fresh cells or frozen cells. Both options have benefits and disadvantages.

### Shipping fresh

Especially for autologous therapies, quality and quantity of cells from patients are often critical. Shipping cells fresh reduces the impact on their viability, maximizing the number of cells that can be used for manufacturing, as well as reducing the time lost to freezing and thawing procedures.

However, it is critical to take into account that fresh cells can only remain stable for 12-96 hours before they degrade, limiting transportation distances from manufacturing sites to patients, and placing time pressures on quality control and release.

### Shipping frozen

For some therapies and cell types it is possible to utilize cryogenic preservation to extend the shelf life of cells from days to years.

The very long shelf life of cells below -150°C allows extended storage of finished therapy and samples. The shelf life of several months at frozen conditions facilitates global distribution and makes it possible to keep samples and conduct quality tests, allowing time for quality control and import/export processes.

This does however make it critical to be able to ensure that the low temperatures can be maintained reliably throughout the transportation and storage processes.

## What are the logistics limitations of cell and gene therapies?

### What we cannot change

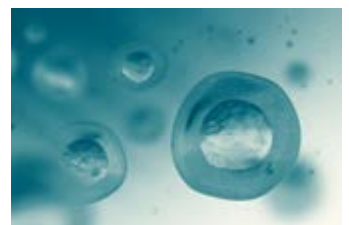
- The patient — disease status and timing of treatment
- The nature of a cell — requirements for survival, growth, and stability
- The size of the world — distances between A and B

### What we can change

- Locations — place, number, and equipment at manufacturing sites and treatment centers
- Shipment and storage technologies — shipper, storage tanks, and conditions
- Treatment management — IT and planning systems

### What we can influence

- Adaptation — if and how we use the available technologies
- Processes — it is up to us to set up scalable and sustainable processes
- Regulations — knowledge and feedback to regulators



## 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.

## About World Courier

World Courier manages the logistics for your precious innovations. Across our global network, we proactively 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.

[worldcourier.com](http://worldcourier.com)

