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Cell and Gene Therapy: Orchestrating Logistics for Specialty Products

The logistics chain for cell and gene therapies is highly complex, requiring extensive coordination across multiple organizations, operational processes, and enterprise systems. This session covers:

- Insights and unique challenges identified from the launch of initial cell and gene therapies through traditional logistical channels.
- Opportunities where digitalization of supply chain processes and orchestration of logistics channel relationships can reduce risk and improve agility for these critical therapies.

You'll also learn how logistics service providers can help lead in these efforts in partnership with life sciences companies and other supply chain participants. Watch the video to learn more.

Featured Speakers:

Michael Sweeney

Global Head of Strategy (CGT & DTP)

TRANSCRIPT

TRANSCRIPT

Henry Ames: Michael, thank you very much for joining us, and thank you for making the trip from the US. I've known Michael for the better part of 20 years, and we're really happy to have him here. We could not have a more storied presenter for you today on a very interesting and emerging topic on cell and gene therapies. Michael spent the last 30 years at World Courier.

World Courier, for those of you that don't know, there are three primary vendors in the space, World Courier, QuickSTAT and Marken. All three have recently been acquired. QuickSTAT, where Michael currently operates and is responsible for the global operations for cell and gene therapies is actually part of the Kuehne+Nagel organization.

We're very pleased to have you here today. Michael is going to start out with a brief presentation and then we'll move to a Q &A. I do have some prepared questions to kick it off, but, obviously, we'd love to hear from all of you with your questions that are obviously welcome. So, Michael, thank you, and please proceed.

Michael Sweeney: Thank you, Henry. It's a pleasure to be here. This has really been a pretty cool conference, different than a lot of the other events that I go to.

It's really a pleasure to work with Henry again. We've definitely known each other a long time, been through quite a bit together. I'm not going to bore you with a lot of slides. I'm going to go through this relatively quickly because I think that Henry has put so much time into preparing and understanding more of what I do than I

think a lot of people do.

I want us to have a discussion about this, and I invite you to be part of that. I think that where we are with cell and gene therapy is truly amazing from a patient perspective, from an innovation, medical. We're in a moment, and we have to figure out some of the intricacies of how it's all going to get paid for.

The bottom line is that we are on a really great trajectory, and I think that's going to continue because it's not just about the CAR-T and the cancer therapies anymore. It's expanded into so many different areas, treating patients that have a number of different diseases.

So, really, this rapid commercialization that we've seen, Joanna Sadowska, I believe she's based in Ireland, does an incredible job summarizing this on LinkedIn, and she updates it and really none of us can keep track of these approvals. They're coming fast and furiously, but I love the way she summarized it.

There's a bunch of really great stuff out there when you dig in to to some of the details, but there is a lot to this and I'll show you some examples. The meat of what I really want to talk about before I start the discussion with Henry is really about how different it is from a standard supply chain and where those high cost of failures come in and what mitigations and what contingencies we can put in place to combat those.

So this is just a really quick snapshot of what the supply chains look like. The first one is autologous, which is really the cells are extracted directly from that patient, and then that's what the drug is produced from.

The other is based on donor materials. So they're not exactly to a T, to every time, exactly how it's going to look, but basically, you're going to have a draw on the autologous side from the patient and that draw will be extremely important. It could be tissue. It could be a tumor. It could be a number of things that are extracted from that patient. It could be a child.

Chances are you're not going to have a second chance to extract. Some of these are one-shot deals. Some of them are maybe two or three treatments.

There's a cycle that happens after that initial draw at the treatment center. You're shipping to a manufacturing location. They manufacture the product, ship it back, and then there's different temperatures involved in both of those legs, which I'll get into in a little bit more detail.

Allogeneic is similar in that it's really critical that the right drug gets to the right patient because there has been a donor and a matching process that's involved depending on the therapy, but those shipments go back, also cryopreserved typically.

This is really what I wanted to show you. When I really started to think about this and try and show this in a graph, I couldn't come up with a prettier way because it's a little bit ugly.

The bottom line is that for the autologous supply chain, we have to provide packaging. The treatment centers don't have the capacity or the wherewithal or the interest to store packaging and especially when it needs to be conditioned. So this is a big part of the process. If we don't have the packaging at the treatment center at the right time, then the whole entire chain after that can fall down.

So that's a big part of what we focus on, and we ship that to the treatment center. Then the materials are shipped from there, as I described previously, to the manufacturer.

I've kind of put the really key segments of these six different shipments into red because they're the ones that if something goes wrong, you're going to have to charter a plane. You're going to have to drive eight hours. You're going to have to figure out another way because these time lines are so tight.

It's not just about the manufacturing cycles, which are obviously costly, but you

also have the patient that is waiting and some stability issues with some of these products. So for us, it's really important to get these packaging materials back as well.

It's not as urgent. It's not as critical, but it's important that we get them back into the supply chain because this is not something that we have just a unlimited supply of. This is an issue that continues to come up just with supply and demand as far as the specific types of packaging that are required for these materials.

So that's something that we spend a lot of time on really working through, what we need, but also making sure that we're efficient, that we're reusing these.

So there's a lot of, I think, benefits to how that process works, but really the point here is just illustrating that for a single patient, six shipments, and it's all precision. These time lines have to be hit, so it's very important. The great thing about that is these could be delivering curative therapies to a patient that is very, very ill. So I think there's positives and challenges throughout the process.

When I started thinking about the technology piece, this is really the key milestones that we measure. One of the things that we use as a true up is GPS. That tells us realistically, is the driver where they're supposed to be? We have a ton of improvements here to make on digitalization going forward, but I think that we're in an interesting place right now. There's a lot of better technology that we may able to leverage.

Part of the journey, this doesn't take into account everything, but my key point on this slide is just to say if anything breaks down in the middle, we do have to figure out is there a way to enact a contingency plan because the customer is going to be expecting it, the patient is going to be waiting. So we have to make sure that this is something that's thought of and planned in advance and agreed in advance.

Nobody wants to charter a plane if it's not planned, but it happens, and it happens for good reason. If you're treating somebody with a therapy that's worth

$1,000,000, you have to consider what is it going to take if something goes wrong. So I think these are the scenarios realistically that we're in.

How scalable is all this? So the allogeneic model will be a much more scalable solution longer term. Science isn't quite there. It's coming. So I have total faith in all of this working and working very well.

Temperature results are another key part of this. They're part of the milestone and really something in my mind we should be tracking throughout the journey and not only tracking, but communicating throughout.

So just to wrap up before Henry and I chat, I think the key for me, and I think that it was Guy in the last segment that mentioned this, the supply chain precision within this sector now is prioritized right alongside of patient care and manufacturing. That's huge because it's no longer under the radar. It's right out in front. It's critical.

Even in investment briefings, you see supply chain mentioned, whether it's a vulnerability, a scalability concern. So this is something that's very much on the forefront. I'll conclude there, and I'll ask Henry to fire away.

Henry: One of your introductory comments was around the volume of shipments. You talked about up to six shipments for a particular treatment. This whole two days has all been about digitalization and the flow of information around the movement of goods or maybe the flow of information that either proceeds, accompanies, or maybe even follows the flow of goods.

Could you talk a little bit about what type of information transaction flows are required to ensure this product quality, patient safety, and ensure these incredibly tight delivery time lines?

Michael: Yeah. The temperature is paramount, but so is the timing. So those milestones that I illustrated when the shipment's picked up, when it's delivered,

but then the the flight segments in between, we're tracking those throughout the process. So, again, if anything breaks down during that process, we need to have visibility.

We have APIs with a lot of our providers, whether it's GPS providers, other monitoring providers, or even with the airlines themselves. That's kind of where I see us making a big leap in the future. We really need to be tied closer together so that there is no question about where something is.

When you're up in the air now, you can't tell in the GPS until it lands, -- was it on the right flight or not? -- but you should have very good APIs with the airline to say, "Yes. It was loaded on this flight," but all of us have had bags or know somebody that's had a bag that was misrouted.

These are flagged. We're using the highest service, the health care or temperature-controlled service available, and that doesn't come cheap and sometimes it's prioritized almost like a passenger would be. That said, we're working with an industry that's pretty broken. So we need to work very hard.

I've worked with airlines my entire career, but I have not worked as much with them in the last 15 years except for the last 2 years. It's just intense. We need to really open the door, explain a lot of this, educate them, and let them know what's in stake and what they could be part of, but also their responsibility is key. So the digitalization and all these steps really does have a way to improve.

Henry: The complexity of associated with cell and gene therapy shipments, and I've been in the broader supply chain for going on 20 years now, it just sounds so incredibly complex.

One of the things you and I talked about was these shipments have very tight delivery windows and quite often they're going to sort of unique treatment centers where they actually need to be hand delivered to maybe the nurse or the clinician that's actually going to be involved in the administration to the patient. We've also

talked about how these therapies are evolving from oncology to autoimmune deficiencies to different treatment elements.

Could you talk about how does that communication flow when you've got a ground...at the end of the day, it's a delivery driver taking something and hand delivering it. Could you walk us through some of the issues there?

Michael: Absolutely. Then it is something that's often overlooked. So I bring it up all the time because if we don't see the right person at pickup or delivery, then the whole entire process that we've gone through can fall down.

It's really important that we know if we're picking up from a treatment center, for example, they could be patient facing like you've mentioned. They could be treating that patient involved with extracting their material. They could be very busy and not available when we show up, so we need to be patient, but we also need to be on time. We can't be there too early. We can't be there too late.

So it's really a precision piece. It's the same kind of concept on the manufacturing side. You want to make sure that, "Hey, this is being delivered to your facility, and I know it has a cycle time that's got to start at 8:00 AM this morning," and we need to hit that window.

We're all working together, so we need to make sure, again, we have...It starts with having contacts in our system, and we're contacting people by phone. We're texting people. We're using all sorts of different, I would say, mostly manual processes because the timing does change based on release from the airline.

You get a shipment you need to move, and then what time do you have it in your hands? Do you want to update the individuals then? They can track on GPS as well, but, again, I think GPS tells you generally where they are, but if they're going to a big hospital facility, we don't want to go to a central receiving location. It's got to be much more closer to that building, that lab, wherever that individual is working.

Henry: The GPS might tell you that you're on the campus, the individual's on the campus, but they might not be at the the right wing or the right department.

Michael: Right, and GPS is really I mean, honestly, we have found so many situations where the airlines don't have the shipment stored in the right location and we find that out in real time and that's really huge. There's been millions of dollars of product that's been saved because of that.

However, it does create a little bit of a panic psyche within the people that are looking at it and kind of wondering what's going on because I think there's always this feeling of, "We don't see it, what's going on?" Because it's in the air, you won't see it until it lands. So there's some, I think, education around that.

Again, this is just the tip of the iceberg. We didn't have this a few years ago. We didn't have Apple tags to put on our luggage. I was talking to a guy the other day that two of his teenage kids were home while he was traveling here, and he could monitor not where they were. He wasn't concerned about that. He was concerned about them not losing the keys. So we had the tags on the keys, and that's where we are.

Technology is incredible and I think about that a lot in terms of what that does for our shipments and really having that accountability. That last mile and the first mile are critical, sure, but what happens in between and knowing if something is being stored in a freezer versus a refrigerator, that's a huge problem. Years ago, not that long ago, really, we didn't have any idea.

Henry: You talked about ancillary supplies, critical components, clearly, that these doers, these liquid nitrogen doers often used in visibility around the movement of those goods. You mentioned that it wasn't as critical, of course, to get them back in a timely manner, but you want asset utilization to improve. You don't want a whole bunch of expensive packaging sitting out there in these disparate networks.

What about information flows with regards to the return and reuse of the materials

required for these types of shipments?

Michael: Again, we put manual resources on that. There's actually a team that we created at QuickSTAT that manages that process. I think that's probably an industry standard because there are a lot of things that can go wrong. There can be damage to a unit. There can be pieces to a unit that are missing. So there's all sorts of accountability checks along the way, but we do use technology to track those as well.

It's tricky because we're not managing this on routes. It's kind of specialized where the patient is, where the doer needs to be, to the manufacturing center. So we have some, I would say kind of hubs near manufacturers because that's where these are being shipped, but most of it can be coming from anywhere.

So if we need supply, if we have a large customer, we had a large order recently that you need to be agile and move and sometimes we have agreements where we ring fence a certain number for a specific client or a specific clinical trial and that's something that works really well, but yeah, it's tricky.

There's a lot going on with managing that, and I do think that we have a lot of, again, positive gains to make in the future and how we can best manage it.

Henry: So opportunities to digitalize some of those activities.

Michael: Absolutely.

Henry: Your role is a global role. So maybe share with us a little bit about what you're seeing in different regions. We talked about sort of regional variances from one country to the next and and sort of just the way these shipments move?

Michael: Probably what I love about what I do the most is the difference in the different people, the different cultures, the different challenges. I will say in cell and gene therapy, it is really heavily engaging in the US. It's moving throughout

Europe as well.

There's obviously a ton of expertise that we're seeing in the Asia Pacific region, but then you have country launches in places like Saudi Arabia or Bahrain that are very challenging, but also very rewarding because these are the first cell therapies being delivered in those countries. So, it's very exciting.

The interesting thing when you think about the challenges that we have around airport security, just this one variable and just the differences, the TSA isn't everywhere. That's a US problem, and I will say a problem because it is, it's a challenge because you can't expect the same exact thing to happen, not even within the same airport.

There might be something different going on in one cargo warehouse versus another. We use passenger terminals as well. We're flying people all the time with these packages when needed, so we have to consider all of this and the information that we're getting too in terms of radiation and can we scan or can we not and do we really know.

There are a lot of variables that we need to to consider and work through. We're only as good as we are on the ground in those locales.

Henry: We talked about a few other sort of specialty logistics service providers in the market, but Quick is really known for being the industry leader in cell and gene therapy.

We mentioned that you've been acquired by Kuehne+Nagel, and interesting to me when we were talking that Quick's historical business as with your primary competitors has been in the clinical industry, clinical distribution, clinical kits, clinical services, clinical trial materials, medicinal products. This is a commercial product. This is different.

Michael: Yeah. The interesting thing about cell and gene therapy just generally is

the supply chain doesn't change. Commercialization doesn't change the need for how the whole flow that I showed, it's really going to be the same. That complexity is why QuickSTAT is in the commercial realm. We're not typically looking to be involved in large commercial distribution.

We have a whole product life cycle within Kuehne+Nagel where QuickSTAT is involved in preclinical through various clinical stages, and then the hand off to to K+N really comes at a point that's kind of customer specific, but it can be product specific because cell and gene therapy often where we are now with the autologous especially in the complications with that that typically remains with QuickSTAT.

There are opportunities when we get into more centralized distribution from certain storage or donation locations that can definitely scale significantly.

Henry: How about the flow of information internally between the organizations, between QuickSTAT and K+N?

Michael: So our systems are different, but they're managing different things and different processes. We have a lot of discussions about this exact topic.

When's the right time for us to to have the handshake occur between we've taken a customer, maybe a smaller biotech that's getting bigger, maybe is acquired at certain points throughout the clinical trial phase, and then is getting ready to commercialize their first product, and how big is that product going to be? That's a discussion we're having pretty routinely, and there's been great successes out there.

I think it's challenging in many respects to kind of work through all of the different intricacies that every customer may have, and just managing a client in this type of arena, you can imagine how tight they are and how much they rely on the people they specifically deal with. So that hand off is very carefully managed.

Henry: I've got a ton more questions for Mike, but I'd like to open up to the audience because this is a great opportunity. Yes, please. Arun.

Arun: Thank you. Hi, Mike. Thanks for the education. A few questions along the same line. How many nodes are we talking about here? Is the patient, the treatment center, the manufacturing location are all different. Right? Or is there three different nodes or are is the patient at the treatment center?

Michael: The patient is at the treatment center.

Arun: The extraction happens at the treatment center, not at home?

Michael: Yes. Never at home in cell and gene therapy at this point. I deal a lot with the direct-to-patient work as well, but that it hasn't been totally crossed aside from quality samples that are drawn, but not the actual extractions.

Arun: OK. The treatment center and the manufacturing location, are they close, same country, different country?

Michael: It's a great question because we spend sometimes months, if not years, mapping lanes for potential manufacturing locations based on the client's expectation of recruiting patients in a variety of countries.

Many of these shipments are international. Quite a few in the US are domestic. There's a variety of ways that people are looking at the manufacturing strategy. Is it going to be centralized, decentralized?

A lot of really...I didn't understand. I looked at this as busy work for us because in my mind, "Well, flight schedules aren't really changing every month and there's a lot of instability in that industry. So we're trying to give you the best option we feel for quality on that lane," but I never really understood they were looking to make decisions on where they were going to recruit patients, which is fascinating.

For me, that's a huge breakthrough for logistics, to be part of that conversation

earlier.

Arun: Last question. Is the paperwork different for if it's in the clinical stage versus commercial stage for the same product?

Michael: Not in terms of customs typically unless you're talking about the valuations, of course, that gets very sticky in places like Brazil, everywhere, really. The valuations of the product because they are very high and how that's being managed.

Typically, the process is the same. The requirements on the statements are going to be the same because the material is the same.

Arun: Thank you.

Michael: Absolutely. Thanks for the questions.

Henry: Thank you, Arun. OK.

Audience Member: Hi, Michael. Thank you for the discussion. It was very informative. I have one sort of discrete question and then something a little bit more open ended. First, on the doers and then the Credo cubes, the NanoCools, are those individually ID'd or are they, every single one, all the time, there is a shipper ID that's somewhere on that box that's unique to that container?

Michael: Absolutely. Yes.

Audience Member: OK. Interesting. Thank you. The more open-ended question, actually, I want to tie this back to the conversation that was happening earlier in the room.

Just curious where you guys are in your AI journey in terms of exploring those capabilities and how they might impact your ability to do route planning or use predictive analytics to say, "Well, if we're looking at these routes in the summertime, they're generally on time. In the winter, though, there's lots of

storms." Are you guys thinking along those lines about how to use that sort of data to make those processes more efficient?

Michael: Absolutely. We have dipped our toes in the water, and we're really hopeful that we can get something that is going to be useful. The challenge we have in looking at it is it's not just about the flight times, it's about the performance as well, like, are they loading the shipments as we expect?

Then beyond that, we also have to consider, I would say it's more of the variations or the instability in the scheduling. I think it's very clear to me now traveling quite a bit over the last year that they're filling up the planes. They're not really flying planes anymore that aren't pretty much up to capacity.

So they're doing some things on their end, but they are canceling flights when capacity isn't where they expect. It's kind of hard for me to envision us looking at the passenger side of this, but we may have to.

Your question is a great one because that, in my view, if we could solve the questions around the performance and, again, have to take the different services that the airlines provide as well into that equation. It gets trickier when you really get into the weeds on it, but that could be a hugely powerful tool. If we could solve that, that would be just unbelievable.

In my view, that's the primary focus in our specific swim lane at QuickSTAT where that's so important to us right now because if there's an issue, there's nothing worse than having to deal with trying to get a shipment back, and then in bad weather or whatever the situation might be, having somebody drive a ton of miles or trying to charter a plane, whatever we can possibly do.

So it's a really great question. We're exploring that quite significantly.

Audience Member: I was going to say the same, Mike. It's a great question. If you think we could use that industry wide, it would be because it's not specifically

relevant to cell and gene therapy.

Audience Member: Only because the transit time, like the half life of a fresh blood product. I mean, maybe you've got 24 hours. So, you could see, like, "Whoa. Why wouldn't Amazon be doing that?" Your t-shirt or your calculator is not going to expire because it got there a day late. Sorry. I'm giving a talk also later this afternoon in the cell and gene therapy space.

Michael: No. It's a great question. I'm glad you brought it up.

Audience Member: Yeah. The shipper ID thing is is interesting too because...Sorry, not to sort of dominate. We can totally catch up later if we want, but saying there's no shipper ID. I just found that surprising that there wasn't one. I know they're using one of the sort of premier containers, and so I wanted to sort of validate that with you.

This is a large pharmaceutical manufacturer telling me there's no ID on the shipper, and I'm wondering why they're saying that because it just doesn't...I'm not there in the room, so I don't have a box on my lap. It just doesn't seem logical because they're not cardboard boxes that you cut up and throw away afterwards. Right?

Michael: Yeah. The ones that we own, and I frankly don't know how much the manufacturers do and how much that varies versus what we do internally. So it could be a situation where we're managing that on our own, but we do track them individually in there.

Swanan: So my name is Swanan, and I'm the product manager for MINT. So I just want to understand from your standpoint of view, how the cell and gene therapy, can you give one example, how it is working right now, and how MINT can solve your problems, some of these delays and all that. So how the MINT can solve that particular problem in your case? Can you just explain quickly about that?

Michael: Yeah. Sure. I think that, for me, it's been really great to be here this week to hear where you guys are, and I don't know all the answers to what you can do to help us solve it, but I can tell you all the problems that we face and all the challenges that we face.

Really, it's just an unforgiving supply chain. We cannot fail. It's something where if something goes wrong, I think our biggest problem, we've heard it throughout the week is communication has to be faster than ever. So we're using multiple tools and sometimes those tools can trip us up because we're managing so many different things.

I think that if we could somehow streamline this and look at specifically what needs to happen, "Well, this needs to get on this flight," and we need to make sure that it's on that flight and that when it arrives, we know that it's there. So anything that breaks down in that process is hugely critical.

It's the same thing with the first mile and the last mile, which are hugely important as well. We need to make sure that there is communication and if we can't find the person we're looking for, we need to have backup folks and we have to have accountability.

Sometimes things get delayed. Patient treatments and prep can take longer than anticipated. Schedules get out of whack. So we just have to have better communication between us and everybody that we're working with.

Seems kind of fundamental in a way, but I think that the the intricacies of the challenge that we face on the pickup and delivery side, I can't overstate enough. Frankly, we load a ton of instructions on our drivers as well because it's different every time. It's not going to be the same exact person every time we go to Stanford or wherever we're picking up.

It's going to be different, and so we need to make sure that we're really clear about it per shipment, and there's going to be likely very detailed instructions

about that day, what's going to happen in that instance.

So it's a little tough to manage because I can't think of a way to just say, "OK, it's all standardized." That's one of the problems we have in the industry as well.

There's a lot of processes that our customers are kind of digging into and kind of doing one way versus another way, and we have our opinions on what we think is the best way based on our own experience, and we'll share that more forcefully than we used to just because we feel like there has to be some commonality because we're just doing things so differently for each shipment that it can cause problems for us to execute.

Audience Member: Just a quick one on the data privacy aspect for the patient. So knowing that now you have more and more direct-to-patient cases with the rise of different trials, similarly with cell and gene therapy, how do you envision that complexity?

Michael: So the complexity that we, manage with direct-to-patient is definitely unique in that we have a blinding capability within our system. So if we know that it's going to a patient's home we can blind the consignee specifically on that trial, that project, every time. So we can see it internally. It's never going to be published in tracking websites. It's never going to be shared externally.

That's just a fundamental logic that we created, but there's been more and more questions around some of the chain of identity and chain of custody identifiers and whether that constitutes patient information or not.

We can blind that as well, but I think we have to have pretty clear directives, and we also have to really think about the informed consent process, particularly with trials because that's something that we're getting approval to go to that patient's address and know who that patient is.

We're not marketing anything with that information. Once that's transaction's

done, that's disposed of. That's not data that we're going to be keeping or using. So it's a really great question and something I've spent a ton of time on. I could talk for another hour about that subject alone.

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