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The Logistics of Cell & Gene Therapy – From Benchmarking to Standardization (Part 2)

Intro:
I'm Chris Riback. This is Logistics Live: Conversations & Insights on the Global Supply Chain.

Today, we present Part 2 of our conversation with Scott Ohanesian and Mike Sweeney on the logistics of Cell & Gene Therapy, or CGT. Scott is QuickSTAT's Senior VP of Commercial Operations. Mike is QuickSTAT's Global Head of Strategy for CGT and DTP. They join me now to discuss the Logistics of Cell & Gene Therapy – From Benchmarking to Standardization.

In Part 1 of our conversation, we outlined these complex, high stakes and labor-intensive supply chains – as well as some extraordinary case studies. In Part 2, we discuss the various challenges – what to look out for and the importance of being prepared. We also look forward and consider not only the sector's growth, but what that growth will mean for supply chain logistics.

To understand that future, however, I started by asking Mike Sweeney to provide the context of when gene therapy began – and, importantly, how we got from there to here?

Mike Sweeney:
Well, we've seen the development of both cell and gene therapy for decades now, and there's been very little true traction in terms of commercialization until the last several years. So it has been a longstanding, I think from years ago, I've constantly remembered samples that were containing RNA. We have been kind of on the periphery, helping some preclinical research happen for many, many years. But I think the interesting thing is that the developers have kind of cracked the code to some extent in recent years, and it's really been something to see. There have been successes prior to that. So there've been several therapies along the way that have come to commercialization, but not to the scale we're seeing now, not to the extent of therapeutic value in different areas that we're seeing now.

So, I mean, it has been quite a journey for the development community. I think that there is a lot more to come, obviously, but I think what we have to be prepared for is the impact this is going to have on our healthcare system, on our patients. How are we going to manage it? Because these are not coming inexpensively. This is very high cost manufacturing. We are part of that and, obviously, the research. In some cases, the research has gone on for decades. So I know there's a lot of debate about pricing and we certainly don't want to touch that, but we have to acknowledge it is a factor in how this is all going to be delivered to the patients that need these therapies.

Scott Ohanesian:
I think you raise a really good point, Mike, and I think that's something that QuickSTAT, as a partner, needs to take into consideration when we're dealing with our clients. So, every client's different, just like every therapy is different. So we need to take time to understand the client. What are they trying to achieve? What's their why? Why are they trying to do things the way they're doing, not just what and how, but why?

And that might sound strange to be like, "Why do you really need to know the why? You just have to make sure these things function and get them there." And the reason why I mentioned that is I can give you an example. With one client, they only have one therapy in their pipeline. It's a very small client. In their phase one study, they have 12 patients. They don't want to have any risk.

Chris Riback:
I imagine they'd hope to mitigate all risk.

Scott Ohanesian:
Now, in the world of logistics, if anybody tells you it's 100%, they're just not being truthful because there's always something that can happen. All you can do is mitigate risk as much as you can. So for that client with 12 patients, they made it really clear. It's an autologous therapy, and I want to do a hand carry for every one of these starter shipments coming in because there are 12 of them. I want to just mitigate any risk, even with using GPS and real-time tracking; I feel more comfortable going that way.

Whereas when I'm dealing with a client, even though their therapy might be hundreds of thousands of dollars a dose that's commercialized and they have thousands of patients, it's still a business. They still have to be profitable and they still have to be sustainable, right, so they can fund more research and reinvest in their pipeline.

For that organization, we need to come up with ways to reduce the cost of goods sold. How do we help them shorten the timeline of manufacturing so you can get the treatment to the patient quicker and so you have a better outcome? And how do you reduce the cost of that? And so what we really need to do is partner. And it takes investment on both sides because, in these supply chains, there could be four, five, six, seven, eight different legs of the supply chain.

And so you might be able to say, okay, I can leverage consolidation on this leg here, and that will reduce my carbon footprint. It will reduce the amount of miles I need to transport it. It will reduce my cost. These legs here; there's nothing I can do to reduce them. I actually need to spend a little bit extra on these to make sure they go seamlessly.

So all those different parts of the puzzle need to be fit together in the right way for the client based upon the why and what are they trying to achieve? And then what we can do is be a consultant to them and then help create the supply chain and then implement it.

Chris Riback:
You both are talking about industry growth. Can you give me some numbers around that or scale it? I mean, we've discussed a little bit the growth over the last, let's call it five, six years. But looking ahead forward over the next, let's say, five years, what are the expectations there? Mike, do you have a point of view on that?

Mike Sweeney:
There's one stat that I like that I read not that long ago with, again, we've got those six therapies that were developed in one quarter and they're coming from three different areas. With gene therapy alone, the FDA and the US alone are looking annually at 10 to 20 approvals just for gene therapies by 2025, so right around the corner.

So, if you think about again, the possibility of the growth, it's just exponential. And the numbers, every time I look at the numbers, I'm kind of amazed some of them are double from the next. It's just incredible when the projections are looking at 2030 or beyond.

Scott Ohanesian:
And I think just to add to that, I think, Mike, like you said, the numbers change all the time. I remember a couple of years ago we looked at it, the numbers, they just keep growing and growing and growing, so the forecasts are growing bigger. And what I just pulled up some numbers here from previous research, and they're saying that the market size in US dollars was 15.46 billion in 2022, with an expectation of a CAGR, so a compounded annual growth rate of a little under 20%, so around 18, 19% through 2032, which would mean that you're looking at a roughly over 82 billion market size.

If you think about it, if 72% of all oncology therapies have the potential to be personalized and 44% of all therapies, if that's the way we go as an industry, in the future, healthcare will be very much a personalized experience. And in some ways, why shouldn't it be? Your body and the makeup of your body is different than other people. If you can create a therapy that takes whatever your background is, the makeup of your body now, your weight, your age, all those things into account, how would you think that wouldn't give you a better outcome? And that's why personalized medicines are so exciting, is because the possibility of what they could do to give you more strategic treatment is just fantastic.

Chris Riback:
Scott, what you are saying, is exactly what I'm hearing as well in a totally different context from the researchers and scientists that are out trying to help and also are providing medical help to actual patients. They are translational medical professionals who are working both in the lab and in the clinics, which all of it makes me think then as well – all of the logistical challenges so that every key player in the value chain, from patient to medical professional to manufacturer, so that everyone can do their jobs to the greatest extent possible.

You seek to extract every detail and headache and working with them, of course, but really take that on. There has got to be a great deal of information and insight around the supply chain data flows, and I'd imagine that takes a great deal of synchronization, yes, but also integration.

Mike Sweeney:
Well, I know we need to do better is my first response to that because I think we're in a good place, but there's more and more coming, as we've discussed over the last several minutes, and we have to be prepared for the amount of information that we should be sharing. To your point though, Chris, I think it's really noteworthy to consider all the players in the supply chain down to that patient that is going to get that treatment. It starts with them and ends with them ultimately. And we all need to be tied closely together. There are what's called orchestration platforms out there today for cell and gene therapy specifically that manages all of that process and more. And I think what we found is there's probably too few. We definitely see because of that, and because of the ability for some to develop on their own, so therapy developers are creating their own systems. It does create strain on the researchers themselves that are at hospitals trying to log into all these different systems.

So if you think about it, if they're, let's say, a renowned oncology center, and they're working on various trials in the cell and gene therapy space, they're going to probably be working with several different developers and potentially several different systems and potentially several different logins for each of those systems. So it's very cumbersome to think about that. In the same breath, I would say that there's also a shortcoming of some of the demand that the developers or the therapy developers have really not been met by the orchestration platforms that are out there today.

So we do have a ways to go on that, but I am encouraged by where we are and how far we've come, particularly in the last five years or so. But there's a long way to go. And I think part of that is really talking about standardization and not making it unwieldly. If there's going to be 20, 30 different systems out there, they all have to be able to connect, and there's got to be an easier way for people to access each of them.

Scott Ohanesian:
Yes, I think you're spot on. I mean, as an industry, Mike, where we are today is not where we need to be, even just a few years from now. We're going to have to see better systems that can do more. And that's not trying to knock what exists. What exists today is far better than what existed just a few years ago. And so those orchestration platforms really are what's tying the manufacturing, the CRO, when you commercialize insurance payments, the distributor of your therapy, they have to be there. The thing from a QuickSTAT perspective that's nice is if you go back historically to 20-plus years ago when small molecules were the name of the game, logistics was usually the last ones invited to the table because regulations weren't as strict around temperature, and the type of therapies that you move weren't as hard to move logistically necessarily. It was more geography and paperwork.

However, that forced QuickSTAT to always have to be able to integrate with other systems because we were usually the last one to come to the table, which actually really benefits us now. After all, if you fast-forward to today, our systems have in our IT team, so we have our own in-house proprietary IT system and our own in-house team; they've created excellent API feeds, and I won't go too much into that, because you'll see how little of an expert and how much of a Luddite I am when it comes to technology. But the system's phenomenal because we can push the data into the other systems. Because our system, QuickSTAT's QuickOnline 2.0, it does a phenomenal job of getting real-time temperature and real-time location. It's tied into flight stats, so you're going to get automatic updates from the airline so you can see where your temperature is, you can see what temperature it's at, which is extremely important.

And what's even more important, not just to see it, is to have a network and a team like QuickSTAT that can go in and intercede when something arises, and that's really what you're paying us to do. But beyond that, we have to push that information to the orchestration platform because they're going to have additional information. Our system also might have patient ID numbers, things like that, but the orchestration platform will have manufacturing information. If it's commercial, it might have payment information. So that's what we have to go into. And to add on to what Mike's saying, it's for the sites, it's going to be extremely cumbersome. If you think about all those new therapies being developed, if sponsors are creating their own IT systems, you can't have these sites. There's only so many sites around the world that can treat these types of patients with these types of therapies. You can't have them having to log into ten different systems.

Also, if you think about a cell therapy, it's shipped in a liquid nitrogen shipper; you can't have 20 of those. They almost look like R2-D2 units. They're big 50 to 100-pound units. You can't have 20 of those inside a site. If you think about a hospital, they're not built to do that. So, you need standardization at the site level. You need standardization at the IT level. And those things will help us as an industry get better, be more efficient, and take some of that stress and burden off the sites.

Chris Riback:
Any other challenges that we should be keeping in mind? What else keeps you up at night, Scott? I mean, everything keeps both of you up at night. You look fantastic, but given what you do for a living, you can't sleep very much. Scott, what other challenges should I know about?

Scott Ohanesian:
So for me, I think as an industry, there's a lot of things I think that are keeping, if you talk to some of the CEOs, it's their manufacturing capacity, right, because they might be smaller. They can't necessarily compete when they outsource their manufacturing, so they bring it in-house.

From a QuickSTAT, what keeps me up at night, right, is really the engagement of our clients. And that might sound like a strange thing to say. Without understanding what the clients need, we can never develop a strong supply chain. An example I'll give you is you can have all the tools that are readily available, but if they're not implemented in the right way and communicated in the right way at the right time, you will not have a functional supply chain.

So what keeps me up at night is how are we engaging our clients and how are they engaging us? Because we truly need partnership within this space. And I think partnership is a word that's often said, but it's not always lived. And that can go on both sides. So, for me, what's keeping me up at night is how can regulators get together and standardize? How can sites standardize? But how can we, QuickSTAT, show our clients that we deserve the trust to become that partner for them and then create a relationship that allows us to succeed?

Chris Riback:
Mike, there's no doubt there is so much there. I mean, you've talked about the transport monitoring and the lane mapping and the chain of identity and the site selection and expertise. There are distinctions between the two, and there are some similarities in some of the capabilities and actions that you need to take around them. But what about, again, turning more specifically back to cell and gene therapy and that space, what about standardization opportunities? I mean, Scott was talking about it a moment ago around the requirements for standardization around technology. It doesn't help anybody if we have 150 different tech platforms out there, but tell me a bit more about the opportunities for standardization.

Mike Sweeney:
They're massive, and I think it's easy to lose that sight because every client that we serve and every project has different variables. So the way I look at this is: we need to be flexible, but we also have to have a standard way of doing things.

So if we deviate from that standard, then really, it should have true justification. And in some cases, it might come down to debating whether it's with our client, other partners. We definitely need to be part of the process to make sure that our processes are fit for purpose, but also that we're not getting into areas that stretches us to a point where it's not sensible or not scalable. And I think a lot of that, when I think about it, it comes down to the execution at the customer service and driver level. We're being asked to do a lot, manage a lot of information, and I know we've talked about this before, Chris, but when I think about how much we load onto the driver, somebody's taking all that information in and saying, "We have all of these different instructions that we've got to do on this pickup or this delivery."

Chris Riback:
Yes, they have a lot to manage.

Mike Sweeney:
And cell and gene therapy is very specific in that way. And in a lot of cases, we're just dealing with specific individuals, and sometimes those individuals are busy doing other things, and we need to wait or we need to dig to find them or reach them. So I think one of the things that I would say about standardization is that, again, going back to the visit that I had earlier in the week, I saw the standardization and the criticality of that from the manufacturing process. And I've learned over the years that I think the closer we can be to the development and the true GMP space, the better we are in looking at our processes and saying, "We need to do it the same way every time as much as possible." So, not that it becomes monotonous for anybody; we want to keep things interesting, but at the same time, we need to have processes that are repeatable and scalable.

And I think that there is plenty of opportunity there, but we're dealing with hospital institutions, medical institutions, I really should say, or medical systems that are fractured and struggling. We're dealing with airlines that have the same challenges and we spend a lot of time with both of those partners of ours. And I think the more we can learn and understand their challenges, the more we can step in to help and probably learn even more standardization that is available to us in a way to aid and kind of bridge some of the gaps that are out there in the supply chain right now.

Chris Riback:
Yes, there are some real key areas and opportunities and requirements around the standardization, the orchestration platforms, the shipping standards and temperature management, the logistics preparation and issue management. But you have to standardize flexibility as well.

Mike Sweeney:
It's flexibility within reason and within negotiation, right? I think that's the bottom line is that we can't just say we know it all and we have the best mousetrap. Things are changing. We have better technology coming in, whether it's temperature control tools that we have through packaging and monitoring.

But again, it's an exciting time to be part of it, but we can't be flatfooted. We have to be agile in the whole environment that we're working in today. It's exciting, it's challenging, and there's much more to come. But I think we have to look at this as, yes, we have to have standards. We have to give our people the tools they need to succeed and to help our customers, but ultimately, we have to be listening to what's going on and what's coming because it's not going to stay the same.

Chris Riback:
Well, you certainly present as imminently reasonable, so I can only assume that it's true as well. But you definitely present that way. Mike, to close out from you, please, could you tell me about any benchmarking opportunities, because that's got to be important. If you're talking about standardization, it has to be benchmarked against something. So could you talk to me about that? And then any parting words or parting ideas that you want to make sure any listeners keep top of mind?

Mike Sweeney:
Sure. So, on benchmarking, I think we have standards in the logistics arena or even the clinical trial logistics arena that have been there forever. It might be around temperature, what percentage of shipments or temperature control, and then within that, which temperatures are you handling percentage-wise? And I think there's a lot of merit to that in cell and gene therapy. As Scott alluded to earlier, there is the ability for some of those drawn specimens to be shipped fresh. Some of them might be cryo-preserved or frozen. So, there are a lot of different things going on depending on the therapy developer demands. However, I think we need to kind of understand what is working and what is not working so well. So again, on the temperature and really the place, the location. So when I think about monitoring, we're talking about the time, the temperature, and kind of monitoring that continuously.

Chris Riback:
Where in the supply chain are we seeing cracks?

Mike Sweeney:
I think one of the things we look at as an industry as a whole is the way we manage milestones. We know when something's supposed to be picked up. And cell and gene therapy, we can't be there too early. And I know we've talked about that before, but that is a measurable milestone that would not have come into our world prior to cell and gene therapy to be something that really you cannot show up at a hospital research site too early and kind of disrupt somebody's job when they're potentially patient-facing.

So it's something that we have to be very mindful of. And I do think that there is, again, evolving feedback that we're going to be having from our customers and our partners and others in the supply chain that will feed into what we need to look at in terms of standardization and best practices going forward.

But though we've come a long way and we recognize there are some differences with cell and gene therapy, certainly, there's going to be many more opportunities going forward. I think, as Scott alluded again earlier to the allogeneic, kind of the idealistic way of managing the scalability within cell and gene therapy to some degree, and kind of where that will take us, how will we be able to best look at that as a supply chain and maximize the benefits and standardization we could put around that. But I do think that there are a lot of factors today, we need to be honest about. Some of that is the instability of hospital systems, airlines, key areas within the process, and hopefully, over time, we'll get back to a better place.

Chris Riback:
Scott, quickly, before we let you go, any parting thoughts? Anything that you want us to keep top of mind?

Scott Ohanesian:
Absolutely. I think one of the things that I learned from a mentor within this space is you should always try to ask for a call to action at the end of any of these sorts of sessions because that is something that people, somebody hopefully will take and run and run with and have an impact.

To me, the call to action within our industry is within cell and gene therapy has to be around standardization to be able to take the burden off the sites and how, when we see this capacity ramping up, how can we educate our colleagues so that they can make an impact on the next cell, gene or personalized medicine therapy. Chris, thanks very much for having Mike and I on, really appreciate your time.

Chris Riback:
Scott, Mike, thank you both so much. Thank you for your time. Thank you for what you do, for what your manufacturers do, what your partners do for patients around the world every day.

Mike Sweeney:
Thank you, Chris.

Scott Ohanesian:
Thank you.

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Outro:
That was Part 2 of my conversation with Mike Sweeney and Scott Ohanesian on the Basics, Future, Benchmarking & Standardization of Cell & Gene Therapy and global supply chain logistics. For Part 1, please go to our podcast page at quickstat.com/podcasts. My thanks to Mike and Scott for joining and you for listening. For more information on clinical trial logistics, visit our website at quickstat.com.