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Setting up a robust CGT supply chain (Part 2)

Intro:
I'm Chris Riback. This is Logistics Live: Conversations & insights on the global supply chain. Today we continue our conversation with Mike Sweeney, Global Head of Strategy for Cell & Gene Therapies and Direct-to-Patient products at QuickSTAT Global Life Science Logistics, on how to set up a robust CGT supply chain.

In Part 1, Mike described the explosion of cell and gene therapies registered for clinical trials – plus the hope and supply chain logistics challenges that growth provides. In Part 2, Mike discusses the benefits of advanced planning, the role of technology, as well as cold chain and chain of custody. We began, however, with his analysis of the ongoing regulatory change globally. I asked Mike: How does QuickSTAT stay on top of it and what type of guidance do they give?

Mike Sweeney:
Well, we're working together with our customers because the science is still well ahead of the regulators in this case, particularly when I think about it in terms of clinical trials. We can't treat cell and gene therapy and the materials involved the same way we would treat other perishables, even materials that are used in clinical trials. We just don't have the time to take longer clearance holds. For instance, if you have materials that are coming into the U.S. and there are FDA holds or similar, and sometimes that's for good reason. We just need to be more accurate, make sure we get it right the first time in terms of the documentation and what the regulators are looking for. But I think generally, there are processes in place, and I could say this about most of the supply chain that could be adapted to cell and gene therapy from the standard clinical trial models, but it's just much more intensive, much less forgiving.

And it's something that we really need to look at every minute and every hour. How are we going to make sure that there are no holds? And if there are, what do we do to escalate that within the regulators? But the regulations themselves are going to evolve. We're starting to see more acknowledgement. And I think the regulators are in a learning phase like a lot of us are. What is actually going on? How do we need to help and facilitate? And that's certainly what they want to do, but it's not something that happens as quickly as the development is happening out there. That's for sure.

Chris Riback:
In listening to you, it feels to me like you wear two basic tool belts. Maybe it's one tool belt with two overweighted sides, one on each. One is the whole preparation side, the planning, the scheduling, the understanding where everyone needs to be at what time, as you just said a moment ago, really minute by minute. And then your other tool belt on the other side weighing you down is the reality that stuff happens, and you have to troubleshoot on the fly, and there are roadblocks. Tell me about that side of the tool belt. How do you prep either in advance or in real time to deal with roadblocks, whether those are experts, whether that's your experience in delivering end-to-end safe transport, digital platforms, the way you partner with the life science logistics experts? Take me through that side of the tool belt please.

Mike Sweeney:
Sure. I think it's a great question because there is an awful lot going on in terms of the technology that's supporting these developers. However, there is a pharma, I'll say, mindset that is really crippling us in some cases. So, just when I think about the fundamentals of what we're involved in, and if you asked a therapy developer, they'd probably have 10 or 20 other things they could talk to you about that they want to move quicker with. But temperature control, the packaging, as well as the monitoring. One thing I would say right from the beginning if there are materials that are of utmost importance and critical, we should always be looking to use GPS monitoring. That is a true account of where those materials are. Things happen out there in the transport world, and we need to make sure we're holding anybody involved, particularly the airlines, accountable.

And this is just another thing that helps them, and it helps us and it obviously helps the customer and the patients that we're serving. But there's also a lot of technology that has started to infiltrate the industry. So those caretakers I talked about earlier in the hospitals, accessing systems that some of the developers have created themselves, the therapy developers, and others are off the shelf. The challenge is you have these caretakers at hospitals that have to log into various systems and various projects or protocols to manage that. And it is a lot to ask. So, it needs to be as intuitive as possible.

On the QuickSTAT side, we've created a new version of our online portal, QuickOnline 2.0, which is definitely looking at some of these pieces from the pure logistics standpoint, GPS integration. So if that's something that's being used, that's something we can bake into what the customer sees on the tracking site. So that's very helpful. And obviously, real-time information that again, it's sort of our true up. When we want to know that things are going as we expect, that the driver is where we expect, that the shipment has been routed properly from the airline. So these are things that we definitely have in play, but I think there is not quite the standardization across the board that we'd like to see in terms of systems use, in terms of GPS. We would say from a best practice standpoint, always use GPS with cell and gene therapy, both the donor materials or the initial materials that are drawn from the patient and then the therapy itself. Certainly, those should be trackable in that manner.

Chris Riback:
What about cold chain and chain of custody, chain of identity? Talk me through those issues.

Mike Sweeney:
That's a really great piece because you certainly want to make sure that the individual treatments that are being delivered, and again, these are personalized therapy, we can't think or say that enough. We need to make sure that we do everything we can to help facilitate making 100% certainty that there is a match that's happening, that that therapy that's being developed for that patient is the one that they are getting. So it sounds simple in theory, but we do need to look at things like with chain of identity. The easiest way to describe that is a security seal outside of the box that basically has an identifier number or alphanumeric. And it's basically a way for us to help see this is the drug that needs to be delivered for this patient.

And there's a lot of that happening throughout the supply chain. But, we're also looking at some innovations there with QR codes where it could be much easier for somebody to kind of look at what's on the outside of the box and not have to crack open the security seal or anything like that but to basically be able to have that on a mobile device and make sure that match is done. So again, I think there's a huge way to go with technology. There's been some great starters on that front, but we're seeing there's a challenge for the treatment folks, the folks at the hospitals that are managing so many different systems. And I think eventually, not to say that everything should be in one basket, that's definitely not what I'd suggest, but a reasonable number, even a half dozen, would be better than what's going on right now.

Chris Riback:
It's funny to me listening to you. On the one hand, technology, GPS, QuickOnline 2.0, and changes that you're making on that digital platform. And then, at the same time, it comes down to numbers on a box and tracking, and it's like anything that's a real challenge when asked, "So what is it? What's the one key?" It sounds like the answer is the one key; it's everything. It's all a key.

Tell me, because I want to transition and be able to ask you as well about global legal documents and customs support. How do you work with those areas? Maybe you can talk as well about how do you think about that intersection of being the right logistics partner plus having the right technology? So first, maybe you could talk to me about global legal documents and customs support. And we've talked a little bit about the global regulatory capabilities, but tell me about that.

Mike Sweeney:
Well, there are certain documents that are required and helpful. Certainly a customs invoice is a starting point to make sure that customs understands exactly how the goods are being declared, everything from values and so on and so forth. So much of this is being done electronic now. We've really come a long way over the last ten years or so where a lot of the customs entries and other agencies that are involved in clearing this material in any country can get access to it in many cases outside of the documentation, the physical documentation. But you're right. I mean, we're still not quite where we need to be. And it's a challenge, too, because when there are system problems, they hamper everybody and there are outages on occasion, whether it's an airline system or it might be a customs system. And sometimes these outages are planned, sometimes they're not, but we're shipping around the clock, and it can be any time that these therapies are being extracted and shipped.

Now, I think the key for us is to make sure that we're just aiding as much as we can in the country knowledge, the specific knowledge that we have on requirements. And we do that routinely. Things are changing. Like I said before, the regulators are behind; they're catching up. Sometimes, we'll get requests from our customers asking, "Hey, we just heard there was new regulations in France or Germany. Can you double-check that for us?" And that's a great thing for us to hear, too, because we want to know if something's changed that we don't know about. And a lot of times there are probably misunderstandings more than anything on what's actually required, but there routinely are changes being implemented. So I think that's one area where we need to keep our eyes very closely on.

The other piece, just to go back real quickly to the temperature control, because I think I mentioned the challenges with the pace in which pharma is moving is sometimes hampered by their validation or qualification of new technologies. Whether it be a new packaging system, they may have qualified a system ten years ago that they've used routinely and it works very, very well, and that's great. But if there's newer technology that can help them with the packaging, maybe, for example, the packaging they use now is good for 96 hours. There are other packaging that's come on the market that might double, triple, quadruple or more than that timeline, give them more insurance. But, it can take up to two years in some cases for new packaging to be qualified and validated. And it's the same thing with the monitoring world. So temperature monitors, location and temperature. So any of those, there's definitely industry standards that have been in place for decades.

So it is important really to look at the pace in which we're qualifying. Certainly, I know there's a lot of movement in this area, but the reality is from a quality perspective and cost even, those are definitely big undertakings for companies to constantly be looking at the latest and greatest technology and moving with that at pace.

Chris Riback:
And even with that latest and greatest technology, you correct me if I'm wrong, but at some point, it likely could all come down to contingency plans and the mantra that we all have to follow "Expect the unexpected." In the biggest case, that was COVID, but that could be weather, that could be political unrest, that could be finding the best routes, plans B, C and D, air flight delays, which you mentioned previously. And what happens with the airlines? Is that the tattoo that you've got on your arm, "Expect the unexpected"?

Mike Sweeney:
Pretty much, yes, because we have to be always mindful of what's going on in the world. And there's obviously conflicts out there today that are hampering some areas of service. But the other thing is, too, a lot of times, the media's take on what's happening is not reflective in what we're seeing on the ground. So again, communicating with our resources to see what's possible. Last thing we want to do, obviously is to put anybody outside of a safety zone. But, we definitely have seen situations where we think, oh, that's probably not possible based on what the client is asking me and what I'm seeing on the news. But we do try to circulate that information internally and with customers routinely. But, it is important to expect the unexpected, have that list, that communication plan if there is a delay over an hour might require a secondary level of escalation.

So there's very specific plans that need to have both the contingency, the communication plan itself, who do we need to contact, and really looking at what escalation points do we need to really step up that level of what we do. And I think that it's really been a great thing to have as far as we've got two or three people we call if we've got a delay over X number of hours. We then determine if it's, we're going to drive it 10 hours, or we're going to charter a plane, or whatever the challenge is presented, we have options. We've considered them, and we've usually really talked about that with our customers. And the collaboration that we got through COVID is kind of a silver lining in some ways.

It's really helped us get closer and for a customer to come to us and say, "Hey, I'm considering going to Saudi Arabia," or some areas where maybe we would not have even had a chance to help them understand what the logistic timelines and hurdles would be. But now we're getting that communication and collaboration early on. So it does help us with the planning, but obviously, yes, the key is making sure we've got a backup plan.

Chris Riback:
And if I'm a biopharma company listening to this conversation, I mean, I feel like I'm thinking a number of things. One is I'm in a really challenging space. I'm in a hopeful space, an exciting space, but really challenging, more complex drug manufacturing. I got to be thinking about market access. I got to be thinking about quality control and process. But maybe the message that you would add to those very real challenges, I'm sure you wouldn't deny any of them, is you better also get your supply chain process solidified, and you might even want to do that first because planning and dealing with the potential roadblocks at the start, that pays off later. Is that a top takeaway?

Mike Sweeney:
Absolutely. Yes. I think what we have seen routinely is that the industry knows where it needs help, but do they have the resource even to manage that? And in the smaller companies that are startups that are evolving, it's tricky. But like you said, the biopharma companies that have maybe gone out and acquired a silent gene therapy developer and brought that in-house, there's a lot for them to learn, too. Because again, even though the model might look similar and a lot of the checkboxes are similar, the actual execution and what's required, and I think really the cost of failure, is so much higher. That's something that you just can't absorb in and say, "Yes, that supply chain could be adapted to what we have." To some extent, certainly, there are processes that would be the same. But, there are a lot of nuances and details, and I think just places of criticality and urgency that we hit on a daily basis within cell and gene therapy that it's just completely next level and for good reason.

And I always try to tell internally, our people, look, the customer is probably a little bit overbearing in some cases. Wouldn't you be too if you understood everything that's at stake from their perspective and their treatment and the possibilities that treatment brings? That brings an incredible amount of pressure. The other part of that, too is with the smaller startup companies or even the medium-sized companies that could be ripe to be acquired, that brings its own challenges and disruption. So I feel for the people in that space, but frankly, there's not enough of them. That's a big problem we have right now in terms of workforce gaps.

If you think about the intricacies we've talked about and then add the science piece to that, as well as the regulatory knowledge over the science as well as the operational manufacturing as well as logistic pieces, it's a huge undertaking and skillset that expands on what's available out there now. So I'm constantly looking to try to steer people towards this because I do think this is the future of science and it's the future of healthcare, frankly. We've lots of work to do to sort a lot of the costs and everything else out, but we have a very bright future in terms of the science.

Chris Riback:
It is the future of healthcare, and as you've pointed out, it is all about the patient from top to bottom. It's a patient-centric effort. It's about hope and maybe it helps just a little bit to have a logistics partner who can deliver. Mike, thank you. Thank you for your time for this great conversation. And given what you just said about this is the future of healthcare, which it is, given all that's happening in the cell and gene therapy space, I'm certain we're going to be tapping into your supply chain knowledge in the not-too-distant future. Mike, thanks for your time.

Mike Sweeney:
Thank you, Chris. I look forward to it. Great to talk to you.

Outro:
That was Part 2 of my two-part conversation with Mike Sweeney on setting up a robust CGT supply chain. My thanks to Mike for joining – and you for listening. For more information on supply chain logistics, go to QuickSTAT.com.