From Clinical Trials to Commercialization: The Pharma/Healthcare Global Supply Chain

“FROM CLINICAL TRIALS TO COMMERCIALIZATION: THE PHARMA/HEALTHCARE GLOBAL SUPPLY CHAIN”

Introduction

I'm Chris Riback. Welcome to a special episode of QuickConversations, featuring a guest speaker from our parent company Kuehne+Nagel. Our podcast explores the extraordinary world of global supply chain logistics: How it keeps business — and life — moving.

The Pharma & Healthcare global supply chain is an extensive and urgent one. As we’ve all seen from the COVID-19 vaccine response, the line from clinical trials to final delivery of medicines and drugs into the marketplace, connecting scientific labs, patients, manufacturing sites, distribution centers and ultimately, patients, requires careful planning, coordination, and execution. Any misstep in temperature controls, delivery times, aviation and ground transportation and more can cause delays and even lives.

Of course, this vital supply chain existed before COVID – and it exists today outside of COVID, delivering myriad life-saving gene and cell therapies and drugs.

So what is required to maintain this global lifeline? What planning and strategy are needed for it to endure? How should various players communicate and coordinate – and how can we be best prepared when unexpected events call for immediate shifts in plans?

Helping to answer all of these questions —and more— are Robert Coyle, Senior Vice President of Pharma & Healthcare Strategy at Kuehne+Nagel and Scott Ohanesian, Senior VP Commercial Operations, Clinical Trial Logistics at QuickSTAT. Together, Rob and Scott’s collective expertise covers the entire end-to-end planning and execution of the process. That’s because in addition to QuickSTAT’s 24/7 logistics and transportation solutions, Kuehne+Nagel covers more than 1,300 locations in over 100 countries, delivering Sea, Air, Road, and Contract Logistics – with a clear focus on integrated logistics solutions.

One Quick ask before we begin our first of two episodes on the topic, this one addressing “Clinical Trials to Commercialization: The Pharma & Healthcare Global Supply Chain.” First, if this podcast inspires a question you might have for Rob or Scott, please reach out to them! Go to quick.aero/podcasts/ and click on the “Ask The Podcasters” link. And if you’d like a transcript of the conversation, you also can download a copy on this page as well. Or visit Kuehne+Nagel’s website at kuehne-nagel.com and search for “podcasts”. .

Thank you. Here's Part One of my conversation with Rob Coyle and Scott Ohanesian.

Chris Riback: Rob, Scott, thanks for joining. I appreciate your time.

Scott Ohanesian: Thanks for having us, Chris.

Rob Coyle: Thanks, Chris.

Chris Riback: Scott, it's nice to get to chat with you again. It was about a year ago. I took the liberty of re-listening to our podcast, which was titled "Life Science Logistics in a Life-Changing World." I guess neither of us knew exactly how life-changing the last year would be. Scott, for those who haven't had the benefit of a conversation with you previously, give us, quickly, your background and your experience please.

Scott Ohanesian: Absolutely. What a year it's been. I'm a Senior Vice President of Commercial Operations at QuickSTAT. I've been within the specialist logistics industry for the pharmaceutical world for about 18 years now. I was based over in Asia for a while, then started my journey with QuickSTAT six years ago, and it's been exciting to be here.

Chris Riback: Yes. That's quite a range of experience, and I'm sure you draw from all of that in what you do every day. Rob, it's nice to get to talk with you. Your background and experience, please.

Rob Coyle: Thanks, Chris. I'm Senior Vice President of our Pharma Healthcare Vertical and I focus on our global strategy for Kuehne+Nagel. I've been with Kuehne+Nagel for three years. Prior to joining Kuehne+Nagel as an employee, I was a customer of Kuehne+Nagel for many years.

I was so pleased to find my passion early in my career because waking up knowing that we're making an impact to patients every day is something that's really something exciting over the last 23 years and I would say the last year, even more exciting because it's very clear what we're doing is helping society and helping people today.

Narration: Given their respective backgrounds, I asked Scott and Rob to take listeners through the life cycle of each of their businesses – how and where they connect – from research to commercialization. Scott began.

Scott Ohanesian: The product life cycle, there's definitely many variables that come into play. It depends on the type of product that you have, whether it's a small molecule or there's a large molecule now we're seeing the evolution of medicine towards personalized medicine.

It kind of changes how the supply chain will come about. It always starts in research and development. There's going to be scientists working on some sort of product to create a therapy and you'll have pre-clinical ... Sometimes there will be testing prior to going into humans.

Then you'll start going from pre-clinical into phase one trials to phase two trials if the therapy is showing efficacy and safety and then moving onto towards, hopefully, being tested in wider populations across more geographies with the hope of treating other patient populations.

From a product life cycle standpoint, QuickSTAT 's very much involved from early on in pre-clinical testing all the way up through commercialization. That could mean shipping API, which is the active pharmaceutical ingredient, to a manufacturer for it to be manufactured into actual therapy that will treat the patient. It'll be involved in clinical trials, meaning we'll send therapies out to clinical sites where patients are treated.

Now more than ever, we're seeing some of the shift, and COVID's been part of the catalyst behind that, we're seeing some of those therapies treating patients actually at their home where they live. QuickSTAT is that bridge connecting the supply chain, doing the transport, understanding the packaging that's needed if it's a temperature-controlled therapy, understanding the regulations needed to import these therapies around the world into different countries.

From a product life cycle standpoint, QuickSTAT is going to help with the preclinical samples where the scientists are working on a project together and once it gets into clinical development and therapies going out to patients where they're going to be treated and then the patient samples coming back to the labs to see if the therapy is doing what it's supposed to do, and then we'll move it into commercialization.

Chris Riback: Rob, obviously, Scott just mentioned the commercialization of it. Tell me about the commercialization side of what you do.

Rob Coyle: Most of our customers in pharma healthcare are working on early stage discovery, as Scott talked about. Coming up with innovative medicines to help cure diseases or address the COVID-19 vaccine. For years, Scott and I have played in this product life cycle space but it's not until just recently that the general population, the evening news is talking about the product life cycle for the COVID-19 vaccine.

This is the way we work and this is how pharma healthcare companies develop new products. It's amazing to see the numbers of how many early stage discovery medicines don't make it down into commercial, into my world within Kuehne+Nagel.

The timing of that process is very critical. You probably heard it early on with the pandemic where there was information coming out that this process usually takes three to four years and it's just been amazing to watch, especially on some of the MRNA drugs that have come out and

some of the traditional vaccine technologies to be released in six, eight, 10 months. This product life cycle becomes very important.

You heard Scott talk about early discovery, clinical trials, and getting that product ready for commercial as long as it's approved through the regulatory process, ready for commercial transition. That's where Kuehne+Nagel typically comes in.

If you think about the supply chain that we support in pharma healthcare, it's working with a lot of the major manufacturers that you know today, in early raw materials into their primary sites or their drug substance sites in the vaccine world. All the components, packaging, raw materials, active ingredients, inbound, outbound there to a secondary packaging facility or a drug product facility and those distribution channels that we're looking at here could be leveraging our air logistics capability, our sea logistics capability, our road logistics, storing within our warehouses that we have globally, and then moving from that secondary packaging into the market, whether it is going to a hospital or a pharmacy or into a market warehouse. We really cover all aspects of that supply chain globally.

Narration: With that understanding of the Pharma global supply chain, I asked Scott and Rob about any tips they might have for clients. Given the various components that go into maintaining well-built global supply chain logistics – timing, temperature, transportation, and more – what best practices or guidance they might give that clients ought to be thinking about.

Scott Ohanesian: I think the collective knowledge of our industry has increased significantly. Just over the past 12 months – I think necessity is the mother of invention. I think a lot of what we've had to do to overcome the challenges from the pandemic, and this is at the pre-clinical, the clinical level, and then onto the commercial level and I think across all aspects of supply chain within the life science phase, there's been a domino effect.

Everyone always hears the cliché statement, plan for the worst, hope for the best. I think what we've seen throughout this pandemic is we need to really invest time in that planning stage. It depends on the type of therapy that you're working within. I'll give you an example. With cell and gene therapies and personalized medicine, a lot of the therapies that we're working on in the clinical stages are dealing with very sick patients that are critically ill. You don't have the luxury of time. You can't wait weeks, you can't wait months.

When the pandemic hit, you saw flights getting grounded, you saw borders shutting, you had to ensure that there were already plans and that there were 5 ways to route the shipments to those patients because they didn't have the time to wait for them.

One of the nice things I would say is that we had a lot of engagement with patients when it comes to those types of therapies. You've already planned out secondary and tertiary routing. In some cases, a fourth or a fifth option. The nice thing is having those in place we actually were able a lot of the time, most of the time, to get therapies to those patients using those routing options.

The other nice thing to do is understand flexibility and the why behind what it is patients are doing. In some cases, I'll give you an example, we had an allogeneic therapy and we needed to get it into the US and it was being manufactured in Europe. It had always been transported via, literally, a hand carry. Someone was flying with the therapy because it only had a limited amount of time from its constitution to dosing of a patient.

When you had the US shut down flights from Europe, no one could actually come in on a hand carry. You had flights coming in with cargo but you couldn't actually have somebody physically carry it. What we did was we worked with a sponsor company, we tried to understand a forecast of what patients really needed treatments quickly. Understood that we had to be somewhat conscious of cost because there is a cost element to what you're doing as well, but at the same time, patients are the center of what we're doing. We need to get these sick patients medicine.

We're able to work with them, the five hospital sites at that time that needed to dose patients in the US, and we were able to come up with a charter solution to bring that therapy over. It was a cost-neutral idea, which is great so there was no additional cost, but it was a way to get the therapies from Europe to those sick patients in the US, mitigating risk of any chance of losing that therapy in transit and then you bring hope to those patients that are getting treated.

Narration: We asked Scott what advice he might have – for himself and other key supply chain players – to help generate creative solutions when emergencies strike.

Scott Ohanesian: I think a tip is really to engage early and engage often. Understand the why's behind what you're doing and if you're on the sponsor side, don't be afraid to innovate and change.

The reason why I mention that is when I see a lot of these supply chains getting designed, a lot of people try to pull on the past but the variables they have for their therapy, the geographies they want to go to, the temperatures they need to control, all of those things are going to be unique to that therapy. You need to take the best practices for what you did in the future and design the supply chain based upon the reality of what you're facing.

I think sometimes one of the best tips you can do is be open to innovation, be open to change, and understand the why of the supply chain that you're creating.

Chris Riback: Rob, what Scott is saying, does that resonate with you?

Rob Coyle: Absolutely. When you think about pharma healthcare organizations, the core elements, and you heard Scott talk about earlier, research and development, you have to have a healthy pipeline.

Then that tech transfer process from clinical into manufacturing, larger scale manufacturing, that manufacturing technology, especially for new innovative medicines is core to a pharma healthcare company.

Do you really want the pharma healthcare companies investing money in the next and greatest supply chain technology? Probably not. We want them investing in the next drug. What can I do to influence to build the best pharma healthcare supply chain to be able to service our pharma healthcare customers so they can invest in the next drug?

That's my biggest tip for logistics professionals. What that sort of feeds into is that you have to then leverage your partnerships effectively and pick the right partnerships and combine those partnerships together to get the best supply chain.

I can go through, Chris, and talk about some of the things we're doing in pharma healthcare around our temperature control capability, our laying risk assessments where we do that pre-planning to assess all the risks that could come in and we monitor on an active basis, on sea logistics and air logistics, when there's disruptions, the standard KPIs that we have, our business continuity planning that we have to be able to assess what risks to maybe start to predict. I wish I could have predicted the pandemic was coming. Obviously, not many of us got that one right.

Then I'm going to mention it, as CAPAs as well in pharma healthcare, we work in a regulated environment. Unfortunately, things do go wrong, weather, technical failures, but having the quick response on a CAPA, which is a Corrective Action Preventive Action, in our industry is critical.

Narration: We asked Rob whether that standardized approach proved useful when the push to make and deliver the COVID-19 vaccines took over the world.

Rob Coyle: Well, you don't just pop into doing vaccines. You have to have a capable network and you have to understand the industry and the regulatory environment. One thing we did ... I remember in August of last year, and we talked about temporary storage. We came up with the concept of our Kuehne+Nagel temperature pods. They are 20 foot reefer sized container, 7 portable, that can get down to -70 Celsius. Creates great agility in the supply chain.

I think the biggest tip that I have after 12 months working in the new world that we live in, is pharma healthcare, even though, we're in a regulated environment. We have iterated so much more in the last 12 months than my first 22 years in this industry and sharing ideas across a very diverse group of companies and people has reaped tremendous reward, right? Six month product on market, supply chains that can reach globally, vaccines, et cetera. We have come a long way. The tip I have is keep that iterative approach in our industry.

Chris Riback: Rob, Scott, thank you. Thank you for your insights and your time and thank you for the work that you and your colleagues do every day.

Rob Coyle: Thank you, Chris.

Scott Ohanesian: Pleasure to be here. Thanks very much.

Outro: That was Part One of my conversation with Rob Coyle and Scott Ohanesian. Part Two will cover communications, expectations, and hidden heroes. Have a question for Rob or Scott? Just ask! Go to quick.aero/podcasts and click on the “Ask The Podcasters” link. They look forward to your questions, so if you have one, please reach out to them today. That’s quick.aero/podcasts/ -- or visit Kuehne+Nagel’s website at kuehne-nagel.com and search for “podcasts”.