IndustryWeek®

LEADERSHIP > PROFILES IN LEADERSHIP

Cracking the mRNA Manufacturing Code with Pfizer's Supply Chain Chief

Scaling up production of the COVID vaccine from zero to 3 billion doses was Mike McDermott's personal "moonshot."

Laura Putre

So far, about 13 billion doses of the coronavirus vaccine have been injected into arms around the world. Making it happen has been a monumental project from many angles. Few know the manufacturing side of it better than Mike McDermott, chief global supply chain officer and executive vice president at Pfizer Inc.

Since the start of the pandemic, McDermott, has been leading Pfizer's efforts in scaling up and manufacturing the vaccine, as well as managing the supply chain activities around it. Just a few of his team's responsibilities have included:

- Working with Pfizer partner BioNTech to ramp up production of lipids (the fat particles that are the key ingredient for the vaccine's safe and efficient delivery in the body).
- Finding the square footage to take the mRNA vaccine from research lab to large-scale production. This has involved repurposing existing space, and building new modular facilities in Texas and transporting them to manufacturing sites for assembly. The first such facility, added to Pfizer's existing site in Kalamazoo, Michigan, was 13,000 square feet.
- Optimizing equipment and processes to produce vaccine in less time and in smaller spaces—but with more precision—than traditional batch manufacturing.

- Figuring out how to keep the vaccine temperature consistent journey across continents and oceans—and sometimes into remote areas that lack freezer capability.

McDermott likens the shift from traditional vaccine manufacturing to mRNA technology to the automotive industry shift from manufacturing gas-powered cars and trucks to electric vehicles. The technology to produce the mRNA vaccine commercially was new, "but we were able to leverage our core capabilities of making high-quality medicine and vaccines, and then apply it in a different way," he says. Unlike with EVs, however, the shift to mRNA vaccines had to happen in a matter of months, not over years or decades. Within a year, Pfizer had surpassed its goal of 2 billion COVID-19 vaccine doses, hitting the 3 billion mark.

McDermott, a 30-year pharmaceutical supply chain veteran, talked to IndustryWeek about the challenges and thrills of working with a superlative team on what he has called his "moonshot."

IndustryWeek: How much did you have to scale up the vaccine initially?

McDermott: Probably best way to describe scale, Pfizer was pre-pandemic a large supplier of vaccines, and on a typical year our entire network globally would produce 200 million doses of all our vaccines combined. So we actually initially set a goal in 2020 when we started our work with BioNtech around the notion of not just developing a safe and effective vaccine but actually one of scale.

We thought, "Well, let's make as much as we have for a rollout of our other products"—so 200 million doses. And once we saw the results, of course, we knew that that was not nearly going to be enough. So ultimately, we expected to produce and distribute in the first year 2 billion doses of vaccine. We actually ended up producing 3 billion doses of vaccine scaleup in one year.

And yes, you would say, "Well, how in the world would you do that?" You had lipid suppliers that had not had any commercially produced and available mRNA products on the market, so they didn't have that capability of lipids. You didn't have the capability for the machines that actually make the lipid nanoparticle. So, in this case, we worked

incredibly closely with lipid suppliers that were very small at the time, and we helped them scale them up, as well as inventing and designing the equipment that needed to be built to bring into our factories to make it.

The areas that were probably fundamental for us were lipid supply, the equipment to make the mRNA and the cold chain. But then of course, all the other suppliers—whether it was glass or vials or syringes—to go from 200 million to 3 billion was quite an experience.

Can you talk about how, in a short amount of time you were able to get production up and running? And what went into designing new systems and facilities? You had whole rooms that you were transporting and designing new equipment. Did you have people on your team that knew how to do that?.

Pfizer has a 170-year history of developing and manufacturing products. So while we were not specifically an mRNA company, our manufacturing capability was very good and very strong and had the ability to serve patients. So using our network of internal sites, I think was critical. I have 35 manufacturing locations around the world, and we repurposed 10 of those almost overnight to produce the vaccines. A typical vaccine development process is 10 years; eight years if you're really good at it. We did this in nine months. So very fast, with one of the largest clinical trials that I've ever run, so it was very safe and effective.

We worked with really talented suppliers that had done projects for us in the past that may not have been exactly mRNA but were close enough that we were able to use their capacity to build the equipment, build the cold-chain capability, build the lipids and rapidly innovate.

One more thing on speed: it was one of those moments where everybody was in agreement. All the suppliers were desperate to focus on this—if not for themselves, then for their families. The governments around the world and the U.S. government were very aligned with us. Our company put $2 billion at risk to make this happen. It wasn’t just collaboration, but this public health need and crisis. Everybody working on the same goal, I

think, is ultimately how you can take a process that could take 10 years and do it in nine months.

How did you innovate around designing and repurposing equipment and facilities?

I have 30,000 colleagues around the world and they brought forward their best ideas and their experience. We took away all the bureaucracy. So there were not big hierarchies in the program. Our CEO was literally managing the project personally. We had team members that were only focused on this. Decision-making was literally, “Go. Just do it.”

One of the other things about innovation is that you also need some constraints. You need a timeline. If you give a team five years to work on something, they’ll work for five years on something, and you may or may not have a great outcome. By time-bounding this, it forced us to innovate in the space of “there's patients that need this.” So things like the size of the vial that we used or the types of shipping containers that were used or the number of files and a pack—all of those were designed for speed. It was a different view of how to approach things rather than just designing the ultimate product. It was fit for purpose. That was a key piece.

The team at Pfizer's Kalamazoo manufacturing site prepares for the release of the first shipments of the vaccine in December 2020.

We use a 2ml vial, which is six doses. "Why'd you pick six doses? Why didn't you pick one dose?" Well, you can imagine, if we pick one dose we need a lot more glass, right? So that was a factor. "Why didn't you do 10-dose?" Well, that would mean a bigger vial, and our lines were not qualified for that bigger vial. We literally picked the vial that was the fastest and was qualified in five different locations within Pfizer. So that was an example of, "If you're gonna use speed, then use your scale. So you don't have to re-qualify the lines."

Use the capability you have and focus your development efforts on the really tough places like lipid nanoparticle or cold chain and don't focus your time on repurposing a packaging line.

Were there shortages of materials? Or issues that popped up that you had to solve immediately before you could move forward?

The short answer is, "All of it popped up." Certainly, you know, freight became a challenge. Ports for stock. Shipping lanes were congested. To move your product around the world was a challenge. Access to important things like glass, cardboard. The packaging was in short supply.

You also had some governments that were restricting movement of goods in and out of their countries. That became a challenge. But I think that ultimately, the way we got through all of this was, one, by having large scale. We buy a lot of glass. It wasn't the first time we bought glass. It wasn't the first time we'd moved goods around the world. It wasn't the first time we needed chips for our shipping systems to be able to track. And then directly appealing to ... industry responded incredibly well. I would call up CEOs of chip manufacturers or glass manufacturers. They were incredibly responsive, to be able to have an impact.

Did you repurpose most of your existing equipment for vaccine production? Or build equipment from scratch?

Before we even launched manufacturing and invested $600 million in equipment and materials, we were repurposing a lot of existing equipment. Taking a warehouse that has finished products and then making it into a freezer farm. There wasn't enough time to build a new building for a freezer farm, so you move some stuff out and other stuff in. There was a lot of repurposing going on. And that helped us with speed. What's nice now is those facilities that we repurposed and built continue to help our pipeline products. We have pipeline products in the mRNA space, but also in the non-mRNA space. So all this capacity we built for the vaccine, as well as for the therapeutic for the protease inhibitor, we're able to use that capacity and our supplier partners for our really strong research pipelines. So it's actually a great time for us to be able to see this innovation, this asset, being used for the future.

What were the challenges with the vaccine cold chain?

The cold chain was an interesting notion as we were developing the vaccine. mRNA is produced by your body, consumed by your body, but it's also very fragile. So the deep freeze is actually to keep the mRNA from dispersing before we give it to a patient. In the manufacturing process and during shipping we want to keep that MRNA really stable, so we put it at minus 80 degrees (Celsius). That definitely presented a challenge. How do you store at scale, right? How do you store 3 billion doses? And while there's large commercial minus-20 freezers for say, produce, there isn't a minus 80. You wouldn't let a person go in a minus 80. These are small-scale laboratory freezers. So we scaled that up.

But just as importantly, you can store it at minus 80, but how do you ship it? And so we had our own packaging engineers and scientists working with the industry. And ultimately, we designed a box with dry ice that could stay at minus 80 for 10 days—and our target of 10 days was "We want to get to the most remote part of the world."

You're producing the vaccine in Kalamazoo, Michigan. How do you get that to Guam? If you calculate the time for loading, putting it on a plane, transferring it to another plane—you could get up to seven, eight days. We were successful in building a container that would hold the product for 10 days at minus 80. We also realized at some locations like remote parts of the world, once you get it, maybe you don't have much [freezer] capability. But we did find that virtually everywhere in the world has access to dry ice, particularly around airports. So we were able to design a system that you replenish with dry ice every five days. You can go 30 days and actually use a storage unit. So the box became a mini-freezer that didn't need to be plugged in. It just needed replenishment and dry ice on a regular basis.

And of course, we wanted to make sure of the integrity of the vaccine, so we put a tracker inside every single box. Every box we've ever distributed around the world has a GPS tracker with a temperature sensor inside and it's communicating constantly with our hosts. And what's beautiful about that is we're able to monitor the shipment, make sure it's fine all the way, but in a rare case it isn't—our shipping accuracy was over 99.5—we're actually able to intercept the shipment before even it gets to a customer and replace it and have it ready for vaccinations. So technology was really a key driver in this as well.

Source URL: https://www.industryweek.com/profiles-in-leadership/article/21259181/cracking-the-

And then last thing I'd say is that we then went further and said "Well, what about literally the last mile?" In some cases getting to a remote village with this box was difficult. So we worked with one of the largest drone companies and we're actually now doing long-range drone deliveries to remote parts of the world. In particular we started a collaboration in Ghana, where we're shipping frozen vaccines via drone into the remote villages.

This ability for us to scale was also a kind of revolution: We can serve millions of patients around the world. Ultimately, we ship the product to 180 countries. We saw that we can even get to the most remote villages. And honestly, that gave us gave us the energy and the vision to our announcement last year which was called an Accord for a Healthier World, where our goal is that we're going to provide at cost all of our high-quality medicines and vaccines to 45 lower-income countries serving 1.2 billion people.

So this notion of "Look, we did this during the pandemic, why can't we continue that?" has really come alive for us. I'd say the pandemic has been hard in many ways but incredibly motivating. Groundbreaking in a way, that we can take this experience and use it to do even more good around the world.