West Pharmaceutical Services Inc. - Vice President Quality Biologics and Steriles at Merck & Company, Inc

Interview conducted on January 22, 2024

Topics

Stoppers, Pharmaceutical Packaging, Pricing Trends, Contract Negotiations, Supply Chain Resilience, ESG Considerations, COVID-19 Impact, Geopolitical Events

Summary

The Tegus Client speaks with a Vice President at Merck & Company, Inc. about elastomer components in prefilled syringes and changing suppliers. The expert explains that stoppers are typically not changed once a suitable one is found, as it requires stability studies and generating three years' worth of data. They discuss the qualification of multiple suppliers, sterilization processes, and product offerings and price points from West Pharmaceutical Services, Inc. The cost of stoppers ranges from a few cents to just below $1. The conversation also touches on the impact of GLP-one products on West and the smaller production volumes compared to COVID vaccines. The expert concludes that GLP-1s do not pose a supply reliability concern.

Expert Details

Vice President Quality Biologics and Steriles at Merck & Company, Inc. The expert is the key and final decision maker for the selection of suppliers and has used seals and plungers from WEST. The expert has more than 25 years experience in this space and can also discuss recent development in terms of global plunger and seal capacities, price evolutions for these products etc. Expert’s company does not make up 5% or more of the West Pharmaceutical Services, Inc.'s annual revenue.

Vice President Quality Biologics and Steriles at Merck & Company, Inc. (MRK). The expert has more than 25 years of experience in the Pharmaceutical Industry at Companies like GlaxoSmithKline, Novartis, and Merck in a variety of Senior Management roles: VP Quality, VP Manufacturing, Director Engineering, Director R&D, and Site Head. They also have extensive expertise with Contract Manufacturing Organizations, as Global Quality Head of Lonza and overseeing CMOs and CDMOs at Novartis and Merck. Merck & Co., Inc. is an American multinational pharmaceutical company. The expert is responsible for all Quality Control and Quality Assurance aspects for development and commercial manufacturing activities for our Biologics and Vaccines, at our internal sites as well as at our contract manufacturers as well as being the key and final decision maker for the selection of suppliers and CDMOs.

Prior to Merck & Company, the expert was Vice President, Global Head of Quality at Lonza Group AG (LONN), leaving in August 2016. The expert was tasked with the development and manufacturing of a variety of pharmaceutical products, peptides, biologics, cell, and gene therapy products, and vaccines.

The expert can speak to interactions inspections by the US-FDA, successful execution of FDA readiness programs and remediations of Quality and Compliance issues at a number of sites in North America, Europe, and Asia, the negotiation of drug shortage situations with Health Authorities from the US, Europe, and Asia as well as the manufacturing of several billion doses of pharmaceutical products.

Q: Are you able to speak to the competitive landscape for seals and plungers used in GLP-1 injectors?
A: I have been working in the pharmaceutical and biopharmaceutical industry for more than 25 years, in Senior Management positions at GSK, Novartis, Lonza and Merck (as VP Manufacturing and/or VP Quality). Since 25 years i have been responsible for manufacturing and development of a variety of peptides, biologics, cell and gene therapy products, vaccines, and therapeutics. I have been responsible for the manufacturing of hundreds of millions of doses of biotherapeutics and billions of doses of vaccines.

Q: Are you able to speak to specific West Pharmaceutical products are used in GLP-1 injectors?
A: More than 98% of these were sterile injectables in vials, syringes or cartridges/injectors. For more than 50% of those, I have used seals and plungers from WEST. I also have experience with the key competitors of WEST, like Aptar and Datwyler.

Q: Are you familiar with the pricing and incremental contribution margin of seals and plungers used in GLP-1 injectors?
A: I am the key and final decision maker for the selection of these suppliers. I have also developed and established the selection criteria. Among these are criteria like quality, technical capabilities, capacities, reliability, supply chain security, reputation, customer service level, innovation potential, breadth of services ("one-stop-shop"), geographical spread, ecological footprint, and finally also pricing. I can also discuss recent development in terms of global plunger and seal capacities, price evolutions for these products etc.

Q: Are you, or have you been, involved in any West Pharmaceutical Services clinical trial that is currently ongoing, or has ended but has not yet been FDA approved?
A: I am not and have never been involved in any West Pharmaceutical Services clinical trial that is currently ongoing, or has ended but has not yet been FDA approved

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Tegus Client
Thank you for taking the time to speak with us today about West Pharmaceutical Services, Inc. We could just start with a minute or two on your background.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Sure. I'm a microbiologist by training. I've been working in the biopharmaceutical and vaccine industry for over 25 years. And I was working at GSK, Novartis Lonza, now Merck. And I have always been in key decision-maker positions as either a Vice President in manufacturing or Vice President in quality. Throughout my career, I produced hundreds of millions of doses of therapeutics and billions of doses of vaccines.

Tegus Client
Great. The purpose of the call is going to be to talk about the elastomer components in prefilled syringes and other pharmaceutical packaging like that. Maybe you could just walk me through when in the drug development process, that starts to become a consideration, and how tied to one manufacturer are you once you've made a decision to go with them?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. I have been responsible for procurement decisions for elastomers for over 20 years. Key suppliers I have been using and I'm still using are West, Datwyler and Aptar. We are not using too many others. And look, we basically decide very early on what to use in preclinical stages or Phase I clinical stages. And then if we have a good stopper that works with our product, we typically don't change that anymore unless we have to yes. So we are really locked into that very early on.

Tegus Client
And if you were to change, would you have to refile the drug master file or do any kind of a regulator work?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
No, it's even more complicated. If we change the stopper for a biological drug or for a vaccine, which is in touch with the stopper within the product, so to say. We typically have to do a stability study that shows that the product is stable in combination with that stopper for the shelf life that's intended. Two years, three years, we have to do a stability study. That includes product stability, but also contain closure integrity, sterility and so on.

And we have to generate three years' worth of stability data. And with those three years of stability data, we can then contact the health authorities and say, look, guys, we have your data, we want to change the stopper. It's three years of work before we can even think about filing a variation with the health authorities. It's a very lengthy process. And we would only do it if we are really like forced to do it.

Tegus Client
And do you generally then qualify two providers to start in case there are supply issues? Or is it sole-sourced?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
It depends a little bit on the product and on where we make it and for which markets and so on, if it's really something where we say this is going to be a blockbuster drug. We may well qualify two different suppliers. If it's not such a big product, we will go with one supplier and one stopper.

Tegus Client
And would you've worked with some large companies, would they ever think about trying to do it internally, making that component of the drug delivery device or it's just an outside of their area of expertise?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
No, these are companies who make rubber stoppers. Their technology is closer to the technology of companies making tires for cars than to pharmaceutical companies. We would not really consider making that in-house, it is very different from what we do.

That's something where we really don't have the expertise, and we just buy from the big suppliers. There is part of the supply chain, which we used to do in-house and now we actually front-load it more into the supply chain.

The way it happens at, let's say, West. They make a stopper. They manufacture the store itself by rubber stopper, heating rubber heating and the extrusion of the stoppers and so on and so on. And they have made the stoppers according to the correct dimensions. Then before we can use it when we buy the stoppers at bulk material, we have to wash it and we have to sterilize it.

Tegus Client
Is that an EO or gamma? How do you sterilize it?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Typically, when we do this in-house, we do steam sterilization. We autoclave the stoppers. We can now, thanks to West and others, they actually offer the stoppers washed and pre-washed and presterilized, they these are the so-called ready-to-use stoppers. The alternative is we buy them washed and we sterilize ourselves. These are the RTS, the ready to sterilize stoppers. But more and more companies are front-loading, really asking West and the others to sterilize the stoppers for us.

Tegus Client
Got it. Maybe now we can focus on West in particular, like just their product offering and just maybe what are some of the price points around those different product offerings and how you think about what's appropriate for a different product?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, we are buying all kinds of stoppers from West. We buy the very simple Westar. We also buy NovaPure, it really depends on the product that we sell. For example, I'm working at Merck and we make KEYTRUDA, so KEYTRUDA is a cancer drug that costs $2,500 a dose. And you wouldn't want to risk having quality issues or stability issues because you put a cheap stopper into the vial. So that's really not an option. We are willing to pay the extra price for the stoppers.

But if you have, let's say, a lyophilized vaccine, so the vaccine is not really in touch with the stopper, we can use the simple Westar because it's as good as the NovaPure for that application. It really depends on the product characteristics. If we can use a simple stopper, we will. If we have an interference between the stop raw material and our product, many stoppers and biological products, they interact with each other, and we don't want that.

Then we have to use a coated stopper, what we call coat stopper, and we take, for example, NovaPure or the equivalent brand from the other guys. So if we have to, we have to, yes, full stop.

And then if you really have a high-profile drug, then you will also use automatically the NovaPure or something similar because if you are filling a cell and gene therapy into a vial, and the single dose cost $2 million, you're not going to save a few cents on the stopper. You will buy the best vial and the best stopper that's out there.

Tegus Client
Got it. Do you think is it possible just to like ballpark, walk through. We started at the lower end at Westar, RS and then go all the way up to NovaPure, just like what the representative cost of the stopper would be for each of those?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
For West. And I would tell you what Merck is willing to pay. The Westar is really in the bigger scheme of things, it's a few cents. For us if we have our drug sell at $2,000 a dose, then cost of goods is maybe 5%, and the stopper contribution to the cost of goods is really a tiny fraction. The most expensive stoppers we are buying are just below $1 per stopper.

Tegus Client
Is that exactly NovaPure?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Exactly. That's really the range that we're talking.

Tegus Client
And then a FluroTec, is that in between the two?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, that's in between.

Tegus Client
It's not like $0.05 to $1 and you got to scale from Westar to Westar Flex, FluroTec to NovaPure?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes.

Tegus Client
One of the things I was trying to get smarter on was, in particular, the how West is impacted by the GLP-one, in particular, the Lilly products just because those are obviously single use versus the NovoPen.

I assume this is 4x the packaging components of an equivalent Novo amount. I'm curious, do you have any idea as to what products would be used there? And if you have such a potentially large order, what volume discounts someone like Lilly could get on the drug of that size?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
I've produced billions of dollars of vaccines throughout my career. And in the last three COVID years, I helped

lots of people get COVID vaccines out of the world. And the COVID vaccines occupy 20% of our fill and finish capacity worldwide.

Tegus Client
At Merck? What you're saying like add in the overall.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Overall pharmaceutical industry. We have used all these COVID vaccines, the in vials, yes, they were made in those vials. But in 2021, the world has delivered 11 billion doses of COVID vaccines, the vaccine world. So 1.2 billion roughly right there. And the stopper suppliers were able to cope with that fairly easy.

The GLP-1s where they are right now, the volumes that Eli Lilly and Novo Nordisk are producing and selling, and I'm deeply aware, not involved but aware there. That is making us laugh in comparison to the COVID vaccines. It's not really making us nervous in terms of supply reliability of vaccines.

And the others, it's at the moment, a tiny fraction of their capacities. You've probably seen the Goldman Sachs report that the weight reduction drug, the obesity drugs will hit $100 billion by 2030. Companies get their supply chain straightened, then we are maybe close to the volumes that were needed for the COVID vaccines, maybe close to it. And then.

Tegus Client
Is the right way to think about the COVID because that was in a vial, like if you said 1.2 billion stoppers that would be like you multiply that by five or six to get to the number of doses of the vaccine if that was.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. It was 10 dose vials or five dose vials, the most common presentation was 10 dose vials. So 11 billion doses of COVID vaccines delivered in 2021, probably used around 1.5 billion stoppers. And the stopper suppliers were easily able to cope with that. The glass suppliers for the vials, they were struggling a bit more. But the stopper suppliers were still not in the dire really deep problems of supply that all the other suppliers to the pharmaceutical industry we're in.

That tells me that West and Aptar, Datwyler still had enough capacity, and we know that they have a lot of capacity. I get the question very often, am I afraid that I might have to compete with Eli Lilly and Novo Nordisk for the stopper capacities.

I go like, well, that one doesn't really make me nervous. When it's about may be more nervous or filters the other things, but stoppers, I'm still quite relaxed about that. I don't think that we will have a stopper supply shortage in the near future.

Tegus Client
Got it. Do you have a guess as to what Lilly is using or if we use the West product portfolio as a benchmark, are they using NovaPure? Or are they using something cheaper than that?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
The peptide that both companies are producing, I'm producing peptides as well. I have a lot of experience with peptides, by the way, I was at Lonza, which is a contract manufacturer, and the site that they.

Tegus Client
Lonza wasn't peptide business right?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, they sold it to PolyPeptide. And the site that Lonza sold to PolyPeptide is the site that is making Mounjaro or the tirzepatide. I know quite a bit about peptide manufacturing and the interactions of peptide stoppers and so on.

I haven't bought a Mounjaro pen and looked at it. But look, I would probably put a higher quality stopper in there because I know that peptides can interact with the stoppers. I wouldn't use this very simple Westar plungers, yes. I wouldn't use the very simple Westar. I would use a coated stopper potentially the NovaPure. And.

Tegus Client
See you'd be like a FluroTec or.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
FluroTec or NovaPure. And look, Wegovy is a multi-dose product, so it needs to really stay stable inside the primary packaging after we open it for a couple days. So then you want to really make sure that in particular, the container closure integrity is kept. So you use a better stopper there as well.

Tegus Client
Got it. It sounds like your guess would be probably Novo would be using NovaPure because and then Lilly might be using that or they might be using FluroTec.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
They might be using FluroTec, they might be using NovaPure, depends on what their stability studies have told them about the stopper interaction with the product.

Tegus Client
And if I get one, can I take it apart and figure out which one it is? Or is that because I'm not trained on that now? Or is it in the drug master file somewhere?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
It is in the part of the regulatory dossier that it's not so easy to get. You might be able to find that in the European Medicines Agency assessments of these products. There's a document called EPAR that's European Public Assessment Report, EPAR, and you'll find a lot of information. You'll find that on the website of the European Medicines Agency and then you should type EPAR and Wegovy or EPAR and Mounjaro, you might find that information.

There is the EPAR. It's available on the website. I haven't looked at whether the information on the stoppers is in there, but you can have a look there. You'll find quite a bit of information I'm not sure it will have the information about the specific stoppers they're using.

Tegus Client
Yes. And this is the one you would expect that to be dual sourced, obviously, to get such a large drug?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
They were caught by surprise because they were single sourced with Catalent. It might be single sourced also on the stopper. I think they were a little bit surprised by the success of the product. They didn't expect that. I'm afraid there might be single sourced on that one. Most companies would use West as the primary stopper supplier. And then Aptar or Datwyler as the second.

Tegus Client
West has on 70% or 80% market share in stopper market?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes.

Tegus Client
Got it. During COVID, you thought overall West was able to do a good job of not just satisfying the vaccine

order demand, but just the normal demand that they would have for their products?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, it was much more stable than many other things. But many other suppliers.

Tegus Client
One of the things they called out in the recent earnings, they talked about like a destocking effect that they were seeing in their customers is definitely. I think some of the investment community were surprised.

I'm just curious for your reaction to that. Does that make sense? Since this wasn't a product that's ever really in short supply and like some of the consumables used in the manufacturing process. Like why would there have been a destocking that needed to happen?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. I hear this destocking story from many suppliers, you can look at Sartorius and Danaher, they.

Tegus Client
But then it's a question of backordered. It will kind of make sense to people like?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
So now the first point is, look, as I told you, COVID vaccines occupied 20% of the world fill and finish capacity. The COVID vaccines went away, they disappeared. And so no supplier who was making a lot of money with supplying the COVID vaccine manufacturers should have been surprised by that demand disappearing. So a big part of the story is actually the COVID vaccines because on stoppers, I'll walk you through the rationale why the destocking doesn't make that much sense for the stoppers. Stoppers are cheap in comparison to many others. I can buy them. I can store them, they're stable for quite a while. I don't have to worry so much. They are stable for a couple of years.

Tegus Client
If you get the sterilized ones, do they also?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Two years. That's the first thing. I don't have my procurement guys knocking on my door every day saying like, “you know the cell culture media, we need to use it up for 100 million on the net working capital, and it expires next month”. I have more time.

Secondly, the decline in demand, one big chunk of that was actually COVID vaccines, then there was a little bit of increase in safety stock because many pharmaceutical companies increased safety stock across the board because they said, whatever it is, we just increased the safety stock. And now since mid-2023, many pharmaceutical companies are starting to destock.

Dramatic on bags and filters and stuff like that than stoppers. What I hear from my colleagues. I'm in touch with many colleagues in the industry, and we are sharing the information because we also want to make sure that we're not doing as an industry stupid stuff to our suppliers, we're trying to help them as well. And I hear people much louder on destocking for many other items, but stoppers is not really the big topic because they're also not so expensive.

Yes. I mean the sterilized ones are more expensive, yes, agreed. But they don't occupy that much space either. They occupy a bit of space in the warehouses because that was a problem with some companies. We had too many vials or syringes, and they were blocking warehouses a lot. And so we couldn't store anything anymore because everything was full of syringes, balanced with syringes. But a little bit of destocking is going on in the space in general.

I think it should be over by end of the first quarter, maybe end of the second quarter 2024, then we should really be done. Also mathematically, when we increase the safety stock, normal safety stocks are three to six

months. Most of my colleagues in the space and ourselves, we increase safety stock to 12 to 18 months. And now we are going back to six months. We started that summer last year. So by mathematically, it should maximally take 12 months to get over on the destocking.

But not everybody started at the same moment. Some companies started earlier, other companies started later. So we are, for example, making KEYTRUDA, which is a life-saving cancer drug. So we are very careful with the destocking across the board. So we are much more cautious, and we will not go back to a safety stock of six months. We will land much higher. And we didn't start as aggressively as other companies which are more focused on reducing net working capital and so on.

So it's not such a big topic for us. So you might maybe see our order pattern still being influenced a little bit by some destocking less than in other companies, but longer than in other companies. Whereas other companies were more aggressive, it's bigger, but they will be over with it faster. So.

Tegus Client
And the only reason this ended up applying to the stoppers was because it's just this blanket order to increase safety stock because there were never any supply challenges with them, but everyone just essentially double or triple the amount of stoppers?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
We were all worried about everything. And I was less worried about stopper supply than about glass. And look, for example, stoppers weren't as much affected as glass last year, in 2022 when Russia attacked Ukraine, and Europe suddenly we run out of gas because SCHOTT, Gerresheimer and others.

So the stoppers are also high-energy consumption production of stoppers, but it's not as dependent on Russian gas. West, for example, has manufacturing in Germany as well. So that was a consideration. I was also in touch with politicians on that in Germany saying, look, keep the gas pipes open to this site and this site, and this site, to make sure we still get glass and stoppers to fill our life-saving drugs. But it's not as severe as for the glass.

Tegus Client
And does that mean if you said it went from three to six to 12 to 18, it probably went up less for the stoppers? You're saying that generally, stocks went from three months to six months to 12 months to 18 months, it probably went up less for stoppers because there was never a.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
It wasn't as significant, the increase in safety stock for the stoppers as for some other items. For some items, we said 18 months, for stoppers, for example, could have been shorter.

Tegus Client
Yes. What would have been like an 18-month item?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
An 18-month item would, for example, be bioreactor bags or glass. And glass, the point is also to buy bulk glass, not sterilized glass. Bulk glass is stable for seven years. It's cheap too. The only problem with the bulk glass. It occupies a lot of space in our warehouses. That was the only problem. That's why we didn't increase it even further. Our warehouses have limited space.

Tegus Client
Got it. So there's possibility to the idea of destocking for stoppers. And then have there been any other industry developments that would cause there to be less demand for West products. Then obviously, COVID is already rolled off and then you have destocking. But is there anything else that you've heard about that could explain that?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Not really. You have a lot of negative news flow on cell and gene therapy, but no for the stoppers. These guys are buying are so much smaller than what the vaccine industry or the company is making monoclonal antibodies are using.

Tegus Client
HUMIRA drugs. Those are good?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
HUMIRA, KEYTRUDA and so on, that's in the dozens of millions of doses. Whereas the entire cell and gene therapy industry makes maybe one million doses per year. So that's a totally different ballgame.

Tegus Client
Right. Versus you are someone like Catalent, and you build out a fair amount of manufacturing capacity for cell and gene therapy because it's intensive in that area that. Then that's gone away would be a much bigger issue. Then not developing would be a much bigger issue.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
But look, the point is for a West. The entire cell and gene therapy industry is maybe 0.001% of the stoppers that they sell. If that higher segment shuts down. West won't even notice.

Tegus Client
Right. It was supposed to double and the settlement grows 30% or 10%, then doesn't that matter?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. And all the big blockbuster drugs are still growing. KEYTRUDA, OPDIVO, HUMIRA. And then you have the GLP-1s now, which are strong as well. And I think there's good reason to believe that there is still a lot of potential.

Tegus Client
What about when you get like by biosimilars like for HUMIRA. Do they do their own stability studies? Does anything change in terms of the purchasing of the stoppers or no?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
No. If you make a biosimilar, you really want to use ideally the same primary packaging material because you know that this is working. You will analyze very carefully the originator product, and you will copy it. And for example, for HUMIRA or KEYTRUDA or others, the biosimilars are not really replacing the volumes even if they were cheap vials and cheap stoppers from China. It's still a drop in the ocean.

Tegus Client
Yes. But ultimately, if you were to ask with, let's say, launching a biosimilar, you would look at the originator and then figure out what they're using?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. You would take their vial or syringe apart, you will take the stopper apart. You would say, look, I'm copying that particular molecule. I know that in the interaction with the West stopper, X, Y, Z, FluroTec, it's working, it's stable. So I will copy that because I know it's working, why should I use something else? Because I know that this molecule, the chemical entity or biological entity and that stopper are stable together.

Tegus Client
Yes. Given that you're a customer or not like a competitor. Contribution margin of like the incremental

stopper or plunger, when you're running your factories, the cost of the rubber is really the only like incremental cost that you have.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. For a typical monoclonal antibody, cost of goods are between $50 and $100. So if I buy a stopper, that's a few cents, we don't care. If we buy a NovaPure, it is more significant. Then it starts to be more significant. Now when you only look at cost of goods, when you look at the cost of goods in comparison with the sales price. We're selling these drugs for $2,000. So the cost of the stopper is a tiny fraction.

Tegus Client
Yes. I was wondering more from the West perspective, how much do they get for every incremental dollar of stock where they sell. I assume it's pretty high because their manufacturing costs are largely fixed in their sales cost?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
I don't know all the detailed financials of the stopper manufacturer, once they have the factory set up, whether the factory makes 100 million or 150 million stoppers you have a CapEx that is right there. And the stopper factory is not super, super expensive, but there is a CapEx cost. And the more stoppers you can produce in that factory, the faster you have your return on investment.

Tegus Client
I've heard that Aptar facilities aren't the most complicated facility. But it seems like you could produce a lot at one facility.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. The processes are super productive.

Tegus Client
One just popped into my mind, just pricing trends. In this sort of thing, the prices generally go up a little bit to year? Do they not really change unless like there's like a new product line introduced or new brand introduced? What are the trends there?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, the what can I say. With COVID, everything became more expensive. Everything that was suitable for manufacturing, injectables became more expensive. Then we have the Russian invasion into Ukraine, and the consequences of that, the geopolitical and geofinancial consequences of that.

All our suppliers, before they called us and said, you need to pay much more because supply is not there. Then after COVID, the prices didn't go down because Mr. Putin had the crazy idea to attack Ukraine. So then we had gas prices inflating and so on. And stoppers, it is a high energy consuming industry to produce stoppers. It's very energy intensive.

And the companies called us and said, we need to increase prices by, let's say, 20%. And we looked at the contracts and said, well, wait a second, we have an inflation adjustment agreement here, a clause in inflation adjustment, which says maybe 2% or 3%. And your 20%, we understand that the energy prices hurt, but we cannot fully compensate that because, look, we cannot just pass it on to our customers because they are patients.

And we cannot overburden the health care system. we had to find the happy middle ground. The discussions have become a bit more relaxed this year, it's less dramatic, but we do have tough discussions on pricing. And we expect a higher-than-normal price increase also this year. And I hope it will stabilize throughout 2024 and then maybe go back to the usual price increases we had before COVID.

Tegus Client

More than usually before COVID that was?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
We had the inflation adjustment 2%, 3% for the same product. And look, the mix has changed. We used much more very simple stoppers in the past. The more value-added stoppers, which are the higher price tag, of course, that allowed West and others to charge much more for the product portfolio that they were selling. The average stopper price increased because of the.

Tegus Client
Yes. I'm more just interested in the like-for-like rather than the mix dynamic. And then just to clarify on the contract. Did have an actual like inflation benchmark in there some kind of price index? It's a 2% to 3% kind of price increase annually and we agreed upon that?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
I worked with three major pharma companies and at the biggest CDMO in the world. And I've seen everything, if you're either aligned with global inflation. Or you have an agreement of 2%, 3% year-on-year. Again, leaning on to global inflation numbers. It's not an automatic 2%, 3% increase. It will say, look, we will go along global inflation numbers but it will not exceed 2% or 3%. And then came 2022, and that turned everything upside down.

Tegus Client
Is that something they're looking to change in the contract going forward? So it just nears whatever inflation is about the caps?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
The suppliers are, of course, saying, look, based on the experience over the last couple of years, we need to change that. We're saying, “sorry, guys, forget that because yes, the sky is not the limit”.

Tegus Client
Are the contracts that you have on this, they just automatically renew every year and then you there's a notice period if you want to discuss or make any change to it? Is that how they are set up? Or is it really like annual or every three years you have to negotiate from scratch?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
I've had both. I had contracts which run over a period of three years and then you renegotiate. Or I have permanent contracts, and we have a three-year forecasting system. That's what we have.

Tegus Client
And you said this is where we think we're going to end up in volume and if you hit that, you have a certain pricing schedule? It's like three years, though, as a general length for these contracts?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. So West or the others have visibility into our demand for the next three years, typically. When you look through the lens of the supplier, for other customers, they might typically.

Tegus Client
Is that a rolling schedule, you provide the three years like every year?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
It's a rolling schedule and we discuss it every quarter. This is really collaborative. We really want them to be aware of what's coming, so they can supply. Or give capacity to someone else if we have less demand. And it's also up to them to really inform us if there's any supply constraints, et cetera. If we increase demand

significantly and then they might say, wait a second, we cannot produce all that.

Tegus Client
Yes. And if you're in just say a permanent contract, when do you have the ability to change terms of the contract? You said some of them are kind of permanent contracts and you provide a demand forecast. If you're in that arrangement, if you want to change something about the contract, is there a window to do that every year? Or do you have a.

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, we can do that as part of the annual business review.

Tegus Client
Got it. Is there anything you think is interesting about West to now or learn?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Look, one thing which was quite interesting was West could use not just stoppers, which were used for the RNA vaccines because the key thing here is container closure and integrity. And you need to ensure that the stopper doesn't become a rock. And mine was 80 degrees Celsius. And their stoppers worked quite okay for the two big RNA vaccines. I think that worked quite nicely.

So that was very interesting for everybody to consider that because that also told the cell and gene therapy industry that these are suitable stoppers for closing vials for cell and gene therapy products. And there, everything gets gold plated. So people would be willing to pay crazy prices for the stoppers there. The other thing is, look what's the doomsday scenario? Where do I get really, really worked in terms of stopper supply?

The one thing that we always need almost most right now is really China and the potential of a Chinese invasion into Taiwan because even for West, somehow their supply chain still depend on China. Some of the come from China. So if China attacks Taiwan and then Biden or underline or others or other politicians are feeling compelled to issue big sanctions against China, it will have impact on everybody.

Then anyway, we have different problems than just stoppers. The other thing that we learned throughout COVID was we were taking the sterilization capacity of our suppliers for granted. And we were really hit by surprise in particular in Europe.

Because ethylene oxide, that's still okay, but gamma radiation, suddenly, we didn't have enough capacity in Europe because Germany shut down its power plants, border. So for the gamma radiation, we depend on running nuclear power plants. So England did Brexit. And then certainly, we were relying on, funny enough, nuclear material coming from Ukraine.

The power plant in Ukraine called Zaporizhzhia, that is changing ownership like every four weeks. four weeks, it's the Russians and then it's the Ukrainians again, then it's again the Russians. So that's really a very tough situation. And in Europe, right now, gamma radiation capacity is really in short supply. If you talk to West, ask them, do you depend on that? And if so, what's the plan? And not in the U.S., there, it's safe.

But in Europe because they do have significant capacity in Europe, they are probably less vulnerable than Datwyler or Aptar, but they still have a lot of capacity in Europe. So if you want to ask them a tough question, it's that one.

Tegus Client
Do you think they have a sterilized stoppers, it's gamma?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes, exactly. How secure is your supply chain for that? You can use ethylene oxide, you can gamma radiate, you can also autoclave. All three are possible. And you can ask them, do you use gamma radiation? What percentage of your sales is depending on gamma radiation? And could you convert that to ethylene oxide.

Tegus Client
Yes, in the U.S., I think there's ethylene oxide capacity is tight, right?

Vice President Quality Biologics and Steriles at Merck & Company, Inc
Yes. In the U.S., there was a big ethylene oxide plant. And it was emitting a lot of ethylene oxide to the environment and then they had to shut it down because the neighbors were getting irritations of their respiratory system because of that. You can ask how much do you depend on those factories. I think that's a smart question to us because that shows the supply chain robustness. And you can ask where does the material, the raw materials come from? And what are the key energy sources for you?

And I think those would be good questions for you to ask them. Talking about all that, our selection criteria, quality, supply reliability, et cetera. They tick out of these boxes. They could all do better on the ESG. I'm responsible for defining our selection criteria. On the ESG side of things, they could all do better. I think that's an important one.

West, they're ready-to-use stoppers in the U.S. They did have for many years, it was where we well known in the industry. They had some issues. So if you had asked me 10 years ago about West or eight years ago, I would have said ready-to-use stoppers, oh, no. Now this problem is solved and they have greatly improved their quality. Yes. So those are a couple of maybe info that would be interesting for you as a potential in Westar and to West and potential questions you might want to ask them.

Tegus Client
Got it. Awesome. Thank you again for taking the time to speak with us today. This was very helpful. Enjoy the rest of your day.