West Pharmaceutical Services Inc. - Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services

Interview conducted on June 22, 2022

Topics

Drug Delivery Devices, Fill-Finish Services, Pharmaceutical Industry, Capacity Building, COVID-19 Impact, Supply Chain Consolidation, High-Value Products, Organizational Challenges

Summary

A Tegus Client speaks with a former Platform Director, Delivery Systems R&D at West Pharmaceutical Services about their professional background and experience working with containers and closures in drug delivery device product development. They discuss the proprietary nature of West's products and how they license materials from Daikyo Seiko for container vials and needle syringes. The conversation also touches on the decline of outsourced fill-and-finish services and the importance of control and timing in the supply chain. They also discuss the process of validating a clean room environment and qualifying equipment and lines, the benefits of modularization and standardization in reducing lead time for capacity expansion, and the competitive landscape. The former director also discusses the changing culture within the company and the challenges of consolidating key executive leadership roles.

Expert Details

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services, leaving on July 7th of 2021.

Current Vice President Operations at Axolotl Biologix, a biotechnology leader in regenerative medicine.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services, leaving on July 7th of 2021. The expert was responsible for overseeing all aspects of R&D, particularly for the SmartDose 3.5ml wearable delivery/injector system.

Q: Can you speak to the true proprietary nature of West’s Proprietary Products segment as it seems as though the company’s distribution relationship with Daikyo supports much of the underlying technology?
A: I could speak to this, yes. I worked on a lot of their proprietary devices. Daikyo is more of a container/components system. They have a lot of other proprietary products just with Daikyo.

Q: What is the nature of the value-add of West’s Contract Manufacturing business? FDA certified plants, spare compacity, other? And why would this present a competitive moat that could not be replicated?
A: Well, a lot of it goes back to their acquisition of the tech group. They acquired a company that had a lot of history that knew how to thrive in the drug delivery space. Yes, there are other opportunities for competitors to enter the market but given that history, their SME, book of business with a lot of the manufacturers, it just gives them a bit of an advantage in terms of their reputation in the business.

Q: In the early 2000s West sold its underperforming drug delivery business, and then in more recent years has acquired back into this area. What makes the company’s new efforts substantially different from the past business plan in this area?
A: Now, in terms of economies to scale and vertical integration, they have more of the pieces of the puzzle and can offer a more comprehensive one-stop service. I can speak to this in great detail.

Tegus Client
Thanks for taking the time to speak. Just to hop right in, want to talk about talk coatings technologies and such. Would be willing to give like a short synopsis on your professional background and how you kind of came to know West and so forth.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes, sure. So I've spent probably, let's see, 16 years now in the industries related to like human factors, medical device, product development, drug delivery device product development usually in a capacity of research and development and project management.

I spent just a little over six years at West and had different roles, including program management lead, site lead, where I ran a group of project managers that were developing proprietary drug delivery devices. And as I finished up my time at West, I was in charge of research and development for one of their drug delivery platforms. And this was an on-body wearable drug device.

Tegus Client
Okay. I guess if you could kind of speak to just the underlying proprietary nature of West's proprietary products segment. And I appreciate that they've had a long-standing relationship with Daikyo Seiko. And from the way that the filing's reported, there's a royalty arrangement. But I guess one way to read the agreement is that a lot of the vial and coatings technologies are actually more kind of proprietary to Daikyo.

And West licensed them and then provides more of kind of the rest of the solution in terms of the elastomer or stopper top and so forth, which, I guess, to me, from the outside, seems a little bit less sophisticated than the actual kind of vial and coatings technology.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. So working on the proprietary device side, I worked with the containers and closures from the standpoint of integration into those overall systems. So my primary role was not in our containers or closure area. That being said, to your point, Daikyo, with Crystal Zenith as the material resin that's being licensed for container vials and needle syringes.

And then they also had some of their own proprietary elastomers that would be licensed as well as coatings. And then West would have their own elastomers and coatings as well. And so my understanding is that, in a lot of ways, it's kind of a way of bringing the Daikyo products to a much larger market using West's sales channels. That was kind of the arrangement.

Tegus Client
Okay. Maybe just kind of speaking somewhat to your current position. But one of the pieces that I've read in the industry is that injectables are one of the fastest-growing kind of product segments within the broader market.

But I guess I was surprised to learn or at least read in this particular piece that what they characterize as fill-and-finish services has actually been on the decline in terms of how much is outsourced, which kind of surprised me in thinking about the general kind of VC-funded biotech. Seemingly just has enough on their plate just doing the R&D. Is that something that you think is an accurate portrayal by this industry piece? Or is that can be taken out of context?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. I think it's a case by case. If you're in the smaller biotech companies, in terms of economies of scale, they're not going to try to vertically integrate fill-finish. It's just way too costly if you're going to do a large fill line, to set up a plant. It's probably a couple of hundred million dollars of investment. And so you really got to have the throughput to make that worth it.

If you read in a report that fill-finish is going down, while biologics are going up, I'm guessing what you're saying is that fill-finish as a contracted CMO is going down, which is implying that bigger companies are vertically integrating that. What I would suspect here is it comes down to a couple of things like control and

timing.

Some of these biologics are incredibly valuable assets, in the order of billions of dollars a year in sales. And if that asset can come to a screeching halt because your fill-finish supplier can't get you line time to produce for 12 months or 18 months, then from a supply chain standpoint, it's too critical of a step to not have control over that and to be fighting with other customers of that fill-finish supplier for line time and priority.

Tegus Client
Does that really matter in the investment case for West? I mean, presumably, they're still providing the West enclosures and such, and the line is just running a line, right, with those kind of components coming in?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Well, it does and it doesn't. So West could take the view of, hey, we're just a component supplier. We give you the container, we give you the piston, you put your drug in it and you get it to market. However, you need to do to get that product finished. It's not so much to say, let's fully integrate and do wholesale finish internally. Because, again, the economies of scale and the complexity and costs there are just too high.

But rather, let's identify some key partners that we can work with so that when we have proprietary containers and we go to sell that to a drug company that it's not up to that drug company now, you get a container, but nobody can fill it. So now, you got to go work with a fill-finish vendor and a machine vendor to develop chain parts and bring all of it together.

I think it's more value-additive if West acts as almost like a general contractor, where you go to them and they can provide the container, they can provide the device, they can coordinate fill-finish services. They can coordinate the analytical testing, and it becomes more of an integrated solution.

Tegus Client
I see. Coming back to, I guess, the business now titled Contract Manufacturing. I guess when I recall the formations of the business, I recall in the early 2000s, West actually selling kind of an underperforming drug delivery business, and then kind of stepping back into that area with the 2005 acquisition of The Tech Group.

At the same time, I think they did the Medimop deal to get the constitution devices, and then a French business, which I'm not necessarily exactly sure what added, kind of later in the early 2000s. But I think the promise was always held out that operating margins would kind of move up. And I guess they have more recently. What didn't work about the first kind of initial foray into that area? And then I think for a long time, The Tech Group kind of struggled to gain traction. So was there anything in terms of capabilities or were they just early? What kind of changed with the way they either were approaching the market or within the market itself?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
So I can probably speak more on the proprietary product side than the contract manufacturing side, as far as gaining traction. I mean I know the contract manufacturing business has just been like steady growth. I mean, it's not huge growth, but it's continuous and steady and increasing every year as I think their reputation continues to build and they take on higher and higher profile clients.

On the proprietary side, if you look at like the adoption of CV as a primary container material or adoption of like the SmartDose platform for drug delivery, I think in general, the adoption curve is just taking a lot longer than expected. I think the pharmaceutical industry is just extremely, extremely conservative.

And everybody is always looking for somebody else to become the first, using a new product or a new device or a new material. And so, it's slow to get those first adopters, and then once you get them, you kind of got to build critical mass. But I think where they're starting to see those increased margins now is a strong pull now on the polymer containers and drug delivery devices. That was late 10 years ago.

Tegus Client
I guess, underlying that, it seems like there's been somewhat of a customer mix shift. I think when The Tech

Group came into West, it was maybe more consumer-orientated type of product.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. Yes, so we're like when they first started, they may have been doing stuff, some medical but also some printer cartridges and other just regular consumer products. Now my understanding is it's 100% medical.

Tegus Client
Okay. And the SmartDose technology, is that an inhaled-type product? Or what would that speak to? Like what kind of therapy would that cover?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes, that would be an on-body injector that's for subcutaneous delivery. So where that's really seeing a lot of adoption is for a lot of the more advanced biologics. In fact, AbbVie just launched their product, SKYRIZI, and their marketing literature shows that their on-body wearable is the SmartDose device. And that's being used for that Crohn's indication.

Tegus Client
Okay. And then is it any particular difference to West if a customer is a true biologic customer versus kind of an off-market generic customer, from either contracting or pricing standpoint? Is that a meaningful differentiation?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
It can be, when it comes to at least the containers and the drug delivery products, so SmartDose is a more premium offering. CZ is a container material and more premium offering. Typically, premium drug container closure and delivery, it does not align with the generic space as much, because they're very, very cost conscious.

So I would say, usually, the customers are interested most in those premium products are the primary drug developers, not generics. Now not to say that West doesn't have a healthy generics business. And it's probably more things that are going to more standard packaging, glass vials that have standard closure systems, nonpremium closure systems. And for any devices, it's probably more auto-injector type devices that West may or may not offer.

Tegus Client
Okay. How about with regards to kind of capacity planning. What's kind of the approximate time line or process in terms of building out additional square footage, putting a new line in, getting regulatory kind of approval and customer validation? How arduous are each of those steps in terms of kind of planning out to bring new capacity online?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. I mean at a high level, you try to do your best at forecasting what's your demand going to be in trying to create a baseline for what that looks like as well as potential upside. And that's accumulation of all the different sales channels and how it all adds up for that product. So anytime you're expanding capacity, though, and especially if there's any automation involved, you need to start it probably two years before you need it.

Yes. At least things that don't have as much automation, where you're just kind of expanding an additional line or additional capacity, you might be able to do a shorter time line. But especially if you're adding a new plant that's going to have clean room, that's going to have automation and custom equipment that needs to be procured, all of which is now getting compounded by tight supply chain, just a lot of long lead times. A lot of times, it could be a long time line.

Tegus Client
Is that the right kind of mental picture to think about, having the space built out and then you have a

regulator through and they test that it's a clean room environment. And then you have to kind of validate some customer samples and so forth?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. You'd qualify the space, and then you'd qualify the equipment and qualify the line. And in ideal scenarios, you try to get that line either funded or co-funded, to some part, by a customer to help offset the cost of that. Just depends on the strategy.

If you're confident enough and multiple customers pulling from that, you want to own the capacity. Or if you're more concerned that it may be a specific configuration, specific product to one customer, in which case, you might have the customer contribute or invest more in that capacity.

Tegus Client
I don't know much about what exactly was outfitted at this Waterford plant, other than it coming up in the discussion of being kind of a more modular plant footprint. But do you think something like that would meaningfully kind of reduce that time line? Or is that kind of more consultant speak in terms of what they've articulated?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
So I was not intimate with our Waterford site. But in general, the strategy of modularization and standardization, and what I mean by standardization, if you say like, hey, as long as your lines fit this footprint and you use these standard pieces of equipment and you have some general processes that you try to standardize, I mean that's just in general operational theory. That's a core strategy to reduce that lead time for capacity expansion.

Tegus Client
Okay. Just kind of two last big areas to touch on. I guess the competitive set, I know that there's kind of subsidiary of the European company. But is it accurate to believe that most of the competition is kind of more regional in nature? Where would a business like West see the most viable set of competitors?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
It depends on the products. It depends if you're talking containers, if you're talking closure components, if you're talking devices. I think in a lot of ways, it's gotten more global. Containers, there's a lot of glass manufacturers out of Europe.

Components. There's component manufacturers in Europe. But also companies like Datwyler that I believe domestic devices. I'd say probably the majority of drug delivery devices are companies that are U.S.-based, but there's definitely a growing group that are not U.S.-based.

One of the keys is, when you're doing a combination product, so that means the drug with the delivery device, with the container closure system, all that together, it takes a lot of complex integration. And so ideally, you'd like to be similar time zone and same language.

And so if you're working with big pharma companies in the U.S., I think the ideal would be to be working with a device and container closure system company that you can work closely with and would have the benefits of, like I said, time zone, language, all that. Not to say that companies that aren't U.S.-based haven't tried to work strategies where they have satellite offices based in the U.S. to try to accommodate that to some extent.

Tegus Client
And then just kind of touching on the COVID experience. Business kind of ramped up to $0.5 billion in short order. And I assume all of the things that we're doing with helping with those vaccines were kind of playing off of existing coatings technologies and things like that.

But from the outside, do you think that there was any kind of lasting benefit to that experience from either a

broadening capability set or kind of a proof point? Speaking to your earlier notion in terms of kind of providing other type of validation to external customers that a company like West can ramp really quickly on something important like this, that needs to come to market in short order. Have you thought much about this area?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
A little bit. I think with COVID, it was a really interesting case study, in that you've got a lot of money and subsidization and government funding, trying to solve a problem by throwing money out as fast as possible. May not have always been like the most efficient use of money, but it was more about time, right? You just buy a lot of components and then figure out how you're going to use them later on.

So I think in West's case, will sales stay at that brisk pace? Again, not being close to that, the speculation would be is, you're not going to have that same peak level spending. But is it higher than what it was before? I would believe, yes, because you've expanded your breadth of business. You've got new drugs, new assets, vaccines that have now come on with these components.

And one thing you learn is, once a drug company validates a configuration, a drug with a container and with a closure system, extremely expensive and time-consuming to change that configuration. And so it creates a bit of a competitive moat that, once you get a configuration approved and it's now out there commercially selling, really don't like to change that unless they're forced to.

So for West, if their primary components on a lot of these vaccines, that means that going forward that should help lock in some of that business. But then, you also think about supply chain consolidation. If you're a big customer and you're going to buy from West, but you're also going to buy from a few other customers, on one hand, you want to diversify your supply chain and have some second sources.

But to take advantage of volume benefits, you don't want to have too many suppliers that you're trying to manage. So if you're going to take on West because they're for one of your vaccines, but in your other businesses, you might take a hard look at moving some of that business to West now to try to consolidate some of your supply chain.

Tegus Client
Yes. I agree with that stickiness of that relationship. I think West, in terms of a party line, would kind of speak to a continued move-up in terms of the curve on value-added products. And I'm not sure if that's talking out of both sides of their mouth or if that's just kind of a natural process that evolves over time. Notwithstanding maybe having to do some type of recertification within that.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. It does make sense.

Tegus Client
So the growth in the higher end of the higher value-added products growing faster than kind of the more standard products, is that due to a mix shift of existing customers? Or is that new incremental customers coming on and signing on, just for more premium product or enclosure devices?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
So is the question, is the number of customers that West's seen increasing? Or is it that the customer base is largely staying the same, but the existing customers are ordering more in higher-value products with higher margins?

Tegus Client
Yes, that's another way to frame it.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. So just given the nature and the industry, it's probably more the latter. Not to say that West doesn't

work with early-stage startups, but just the nature of the pharmaceutical and medical device business in general, start-ups get going. And once their products have viability, they're usually acquired.

And it's like all tributaries ending in the Mississippi, they get acquired and a mid-level guy acquires them, and then they get acquired by the big one. And so for West, they've got a lot of their key big accounts.

I'm not exactly sure if they're seeing the number of customers increase, but definitely, the mix of higher-value products is increasing and the demand for those products. And maybe that's just with more and more, like you said early on, with the growth in biologics and a lot of these injectable drugs, it's driving that high-value business.

And the interesting thing with those injectable drugs, because one could say, like, well, what happens if they just formulate that drug away from an injectable to an oral tablet that you could take? And understanding biologics, just by nature, they're often made up of proteins and other organic compounds that can't be ingested, because once you ingest it, the digestion process destroys those proteins, and so you lose the efficacy of that drug. So that's why it's injected and probably always will be injected.

Tegus Client
That's good to remark on. I would imagine that you noticed the announcement with the Corning relationship. Any kind of big-picture thoughts in terms of the relative importance of that? Or why Corning kind of sought out West or vice versa? What that maybe could manifest into?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Corning's, my understanding, they're big glass manufacturer, right?

Tegus Client
Yes.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Glass containers. So I think it makes sense in that not everybody is going to want a high-value product. Not everybody is going to want CZ. And so knowing that there's a big chunk of the market that you could potentially be missing, to be able to partner with somebody else and kind of going back to actually a further point you made earlier about fill-finish. Fill-finish, a lot of the big CMOs, they almost primarily work with glass.

In fact, I know a couple that would only work with glass. And working with polymers was either a little bit out of their comfort zone or there's going to take a lot of engineering work to adopt that and bring that in. So I think by expanding and doing a strategic partnership with like a glass manufacturer made a lot of sense.

Because now, those that were on the fence because they're really risk-averse or just really conservative and wanted to stay in glass could still do so, but then still utilize West for all their other components, devices, analytical services and come into that whole suite of services.

Tegus Client
So I've almost read like people can't use glass in that there's micro contaminants that are possible. Obviously, breakage is more of an issue. But you're of the opinion, from your statement there?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
I think it's the broadening of the portfolio and just able to reach more customers. Because each drug is different, too, and reacts with the container system differently, so there'll be some drug assets that will work with CZ and some that may be better off and more cost-effective to go with glass. And so by now, because West wasn't going to go off and become a glass manufacturer. I think it made more strategic sense just to partner with one.

Tegus Client

Tying into the intuition of generic companies maybe just having less of an ASP halo to really kind of buy into the more premium subsets, and thinking about the promise that you keep hearing about in terms of biosimilars. Does that seem to line up more with kind of this glass solution perhaps?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. I believe so.

Tegus Client
Okay. I don't know if I had any special insight that's relevant.

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. The culture is changing, yes. And just my opinion, I think the way it's structured actually encourages a little bit more of a political environment, which can be counterproductive. It's also interesting that there seems to be consolidation in some of the key executive leadership roles.

Where usually, for example, you'd have a discrete role of your Chief Information Officer and your Chief IT guy and your Chief Technology Officer. A person that's going to champion the product technology. In West's case, those are consolidated into one role. I think that can be challenging because those are two very different skill sets.

Tegus Client
Yes. When you say political, does that mean kind of fighting over assets? Or what does that imply?

Former Platform Director, Delivery Systems R&D at West Pharmaceutical Services
Yes. Fighting over assets. Cross-functionally, the first time that all functions report into one general manager, when I say functions, operations and all that. When they're coming together, that comes together for the first time under the CEO, so you can make cross-functional management of products and whatnot, can be challenging.

Tegus Client
Okay. Well, I appreciate the discussion. Thank you.