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Improving Performance and Resiliency in Your External Manufacturing Network Through Supply Chain Digitalization



Evolving global markets, the introduction of new and innovative medicines, and ongoing product supply disruptions challenge supply chain leaders every day. These challenges result in increased pressure to architect external manufacturing and material supply networks that ensure supply resiliency while meeting strategic business performance mandates. How can a digital external manufacturing network provide critical visibility, collaboration, and intelligence?

Watch this video with Frank Binder, Head of Global Supply Chain Management at Santen, and you will learn:

- How the external manufacturing network has evolved, with a focus on how planning and operational changes impact life sciences companies.
- How digitalizing supply relationships with contract manufacturers and material suppliers helps brand owners meet corporate goals for supply chain resiliency, operational performance, and customer service.
- How digitalization can be a "win-win" for both sides of the supply relationship.

Binder also provides recommendations on how to start conversations about

digitalization with manufacturing partners and material suppliers. Watch now!

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TRANSCRIPT

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Frank Binder: I'm very happy to be here and share a few thoughts on the topic I think is really important. How can we improve performance and resilience of external manufacturing networks through digitalization?

I will briefly introduce Santen. We are a Japanese company, and I think well, you probably don't often see companies who have as a core principle a quote from Confucius. That's the case with us, and it's quite fitting to the environment.

We have a lot of discussions sometimes about the interpretation of this quote, and the official one for me is really a commitment to science-based medicine to contribute to people's health, I think something I really stand behind.

We are a company focusing on eye health, so ophthalmology and happiness with vision as our core principle, as our statement, is really relevant. Vision is one of the most important human senses. There are severe ailments that affect or impair vision at a large scale. Of course, you have glaucoma, you have age-related macular degeneration, retinopathy and so on.

There's hundreds of millions of people suffering from that. The ophthalmology is a niche but a quite relevant one, I think.

Then there are conditions like myopia. 2.6 billion people on earth are suffering from myopia. It sounds like, OK, you just put on glasses and so on, but severe myopia is extremely impairing for vision. It is on the rise with children and young

people quite dramatically foremost throughout Asia, but also in Europe and the US, this is increasing.

Of course it comes from things like from childhood on, you look on small screens from close distance. The other element I just read recently is that children spend too much time indoors, and it seems that the daylight plays an important role in the development of the eyeball. So there's malformation of eyeballs by spending too much time indoors as a child.

This is a huge this development. Myopia is one of the areas that for us as a company will become really important in the next few years. We are focusing uniquely on ophthalmology. We are present in over 60 countries, and we have an overseas sales ratio, of course seen from Japan, of 42 percent and growing, so we are a truly global company.

We are number one by far in Japan, also number one in China, and in quite a number of Asian markets, and also really well positioned throughout Europe and growing further. Our annual production is 400 million units, 400 million packs.

Most of that we make in our own manufacturing plants in Japan and China, but a very important part we make with CMOs, so dealing with CMOs external manufacturing networks, that's actually part of my life. Yeah, sometimes it's nice and sometimes it's challenging, isn't it?

I wanted to talk a bit about just giving my five cents and this is not a kind of consulting study or whatever. This is just what I see as drivers or important elements on external manufacturing. I believe there's a couple of trends in industry and across industry that will continue to ensure that CMO's stay relevant and probably even grow in importance.

There is technology. We have new modalities, biomolecules, cell and gene therapies, and so on, where there's really little synergies with the classic small molecule manufacturing sites that many pharma companies have. Unless you have

a portfolio of these new modalities that is big enough to justify building a new site, I think the only way is really to work through specialized CMOs.

Then we have cost and time pressure. Actually it comes down to cost pressure. As an industry, we are faced with margin erosion, regionalization, and we have troubles especially, well not only the mid-sized but I think even the bigger pharma companies have more challenges in doing large scale investments to build own sites, and the high overhead that comes with that.

We would need a very high capacity utilization. Then there is of course a significant lead time to build a site. And with the, I would say, the uncertainty that we have in the overall environment, also things like governmental price pressures and so on, make it difficult to do such an undertaking, more difficult than in the past.

I think all that calls for more flexibility, and that's where I believe that CMOs definitely play a role and will continue to play a role.

Then another thing as you can see here in this scene, business development goes out shopping and they buy some products. By the way, this is exactly how it happens. This is a real life picture. We have seen that in our company, but this is common in the industry. Mid-sized and larger companies go out and acquire products that are in development. They acquire them from small companies.

I would say, nearly 100 percent of these cases, the small companies who have been developing the product, who have been putting it through phase 1, phase 2, and maybe even are in phase 3, they will work with CMOs. I mean they have really no other choice.

That means when we, as a company, we acquire such a product, it typically comes with a CMO attached. It might be too late to change to an internal site, or it might just be not practical. Definitely we are inheriting CMOs in that way. That's what's happening at Santen to quite some degree. Then I believe there's a global trend.

Supply chain risks become more apparent. Risks of major trade lines being blocked, risks of country where you have manufacturing, all of a sudden being involved in a war, and so on.

That's one thing that drives regionalization of supply chains. That's a big trend I think you can certainly see as well. On the other hand, we have business continuity planning which becomes more important. I would say the gold standard in business continuity is to have a backup site, but a backup site that you actually use.

That means you have to split your volume, your global volume, across two or more sites. It becomes increasingly challenging then, or impractical to have one global site where you make all your products for the entire world, so these economies of scale don't hold anymore. I also think that's an area where CMOs can benefit, for example, becoming an active backup for a product.

This external manufacturing will continue. We will continue to outsource our products to CMOs. I believe this is not something we can just say, OK, we outsource manufacturing and that's it. This is a hugely important step because the product is everything. For us as a pharma company, our product impacts our patient's health, and it impacts our company's revenue, our reputation, and if things go wrong then our license to operate is at risk.

Outsourcing a finished product to a CMO is a momentous decision. It's huge. If we run into a situation where we then have issues, supply issues or quality issues, that is extremely negative. So CMOs are very important in our pharma supply chain. Then I'm wondering, do we treat that adequately? Do we collaborate with the CMOs in a way that is appropriate given the importance of what they do?

I will argue that today not really, but we can do better. Yeah, let's look at integration between pharma companies and CMOs from a conceptual standpoint. I would say today we are in a situation very often where there's a loose integration. Like you see these two guys there, they are at arm's length distance.

Commercially, no doubt that is OK.

Two different companies with different interests. But operationally, we are also at arm's length distance, and that is an issue. So these two guys, yeah, they can collaborate, they can do things together, but there are limitations. There are things that they cannot, which I will also conceptually show.

What happens is, of course, we have different systems. As a pharma company, as a CMO, we have our own ERP systems and such. We recognize that the supply chain consists of the whole network of enterprises that are involved. But in a way, we don't walk the talk. We have understood that collaboration is very important, but we don't really do it often.

What we have typically, maybe for large, for important CMOs that we might call strategic, we have some interfaces in place, maybe, or often in fact, but these are limited. There's too few message types, too few data exchanges, and they're also not so easy to set up.

Once you have them, you stay with them. More fundamentally, I would like to challenge whether there are CMOs that are non-strategic. If you consider that even a CMO that we don't have so much business with, we still have entrusted them with making our products. I believe we should do better. It is never the case that the CMO is like in the commodity corner of the procurement matrix. It is always very important.

Then most of the interaction, also in addition to interfaces if we have them, happens by email, by sending back and forth excel sheets. This is definitely not digitalized at all. This is completely manual. This is breaking the process, which is digital in the ERP, and then all of a sudden it becomes completely manual.

We augment that with review meetings typically because email and Excel sheets is not sufficient. But it is a process that is inefficient and slow, and you can completely miss some issues. If you think about it, we place an order today, and

we expect delivery of the product in three or four months and in between we don't really know what's going on.

Of course we have maybe regular meetings. We ask the CMO is there anything special to report, but that's not really visibility. If I would explain that to a colleague in finance or in commercial, they would probably be quite horrified that I place an order and I hope that in four months it will be delivered. But until then, I don't really know.

So visibility is very limited. There's also a lack of granular data, so process optimization is not really possible. Then when we look at KPIs, for me, OTIF on time in full, that is by far the most important one that I have looking at the CMOs. This is rear mirror view. We are seeing the OTIF of the months, of the past periods. This has very little prognostic value.

If I say, well the whole year this and this CMO has had a good OTIF, that doesn't tell me anything about whether the orders that I have placed and I expect delivery in the next months, will they be on time or not? I don't know. We can have a hunch based on the KPI, but we don't really know.

If we see issues with this KPI they're always in the past, so we drive actions based on what happened in the past. So performance and resiliency are certainly not served ideally.

I think this is not satisfactory. As mentioned, the importance of CMOs is really enormous. We entrust them with the most important thing that we have as a pharmaceutical company, and then we have this kind of really near disconnection. Not great, and I think we can do better.

Even though there will always be diverging interests between the companies. There's no doubt about it, but we still can do better.

Conceptually tight integration would look like that. These guys are really close to each other, and by the way there was nothing inappropriate going on with these

guys, and I know that because I did the photo shoot myself. Since they are close, they can coordinate, they have a much better understanding of what they are doing mutually, and they can do some heavy lifting. That's what these guys who are on arm length distance cannot do.

What does it mean? Of course I'll have some discussion on that, but one of the ways to get to that tight integration is definitely through digitalization across company boundaries. What I think what we should strive for is to achieve the same level of process and data integration with a CMO as with our own site.

With our own site, I can look in our ERP system, I can get reports, and I can see what's really going on in detail, even within the manufacturing process if I wish to. I think we should get to a stage where we can do the same with CMOs. That would mean between the pharma company and the CMO, we design the key processes together across the systems.

Then we set up data flows that are highly standardized, and that allow us based on the common understanding, common business process, to have to be up to date. Then when we see the status and the process, the progress of what's going on, we are able to develop forward-looking metrics. So detect issues early on, and detect them through reports instead of emails and meetings. I think that would be a game changer.

Partly, companies are already getting there, but this is overall for the pharma supply chain that would be a game changer. One area I believe would be highly relevant is if we can define between the companies the life cycle of a purchasing and manufacturing order. From placement, confirmation, firming up, procuring materials, scheduling it, dispensing, and so on up to delivery.

If we have this common process, and we would understand what are the milestones, and what is the timeline, and we had the data flows, then we could have reports that tell me as a pharma company, oh, at CMO A, there's a couple of orders where the material should have been procured already, but it hasn't been

procured.

Then I guess, well there's probably something that is going wrong and in a couple of weeks that might result in a delay in delivery. That would be through automated reports, through automated warnings, forward looking.

Or we could also think about improving the exchange of planned data in both directions. Do it on a daily basis over a 24 or even 36 months horizon. Then on one hand the CMO would be able to detect capacity issues 18 months from now, which would be hugely important to know of course.

Or we ought to be also could really get rid of the whole purchase order administration process. Because in fact, if we have defined the business process well, and we have defined the milestones, then we know exactly which demand from the pharma company will get manufactured is being committed, and can therefore be manufactured by the CMO.

If that is the case we could generate the purchase order really very late in the game and just use it as an accounting document, as a document for customs clearance. And you would get rid of a lot of administration like purchase order change, purchase order change confirmation, and so on. If we do that, we gain in efficiency and we are able to predict issues early.

So we could have a KPI that tells me how many orders are off track at a certain CMO. Orders with a future delivery date versus looking at how did they do with the orders in the past few months. That would be a game changer, I believe.

If we believe this makes sense, how could we get there? I think it's really about everything in business. We need to show the value. We need to show the value within our company, within a pharma company, within the CMO, and between them. There has to be a win-win.

Nobody is going to undertake process integration just for the beauty of it. Just for

the beauty of the concept. In the end, it's about money, it's about performance.

I think there's some really good cases that one can make in a concrete example. Efficiency increase for both sides, reduction of resources, costs, and time because we eliminate manual transactions. We eliminate communication, we eliminate meetings. Not just making them efficient, but they are completely unnecessary. The meetings would then be on value-added activities.

For example, we have detected there is an issue happening, and then we will have a meeting to discuss how can we avoid that issue that would happen in two or three months from now.

For the pharma company, there's a huge value in having forward-looking monitoring. In this case, we don't look at the rear mirror anymore. We have a heads up display that tells us, oh, that car is getting onto our track, so we better brake or we better steer, whatever. And so that is one thing. If we can see which orders are getting off track, that's we can we can react.

Likewise, the CMO, if they can see there's a capacity bottleneck in 18 months, they can also take the right measures. When we have data available, we can drive joint process optimization with benefits for both sides. What is very important, I think is a prerequisite from a business perspective, the entry and exit barriers must remain reasonable.

If we build up something that locks the pharma company and the CMO in, that is a problem because CMO relationships are not forever. We need to keep that flexibility, but while we are working together we have to optimize the way we are working.

Finally, what I think, and that also fits quite into FutureLink, it is really essential that this linkage of companies, that this is done in the most efficient manner without excessive costs, without excessive effort. That means for once, we can't have multiple interface with multiple systems. Also we have to have an optimized

network and not millions and millions of connections.

Standardization is extremely important on the business side, but then also on the connectivity side. Because in the end, it's about effort and cost, and we have to drive. We can only make progress in supply chain interaction if it becomes easier in a way that we can also make a good case for tightly connecting with CMOs that are not the biggest one for us.

The idea, the technology is there. There's examples already there, and I'm very confident that we can move ahead and improve the pharma supply chain.

Dan Walles: Thank you, Frank. Just a quick question is I agree with you that there should be a really good relationship between the brand owner and the manufacturer.

I was just wondering if you can provide a couple of recommendations on how to set up that expectation at the start of the project. Is it through an MSA? Is it through the quality agreement that you upfront tell your manufacturer what you expect in terms of that integration?

Frank: I think it's important to build the relationship at various level at the level of the people who are actually going to do the work but also at the sponsor or governance level in both companies. There has to be clear communication of expectations that if you jump directly into the contract that then you get lost into all the legalese.

I think there must be a couple of business meetings before where we really talk about what do we want to achieve and where the CMO of course also has the opportunity to bring their important points. I think we have to involve people at the operational and at the governance level on both companies.

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