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Strategic Opportunities for the Contract Manufacturer-Life Sciences Company Relationship



With increasing pressure to improve service levels, rapidly respond to changes in demand, and reduce costs, the need for life sciences companies and contract manufacturers to form highly efficient strategic partnerships has never been greater. In this panel session, we explore:

- The changing nature of the external manufacturing relationship with a focus on the contract manufacturer perspective.
- Opportunities for digitalizing transactions and orchestrating shared business processes in partnership with life sciences clients.
- Potential business, operational, or technical barriers for contract manufacturers making this transformation and how to overcome those challenges.

You will also learn where to begin the journey to create initial value and demonstrate early success. Watch now!

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Featured Speakers:

Eduardo da Fonseca

VP Global Supply Chain & External Manufacturing

Bioeq

Paul DellaVille

Director Digital Solutions and Services

Cold Chain Technologies

Arun Giddu

Director of Supply Chain

Thermo Fisher Scientific

Shashidhar Lingaraj

Executive Director & Head of Business

Arcolab

Lauren Brethauer

Life Sciences and Strategy Consulting Manager

Accenture

TRANSCRIPT

TRANSCRIPT

Lauren Brethauer: Good morning, everyone. As Dan shared, my name is Lauren Brethauer. I am a life sciences supply chain leader from Accenture, and I will be our moderator today for this panel. Very excited to have all of you. Before we kick it off, would love if each of my panelists could give a quick introduction. Shashi?

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Shashidhar Lingaraj: Thank you. My name is Shashidhar. I lead a business called Arcolab. It's basically a life science capability center. We manage services, consulting, and tech solutions for mid-size pharma companies.

We cut across all the vectors of oral dosage, API, sterile injectable, and biologics. We try to help the mid-sized companies to build capabilities. I'm happy to be here. Thank you very much.

Eduardo da Fonseca: My name is Eduardo da Fonseca. I work for Bioeq. Bioeq is a biosimilar company. We're a virtual manufacturer in the field of ophthalmology. Of course, we depend on our contract manufacturing partners for everything we do. My role is to lead end-to-end operations, including procurement, manufacturing, planning, delivery to the customer. Very happy to be here.

Arun Giddu: Hi. I am Arun Giddu. I am the director of supply chain at Thermo Fisher. I'm a software developer turned supply chain professional. Today, I'll be wearing the CMO hat, but my interests are in making the supply chain smooth and predictable, both internally as well as externally with customers and our suppliers.

Paul DellaVille: Hi. My name is Paul DellaVille. I'm with Cold Chain Technologies. We're a thermal packaging provider. We provide services to both CMOs and direct pharma manufacturers. I think my role up here is really to speak to, as a supplier to both sides of the world, what visibility and connectivity actually adds to those relationships.

Lauren: Awesome. Thank you all. As we've highlighted, I think the life sciences industry is ripe for significant change in this space. Through Accenture, we did do a survey with 200 brand owner and contract manufacturers, asking where they felt the state of CMO collaboration was.

While over 95 percent of those brand owner respondents said they had expanded and would continue to expand CMO usage, less than 15 percent of those same respondents said they were very satisfied with their contract manufacturing

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relationships, citing accurate planning, reliable data-sharing, and early issue identification as some of the biggest areas of opportunity.

Arun, from your perspective as a contract manufacturer, do you agree that we are continuing to expand, and if so, why?

Arun: Contract manufacturing, my opinion, it will be more and more used, basically for two reasons. One is cost efficiency, and the second is speed to market. As a contract manufacturer, we can have the same teams of manufacturing regulatory quality all be working for different customers all at the same time using the same equipment. That is getting a lot of cost efficiencies.

The other thing why I think the CMO's role will be on the upscale or expanding is because of speed to market. Many of the new drug discoveries that are made are made by small and medium-sized companies who may not have the manufacturing capability.
To get to the market faster, I think hiring a CMO to do that will be helpful. That's why for these two basic reasons, I feel the CMOs will be used more in the future.

Lauren: And any other thoughts from the panel on that?

Shashidhar: I think Frank, in the previous presentation, took away a lot of points. [laughs] I think that was fantastic, some of the points that he mentioned. The way I see it is the CMO needs to be...they're moving up the value chain. Now it's a CRDMO. They are up to research, they're up to development and manufacturing.

I think that's one big value that CMOs are bringing in. The demand for that continues to be there. The other aspect here is in our business, we call it as supply network optimization. How many plants do you have, and how do you actually optimize that?
CMO integration into that is another aspect. That you keep building capacity, as Arun mentioned, just not about speed and cost, but also how do I optimize my network? I think they play a significant role in that.

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The demand continues to be there. In fact, they're moving up the value chain, and some of the CMOs are becoming one-stop shop service for pharma science now.

Lauren: As we discussed, when you begin to work with a CMO, you are establishing a partnership. Eduardo, from your perspective, what do you believe creates a successful partnership between a brand owner and a CMO?

Eduardo: I think the best relationships are those that started off by identifying common strategic interest. The CMO is not only strategic for the customer, and I liked very much what Frank said earlier, that there's no CMO that is not strategic.

If the CMO is producing for you, then your reputation as a pharmaceutical company is at stake, even if that CMO only does one package every year. The CMO is strategic for you as a customer. The question is, how can you as a customer be strategic for the CMO?

It's not always a given that you will be strategic for the CMO, and we need to understand that, especially if you're a small pharmaceutical company like us. It's human and it's natural that they will focus on their bigger accounts.

Now, can we identify areas with the CMO where the CMO wants to further develop themselves? For example, we have established very solid partnerships with much bigger CMOs than what we are, but it was because they were not in our business segment, for example. They were not in ophthalmology. They wanted to be or enter the ophthalmology space.

Basically, we took the risk of hiring a CMO that did not have a lot of experience but was highly motivated. We had importance all the way to the CEO of the contract manufacturer, and he was personally involved in making sure that it would work and that our operation was safeguarded.

For me, that is one of the most critical elements, right from the beginning, to establish a good partnership.

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Then the second one, maybe going all the way to the other side, to the operational side, is to be sure that as clients, we make the life of our contract manufacturers as easy as possible.

This sometimes is very small details, such as send your forecast on time, give visibility to the contract manufacturer how many volumes you're going to need for the next 12, 18, 24 months, place your purchase orders on time, be disciplined, give your technical information on time, involve your SMEs on time with the CMO, not only after you already have a deviation.

Most importantly, pay on time. Get your CFO to be sure that your bills are paid on time. If you work on these two elements, from a strategic standpoint and from an operational standpoint, being able to work with your CMO to create win-win situations, I think you're off to a great relationship that can last many, many years.

Lauren: Thank you. You touched upon the importance of supporting your CMO, being aligned, delivering things on time. Shashi, from your perspective, how do you ensure alignment and an incentive between brand owners and CMOs so that each can show up for each other as they need?

Shashidhar: Absolutely. I'll just extend what Eduardo mentioned. I think it's the criticality of shared risks and shared benefit. That's the cultural change manufacturers should work with CMO, that we are equal partners.

While there are MSAs, and contracts, and global statements that we all make about importance, if your product is manufactured and you have no control over it, and the compliance and the financial risks around it is yours.

While we talk about various metrics and KPIs that we want to build in, I think it's important that we build an operating model, build an operational framework saying what is negotiable and what is not negotiable. That is one.

The second most important piece is going to be the trust. Once you start building

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the shared risks and shared benefit model, trust would probably take a better shape.

The other big piece that I see that we are not talking about is, what are the capability gaps that you have in CMO? Why don't we take that assessment and help them to come up the value chain? Because they're part of a value chain anyway.

If you have a better capability, why don't you build that capability with the CMO and integrate that? Probably that will strengthen the partnership, is what I believe.

Lauren: I know a big topic of discussion today, of course, is information-sharing, data-sharing to create better alignment among partners. Eduardo, today, what information do you request from your CMOs and direct material suppliers, and what's the impact of not having that information?

Eduardo: Again, information is a flow in both directions. We need a lot of information from our CMOs very early, for example, on capacity. When we submit our long-term forecast, we want to be sure that the contract manufacturer will have capacity in 18 months or 24 months down the road to supply us.

Then of course, we need purchase order confirmations, but then there's also another layer of information that is a lot more complex, which has to do with the manufacturing process itself. We're talking about executed batch records, master batch records, kappas, deviations, and so on and so forth.

That is probably an area where still, even the big pharmaceutical companies, I haven't seen yet they're being able to digitalize that part of the value chain or of the information flow. I would probably group them in these two big groups.

One, which is a more transactional data, which of course, it probably is easier to automate, and another one where is really the headache, and we have armies of people exchanging information via email, going through thousands and thousands

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of pages of documents to be able to release a batch.

A solution there will definitely, if one day it comes, and I trust that it will, that will be a game changer.

Lauren: Paul, representing the other big player on the stage here, as a direct material supplier, how do you get alignment with both the brand owner and the CMO who you're working with together?

Paul: It's a good question. I think earlier in today, we heard a lot of people talk about that single point of truth for data. One of the issues that we run into often is that we have relationships with both the supplier, the CMO, or in the clinical space, the CRO.
In those instances, if we're not getting good data in in terms of forecasts and utilization, we're either undersupplying or oversupplying.

The importance of good data to us as a vendor and to both players is that it gives us the ability to provide the right information, the right supply, the right material, and when doing so, we can offer more unique and better services, just-in-time services, reusable services that lower down cost, improve ESG goals.

For us, that source of data in real time is paramount to helping our partners be successful up the chain.

Lauren: Paul, another question back to you and Arun as well. I'm sure you also get asked for information and for data from your customers. What is that data, and have you seen any standardization yet coming from the industry on those requests?

Paul: I'll go and then maybe you can pass it over. I don't think we've seen a lot of standardization in the requests. From a packaging provider, we're getting a lot of questions on business continuity, ability to supply, ability to flex up or down as supply chain items change.

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For us, that will vary from group to group, but the important part from my side in a digital stance is to figure out how to provide that information in a reliable, real-time manner up the chain. That bidirectionality of data is very important for us.

Customer A might have a really important one part of the supply chain, it might vary for another. Just that clean ability to pass good data is what we focus on.

Arun: What customers mostly request is just like anybody else, they want to know, "When is my order going to ship?" Just like anybody. When I place an order with Amazon, I would like to know when it is coming in.

Similarly, most of our requests are centered around, "Where is my stuff, and when is it going to ship?" I think that can expose our systems a bit. If you do not have your internal systems all connected, then that information becomes more difficult to pass on to the customer.

Then similarly, other request is like, "OK. What about all the future orders months from now?" That is where, as Eduardo said, capacity planning becomes important. If we get forecast from our external partners about how much they would want to make in the future, then we can size our capacity according to what they want.

Two of the biggest requests, I would say, in summary, is where is my stuff? Then also about future, what are the things that can hamper future orders from being supplied on time?

Lauren: Have there been any information or data requests that you've seen to date either from customers that you cannot provide or do not want to provide, and why?

Arun: I think Eduardo and I were having a discussion just off stage about this, is thinking from a CMO perspective.

The external partner or the customer knows so much about our manufacturing,

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about our process, about the costs of raw materials and all the things. Our ability to make our desired margin depends on how efficient we are, and that would be making payoffs between different facets.

For example, in supply chain, inventory, in manufacturing, maybe having one shift, versus two shift, versus three shifts. All these kinds of things is what we would not prefer to share because we want to know what the customer requirements are and work to that requirement based on what we can optimize internally.

Internal optimization, if you were to reveal that, what happens is then there is this aspect of, "OK, but don't do that, do this." Without knowing 100 percent of what happens within the walls, these kinds of, even though they may be well-intentioned, requests or suggestions, would be counterproductive because they do not know the whole, what are we trying to optimize?

We might do something here and take away something from there, and to get them what the customer wants. Sharing everything within the walls of the CMOs may be counterproductive. That is where I think good contractual requirements, for example, this should be the service level and this should be the back order level. Back order dollars, for example. Those are the kinds of things.

Then incentivize. If you go below this much back order level, there should be some incentive. Consequently, if you have an OTIF below certain targets, some other kind of incentives/penalties. That would make us be more aligned with what our customer wants rather than trying to manage aspects within the walls of the CMO.

Eduardo: We had a chat before, and it was actually a very good chat because Arun is on the CMO side, I am on the customer side. We customers, we always blame everything on the CMO. You guys probably always blame everything on the customer.

[laughter]

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Eduardo: It's fine. We've established that.

Arun: No, we do not.

[laughter]

Eduardo: We actually were talking about a very specific example, which is does the CMO have all the raw materials that they need in order to produce on time?

Of course, this is something that as a customer, I am worried about. Arun was saying, "OK, but why don't you let the CMO worry about that? That's why you outsource this activity. Let the CMO worry about."

When I think about it is yes, if I trust the CMO and if we have built a relationship of trust, then I don't worry about it, but as soon as I see that my CMO is struggling, then I will duplicate the effort, and I will want to know, "What is your inventory level?" to be sure that they have the right raw material, especially the customer-specific raw materials for my production.

This does create some duplicated efforts, both on the CMO side and on the customer side, because there's no trust.

Now here, where technology could help is that when I look at a dashboard, I know that people have gone through the workflow, and they have secured enough raw materials without us as a customer having to call the CMO and actually bring them into a meeting, and ask for a report, and go material by material.

Technology already shows me, OK, for all of these manufacturing slots for the next six months, that has been taken care of, with the exception of this specific date. Then when we talk to the CMO, we only talk about that specific date.

There might be good reasons for it. Maybe the supplier or the CMO has issues and the CMO is actively already working on it. I think this could be one of the advantages of technology, is to focus our time and resources with the CMO to

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solve problems rather than double-checking and triple checking because there's no trust between the parties.

Arun: One final point. Trust is really important, and I think the trust is earned by what you have done in the past. It's the responsibility of the CMO to engender trust in the customer so that they know that whatever we are doing is in the best interest, or at least in the interest of meeting our targets for the customers that we have acquired.

Trust is very important, and I completely agree with Eduardo on that. It's up to the CMOs to engender that trust.

Shashidhar: I think I should have sat there because if you're a CMO and his a manufacturer, I can integrate your problems in one place.

[laughter]

Shashidhar: Actually, that's probably what it is. Just to summarize, we're running short of time. There is a process level integration, then there's a digital layer. Then we talked about the data that comes out of it. Probably the top of it is the trust. That's the focus that we look at.

You build smart quality systems. Can I integrate that smart quality system with my CMO partners as a solution provider? Then you build your collaborative way of doing planning and the manufacturing piece.

There is something called golden batch process, which is, what is the best process? How do I minimize the process deviation that is going to come in? Can I spend the time with the CMO? Build that. These are all tools available that we can actually integrate.

Then comes your entire supply chain layer. The biggest problem in CMO is your planning, your stock inventory, availability, the purchase order gaps. What I heard

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and what I saw in the last two days, probably a product like MINT can, to a large extent, address some of the data issue that we have been talking about.

It takes away visibility. It brings in a lot of transparency, but I think you need to build more solutions around it. Multilayer approach is what I believe. You can integrate this, just not purely on our supply side. The process side, the quality side, and the supply side, I think these are three components of a CMO, is probably what I believe.

Lauren: Shashi, as you called out, maybe you should be sitting in between those two. I know your company also works on aligning IT and business when you work together with them. What are the barriers, from your experience, both business and technical, to be able to achieve this type of data-sharing and information-sharing we're hoping to get to?

Shashidhar: Obviously, the first thing is the cultural barrier, I would say. When I say cultural barrier, I'm talking about misplaced KPIs, misplaced operating models. They're not part of your overall deliverables and outcomes. That's one part of it. The other part of it here is the technology itself is overwhelming.

We talk about AI. We talk about the cost of technologies is expensive. You cannot enforce technology on a CRM or expect them to build a big piece around it. What is important here is -- I keep saying this in various forums -- with the technology trends that we have seen, people think they have the solutions already there, and figuring out the problems. It should be the other way.

Understand the problems, then you build the solutions around it. That's a big piece that we should look at it while there is enough technology. How do you make sure that your point solutioning gives that comfort to the CMOs or any manufacturer, for that matter, and how do you integrate it further?

That's probably, I would say, an incremental approach to address all these barriers of transparency and lack of data coming through, etc.

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Paul: From my end, you asked about one of the issues with technologies. Between different groups, whether it's the supplier, or the CMO, or the pharma, the differences in level of understanding of technology varies.

Earlier today, again, we heard about talking about finding the right people within your organization to implement technology. As a pharma supply chain as a whole, we're slowly moving toward that, but that mismatch of level of understanding stops organizations from talking.

If you have somebody who is very data-forward of talking to somebody who isn't, that disconnect can be very hard to bridge the gap. Once you start to pull that information together, you put yourself in a position to start speaking the same language.

To your point earlier, we have requirements that we all try to work toward. When we get tasked just understanding the requirements and start to understand the why through that better data exchange, better solutions come about from that. I think that leveling up across the board of technology-forward individuals at all parts of organizations will help get us there.

Lauren: Thanks, Paul. All right. I think we have time for probably one or two questions in the audience.

Audience Member: Thanks. My name is Swannan. I have a question for Arun. Which specific areas of the supply chain do you think mean to have the greatest impact, like the logistics, compliance, or the risk management?

Arun: Good question. This is actually a loaded question because which...Impact of what should be computerized first. That was your question. Depends on how good your master data is in that function.

One of the things which I wanted to talk about also is how do we go about this task of making the supply chains smooth and predictable? The starting point for all of

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that is good master data. Then if you have good master data, then we can automate processes and make it more smooth and predictable.

I always think about that all of us should aspire for lights out manufacturing. That means our processes are so smooth and predictable that we don't even need lights to conduct our manufacturing process. If you aspire for the stars, you may perhaps land on the moon.

Now, as to your question, what should be automated first or computerized first depends on what aspect of your master data is complete.

[background music]

Arun: I would say the one which is more complete master data which lends itself to automation should be your starting point.

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