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External Manufacturing: Orchestrating Processes Between Life Sciences Companies and CMOs



Reference

Link: <https://www.tracelink.com/resources/tracelink-university/opus-orchestration-architect-foundations-presented-futurelink>

Tereance Puryear: We're going to dive into external manufacturing. This is the orchestration that probably has just as many transactions as logistics does. From you all's seats, who all interacts with CMOs or is a CMO? Who are the CMOs in the room? We got one. Who works with CMOs directly from their role? One, two, three, four, five, six. OK.

Moiz Khanbhai: Just going through external manufacturing, we've got quite a few people that work on one side or the other side on this particular orchestration. Typically, the majority of conversations we're having with customers at the moment is around external manufacturing. It seems to be, I want to say, a bit of a pain in some respect from what we're hearing.

It's definitely got its challenges. Again, similar format to the other orchestrations that we've been through, these are the transactions that we typically discuss. Now again, like the other orchestrations as well, there'll be some that maybe some companies don't want to exchange with their partners.

In terms of all the lessons that we've learned in terms of talking to customers, this is the full set of transactions starting with the forecast planning schedule going right down to remittance. Quite a few of these we've gone through already. It's the same transaction but a different pairing. This time, it's MAH and CMO that we're talking about and bidirectional.

The same transaction can be used in different pairings of different companies.

Tereance: I had a question. We have a CMO here. We talk about from the MAH perspective of how to interact with different partners. From a CMO perspective in a digital space, how do you all view the supply chain, if you don't mind, from your perspective looking down to your customers who are ordering from you? Is there a digital struggle?

Is there a challenge with the manual interaction of transactions, or any thoughts you want to share?

Audience Member: I'm from Thermo Fisher. I'll be actually speaking on this tomorrow. We do interact with our customer digitally. Some of the transactions which we have put forward, some of them we do. The one that's most important is the forecast because it takes time for us to produce it. Forecast is something which we really look forward to.

Then, after that, is the actual order itself. One of the things which I think we can do better is in terms of when is the product going to be shipped to the customer. Right? Every customer wants to know, "Where is my stuff? When is it going to get shipped?" That is the most important. There is not that much of a visibility.

For example, 90 percent of the items ship on time. 10 percent of the items that do not cause almost 100 percent of the noise. How do we get visibility into that 10 percent because other 90 percent ships on time? Nobody perhaps even sees it. The others is very like the visibility. This is going to ship, or this is delayed because of this reason.

It's going to ship on this particular date. How much in advance can you give that information to the customer? That is what our customer will really appreciate. That's what I think the customers are looking for. Any customer here would like to say yes or no to that?

[laughter]

Moiz: For that 10 percent then, how do you communicate those delays with your customers?

Audience Member: Yes. It is Excel help. When these orders get delayed at all levels, there is communication between the manufacturer, the CMO, and the customer. At all levels, people are trying to figure out why it is late. The planning team will talk with the customer-service team and then up the chain.

I would say, there's a lot of work for that very little return because that data doesn't exist in a format that can be shared easily with the customer. That is why we have this struggle. I've seen this in multiple places. That is where, if we can take care of that and have something like what...I don't know if I can name my previous to previous to previous employer.

[laughter]

Audience Member: They did what is a project called WIMS -- Where is My Stuff? It was a three-year...

[laughter]

Audience Member: It was a three-year endeavor so that whatever happened inside was communicated to the customer. At any point of time, whether you call or whether you look online, you'll get the same exact info. What we saw was the amount of calls to our customer-service team really decreased because of this. It was available online. It was accurate.

Moiz: Online. You mean through some sort of portal...

Audience Member: Portal. Exactly.

Moiz: that was built in-house?

Audience Member: Yeah.

Moiz: All right. There was a team managing that portal, making sure it's all up to date...

Audience Member: Right. Basically, it was getting the data out of SAB.

Moiz: All right. Brilliant. Thank you.

Audience Member: OK?

Moiz: The last couple of transactions that we haven't discussed is forecast planning

response. You sent your schedule out. Did it get received? Has it been checked? You want some sort of response. We're hearing this all the time in similar format. We've got key data fields there. The response today is maybe a telephone call.

[laughs] It's crazy that today we actually hear companies using WhatsApp. Great for social communication, but...

[laughter]

Moiz: I'm not sure it's great for real business. It's true. People are using it. Going back to fax, sometimes it's still fax machines. Getting your forecast plan response directly into your system of record, your enterprise system, is something that's absolutely key and what customers really want to receive.

Then batch creation. This is also quite tightly linked to some of the batch-creation transactions we also have on our tracking trace side of the solutions as well. Just a show of hands or anyone can explain, did you receive batch-creation transactions today from your CMOs?

Woman 1: I'd imagine that's a lot of headshaking in that.

Moiz: Yeah. [laughs]

Woman 1: Would you like to?

Tereance: Spreadsheet PDF?

Woman 1: [laughs]

Woman 1: Spreadsheet PDF? Any batch data come over once a batch is completed?

Moiz: Because you want the batch number.

[crosstalk]

Audience Member: It's too late. Right? It's later?

Moiz: Right. What's too late?

Audience Member: I mean it's not on the day or the day after that it has been produced. It's rather in a month or whatever.

Woman 1: [laughs]

Woman 1: Because the batch number or the lot number is put onto your products through production. Right?

Audience Member: Exactly. They should tell us immediately, right?

Moiz: Right.

[laughter]

Audience Member: We've created this.

Moiz: Sorry to pick on you, Thermo Fisher. Sorry. What would you do with this as a CMO in terms of giving that batch details to MAH customers, if you don't mind?

Audience Member: Like he said, by the time we create the batch, for the ones for which it's on time, it doesn't add value to them. For the ones which are late, it's too late by the time we create the batch. Basically, it's already late. The thing is that a batch creation, for us at least, is that there are multiple batches which are created, but they are not for the finished good.

It's for the in-between steps. Batch creation by itself may be helpful, may be confusing.

What would be good is, "Hey. When is my order number Y, line number X, going to be delivered?" That is what the customers are looking for. Batch creation may be helpful. It can be confusing, too, because there are a lot of batches which are created which go into the finished good.

Moiz: Correct. I suppose it depends on the volumes as well and how many batches that particular MAH is putting through your company as well. That can also be managed directly through your enterprise system on the MAH side and how that's set up within your ERP system. Again, if you're working manually, that can be quite challenging.

Having the data feed through digitally can definitely help with that overall process. Any other thoughts or questions?

Tereance: Is there a quality person in the room? [undecipherable] OK. We hear from a lot of the quality professionals as well. Having the batch data would help them do a lot of work that they do manually today. They can do it a lot quicker. They have the batch information on time. They do quality checks.

If there is a recall, they need information around it. To the both points made, it can be cumbersome. In a digital format, once you understand what data can come across in a batch file...I mean batch-creation file. I'll delineate those two. Batch-creation file, you can now look at your other organization and say, "Who uses this data?"

I think it was around this last transaction. That's a lot of the thought we think about with these transactions. As you look at the data fields that are possible in here, you can reach out to other departments -- finance, even IT if you think about it.

Finance, IT, supply-chain quality, the warehousing supply-chain product groups, what data can be used across multiple areas in your business that may be...I won't say buried. It's a subset of information that you didn't know your counterpart even used. Keep that in mind as we talk through the remainder of these.

Moiz: Again, we've discussed the purchase order, the invoice, and the remittance advice. We're not going to go through all of these transactions again but can be used in this external manufacturing financial flow. Likewise, the forecast-planning schedule we spoke about in the previous orchestration and just went through the response now and then batch creation.

One thing I just want to highlight on the inventory side of things is we have a lot of conversations today around MAH buys API material or excipient material on behalf of the CMOs. Just a quick show of hand, who does that here or who outsources it to the CMO to buy all the raw materials for the products? Was it a mix of both? You purchase it or do...

Audience Member: Not all of it.

Moiz: Not all.

Audience Member: Some part of it purchased by the...

[crosstalk]

Moiz: OK. There's some government agencies that demand a report within 24 hours on materials that are issued, produced and consumed, which is a flavor of the inventory transaction that we have here and was something that tracing supports today as well. You have 24 hours. This is specifically a customer I was speaking to in Germany.

They couldn't do it in 24 hours currently with the all the manual spreadsheets, emails going through different inboxes. Some people were on leave -- all that usual stuff that you hear about. Then you're fined by the regulations if you can't support or show how much API was

sent, how much was used, how many kilograms of powder, for example.

It can become very, very difficult, especially if you have a large SAP, ERP. It's hard to get that data out. Having those transactions that supply that data in an area with your ERP that you can easily surface and run a report...

[background music]

Moiz: can save you time, save you money, and be compliant with the regulators.