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Transforming Track and Trace at Enterprise Scale: How Amalia Technologies Guided Fresenius Medical Care's Transition to TraceLink

Featuring Thrasyvoulos Kotsonis, Managing Director at Amalia Technologies

Fresenius Medical Care's successful transition to TraceLink for track and trace required more than technology—it demanded a unified, trust-driven partnership. Thrasyvoulos Kotsonis, Managing Director at Amalia Technologies, shares how the organization navigated divestment, untangled complex legacy dependencies, and activated new greenfield capabilities through strong governance, empowered teams, and disciplined Mission Control oversight. He explains why TraceLink's platform and OPUS-based digital capabilities offered a more scalable, future-ready foundation—and highlights the behaviors that make large transformation programs succeed: clear requirements, early communication, and cross-stakeholder alignment.

Key Moments

- **00:12 -** How did Amalia Technologies get involved in Fresenius Medical Care's

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transition to TraceLink?

- **01:22 -** What made the partnership between Amalia, Fresenius Medical Care, and TraceLink a success?
- **02:17 -** Why did Fresenius Medical Care move to TraceLink for track and trace?
- **03:29 -** What were the key learnings from Fresenius Medical Care's transition to TraceLink for track and trace?
- **04:45 -** How do you see TraceLink expanding its value beyond compliance?
- **05:27 -** What is your advice to organizations starting a track-and-trace or supply chain digitalization project**?**

Watch the full interview above, or explore some selected highlights below.

How did Amalia Technologies get involved in Fresenius Medical Care's transition to TraceLink?

Fresenius Medical Care’s divestment from the broader Fresenius group required separating from shared serialization and track-and-trace systems. Thrasyvoulos Kotsonis describes how Amalia Technologies led this transition—providing project management, validation, and technical expertise to support the organization’s move to TraceLink and the implementation of new greenfield track-and-trace capabilities.

Why did Fresenius Medical Care move to TraceLink for track and trace?

As Fresenius Medical Care reassessed its track-and-trace approach, the organization sought a platform that reduced operational complexity and made ongoing changes easier to manage. Thrasyvoulos Kotsonis explains why TraceLink’s platform—supported by deep regulatory expertise and OPUS-driven

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digital capabilities—offered a flexible, future-ready path.

What is your advice to organizations starting a track-and-trace or supply chain digitalization project?

Before embarking on any track-and-trace or digitalization project, Thrasyvoulos Kotsonis stresses the importance of clearly defining your processes and requirements. He explains why early, precise communication with partners—and giving teams ample time to plan resources—is essential for coordinating stakeholders and ensuring a successful, low-friction implementation.

TRANSCRIPT

TRANSCRIPT

The most important thing that made this project a success was trust and the partnership modality that was created between all the teams.

Fresenius Medical Care is a medical device manufacturer primarily, but it also has some fluids that are used with their devices, and those fluids require sterilization.

Fresenius Medical Care was part of the Fresenius Organization, but have started a divestment process for the past two years. The organizations were quite connected using the same serialization systems based on SAP systems. Fresenius Medical Care has been divesting from the Fresenius Organization for the past two years.

They were quite interconnected using the same systems for serialization and track and trace, and now are in the process of moving from SAP to TraceLink. Here's where Amalia came in about 15 months ago, where we started the project to support them in this transition, to consult them.

We brought project managers, we brought a validation team, we brought

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administrators. We're supporting the whole transition from SAP to TraceLink and implementing several greenfield projects for track and trace.

The most important thing that made this project a success was trust and the partnership mentality that was created between all the teams. This was a huge project. It included several departments within the organization itself. It included a lot of the partners, be that CMO or even other technical partners other than TraceLink.

Having that trust and having this mentality that all the partners are part of the project and can contribute was really important. We defined single points of contact everywhere. We empowered those people to actively take a role in the project we're dealing with and to include things they would like to improve throughout the project.

That has made us quite successful and has allowed us, now that we're going live with the project, to make it happen within the timeline defined by upper management, which was quite short.

Fresenius Medical Care was using SAP supported and supplied, let's say, by other Fresenius companies. The SAP can be quite bespoke, can be quite complicated and expensive to manage. It requires a lot of resources to be there to operate and every small change to develop it and roll it out.

It also requires supportive systems like SAP Solution Manager, especially if you're using the Focus Build functionality, to be able to do your change management, documentation, everything within that place. Not that the systems are exactly mandatory, but they are advisable to do. That creates a huge, huge team requirement to be able to manage that whole thing.

It was quite simple, I think, for Fresenius Medical Care to decide to go to TraceLink, a software as a service supplier and a provider and quite knowledgeable team from TraceLink about all the regulations on track and trace, but also with the

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capabilities we're seeing now with the OPUS platform for POET, for MINT, to really go a step further from track and trace and enhance your supply chain.

Throughout the project, there were many, many learnings from the team being set up anew. Bringing people completely that haven't worked before with one another together and creating that governance, which was quite important.

We got a lot of issues coming into it from processes that we weren't aware of, or maybe in some cases, the organization wasn't aware that we had to implement. There were a lot of findings, "Oh, this also has to happen, and this also has to happen."

For us and for this project or program, it was important to a tool that we created and we called Mission Control. In Mission Control, we were able to bring our RAID log and have all the information there and track them. We were able to have our stakeholder management with power/interest matrixes.

We were able to have our cutover plan, our high breaker plan, our test strategy, our documentation tracker, our lessons learned to be happening throughout the project.

By having it as an Excel and not a more complicated system, we empowered the team to add information on a day-to-day basis. That was quite key for us to be able to overcome any challenges we faced.

TraceLink, in my opinion, has made the right move, moving a little bit beyond the track and trace and regulatory mandatory kind of thing by going and seeing what pharmaceutical companies and life science companies really need, and by really working with the network they have already created.

Here, we've worked quite a lot both on MINT projects and POET projects already, and we see how that can have an impact on the ability of teams on the ground to manage their day-to-day operations without a lot of burdensome manual email and

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spread seductions.

My advice to anyone starting to work on any project, be that a track and trace project, be that a greenfield TraceLink implementation or a more mature or even a greenfield MINT or POET implementation, first, learn what you want.

If you don't know what you as a company, as a group, as a team need to be doing, you can't move forward. When you know what you want to do, when you have defined your processes, you have defined well your requirements, communicate that early to your partners.

Everyone has a life and a daily business they're doing. You can't go to them a week before and go, "Now we need this." Notify them three months in advance so they can plan their resources accordingly. It's the humane thing to do.

Communicate clearly exactly what we said before, what you want, when you want it, what does that mean for them. That makes a difference, and that makes any project that has to do with a lot of stakeholders and a lot of different teams a success.

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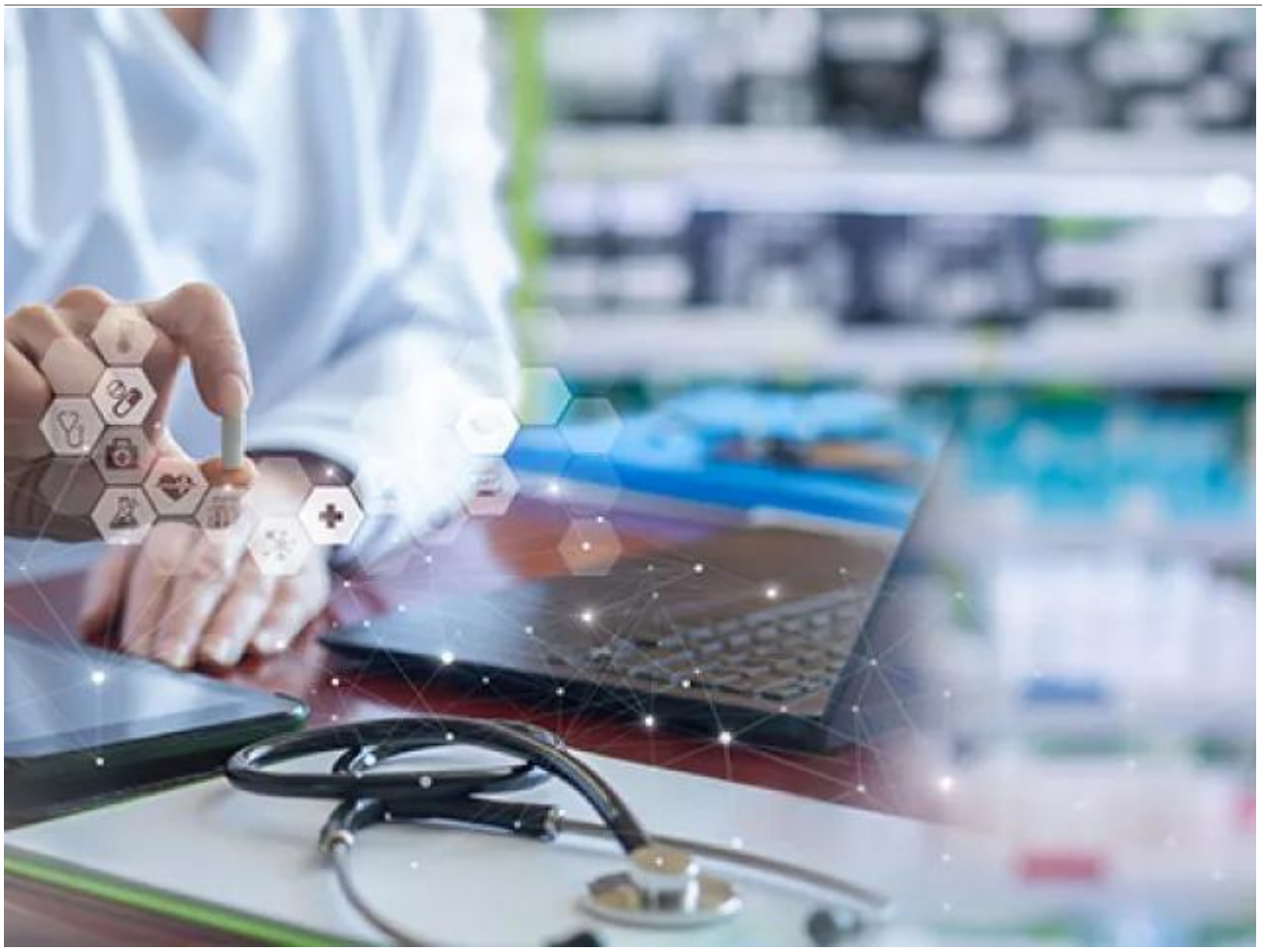
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