

Emerging Global Track-and-Trace Regulations and Building a Flexible Global Compliance Platform

Serialization, track and trace, and related compliance requirements, such as e-Invoicing and e-Leaflets, continue to evolve across the globe. These regulations and their related business requirements put significant pressure on supply chain, operational, and IT leaders to ensure continuous compliance while meeting business performance and KPI goals. This session covers:

- Insights on new and evolving track-and-trace and related regulations.
- Lessons learned from more than 10 years of meeting diverse serialization, traceability, and government reporting regulations.
- Guidelines for creating a comprehensive yet flexible global compliance platform that can orchestrate compliance data exchanges and business processes while meeting “business-as-usual” operational requirements.

Speakers also provide recommendations for how companies can prepare for compliance while creating a technical and operational foundation to take advantage of these investments to create supply chain value. Watch the video to learn more.

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Featured Speakers:

Lars Boorberg

Senior Specialist Supply Chain Compliance & Risk Management

Cheplapharm Arzneimittel GmbH

Gert Vleugels

Director, Head of CoE Track and Trace

Merck

Zeeshan Ahmed

Founder and CEO

CosmoTrace

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Allan Bowyer: What I'm going to do is ask each of our panelists to come up one by one and introduce themselves. I'm Allan Bowyer. I lead community for TraceLink, and I'm leading track C for today.

This session is about compliance platforms and actually taking advantage of the investments many of you have already made in the past 10 years, and putting them to work for tomorrow. We're going to have three points of view on this topic. Without further ado, we'll begin with Gert. Gert, tell us about yourself. Come up and present yourself to the audience.

Gert Vleugels: I'm Gert Vleugels. I'm leading the COE track and trace of Merck, and I've been leading for over 10 years the track it program for Merck, working since 2014-'15 also with TraceLink.

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Allan: 10 years is about right when we say it.

Gert: 10 years is about right., yeah.

Allan: Good. Lars, would you please take the second seat next to next to Gert? Lars, tell us about yourself. What is your role?

Lars Boorberg: My name is Lars Boorberg. I'm working at Cheplapharm. I came to serialization by accident, to be honest, but I'm now three years with serialization, into it. I was responsible for the whole Cheplapharm group in terms of that, for the whole serialization topic. I did some projects in that field together with CosmoTrace, and that's why I'm here speaking about my experience.

Allan: Wonderful. I think you have a partial introduction. Zeeshan from CosmoTrace. Tell us what you do, Zeeshan.

Zeeshan Ahmed: Hello, everyone. I'm Zeeshan. I'm the founder and CEO of CosmoTrace. We are a consulting and services company specializing in product serialization. We're headquartered in the UK with offices in Europe, US, India, and the Middle East. We support a lot of TraceLink customers on serialization operations and different activities.

Allan: We're going to talk about learnings from the past 10 years, but we're not going to go overboard on it. We actually want to be very forward looking. Before we do that, I want to hear both from Gert and from Lars just a little bit about your businesses. What type of patients do you serve? What are the main challenges you've been addressing in the last 10 years in your role?

Gert: I'm from Merck, not as Joel said, the real Merck but the original Merck, the German Merck. It's all prescription drugs, or we're selling products world to world. We started implementing track and trace before 2010, starting in China, and then in 2011-2012 for Turkey. After that, we set up our process to implement worldwide in a global approach.

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Allan: Lars, how about Cheplapharm?

Lars: Cheplapharm is mostly in the M&A business. We're acquiring products from Roche, from AstraZeneca and all these big pharma companies. Also something, a note from the past, we integrated in our portfolio, it is sold the next 10 to 15 years, and make it sustainable in the supply chain.

In new serialization requirements upcoming, I was responsible to integrate them in the portfolio. Also, when new CMOs are coming, they needed to be integrated in TraceLink. That's what I'm basically doing.

Allan: Back to you, Gert, -- I will get to you, Zeeshan, in just a moment -- you mentioned Turkey. Turkey was the pioneer in a national traceability mandate. What do you do differently now that you didn't do when Turkey was coming on the horizon?

Gert: We do everything different.

Allan: Do tell.

Gert: When we started with Turkey, there was nothing implemented on our lines. We had nothing global so we outsourced. We sent products to Turkey, and we had a local partner that was doing everything, serialization, aggregation, and reporting.

For what we're doing for other countries now is, we centralize, we do everything internal. We're also back sourcing, I'm not sure if it's the right term, what we're doing in Turkey, bringing back the activities of serializing and also reporting as much as possible directly internal.

Allan: Was there a certain point that you said, we can't outsource traceability, for example, we need to centralize? What was the critical tipping point for your company on that decision?

Gert: It was mainly the preparedness or readiness for Europe where we saw this is

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a big market, we can't just send to every country and try to find a solution. We need to find a global solution and try to find our way. How are we going to make sure that we serialize, that we put data matrix, that we standardize, that we do everything in one single way?

That's what we convinced the company we need one global program to set this up company wide, which was initially looking at manufacturing, but then also the reporting and the supply chain.

Allan: Lars from what you spoke about the Cheplapharm business model, you're inheriting, maybe inheriting is the wrong word, but acquiring products, and perhaps, that were being serialized by different processes. What is your approach? Do you harmonize everything centrally? Do you leave the serialization as it was? How do you manage all of these new products coming into your portfolio?

Lars: The idea of Cheplapharm is to keep the products mostly as they are, as we get it. We don't want to change a lot. We take it as is and integrate it in our system. However, we can't have this full global picture, we need to be agile on it and flexible because every new product brings new requirements, new challenges with it.

We need to be flexible on it and also align with the partner how we do it if we serialize it or not, if it is required, and if it is upcoming also in the next year. It's an ongoing discussion and communication during the projects we are doing, how we deal with it. There's no one fit all solution for us.

Allan: Thank you. Zeeshan, maybe you can speak a little bit to how you you've been helping Cheplapharm and Lars navigating this, I know it's a the wrong word, inheritance, but managing all of this data worldwide. What is your approach?

Zeeshan: To answer the first question where you said, what has changed since 2012 with Turkey? There have been a lot of companies which have come up, lots of different regulations. Every regulation is not the same. We started with

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serialization, then we had aggregation, and then comes Russia, which is crypto codes. It kept changing, and it's still evolving as we go.

The companies, likes of Cheplapharm, falls into tier two bracket. When you look at the tier one companies, they have mostly tons of people internally doing things. They have an ecosystem which is self-sufficient, but when it comes to growing companies like Cheplapharm, they're always growing. It's like Lars said, they're adding more products to the portfolio.

The right word to use is they have to be agile. What they have seen and which we collaborated nicely with it is, they don't want to hire a lot of people for this to onboard all the companies. This is where we come in as expertise, bring in for Russian, for other markets. We help Cheplapharm and other similar companies with onboarding activities, troubleshooting, managing their alerts, exceptions.

We get into the end-to-end serialization. It really helps from a Cheplapharm perspective, and I'm sure Lars agrees that there's a continuity. It's not just providing resource to do all the activities, but have a COE behind it so there's always continuity for the customer. If somebody changes, goes on a vocation, then we have our team who takes it up.

One of my colleagues is attending the future link, but then the operations for Cheplapharm is not disrupted because we have the backup who just jumps in and does the activity.

Allan: You said COE, Gert, does Merck have a COE?

Gert: Yes. I'm leading the Merck COE of track and trace. We started scattered in the organization. We had a big project, as you say, so not a small project, which was based originally in engineering to, let's make sure the lines work and then to try it front and wait, get to the system.

It was engineering IT, but then after a while we said, no, this is a supply chain

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topic. We moved to supply chain and then from the projects phase, we moved also to the operational phase. For the operational phase, we say no, we need a COE to follow-up what is happening worldwide.

We're very happy joining the TraceLink meetings, this is happening, that's happening and of course also with GS1. We learn a lot of what's happening in the world. We centralize everything in this way to make sure...

[crosstalk]

Zeeshan: Just one comment to add to Gert and put a very valid point here from implementation to operations, and this is where a lot of companies we see struggle because every company started with the EU FMD, a lot of companies and a lot of customers sitting here probably. Somehow, a lot of them come from supply chain, a few from IT, and they somehow managed to implement it.

When they got to operations, it was a different world altogether. Now they're saying, we have done the implementation, and there are a lot of many things coming up now, things such as partner onboardings, things such as dealing with issues. They're sitting there thinking, I do my supply chain job, and now I've got to troubleshoot this file, I'm no expert, and I don't do this.

Also, what happens is, when there is a person working on these activities for three, four years, they leave, and then there's a big gap. It's different challenge from implementation and operations. I think operations is the bigger piece where companies need support, they need a bit of hand holding and the technical expertise where...

Allan: I heard operations, organization processes. The one word I haven't heard yet is data. I imagine, like many companies, you've amassed gazillions of terabytes of data over the last 10 years. Does your company have a data strategy? I'll start, Gert, with you. First of all, do you have a data strategy, and what is it?

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Gert: For the strategy regarding using data of track and trace, so that's not really completely my field, that's more, Alessandro and Marco who were presenting yesterday, how can we use it? We have been in discussions also in the past with tracing, how can we use this data, because there's a lot of data out there.

In the past, we had just sales, and normally, we had quantities. Now in theory, we could potentially know every single product where it is. We don't. We have had discussions how can we use this, how can we know where our data is as companies.

In the end, we currently pay quite a lot also to external companies to tell us where our products are while the data is already out there. It's still an interesting topic to try to find our data and where our products are.

Allan: Lars, I'll ask you the same question because you're amassing more and more data as time goes on. What are you doing with that data?

Lars: To be honest, we were really focusing on implementing all the countries and the serialization in these countries. Certainly, we left some potential there as well during the wave.

Merck is ahead of us of obviously in these kinds of things, but that might be the next step for serialization as well to gain this data and see the potential out of it, what can be done, and explore the possibilities there. That's where we are at the moment.

Allan: Maybe there's been a lot of talk about there's data, but then there's also the network and the connections through which data is exchanged. How have you maybe leveraged the network over the years Gert, with Merck and your different trading partners, CMOs, etc.?

Gert: We had an initial locally developed solution as a repository. We started working with TraceLink when we realized we need to connect to our CMOs. That's

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where we started working with you. Then after a while, we realized it's a good solution. I'm not trying to sell to you. Also, we needed to connect to our partners.

We're connecting also with our CMOs, not just for serialization data, but also for exchange on other documentations with CMO collaboration. Now in multiple countries, we are connecting with our 3PLs, our distributors. It's not a requirement in Europe, the aggregation, but some hospitals do have the requirement.

In some countries in Europe, this is a little bit more important for us where we see, there might be a risk in case we lose standards. Even if it's not a requirement, it's still an important factor, the potential of delivering aggregate information, so we get connected to some of our 3PLs in the countries. What was the rest of your questions? Sorry.

Allan: It was about not the use of the data itself, but the use of the connections to the network you created. I think you explained it perfectly. Lars and Zeeshan, I'll have you comment. I know you're actually implementing MINT for some transactions, and I'd like to hear about what sparked that.

Zeeshan: On the data part, like George said yesterday, where he said, your service providers have the data, ask for it. There is data, and tons of data, that every company is sitting on, it's just not utilizing it. To add to Lars' point as well, there are so many regulations, so many things that these companies have to do.

I think they still haven't got to that stage where they sit back, reflect, and say, I've got all this data, how do we use it? I think one country finishes and then other thing comes up. These are the regulation that happen, but then again, apart from that and on the question about the network value, when we talk about MINT, I'll put that into three buckets. How I see it is, one is you have the visibility.

Basically, you have the visibility of end-to-end supply chain, that's the first part. The second part I would say is collaboration. You're collaborating with your partners. You have clear visibility, you're collaborating. The third part is the

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analytics. Basically, you're having the reporting and the dashboard. If you have that network already in place, we see our customers jumping on the train to supply chain visibility.

Definitely, there will be effort in there where TraceLink would take it up, but also there will be effort on the other side wherein they would need some support in trying to build up the reports, trying to build up that data, the dashboards, where probably, we will be looking to help customers on the ERP side as well for from this side.

Allan: Understood. Lars, Zeeshan was a little bit explaining about some of the criticalities, the operations, and data analytics. I know you've been involved in some of the early MINT work. What was your business objective for using partner collaboration in MINT?

Lars: We had some experience already with serialization in this digitalization field. With that, we learned that large data and large amount can be done also that way, and it's another approach how to work with data. Normally, we do a lot of emails, a lot of meetings and calls, but you can do this much faster, for example, if you use a digital solution there.

We are saying, maybe we take the serialization approach we had to do by accident or by regulation, take it in a step forward, also digitalize our supply chain more, and use the processes we have already in a manual way, more in a digital way.

Allan: Thank you. We're going to shift gears just a second here because I want to look towards the future. It sounds as though we're at the beginning steps of using data and the network connections. We haven't taken full advantage maybe quite yet. Hopefully, in the next couple of years, it'll be a very different story.

Let's get back just one second to the future of serialization and supply chain digitalization. What scares you? What do you think is coming up as the newest challenge, or is it all old hat, like been there, done that?

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Gert: No. There are still quite a lot of things ongoing. We'll see what happened with Italy if they really want to connect, also the Bolino, which I think it's impossible. Then there's a lot of discussion ongoing in Europe also. It's included in the new pharma legislation, primary pack coating, which isn't serializing yet, and hopefully, will not become.

Also South Africa, the draft regulation at primary pack coating and serialization. We're now implementing at Merck for Canada because of an agreement in the pharma supply chain in Canada. There are several countries that are working in this direction. Then there is of course everything that is electronic information or electronic leaflet, is it possible to use?

We already have a lot of data, so we have digit in, we have the batch numbers. Can we link this somehow with electronic information? It's already there, so why recreate it?

Allan: What is the challenge there? I often hear supply chain professionals like you saying, oh my gosh., we had to change the leaflet, we had to redo the boxes, etc. Why not push for electronic patient information? Isn't it easy to do?

Gert: Technically, I guess it is. From a regulatory perspective, the health authorities have probably some doubts. Also, not all patients are digitally literate enough to use their device and see where is this coming from?

Do you want an application in your phone from Merck, an application from Cheplapharm, and an application from GSK or whatever, or do you want some kind of global solution that works for everyone and you don't have to download 10. Hopefully, you don't need 10 different medications?

Allan: Well, I was just reflecting on, many of you probably came to this conference and maybe there was a prescription medication that you brought along with you. How many of you also brought along the leaflet? Would you go back to that leaflet to be able to look for information? You'd probably be looking for it on your phone,

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but as you said, maybe it's a different demographic here.

Gert: Yeah. I think here it's a very different demographic.

Allan: Lars, I'll ask you the same question. Is there a particular regulation or maybe upcoming requirement that you say, we haven't seen that one before, or have you fought all of those battles and nothing's new anymore?

Lars: As I learned in the last three years, in this field, there's always some change and always changing. The moment you think you are done with it, you will see a new regulation or a new requirement where something comes up.

I think the field of serialization will not stop, it will expand and will change ongoingly. You need to have a road map about that, what is going on there, and the vision, where you want to go and where you want to build the serialization there, and that's the point.

Allan: Zeeshan, you've helped many companies, not just Cheplapharm. I wanted to understand what organizational models have you seen to support the types of ambitions that Gert and Lars have expounded? Things about using data or collaborating with trading partners, with CMOs, etc., what works organizationally? Is it a dispersed model? Is it a centralized model?

Zeeshan: I think it is more centralized model, when you have that. Again, it depends from companies to companies. They've got different set. There's smaller companies who are just one person doing everything. Then there are companies who has got few people around there. It really depends.

Again, I think what is more important is the collaboration or working together with the people involved in serialization. The companies that has internal lines, you see a lot of times they're working in silos. What works great, and which we have seen from other customers, we work with CMOs, MHs, 3PLs, we've seen all kind of different parties.

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When you have that collaboration, when you have that interaction, it works best. The most important thing also is to standardize things, have SOPs, the processes, documentation. Like I've mentioned before, there's one person doing everything, and everything in his or her head.

There isn't any documentation there to manage these things. It is always important to have this documentation and knowledge sharing within the business.

Allan: Thank you. I'm going to let the audience launch some questions at you. Who would like to ask our panel a question?

Audience Member: I'd like to ask a question about the electronic leaflets that you touched upon. Have any of you worked with Asian markets that are actually pushing a lot more? I think Japan is already actively endorsing things, Taiwan, Singapore. Have you done any work on that?

Gert: Well, it's already implemented in Japan, so it's mandatory I believe. At least, we implemented in Japan. We're discussing also currently internally how do we want to do this in Singapore. In Japan, it's an easy solution because it's driven by the health authorities. You have also the app that is developed by the health authorities.

You have the storage, I believe, is also driven by the health authorities. It's all based on GS1 standards. It was developed by the industry together with the health authorities. For others like Singapore, you need to store it on your own website or your web page, whatever, so it's a little bit more complex. We're working on it. We're looking at several countries currently.

Audience Member: Thank you. I think a question more for Gert. You've been talking about the COE. I presume it's center of excellence.

Gert: Yeah.

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Audience Member: What kind of questions do you cover at your company. What other departments do you involve? Because with serialization, it's new and the regulations are changing. I'm just wondering how we can change reactive approach to proactive approach?

Maybe you have already in your company some ways of working how we can do better serialization, be more proactive and apply different best practices. Thanks.

Gert: Thanks for the question. I'm not sure I will answer completely, but partly also referring to something that Zeeshan said, of people are leaving sometimes. Now we have the advantage in Merck that the program that we set up to implement track and trace was also led by me, and now the COE is also led by me, so it's a continuum. That's an advantage.

Also, when we set up the program, we involved, of course, engineering, supply chain, warehouse and distribution as part of, but also engineering, regulatory affairs, government affairs. We still have all these connections. Also, we have still our weekly meetings with all the departments involved to make sure that we follow-up.

We're participating to multiple platforms like those from TraceLink or from GS1 on what is ongoing worldwide on track and trace. Quite often or most of the time, we're informed in advance of our local regulatory affairs of what is coming.

It's a continuous effort to find out what's happening in the world. If you look at South Asia, Kazakhstan, Azerbaijan, we have a lot of exchanges also together with other companies on what they are doing. It's quite a big network also of companies that are working together, experts from other companies that are working together also to share information.

Allan: Lars, maybe could you provide your thoughts on that question as well? How do you cull knowledge and implement best practices for the multitude of products that you have as well?

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Lars: What we always did in serialization to bring the different departments together, similar to Merck, we have weekly meetings with several departments, regulatory affairs, but also quality and information technology specialized in the TraceLink application to have some kind of exchange there and also get updates about regulatory changes there.

Sometimes it's not 100 percent clear what the changes are and what the requirements are, so there needs to be a continuous flow about information that is maybe best done in weekly meetings.

Allan: We're almost at the end of our allotted time. I'm going to give you each 30 seconds to tell the audience what you want them to remember.

Gert: Well, they're looking at me, so you want me to start.

Allan: Zeeshan, we'll start with you, and then we'll make our way back.

Zeeshan: For me, a couple of things to remember is prepare in advance because the regulations are evolving, and this will spread. We're just talking Europe now, a few countries, China, Russia, but then the whole Africa is there, so that's going to come. Asia is there, that's going to come. If you're a multi-market, if you're supplying in different markets globally, then you got to be prepared.

It takes more time than we estimate. Be prepared in advance. Have some kind of support system which can provide you updates on what's happening in different countries or local support. Probably from a CosmoTrace perspective, when you're managing different things which is less value add for you as probably a supply chain manager, doing alert management might not add a lot.

Probably that heavy lifting can be done with your partners or help them with these activities.

Allan: We didn't really touch so much on alerts.

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Zeeshan: Yeah, your favorite topic.

[laughter]

Allan: It's just a well-worn topic. Lars, what are your words of wisdom for our audience here?

Lars: I think you need to be open also for new opportunities and challenges. You need to find solutions at the end of the day very quickly. Being creative is also something you need to consider in serialization to bring your projects to a successful end.

Allan: Gert, the final word is yours.

Gert: Thanks. Partially, Zeeshan touched about it because we're working on track and trace since many years, most of us are. We implemented track and trace for about 80, 85 percent of our products or 85 percent of the markets. The last 15 percent or last 20 percent is still important because that's in the end what we're doing it for.

We're doing it for safety of the patient, and that's what I believe we all need to keep in mind every day.

[music]

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