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Rising to the Challenge of Russia Compliance: An Interview with Santen Pharmaceutical's Pasi Kemppainen





Russia's serialization and track and trace regulations—characterized by complex reporting choreographies and an enormous reporting burden placed on manufacturers—are the most demanding in the world. But Russia is also the fastest-growing market in EMEA for Santen Pharmaceutical, says Pasi Kemppainen, Director and Head of Global Supply Chain Traceability and Digital Strategy for the Osaka, Japan-based manufacturer.

*That's why **achieving serialized operations excellence in Russia**—and avoiding or mitigating costly compliance issues—is a top priority for Santen, which recently shipped its first serialized products into the country.*

*TraceLink's **Serialized Product Intelligence** team interviewed Kemppainen to find out how Santen is managing through the compliance issues that arise as its serialized products flow into the Russian marketplace for the first time. He also shared his thoughts on how Serialized Product Intelligence could potentially help*

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companies like Santen successfully navigate ***Russia's challenging regulatory environment*** *in the future.*

What kind of information are you tracking most closely as your serialized products move through Russia?

Pasi Kemppainen: We want to closely track, not actually the serial numbers, but the number of logistical units and products we are shipping. You can imagine that when the customs check is being done by the customs official, they will check potentially to see how much product is on a truck versus what's been reported in the system—and those numbers need to match.

The customs officials want to know, first of all, what products are there, and what is the total amount per product. They also want to know what the amount is per truck. We need to have the same information from the serialization point of view. **If the numbers don't match, they will block the shipment until we have solved it.**

If we have been planting trees with serialization and traceability, now we are seeing the forest. It's time to take a walk in the forest and get real value out of the data, out of the network, and out of the capability to connect with our partners.

What happens after the product successfully passes through customs in Russia?

Kemppainen: The next place where it could potentially get blocked is at our 3PL when they start scanning the Serial Shipping Container Codes (SSCCs) at the pallet or shipper case level. For example, if for some reason the CMO hasn't reported all of the SSCCs to us, it can cause problems. We had a case where that happened, actually, and so the reconciliation wasn't 100%. As a result, our Russian 3PL couldn't accept that delivery until we solved it.

What are some of the other compliance issues you have run into in Russia?

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Kemppainen: We have one case of partial reporting at the moment. We just noticed recently that there were three pallets of this product. Two of the pallets were reported correctly, but the last pallet was reported only partially. We are investigating to find out the reason because partial acceptance means the product is stuck until the root cause of that issue is resolved.

We also noticed that one of the shipper cases was partial as well. Our requirement for all of our CMOs is that we don't accept partial shipper cases. We only accept full shipper cases and that is our minimum selling quantity in Russia. We need to understand why they are sending us partial shipper cases, because we are not able to sell it. But these things happen, and they will happen.

Do you think Santen could potentially benefit from a solution like Serialized Product Intelligence, which is designed to help you proactively monitor the serialized supply chain and speed up the root cause analysis and resolution of compliance errors?

Kemppainen: At Santen, we have been working with serialization and traceability for almost four years now. And we have implemented this globally across different regions and connected with a lot of supply chain partners, from manufacturers, CMOs, and CPOs to 3PLs and wholesalers. But we haven't really had time to look at the big picture and see how we can use the serialization data to drive value. Any time we have needed this data, it has been really challenging to get the information, and when we get it, it's not as consistent as we want.

Serialized Product Intelligence provides us a fantastic opportunity to have all the serialization data available for our operations in real time. If we have been planting trees with serialization and traceability, now we are seeing the forest. It's time to take a walk in the forest and get real value out of the data, out of the network, and out of the capability to connect with our partners. We are really stepping into a completely new era here, and **I'm really looking forward to checking out Serialized Product Intelligence in more detail at Santen**.

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