RESOURCES

Meeting Track-and-Trace Regulations Around the World: Kedrion Biopharma on the Benefits of a Global Compliance Platform



Navigating the constantly shifting landscape of global track-and-trace regulations requires collaboration, strategic partnerships, and a global compliance solution that adapts as requirements evolve, according to Nicholas Salotti, a Serialization Specialist at Kedrion Biopharma.

In this video, Salotti explains how Kedrion meets complex serialization and track-and-trace demands in more than 100 countries around the globe. He also discusses the benefits of leveraging the TraceLink Global Compliance Platform over individual country compliance solutions. Finally, Salotti offers valuable insights and advice for industry peers facing similar global compliance challenges. Watch the video to learn more!

Video Highlights:

00:11 - Could you share some background on Kedrion Biopharma and your role there?
01:18- How does Kedrion manage the complexities of achieving regulatory compliance across different countries?

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02:06 - What are the benefits of using a global compliance platform like TraceLink?

02:40 - What advice do you have for peers facing global regulatory compliance challenges?

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Kedrion is one of the largest world players in the production and distribution of plasma-derived therapies, such as immunoglobulins, human coagulation factors, for the treatment of rare and ultra-rare diseases and conditions. Kedrion now counts more than 5,000 employees and serves patients in more than 100 countries in the world.

About my role, I'm part of the Global Supply Chain Team in Kedrion, mainly focusing on serialization and track-and-trace operations as the process owner and the TraceLink company administrator for Kedrion SpA.

This entails the management of the system, collaborating in the project activities with Kedrion sites or partners, such as CMOs or 3PLs, and also monitoring the evolving regulatory landscape in order to address the impacts on the adopted framework.

Talking about track and trace: Even if serialization is basically the foundation of most of the regulations, the requirements can differ a lot across the various countries. And in addition, especially in some countries, the regulatory landscape is continuously evolving.

In order to address these challenges, we strongly believe in collaboration between

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different departments, along with the involvement also of external local contacts if needed. In addition, I think that having reliable partners can make the difference in addressing these challenges.

I think that the main advantage of adopting a global compliance platform like TraceLink is the scalability and the flexibility of this kind of solution compared with individual compliance solutions.

In addition, from an end user perspective, I think that administering and operating on a single comprehensive solution is more comfortable than using multiple systems.

Due to the nature of the track-and-trace processes, the main advice is to start building up a strong cross-functional team, not only in terms of completing the implementation project, but also to proactively monitor the regulatory landscape. So, this is probably one of the first pieces of advice.

And, in addition, build a network of reliable partners. This really can make the difference between successful projects and struggling in achieving regulatory compliance all over the world.

VideoEuropean Union Falsified Medicines DirectiveGlobal Track & TraceRegulatory/Compliance, Serialization
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Thank you for contacting us; we'll be in touch shortly.

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