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Case Study: Siegfried & Nubinno's Path to Serialization and Operational Excellence



Background

Siegfried, a global leader in Contract Development and Manufacturing Organization (CDMO), operates across 13 locations worldwide, providing high-quality drug products. To meet increasingly complex regulatory requirements, Siegfried partnered with TraceLink and Nubinno, a consulting firm specializing in supply chain and serialization solutions, to transform its operations and ensure compliance with global serialization mandates.

The Challenge

With the introduction of the EU Falsified Medicines Directive (EU FMD) and various other regulations, Siegfried faced the challenge of implementing serialization across its supply chain. This business-wide undertaking involved integrating new systems, automating workflows, and ensuring compliance across different countries, each with unique regulatory requirements. The team realized that managing this complex landscape required a strategic approach to serialization and a robust digital solution to streamline operations.

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Solution

Siegfried selected TraceLink's network-based platform to manage serialization and ensure compliance across its global operations. Working with Nubinno, Siegfried began a three-phase journey:

1. **Implementation of Serialization**: Initially, Siegfried integrated TraceLink's serialization solution, meeting EU FMD requirements and setting up B2B connections with customers. By harmonizing communications and automating processes between ERP systems and packaging lines, Siegfried could efficiently manage compliance and enhance customer connectivity.

2. **Optimization and Evaluation**: In this phase, Siegfried moved beyond initial compliance to focus on optimizing its serialization processes. This involved evaluating its initial solutions, team structures, resource allocations, and work instructions, questioning whether these elements were effectively set up to support long-term success. Additionally, typically this phase is when financial departments analyze the total cost of ownership (TCO) over a typical three- to five-year period to determine if the current solutions were sustainable and cost-effective.

3. **Leveraging Benefits and Expanding Digitalization**: In this final phase, Seigfried is shifting its focus to fully realize the benefits of its investment in serialization. Having optimized the initial setups, the company now seeks to enhance value by digitizing the entire supply chain—not just serialization and track-and-trace activities. For Siegfried, this means exploring new opportunities for improvement across all markets and customer interactions, using TraceLink to expand digitalization efforts and drive further efficiencies.

Results

Through its partnership with TraceLink and Nubinno, Siegfried has created a

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scalable, compliant, and efficient serialization solution. The company now operates with a strong governance framework, enhanced resource planning, and a seamless support system that allows it to adapt to evolving regulatory landscapes worldwide. The project's success has also paved the way for ongoing digital transformation throughout the business, as Siegfried explores further automation and digitization to improve agility, reduce human error, and drive operational excellence.

Future Outlook

Siegfried is focused on continuous improvement by expanding automation and digitalization efforts across its supply chain and manufacturing processes. To prepare for these next steps, Siegfried is analyzing current workflows across multiple departments—such as inventory management, procurement, and customer support—to identify challenges and establish a baseline for future improvements. This groundwork will support a more streamlined and interconnected supply chain that aligns with its ongoing digital transformation goals.

Customer Perspective

> *"Having a unified approach to governance and balancing local and corporate responsibilities" has been essential to Siegfried's success*
>
> **Mark Dalli**, Head of Operations and Technology at Siegfried

Jaroslaw Radzikowski, CEO of Nubinno, highlighted the benefits of involving the entire team in the transition process and continuously reviewing operational efficiencies.

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Key Takeaways

For those beginning a serialization journey, focus on three key aspects: understanding project requirements, secure user buy-in, and carefully plan resources. First, it’s essential to clearly define what the project entails and pinpoint user needs—having support at every level will make the process smoother and more effective. Next, meticulous resource planning is crucial; ensuring the right resources are available at the right times will prevent potential setbacks and keep the project on track.

In addition, create a strong foundation by engaging team members across departments, such as supply chain and procurement, to uncover real challenges and areas for improvement. This could involve gathering input through workshops, which also helps make the most of the network that’s already built. Start with proofs of concept and small experiments—these early steps will guide and strengthen the journey toward a resilient, digitized supply chain.

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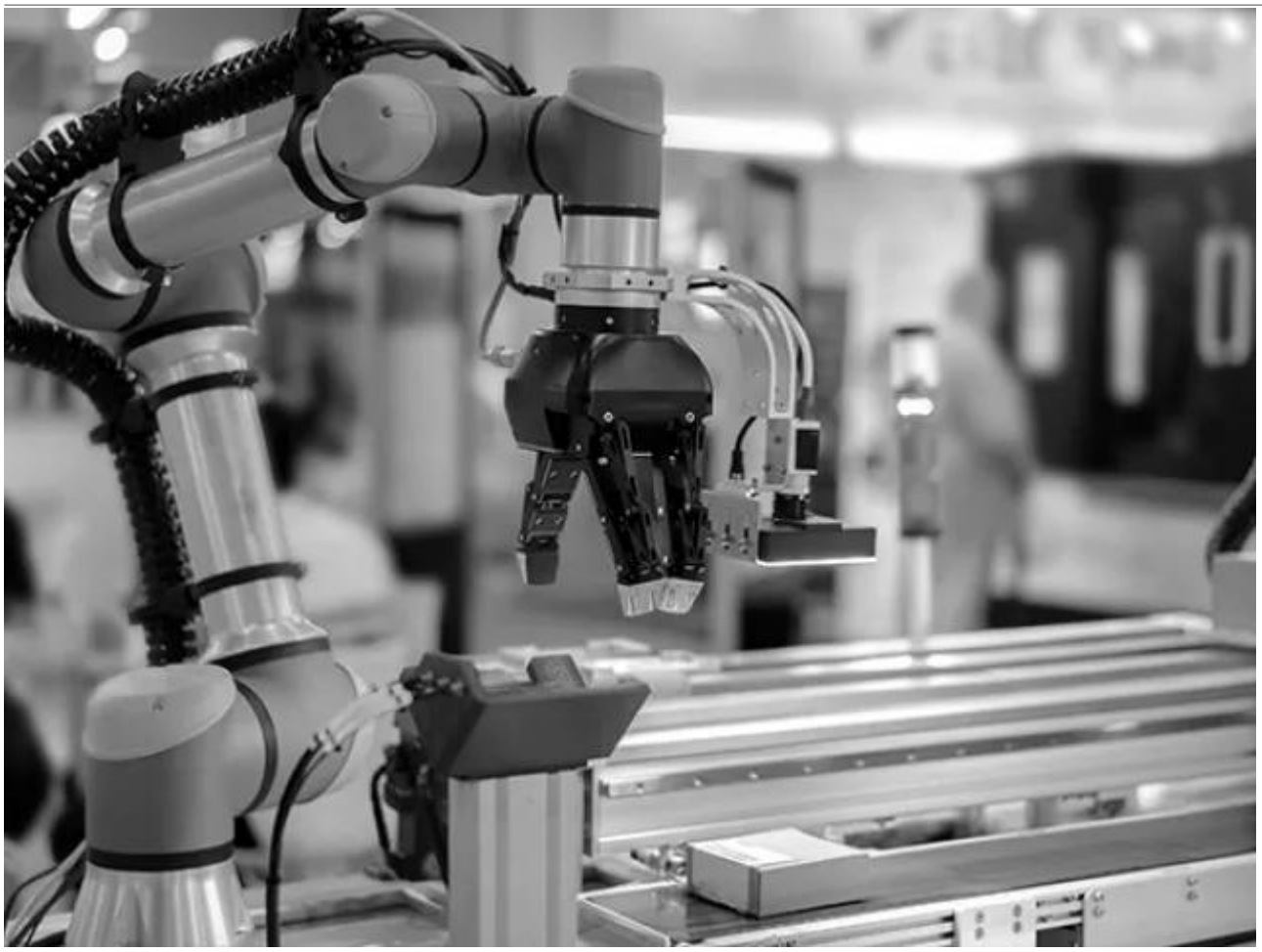


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