

CASE STUDY

Track & trace partner of choice for virtual manufacturer

When Amici Pharmaceuticals launched, the DSCSA had just been signed into law. After evaluating potential partners to address requirements, the company selected Systech for its comprehensive solution and proven track record with CMOs. A decade later, Systech remains Amici's partner of choice to navigate the complex landscape of traceability and compliance.



Customer

Amici Pharmaceuticals is a US-based virtual generic pharmaceutical company founded in 2014. The company markets 10 product families including ophthalmic, oral solid and oral liquid products, working with both domestic and global partners to supply affordable prescription products to wholesalers and distributors across the United States.

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Amanda Samojedny

VP of Operations



Challenge

Scalable serialization for a virtual manufacturer

When Amici Pharmaceuticals launched, serialization was baked into the initial plan. The Drug Supply Chain Security Act (DSCSA) had just been signed into law. As a smaller player entering the generic pharmaceuticals market, Amici faced the decision of whether to build an in-house serialization system or seek an outside solution.

Amanda Samojedny, VP of Operations at Amici, explained, “We were such a small outfit, and we were so new, we didn’t really have that burden of needing to bring a large portfolio up to speed. However, we had limited internal resources, and there was a lot of uncertainty around how the regulatory requirements would continue to evolve.”

“ [Systech] became an extension of our team, providing the expertise and support we needed without having to build an extensive in-house infrastructure. ”

- Amanda Samojedny
VP of Operations

Solution

Systech’s UniTrace traceability platform and VRS

After evaluating potential partners, Amici chose Systech to help guide them on their compliance journey. Its [UniTrace® suite](#) delivers scalability, rapid implementation and a comprehensive solution. Plus, Systech’s proven track record and strong relationships with contract manufacturing organizations (CMOs) were key factors in the decision.

“Systech was the clear choice for us because they offered a more personalized approach to deploying a serialization solution, which was critical for us as a small company,” said Samojedny. “They became an extension of our team, providing the expertise and support we needed without having to build an extensive in-house infrastructure.”

As Amici’s business grew, Systech’s [Verification Router Service \(VRS\)](#) solution came into play to enable saleable returns verification. The implementation went smoothly, thanks to close collaboration with Systech’s engineering team. VRS further enhanced DSCSA compliance capabilities, allowing Amici to efficiently manage product returns in line with regulatory requirements.

Systech’s strong relationships with CMOs ensure seamless implementation and data exchange. As Amici’s Senior Manager of Technology Paul Baluyot put it, **“You trust your CMOs, and they trust Systech.”** This trust network simplifies the complex web of relationships in the pharmaceutical supply chain.



Why Systech for Virtual Manufacturers?

Amici’s experience highlights why Systech is the partner of choice for virtual pharmaceutical companies. Systech serves as an extension of the team, providing the expertise and support that virtual manufacturers need without requiring extensive in-house resources.

Systech’s UniTrace is a comprehensive supply chain track & trace platform, providing a complete solution with a low TCO and rapid implementation. The system’s flexibility and scalability allow for seamless connectivity to new trading partners, including warehouses, 3PLs, CMOs and CPOs.

Virtual manufacturers benefit from Systech’s best-in-class service and support, with 24/7 availability and personalized attention. Systech enables efficient connections that help businesses grow.



Results

Early DSCSA compliance and streamlined operations

Amici was an early adopter of DSCSA guidelines, serializing products and exchanging data well ahead of regulatory deadlines. This preparedness positioned the company as an ideal partner for pilot programs with other businesses still developing their implementations.

The company's proactive approach led to improved relationships with trading partners. Baluyot explained, "We were the first McKesson 3PL client serviced out of the Mason, Ohio warehouse, which strengthened our relationship with them. Our collaboration with Systech has not only deepened our understanding of the complexities of DSCSA but also improved our joint processes."

The implementation of Systech's UniTrace alerts resulted in significant improvements in inventory handling and distribution. "Thanks to Systech, our products are processed and distributed faster, allowing us to minimize supply delay penalties, which is crucial in our industry," Baluyot added.

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– Paul Baluyot
Senior Manager of Technology

Systech's traceability solution not only supported Amici's initial compliance but also established a framework for continuous compliance as regulations evolve. The system's risk-based approach to validation aligns with pharmaceutical industry best practices, allowing Amici to efficiently manage compliance without overburdening internal resources. Comprehensive documentation—including validation plans, test cases and summary reports—further streamlined Amici's compliance efforts.



As Amici expanded its business, the scalability of UniTrace proved invaluable. Systech's complete solution provided Amici with compliance, exceptions management and rework capabilities, resulting in time savings and resource reductions. This comprehensive approach ensured a low total cost of ownership (TCO) for Amici, and the ability to focus on the core business while maintaining DSCSA compliance.

The Amici Advantage is Systech: An invaluable partnership

For Amici Pharmaceuticals, partnering with Systech has been transformative. Systech's expertise, technology and support was foundational as Amici achieved DSCSA compliance, enhanced operations, strengthened partnerships and positioned itself as an industry leader.

As virtual manufacturers navigate the complex world of pharmaceutical serialization and compliance, Systech proves to be an invaluable partner, with the solutions and knowledge that spell success in this rapidly evolving regulatory landscape.

Speak to a track & trace expert, today!

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