

CONNECTING MILLA PHARMA FOR DSCSA COMPLIANCE

CASE STUDY

About the Customer

Milla Pharmaceuticals is a developer of generic prescription drugs for the U.S. Pharmaceuticals & Life Sciences market focused on niche injectables and solution products for hospitals and clinics. Leveraging global partnerships with manufacturing facilities approved by the Food & Drug Administration (FDA), Milla is on a mission to deliver high-quality medicines at affordable prices via a world-class supply chain.

Project Summary

To meet upcoming compliance standards of the FDA's Drug Supply Chain Security Act (DSCSA), Milla Pharmaceuticals sought a serialization and aggregation solution that could simplify its complex operations and improve efficiency. Engineering Industries eXcellence configured and integrated Movilitas.Cloud, our proprietary Software-as-a-Service (SaaS) solution, to help the drug developer connect and manage contract manufacturing organizations (CMOs) and 3rd party logistics (3PLs) on an easy-to-use platform.

Project Activities

- Connected CMOs in Europe and Asia as partners on Movilitas.Cloud.
- Connected 3PL distributors in the United States on Movilitas.Cloud.
- Registered Milla as an Authorized Trading Partner (ATP) using CARO credentials.
- Registered products in the Verification Router Services (VRS) lookup directory.
- Enabled VRS to respond automatically to authentication requests.

Business Drivers

- Comply with U.S. FDA's Drug Supply Chain Security Act regulations.
- Enable end-to-end visibility of drug manufacturing and supply chain.
- Connect complex global supply chain networks on an easy-to-use platform.
- Improve operational flexibility in the serialization and distribution of products.
- Ensure consumer safety and supply chain integrity.

More About The Project

Our team implemented Movilitas.Cloud, a comprehensive cloud-based serialization solution designed for ease of use and configuration. Utilizing its Serialized Manufacturing and Serialized Logistics applications, our Movilitas.Cloud team enabled Milla to effectively manage serialization, aggregation, and compliance reporting while integrating seamlessly with their broader supply chain ecosystem.

To help the drug developer efficiently manage Serialized Manufacturing operations, our experts provided configuration support for Movilitas.Cloud. This included assigning unique serial numbers to individual product items, enabling batch traceability and managing aggregation processes to maintain visibility across multiple packaging levels. Movilitas.Cloud integrates seamlessly with CMOs, allowing real-time serial number exchange and commissioning details. Additionally, the platform facilitates automated in-line printing and serialized label generation, ensuring compliance with DSCSA standards while optimizing production workflows.

On the logistics front, Movilitas.Cloud's Serialized Logistics application provided Milla with the tools necessary to manage shipment and warehouse operations for serialized goods. The platform supported automated responses to verification (VRS) requests and EPCIS generation for ownership changes, ensuring compliance with DSCSA-mandated traceability. Through integration with 3PL providers, the system enabled seamless tracking of serialized shipments, allowing the drug developer to respond to traceability requests in real time. By implementing secure file transport communication, our team ensured that critical serialization data could be exchanged reliably with logistics partners. This resulted in full end-to-end traceability, allowing Milla to confidently distribute their first serialized products in the U.S. while meeting all regulatory requirements.

Engineering's Advantage

As regulations for serialization and demands for product traceability grow in size and scope, so will the value of integrated technologies for Track & Trace. The strong technical expertise, profound industry knowledge, and successful delivery record of our Movilitas.Cloud specialists make Engineering Industries eXcellence a power player in the arena of serialized manufacturing and logistics. We will continue our mission for digital transformation to help industrial enterprises meet the demands of today's dynamic economy.

Engineering Industries eXcellence

Engineering Industries eXcellence is the global division of the Engineering Group specialized in the development, integration and implementation of holistic digital transformation solutions covering the end-to-end lifecycle and supply chain of all industrial products and processes. A leader in digital transformation, the Engineering Group is a global software maker, a system integrator and a leading provider of technology solutions and services. With an annual revenue of over \$1.7 billion and around 15,000 professionals across 70 office locations worldwide, the Engineering Group manages projects in over 50 countries by designing, developing and implementing innovative solutions for the business areas in which digitalization is having the biggest impact today.



Delivering the Digital Thread for Industry X.0



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End-to-End Technology Solution & Service Capabilities

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