

CASE STUDY

DSCSA compliance in just 30 days

PHARMACEUTICALS

Loftware™

Hudson Scientific standardizes pharmaceutical labeling and achieves DSCSA compliance in 30 days

Loftware improves accuracy, reduces manual effort, and supports future growth

Overview

Founded by FDA and ISO regulatory experts, Hudson Scientific LLC offers a seamless concept-to-market solution for medical device and drug companies. The organization supports pharmaceutical manufacturing and operates in a highly regulated environment where every drug must be traceable from manufacturing through to the end user.

Managing serialized pharmaceutical labeling is essential to maintaining compliance and ensuring product integrity throughout the supply chain. Prior to implementing a new product identification solution, labeling processes were handled manually, creating inefficiencies and increasing the risk of human error. To improve operational productivity and support future expansion plans, Hudson Scientific contracted IPSi to deploy Loftware and standards-compliant traceability platform, TrackVision AI, as part of its pharmaceutical track-and-trace environment.

Challenges

Manual processes and server dependency

Pharmaceutical manufacturers must be able to trace products from manufacturing through to the end user to meet DSCSA compliance requirements.

Hudson Scientific specializes in small batch pharmaceutical runs, with each drug requiring multiple label designs. As its operations grew, manually controlling labeling and serialization became increasingly complex and inefficient, limiting the company's ability to scale production and growth.

Each batch required employees to generate unique serialization codes, create labels, print them, and individually verify each product manually by scanning every code to ensure accuracy and compliance. This approach required significant time, human involvement, and effort for every production batch. Despite these efforts, the process still left significant room for human error.

> **"As our pharmaceutical operations expanded, manual serialization and label verification became increasingly time-consuming and complex, creating a need for a more scalable, accurate solution."**
>
> *Yasser Sadek, CEO, Hudson Scientific*

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Hudson Scientific's senior leadership team knew they needed to focus on three key priorities to overcome their existing challenges:

Time saving
Automate serial number generation, label printing, and verification to free the highly skilled team from hours of manual work and streamline production

Accuracy and standardization
Replace individually executed manual labeling and verification activities with a consistent, repeatable process that improves accuracy and supports compliant product traceability

Scalability
Establish an efficient labeling foundation that can support faster, larger production lines and the company's planned future growth

Solution

Hudson Scientific selected Loftware as part of an integrated track-and-trace solution introduced through its partnership with IPSi (a Loftware certified partner). The full solution includes:

- **TrackVision AI** - serialization, batch tracking, and trading-partner data exchange
- **Loftware** - compliant label design and printing
- **Integrated Productivity Systems, LLC (IPSi)** - integration partner of Loftware and TrackVision, enabling one-button printing of DSCSA-compliant labels for both drug packages and shipping boxes

Hudson Scientific uses Loftware to pull data from TrackVision AI to print serialized labels. IPSi seamlessly connected the two platforms to reduce product verification failures and to significantly improve the labeling process with supply chain traceability.

CUSTOMER HIGHLIGHTS

By integrating Loftware into its pharmaceutical manufacturing workflow, Hudson Scientific can:

- Design labels using accurate data and approved imagery
- Print labels with dynamic data for entire production batches, including unique serial numbers
- Simplify verification and compliance requirements
- Support more efficient manufacturing workflows through automation

The complete solution automates the generation of unique serialization numbers, label production, and batch processing activities. The implementation provides a streamlined approach to pharmaceutical labeling while helping ensure the accuracy and traceability required by industry regulations.

"Loftware gave us an automated way to generate unique serial numbers, print labels by batch, and simplify the verification process, helping us improve accuracy while reducing manual effort."

Yasser Sadek, CEO, Hudson Scientific

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Results

Following implementation, Hudson Scientific realized immediate operational improvements and standardization across its pharmaceutical labeling processes.



Significant time savings

Manual labeling activities that previously required hours of effort for production runs were dramatically reduced through standardized processes and automation. The ability to automatically generate serial numbers, print labels, and verify batch information significantly accelerated production workflows. In addition, product recall look-up time from four hours to one minute.

Improved accuracy and compliance

The solution implementation took only 30 days from contract to full DSCSA compliance. Loftware eliminated many opportunities for human error by standardizing and automating the labeling process and ensuring unique identifiers were printed for every product. This increased confidence in the company's track-and-trace processes while simplifying verification activities. There have been zero verification failures since go-live.

Greater manufacturing efficiency

By removing manual steps and reducing employee involvement in repetitive labeling tasks, Hudson Scientific improved operational efficiency and lowered labor-related costs associated with labeling activities.

Simplified processes

By focusing on 'the right process first', the company reported that the overall workflow became simpler and easier to manage, helping employees spend less time on administrative labeling activities and more time supporting manufacturing operations.



"The time savings were huge. What was once a manual process involving individual serial number generation, verification, and scanning is now automated. It's much faster, more accurate, and supports the future growth of our manufacturing operations."

Yasser Sadek, CEO, Hudson Scientific

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Future

Hudson Scientific views Loftware's labeling solution as a strategic enabler for future growth.

The company is currently planning a significant manufacturing expansion and developing additional production capabilities for larger production runs. As volumes increase, Hudson Scientific expects Loftware to play a critical role in supporting larger-scale operations by providing the efficiency, automation, and scalability needed to manage increased labeling and serialization requirements.

By establishing an automated labeling and track-and-trace foundation today, Hudson Scientific is well positioned to support future manufacturing growth while maintaining the accuracy, compliance, and operational efficiency required in the highly regulated pharmaceutical industry.

Partners

About IPSi

IPSi is dedicated to reducing friction, improving efficiency, and enhancing business processes for companies in the core areas of Mission Critical Labeling and Barcode Data Collection. We are passionate about helping our customers leverage technology to develop simple, cost-effective systems that ensure their operations run efficiently every day.

We offer barcode data collection and label solutions for manufacturers and distributors in the continental USA.
ipsiscan.com

About TrackVision AI

TrackVision AI is a state-of-the-art cloud system for product traceability and product digitization through the use of QR, RFID and NFC codes. Built by supply chain experts and based on the latest open standards from GS1 - EPCIS 2.0 and Digital Link - TrackVision AI delivers end-to-end traceability across any supply chain to address some of the most pressing business problems today, including product recall management, traceability legislation compliance, ingredient provenance monitoring, diversion protection, carbon footprint calculation, and more. Scalable, performant, configurable and cost-effective, TrackVision is ready to meet the IT requirements of businesses of all sizes.

trackvision.ai

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Loftware™

Loftware is the global leader in product identification. Our cloud-based solutions power real-time collaboration, ensure compliance, improve authenticity, and deliver supply chain traceability from product development to consumer engagement. We provide scalable, data-driven labeling and packaging technologies that help companies boost speed to market, enhance efficiency, and connect physical products to digital experiences. Trusted by global brands and backed by over 40 years of innovation, Loftware supports customers across industries with offices in the US, UK, Slovenia, China, and Singapore.

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