

How a Contract Manufacturer Achieved FDA-Compliant WMS Validation to Improve Traceability and Support Future Growth

1 Introduction

A leading North American contract manufacturer specializing in next-generation consumer products experienced rapid growth while maintaining strict quality and regulatory standards across its manufacturing operations. Although its production environment and ERP system were highly advanced, warehouse operations still relied heavily on manual, paper-based processes. To improve traceability, support regulatory compliance, and prepare for future expansion, the company partnered with Alpine Supply Chain Solutions to validate a new warehouse management system (WMS) that would meet FDA and Health Canada requirements while providing a scalable operational foundation.

2 Challenges

While the company's manufacturing operations were highly automated and operated under rigorous quality standards, warehouse processes remained largely manual. Paper-based workflows limited consistency, inventory visibility, and operational efficiency across receiving, storage, production support, and shipping activities.

As a contract manufacturer operating in a highly regulated industry, the organization required a fully validated WMS capable of meeting FDA and Health Canada compliance standards while providing complete product traceability throughout the supply chain.

3 Solutions

The new system also needed to support multiple departments, withstand regulatory audits, and establish standardized processes for future growth.

Complicating the initiative, the company's existing consulting partner lacked the specialized expertise required for WMS validation, leaving the organization without the guidance necessary to execute a compliance-driven implementation successfully.



Alpine Supply Chain Solutions led the complete WMS validation initiative, providing the specialized regulatory and warehouse expertise needed to ensure a successful implementation. The team developed a comprehensive Validation Master Plan that defined the project scope, governance structure, testing methodology, documentation requirements, training strategy, and deviation management process.

Working collaboratively with the client, the software provider, and implementation partners, Alpine designed a structured validation framework that aligned with FDA and Health Canada expectations while following quality software engineering best practices. Functional specifications, validation protocols, and testing documentation were developed to ensure the new WMS satisfied both operational requirements and regulatory standards.

4 Implementation

The project began with collaborative requirements workshops and system design sessions to document current-state operations and define future-state warehouse processes. Alpine worked alongside the client and software provider throughout system configuration, ensuring warehouse workflows supported both operational efficiency and regulatory compliance.

Over the course of the engagement, Alpine directed the entire validation process, including functional testing, end-to-end user acceptance testing, documentation review, and validation oversight. The team also worked closely with internal subject matter experts to provide training, knowledge transfer, and detailed documentation that prepared the organization to independently manage the validated system after go-live.

By project completion, Alpine delivered a complete validation package, established repeatable testing protocols, and ensured all documentation was audit-ready for regulatory review.

5 Results

The organization successfully implemented a fully validated warehouse management system that satisfied FDA requirements and was prepared for Health Canada audit approval. The validated environment significantly strengthened warehouse operations by improving traceability, standardizing processes, and providing a repeatable validation framework for future system enhancements.

Beyond achieving regulatory compliance, the new WMS established a scalable operational foundation capable of supporting continued business growth and increased production capacity. With improved system controls and complete product traceability, the organization strengthened its competitive position while creating the infrastructure needed to expand operations, support future facilities, and confidently pursue new business opportunities in highly regulated markets.



Through Alpine's structured validation methodology and deep warehouse management expertise, the company transformed its warehouse operations from manual, paper-based processes into a compliant, scalable environment built for long-term growth.

