Weiler Labeling Machine IOQ Execution and Qualification Improvement

Author: Oscar Lorenzo Villanueva
Advisor: Dr. Rafael Nieves
Master of Engineering in Manufacturing Engineering

Abstract

This project presents the validation and qualification of new Human-Machine Interface (HMI) functions added to the Weiler 1602 FS pharmaceutical labeling system. Features such as Zero Position and Dry Run were validated under GAMP 5 and FDA guidelines, including role-based access and audit trail verification. Results confirmed system compliance, operational reliability, and improved diagnostics.

Introduction

Labeling equipment in pharmaceutical packaging must operate with precision and data integrity. The Weiler 1602 FS, a pressure-sensitive labeler, was upgraded with new HMI functionalities to improve diagnostics and minimize downtime.

Background

Validation was based on ISPE GAMP 5 and 21 CFR Part 11 standards. The goal was to confirm operational reliability of the updated HMI system and ensure that electronic records and signatures complied with regulatory requirements.

Figure 1
Pressure-sensitive Labeling Machine

Problem

New HMI functions such as Zero Position and Dry Run required validation to ensure proper function and role-based control. Failure to validate these could lead to compliance risks and production inefficiencies.

Methodology

Installation Qualification (IQ) confirmed proper installation of software and hardware components. Operational Qualification (OQ) included validation of Zero Position, Dry Run, and Reset Encoder functions under different access levels. Screenshots were captured as objective evidence and documented following ALCOA+ principles. Backup and restore procedures were tested using checksum comparison to ensure data integrity and recoverability.

Table 2
IOQ Qualification Results Summary

Activity	Outcome
Document Verification	Pass
Software Installation Check	Pass
Backup Validation	Pass
Source Code Review	Pass
Security Access Control	Pass
Functional Test (Dry Run)	Pass
Functional Test (Zero Position)	Pass

Figure 2
Installation Qualification Summary

Figure 2 shows the Installation Qualification (IQ) results, confirming that the hardware and software components of the Weiler 1602 FS labeling system were installed in accordance with manufacturer specifications and system design documents. Verifications included electrical wiring, network connections, control panel configurations, and software deployment. Environmental conditions were also assessed to ensure system operability. This phase established the foundation for functional testing and ensured that all baseline conditions were met before proceeding with operational testing.

Results and Discussion

All functional tests passed as per the defined acceptance criteria. Zero Position and Dry Run features functioned without faults, both with and without product. Role-based access controls were confirmed to restrict sensitive operations to authorized users, complying with 21 CFR Part 11. Operator feedback indicated faster fault diagnostics and reduced troubleshooting time. The screenshot-based training protocol enhanced user comprehension and minimized onboarding time.

Table 1
Operational Test Results for Zero Position and Dry Run Functions

Functionality	Expected Result	Outcome
Zero Position	Homing completed without fault	Pass
Dry Run (with product)	Simulated flow through label station	Pass
Dry Run (no product)	Labeler runs empty cycle	Pass

Figure 3
Operational Qualification Summary

Figure 3 illustrates the Operational Qualification (OQ) test results for the upgraded HMI functionalities. The tests focused on validating user interface responsiveness, Zero Position homing, Dry Run behavior, and role-based access control for regulated actions. All functional test cases passed, and access restrictions aligned with 21 CFR Part 11. Each test step was documented using screenshots and supported by a traceability matrix. Additionally, audit trail generation and security lockouts were validated under various user role conditions (e.g., Operator, Supervisor, Administrator).

Conclusions

The validation of the Weiler 1602 FS labeling system's HMI upgrades was successfully completed, confirming functionality, compliance, and usability. All test cases met their acceptance criteria, including Zero Position, Dry Run, and access control functions. The implementation of ALCOA+ principles and traceability matrices strengthened documentation integrity. Screenshots served as audit-ready evidence and training support. Additionally, role-specific access testing ensured full alignment with 21 CFR Part 11 requirements. Operational teams reported improved fault response times and simplified diagnostics thanks to the updated HMI. This project not only validated the new features but also demonstrated a replicable strategy for computerized system validation that can be extended to other labeling platforms in the facility.

Future Work

Future improvements may include implementing real-time dashboards for performance alerts, enabling centralized monitoring of labeling system activity. Additional HMI features, such as diagnostics logging and multi-language support, could further support operational efficiency. It is also recommended to roll out this validated HMI upgrade to other Weiler systems within the packaging line.

Acknowledgements

Thanks to Dr. Rafael Nieves and the validation and automation teams for their support and guidance.

References

[1] ISPE, GAMP 5: A Risk-Based Approach, 2nd ed., 2022.
[2] FDA, 21 CFR Part 211, 2023.
[3] FDA, 21 CFR Part 11, 2023.
[4] EMA, EU GMP Annex 11, 2022.
[5] ICH, Q9/Q10 Guidelines, 2008.
[6] PDA, TR No. 54-5, 2021.
[7] MHRA, GxP Data Integrity, 2018.
[8] WHO, Data & Record Management, 2016.