Weiler Labeling Machine IOQ Execution and Qualification Improvement

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Abstract — *The pharmaceutical industry requires rigorous equipment to ensure regulatory compliance and operational reliability. This article outlines the Installation Qualification (IQ) and Operational Qualification (OQ) of the Weiler Labeling Machine after system modifications. New functionalities such as Zero Position and Dru Run were introduced via the Human Machine Interface (HMI). The validation process included documentation checks, software installation, source code review, security access verification, and full functional testing. The results confirmed regulatory alignment and enhanced troubleshooting capabilities, reducing downtime and improving packaging reliability* [1].

Key Terms — *Dry Run, Equipment Qualification, Labeling Machine, Zero Position.*

INTRODUCTION

In pharmaceutical manufacturing, the reliability of labeling equipment directly impacts product traceability, regulatory compliance, and patient safety. Labelers must operate within strict quality and performance standards, especially in high-throughput packaging lines. As the demand for automation and real-time diagnostics increases, Human Machine Interfaces (HMI) and Programmable Logic Controllers (PLC) are playing a more central role in ensuring system responsiveness and traceable operator interaction. This system is illustrated in Figure 1, showing the main labeling station used in the pharmaceutical packaging line [2].

The Weiler 1602 FS is a pressure-sensitive labeling machine widely used in the pharmaceutical sector (Figure 1)[3]. It features modular controls and Allen-Bradley PLC logic, designed for both semi-automatic and fully integrated production environments. Recent upgrades to its HMI interface introduced two new functionalities: "Zero Position" a homing function used for labeler recovery, and "Dry Run" a move that allows simulation of labeler motion without applying product. These upgrades are aimed at reducing downtime, support troubleshooting, and minimizing material waste during changeovers or system resets.

Given the criticality of these changes, a comprehensive Installation and Operational Qualification (IQ/OQ) process was developed and executed. This validation effort was aligned with FDA regulations (21 CFR Part 211 and Part 11), ISPE GAMP 5 (International Society for Pharmaceutical Engineering Guidance aims to safeguard patient safety, product quality, and data integrity version 5) guidelines, and internal engineering practices. The validation protocol included documentation verification, security access checks, functional test execution, source code control, and system recovery simulations [4].

This article presents the validation project performed on the upgraded Weiler Labeling Machine, highlighting the technical steps, regulatory standards, and outcomes that confirmed system compliance. Emphasis is placed on the integration of risk-based validation practices and the enhancement of operator diagnostics through improved HMI functionality [5].

Figure 1
Pressure-Sensitive Labeling Machine

LITERATURE REVIEW

AMP 5 (Good Automated Manufacturing Practice) and 21 CFR Part 11 provide a framework for validating computerized systems used in GxP environments. These standards require documented evidence that systems operate as intended, with reliable data integrity and audit trails. In this project, ISPE and FDA validation standards were followed to ensure that every new function introduced in the labeling machine's HMI met predefined acceptance criteria. Additionally, proper access control, backup protocols, and operator interface behavior were evaluated to meet regulatory requirements [6].

Beyond 21 CFR Part 211, equipment qualification must also comply with 21 CFR Part 11, which governs electronic records and electronic signatures (ERES). This regulation ensures audit trails, restricted user authentication, and secure storage of records. Complementary to U.S. regulations, the EU Annex 11 guidance defines similar expectations with an emphasis on system availability, change control, and documented verification of software functions. These overlapping standards shape the expectations for HMI system validation in both domestic and international pharmaceutical operations.

ICH Q9 and Q10 provide a global framework for quality risk management and pharmaceutical quality systems. ICH Q9 promotes risk-based thinking throughout validation and change control, while Q10 supports a structured quality system approach for system lifecycle management. In the context of this project, risk assessments helped prioritize which validation elements required deeper scrutiny, especially user access and alarm functions [7].

Furthermore, recent guidance from the FDA and industry publications has emphasized the need for cybersecurity considerations in automated manufacturing systems. Human-Machine Interfaces and PLCs may be exposed to cyber vulnerabilities that could compromise data integrity or equipment behavior. To that end, validation teams increasingly evaluate access control layers, firmware verification, and network isolation as part of the computerized system qualification process.

In addition, data integrity principles based on the ALCOA+ framework (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available) have become the cornerstone for computerized system validation. These principles ensure that each digital interaction is reliably recorded and traceable to the appropriate individual or event.

Traceability matrices were used in this validation to link user requirements with specific test steps, aligning the project with good documentation practices (GDP). The validation lifecycle from development of the Validation Master Plan (VMP) through IQ/OQ protocol execution and report generation was supported with detailed documentation and reviews. IQ/OQ/PQ refers to the 3 activities that must be performed on equipment and machines as part of the validation of manufacturing processes: Installation Qualification (IQ) [Figure 2], Operational Qualification (OQ) [Figure 3], and Performance Qualification (PQ) [Figure 4]. Periodic review plans and change management protocols ensure that system status remains in a validated state, even as updates or enhancements are implemented post-deployment. The overall process followed the IQ qualification structure described in Figure 2, including verification of installation, calibration, and environmental checks.

Figure 2
Installation Qualification Summary

Figure 3
Operational Qualification Summary

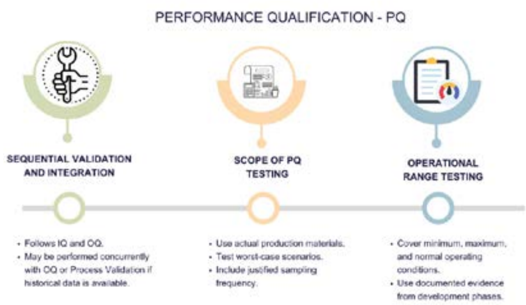

Figure 4
Performance Qualification Summary

METHODOLOGY

The validation approach adopted for this project followed a structured lifecycle methodology as defined by ISPE's GAMP 5 and internal GMP-compliant procedures. The process began with the development of a Validation Master Plan (VMP), which defined roles, responsibilities, documentation requirements, and acceptance criteria for each phase of qualification. Specific test scripts were derived from functional requirements, and a traceability matrix was developed to ensure full coverage of all identified specifications.

Key qualification activities included Installation Qualification (IQ) to verify the proper integration of hardware components such as the Allen-Bradley PLC and touchscreen HMI, as well as Operational Qualification (OQ) to evaluate system responses, access controls, and software functionality. The IQ phase involved checks of wiring, controller firmware, software installation logs, and interface operability. Photos and screenshots were collected as evidence and stored with timestamped audit trails.

During the OQ phase, each new functionality Zero Position, Dry Run, Encoder Reset was tested under different user roles. The security matrix was cross-referenced with access restrictions embedded in the FactoryTalk View ME application. Simulated fault scenarios were executed to verify that alarms triggered appropriate screen transitions and data entries in the audit logs. All tests were witnessed and signed by qualified validation personnel.

Backup protocols were verified both before and after execution using site-specific tools, confirming that project files were version-controlled and recoverable. The PLC logic was cross-checked using checksum analysis to validate the integrity of installed versus archived configurations. Recovery simulations further confirmed that system status could be restored after test or fault events.

Data collection was performed using pre-approved protocol forms, with designated fields for test step number, actual result, expected result, and pass/fail outcome. Deviations, if any, were documented, evaluated for risk, and resolved before proceeding. Daily validation activities were reviewed with quality assurance to ensure compliance and alignment with SOP requirements.

The entire process was documented and archived, with digital backups stored in the validated document management system. Upon completion of execution, a summary report was prepared, confirming that all planned qualification activities had been performed, results reviewed, and all requirements met. The project was closed out with the final approval of engineering, QA, and system owners.

RESULTS AND DISCUSSION

In addition to passing functional and qualification tests, the system's HMI enhancements were evaluated for responsiveness, user training effectiveness, and integration with supervisory control systems. The Zero Position feature enabled operators to recover the equipment more quickly after a mechanical stop. Dry Run functionality supported line clearance and changeover simulations without product, reducing waste and improving operator confidence.

Screen navigation tests confirmed that transitions between HMI interfaces were fast, logically grouped, and displayed consistent messaging. Security access control tests simulated logins across user levels (User, Operator, Technician, Engineer, and Administrator), ensuring access was limited to intended features only.

Additional validation steps included audit trail review and screen navigation path testing. The audit trail evaluation confirmed that all user interactions, including function activation, login attempts, and alarms, were recorded and stamped as per 21 CFR Part 11 compliance. Screen transition timing averaged 1.2 seconds, ensuring rapid operator response. The system passed all functional test cases as outlined in (Table 1), including simulations of Dry Run and Zero Position Homing.

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

Operators provided feedback indicating that Dry Run features improved their ability to troubleshoot downstream label alignment issues. Data loggers captured encoder position resets, and their correlation with the label placement step validated timing consistency. A summary of IOQ execution outcomes is presented in (Table 2), confirming successful completion of all qualification activities.

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

Discussion

In addition to regulatory alignment and operational improvements, the validation contributed to a cultural shift in how equipment diagnostics are approached. Operators developed greater confidence using the HMI screens due to clearer screen design, visual prompts, and improved accessibility. Cross-training between engineering and operations was enhanced because of the Dry Run feature, allowing line personnel to observe system behavior without risking product waste.

Another observed benefit was in preventive maintenance planning. Because Zero Position routines could be triggered post-alarm or during downtime, maintenance teams were able to document recovery sequences and evaluate hardware wear trends. This functionality also created opportunities to log encoder wear and timing variation which, when trended over multiple runs, may support predictive maintenance programs in the future.

The qualifications also confirmed that system changes could be made while maintaining GMP compliance and traceability. Each version of the PLC logic was archived and compared using checksum analysis, while the FactoryTalk HMI project included detailed audit logs of operator interaction. These records were validated for 21 CFR Part 11 integrity and made available for quality assurance review.

In terms of knowledge transfer, screenshots captured during test execution were used to develop quick reference guides for operators. These visual aids reduced error rates during training and reinforced the utility of the updated HMI screens. One unexpected positive outcome was reduced downtime during product changeovers, as the Dry Run mode helped verify label sensor alignment in advance of live production.

Furthermore, the validation established a robust framework for managing future changes. By incorporating traceability matrices and aligning with GAMP 5 principles, the project team ensured that all functional changes were documented, tested, and justified. This approach supports long-term compliance and encourages scalability of the system configuration for additional labeling stations or future feature additions.

Conclusion

The successful execution of the IOQ validated the upgraded system's compliance and functionality. Both the Zero Position and Dry Run features demonstrated strong operational performance, allowing operators to simulate production and recover from faults with minimal downtime. These enhancements supported better line efficiency, operator confidence, and reduced material waste during changeovers and diagnostics.

In addition to meeting regulatory requirements, the validation process reinforced the value of structured documentation, traceability, and user access control. The qualification showed that GMP compliance can be maintained during software and interface upgrades when guided by risk-based validation strategies such as GAMP 5 and traceability matrices.

As a result of this validation, key lessons were identified: functional testing should be incorporated early in system design; access levels must align with operational risk; and audit trail reviews should be part of routine validation reporting. Screenshots and execution data collected during qualifications are now being used to create training modules and visual SOPs for operators.

Future recommendations include the adoption of real-time audit log alerts, further segmentation of user access rights, and integration of predictive analytics to monitor encoder performance. Additionally, this framework could be adapted and scaled for other labeling platforms and packaging lines across the facility, supporting digital transformation and long-term equipment reliability.

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