Validation Exercise for a Non-Destructive Inspection Device for Blister Pack

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Abstract

This project focuses on the validation exercise of a non-destructive vision scan system for blister pack leak detection within a regulated environment. The methodology included a systematic approach, following the System Life Cycle for validation equipment. Collaboration with the team facilitated the delineation of project objectives and success criteria, ensuring alignment with regulatory requirements. A Risk-Based Approach guided validation strategy development, optimizing resource allocation and validation efficiency. The qualification phase involved testing and documentation, verifying system components and functionalities to ensure operational suitability. The project highlights the importance of thorough planning, risk management, and stakeholder collaboration in achieving validation success within regulated environments. The lessons learned from this project will inform future validation efforts, contributing to continuous improvement and adherence to best practices in validation methodology.

Key Terms — Decay test, Gross test, Leak Detection, Validation of Equipment

Problem Statement

The leak detector device is used to detect leaks and weak seals in individual pockets of blister packs in the primary packaging area. A defective seal on the blister is identified as a critical defect. As part of continuous process improvement, the current leak detection technology device was identified to be obsolete. In addition, the current leak detection uses a destructive method to identify any faulty sample. Therefore, the site is on immediately needs to acquire an alternate solution for leak detection. The new non-destructive device for the blister pack used a vision scan system and is ideal for selective in-process inspection. This project wants to present the complete validation exercise for this new equipment.

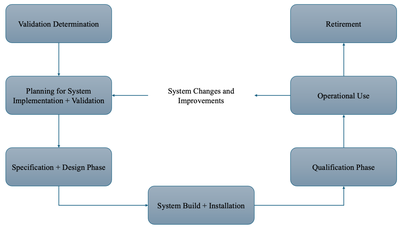

Figure 1: System Life Cycle for Validation of Equipment

RESEARCH DESCRIPTION

This project aims to validate a newly introduced non-destructive vision scan system for detecting leaks and weak seals in individual pockets of blister packs in the primary packaging area. The proposed vision scan system offers a non-destructive approach. This research presents a comprehensive validation exercise to assess the performance and suitability of the new equipment for industrial application.

RESEARCH OBJECTIVES

The purpose of the validation exercise is to:

- Evaluate the effectiveness of the non-destructive system in detecting leaks and weak seals in blister packs.
- Perform a full validation of the equipment ensuring proper documentation during the activities

RESEARCH CONTRIBUTIONS

This research contributes to the validation of a non-destructive vision scan system for blister pack leak detection, offering a viable alternative to traditional destructive testing methods. The findings will support informed decision-making regarding the adoption of this technology in the primary packaging area, leading to enhanced quality control and process efficiency.

Methodology

This project will focus on the development and execution of the validation of the new leak tester. First, an initial assessment and definition of project scope will be established. The project will continue with the qualification phase which includes Installation and Operational Qualification. To ensure the release for operational use, verification of several GxP programs including maintenance and calibration will take place. Validation SLC Phases and activities/ documents may be omitted, combined, or performed in parallel.

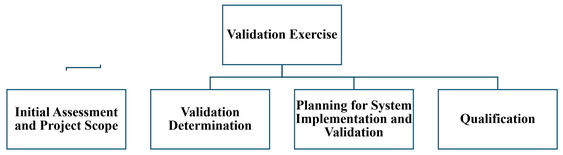

Figure 2: Step in the validation exercise

The requirements for performing the qualification activities will be documented in a Validation Protocol/Report. The document is based on the User Requirements and Risk Assessment. The validation protocol will be a combined document. The Method for each presentation of blister pack was develop by the vendor and will be tested in the Operational Verification test. The following Table 1, summarizes the test cases that will be part of the protocol:

Table 1 Installation and Operational Qualification Test Cases

Test	Justification
Test equipment / calibration	Record calibration and certification information.
Hardware and Software Verification	Verify the proper installation of the system hardware and software. In addition, this test includes the verification of the hardware components at system level.
Application Configuration Verification	Verify that the system application is configured properly.
Screen Navigation by Access Level Verification	Verify that the system application allows the users to navigate through each screen and verify that each user level have the corresponding access.
Access Level Security Verification	Verify that the system functionalities are restricted according to the privileges configured per access level.
Local Users and Groups Management Verification	Verify that the local users and group management functionalities are working properly.
Access Control Verification	Verify that the system functionalities access control functionalities are working properly according to its design and configuration.
Time Synchronization Verification	Verify that the equipment can synchronizes with site's time server.
Configurable Boundary Limits Verification	Verify that the configurable boundary limits for the numeric entry fields are working properly.
Warnings and Alarms Verification	Verify that the system triggers the warnings and alarms when the corresponding thresholds or conditions are activated.
Sequence of Operation and Batch Report Verification	Verify that Test Application operates according to the system specifications. In addition, this test verifies the Batch Report generated by the system.
Alarm Report, Audit Report, Calibration Report, Method Report and User Report	Confirm that system is capable to provide an Alarm, Audit, Calibration, Method, and User report in a printable format with the corresponding data.
Non-Destructive Test Verification	Verify that the Leak Test analysis is non-destructive.
Power Failure Verification	Verify that the equipment can recover from a power failure event.
System Application and Database Backups	Perform and document the system application and database backups.
Interlock Verification Test	Verify the safety interlocks
Operational Verification	Verify and document that system can successfully detect 50-micron leak Blister Product.

Results and Discussion

The implementation and validation of the non-destructive vision scan system for blister pack leak detection proceeded according to the outlined methodology. The project commenced with an initial assessment and project scope definition, which involved a thorough evaluation of existing leak detection technologies and the identification of suitable alternatives. Collaboration with subject matter experts (SMEs) facilitated the delineation of project objectives, deliverables, and success criteria. The project scope was narrowly focused on the validation and integration of the new system. Table 2 presents a summary of the individual activities performed in the protocol. The execution of them generates nominal attribute data: pass or fail. The entire timeframe of the validation was 10 months. For the complete validation exercise, a total of 908 steps were executed of which 905 were satisfactory. Only 3 steps failed, and deviations were generated.

Table 2 Test Result (IOQ)

Protocol	Steps passed	Steps failed
Test equipment / calibration	11	0
Hardware and Software Verification	24	0
Application Configuration Verification	114	0
Screen Navigation by Access Level Verification	130	0
Access Level Security Verification	40	0
Local Users and Groups Management Verification	52	0
Access Control Verification	56	0
Time Synchronization Verification	1	0
Configurable Boundary Limits Verification	156	0
Warnings and Alarms Verification	34	2
Sequence of Operation and Batch Report Verification	89	0
Alarm Report, Audit Report, Calibration Report, Method Report and User Report	65	1
Non-Destructive Test Verification	7	0
Power Failure Verification	7	0
System Application and Database Backups	2	0
Interlock Verification Test	8	0
Operational Verification	112	0
Total	905	3

The deviation included a detailed description, the identified root cause, and corrective action. After an evaluation of the root cause, there was no need for re-execution. The discrepancies were identified as not critical, and the data was retrievable. The root causes were identified as protocol generation errors. Errors in the protocol are due to the lack of information available for some of the tests.

During the evaluation of the operational verification, the system was able to successfully detect a 50-micron leak in the blister product. The total of blister packs evaluated was 200 blisters with a total of 1,200 pockets evaluated. Figure 3 shows the test results of the entire batch. The points represent individual pockets with a value of gross and decay in volume units. The decay limit is 255 mm^3 and the gross limit is 442 mm.

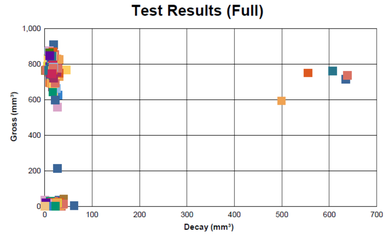

Figure 3: Operational Verification Test Result

The execution of the validation process employed in implementing the non-destructive vision scan system for blister pack leak detection was satisfactory. By adhering to established GxP principles and leveraging supplier documentation for user requirement definition, the project maintained a clear trajectory toward validation success. The Risk-Based Approach adopted in planning and executing validation activities ensured that resources were allocated judiciously, focusing efforts on areas of highest risk. This approach not only streamlined the validation process but also gave confidence in the system's compliance and performance.

The qualification phase, characterized by the creation of a detailed Validation Protocol/Report, provided a structured framework for conducting IQ and OQ tests. By systematically verifying system components and functionalities, the validation team could ascertain the system's suitability for operational use.

One key lesson learned from this project is the importance of thorough planning and documentation in the validation process. By conducting an initial assessment, defining clear project scope, and developing a detailed Validation Plan, the project team established a solid foundation for validation activities. This meticulous planning enabled the team to identify potential risks, allocate resources effectively, and ensure compliance with regulatory requirements throughout the validation process.

Conclusions

The validation of the non-destructive vision scan system for blister pack leak detection used a rigorous and systematic approach to implementing critical systems within regulated environments. Through planning, risk management, and stakeholder collaboration, the project achieved its objectives while ensuring compliance with regulatory requirements.

An important aspect of the validation process was the adoption of a Risk-Based Approach, which guided validation strategy development and resource allocation. By assessing risks associated with equipment use, data integrity, and patient safety, the project team could prioritize validation activities effectively, optimizing validation efficiency and mitigating potential risks.

The qualification phase was characterized by the creation of a detailed Validation Protocol/Report, which includes Installation Qualification (IQ) and Operational Qualification (OQ) tests. Through meticulous testing and documentation, the team verified system components and functionalities, ensuring the system's suitability for operational use. The validation exercise provides documented evidence that the new Leak Tester is working for its intended use. Moving forward, the lessons learned from this project will inform future validation efforts, to continuous improvement and adherence to best practices in validation methodology.

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