Valiation, Verification, and Monitoring of Tablet and Capsule Blister Pack Inspection Systems

A blister pack inspection system must function properly to ensure the quality and accuracy of blister-packaged pharmaceutical tablets and capsules. This article explains how validation, periodic verification, and ongoing monitoring can keep an inspection system operating as intended and ensure that products are adequately and accurately inspected, while keeping accurate inspection records.

In the automated, high-speed process of blister packaging tablets and capsules, errors can result in blisters being incompletely filled or damaged tablets or capsules being packaged. If these errors reach consumers, they can quickly damage a brand image that has been carefully built over years of successful production. In addition, pharmaceutical manufacturers need to meet the specific regulatory standards mandated by the countries in which they operate or risk recalls, and they must also protect themselves from damaging liability lawsuits.
The preventive controls most often used to identify blister packaging errors and mark the packages for rejection are in-line X-ray and machine-vision inspection systems. These systems quickly and efficiently detect missing or damaged products and defective packaging and remove them from the production line.

The software that operates these systems also collects data on their performance, recording successful and unsuccessful inspections. This data provides a valuable record in the event of a regulatory agency inspection or lawsuit. But to maintain their full effectiveness, the inspection systems must be validated, verified, and monitored on an ongoing basis to ensure that they are performing as intended.

Verification

Verification is the process of periodically confirming that the inspection equipment being used on the production line is still operating as effectively as when it was first validated. Verification uses standard, established tests performed at regular intervals to provide evidence-based confirmation that the system continues to function as specified. Formal performance verification is typically done annually to support audit requirements, but it may be conducted more frequently, as regulators require. Verification should continue throughout the productive life of the system.

Both validation of installed systems and periodic verification of operating systems can be conducted either internally by the end user or externally by the equipment supplier. Validation and verification services are often included as part of equipment purchase contracts. This relieves onsite staff of the responsibility for conducting tests they may not be familiar with.

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The terms validation, verification, and monitoring are often used interchangeably, creating confusion within organizations and across industries when they are interpreted and used in different ways. In fact, each term identifies a distinct process with a clear purpose that occurs at a specific point in the equipment lifecycle. It is important to understand the differences to ensure that each process is performed in compliance with regulatory requirements, particularly where the equipment is designated as a critical control point (CCP) in a larger production line system.

Validation

When applied to an inspection system that is part of a tablet or capsule manufacturing or filling line, validation is an objective, data-based confirmation that the inspection system does what it was designed, manufactured, and installed to do. The International Featured Standards (IFS) organization defines validation as “confirmation through the provision of objective evidence, that the requirements for the specific intended use or application have been fulfilled.” An important part of the validation procedure is the production of detailed data that demonstrates to line managers and regulators that the system is operating as designed.

The inspection system manufacturer will validate its performance before delivery, testing it with generic products and packaging similar to what the end user will be producing. But that is only the beginning of the validation process. That same system needs to be validated onsite after installation by inspecting the specific products the production line will be processing and/or packaging. Ideally, this is done at the time the system is originally installed in the production line.

It is critical for manufacturers to remember, however, that the original onsite validation relates only to the specific products tested at the time. As new or additional products are developed and introduced onto the production line, or as the packaging type or size (including labeling) changes, the system will need to be re-validated for each change.

Photo 1: This X-ray image from a blister package inspection system reveals missing and damaged tablets.
Reliance on experts

Manufacturers should remember that, while they are knowledgeable experts regarding their products, their equipment suppliers are the experts regarding the capabilities and qualification procedures of their equipment. That expertise makes them the best source of reliable recommendations on questions about the most effective inspection equipment type for specific product needs, where to place that equipment on the production line for optimal results, and how to validate, verify, and monitor the equipment's performance.

Relying on the equipment supplier to conduct onsite validation and advise on conducting periodic verification and ongoing performance monitoring can reduce both the validation time and the time needed for verification and ongoing monitoring procedures, increasing productivity.

Companies can also rely on these experts to be knowledgeable about the most current regulations and the technology that affects equipment validation. It is critical for a supplier's success to stay current on those topics, and sharing that knowledge is a valuable part of their service.

Robert S. Conrad (robert.conrad@mt.com) is sales director, pharmaceutical, at Mettler-Toledo Product Inspection (800 447 4439, www.mt.com/pi), which consists of CI-Vision, Hi-Speed, Safeline, and PCE. The company supplies in-line checkweighers, metal detectors, machine vision systems, x-ray inspection systems, and track & trace solutions to the food, beverage, pharmaceutical, nutraceutical, personal care, plastics, and chemicals industries.

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Monitoring

Routine performance monitoring, as distinct from periodic verification, consists of a series of frequent, regular performance checks during production. These checks confirm that processes are performing within acceptable limits and that there hasn’t been a significant change in the system’s performance level since the last successful test.

The monitoring frequency may be as often as every two hours, depending on company standards, industry standards, and/or retailer codes of practice. If the monitoring process finds that a particular device is out of specification, all product that has passed through the production line since the last successful routine performance-monitoring event must be considered suspect and should be quarantined and re-inspected.

In many cases, line operators conduct online performance monitoring. However, many of today’s more sophisticated product inspection systems incorporate built-in performance monitoring software that automates this process and alerts operators when deviations occur. This valuable software feature removes any human error factor from the monitoring activity to help ensure that inspection processes are still being performed properly. The software also provides documentation that will guide the end user’s quality assurance groups in their continuous improvement efforts and that will also be a valuable asset in the event of a regulatory inspection.

Routine performance monitoring can also have a direct impact on a production line’s overall equipment effectiveness (OEE). Installing a system with built-in condition monitoring capability that automatically detects when the system may need correction and communicates that information directly to line operators, reduces the required frequency of verification testing, maximizing the line’s production uptime.