

INSPECTION

Automated Inspection Widens Its Scope

Manufacturers can reduce liability exposure by improving QA practices.

By Joyce Laird
Freelance Writer

Is 100% inspection possible? According to industry experts, 100% inspection is definitely possible. It's just not possible using a single system. Different methodologies are required to inspect specific areas. The key is to identify what best meets your needs and then utilize those systems to their fullest capability.

Product Inspection

High-quality solid-dose vision inspection has been available for some time, but the issue with single-file optical inspection has always been speed. However, today's latest bulk optical inspection systems can perform 100% in-line inspection using high-performance color cameras at line speed.

Symetix (Walla Walla, WA) is a leading manufacturer of automation systems for the inspection of solid-dose pharmaceuticals. Its vision systems grab an image of each dose on the line and apply a series of measurements to that image to ensure a perfect product fill, with no foreign events such as tablets or fragments from previous product runs. The ultrahigh resolution (defined as 0.17-mm-sq pixels) of the systems can detect the smallest color and shape defects, including air bubbles, stained capsules, and misshapen product. This is achieved by using four cameras located both above and below the product stream. These systems can inspect up to 1 million tablets or softgels per hour.



Pharmaceutical Kit Pack Inspection: CIVision inspects each kit to ensure that all elements are present and in proper position, and to verify UV codes (visible here as light blue dots).

"A detailed report is provided of every tablet that passed and every one that failed and exactly why it failed. Those that failed are automatically ejected by the system so they are out of that final batch for shipment to packaging," says Jon Donovan, product manager. "Our latest offering, VeriSym, provides this complete integrated inspection in half the footprint."

Custom Production



VIDEO: [Click to see the Smarteye X-PRO XPC sensor from Tri-Tronics in action.](#)

Multiple venues can require different inspection methods, e.g., container and seal inspection, fill validation, and inspection of all printing. Some companies provide systems that address multiple tasks.

CIVision (Aurora, IL) offers standard off-the-shelf machine vision systems for specific applications such as label and package inspection. "But, we also offer custom turnkey vision solutions designed to meet any particular set of inspection requirements," says Brian Mack, sales engineer. "We work closely with customers to assist them in developing a set of specifications to include current and future needs."

Scott Stone, marketing director, says that CIVision has broken its equipment and services down into three different inspection categories to keep things simple: rigid containers, flexible fills, and other categories such as pill counting.

Sidebar:
[X-Ray Inspection Helps Pfizer](#)
[Tri-Tronics Sees the Way with Smart Sensors](#)

“For rigid containers, for instance, we can make sure that the right closure and the right vial and the right color on each have all been installed properly,” Stone says.

“The customer tells us the specific area where they need an inspection solution,” Mack adds. “The hardware is the same; it’s just in the way it is being deployed. The software may change slightly, per application, but using it remains the same, tapping into a library of recipes. Customers have consistency of use from one application to the next.”



Laetus’s packaging security systems were also designed to deliver easy integration, are very user friendly, and has software that is easily validated.

CIVision is starting to combine its vision expertise with off-line gaging. “It will inspect all bottle dimensions and attributes—all the dimensional gaging of the product. On-line gaging inspection is truly where I see CIVision going in the next step,” Mack says.

Thermo Fisher Scientific offers pharmaceutical and medical device manufacturers metal-detection, x-ray, and checkweighing systems for 100% product inspection, depending on the project need. “Incidents of contamination don’t happen very often, but they still do,” explains Bob Ries, lead product manager for Product Inspection at Thermo Fisher Scientific. “It is almost always a random occurrence—a machine breaks, materials are contaminated by their container, and simple normal wear and tear happens. Companies still need that insurance policy, if you will, that ensures product quality and therefore brand protection.”

The pharmaceutical industry in particular has always been concerned with maintaining product quality, Ries says, and it keeps setting the bar higher and higher. “In the past, we inspected for contaminants measuring a half-millimeter. Now, we are looking for a quarter-millimeter. In the future, needs will be even more sensitive.”

Ensuring Print Quality

Lot codes and expiration dates on labels plus correct product use information on packages, inserts and outserts, all fall into this category. Companies including Laetus packaging inspection systems (Rockaway, NJ), Label Vision Systems Inc. (LVS; Peachtree City, GA), and Microscan (Renton, WA) offer the latest in vision inspection systems that virtually eliminate potential liability owing to misprinted materials.



The LVS 7000 Print Quality Inspection System.

Laetus specializes in advanced control systems for verifying identification codes such as a National Drug Code (NDC) in a human-readable or bar coded form. Jeff O’Neill, director of Laetus, North America, says. “Our Laetus Polyphem wt and Inspect wt are web-based packaging security systems that give customers the flexibility to mix and match many inspection devices and software tools on one system for virtually all on-line inspections applications.”



Inspection catches broken tablets in blister packaging.

High-resolution cameras work hand-in-hand with code readers, compact high-performance computers, and user-friendly touch screens to identify incorrectly packaged or labeled pharmaceuticals, recognize all codes and colors, and compare them with predefined standards.

LVS also manufactures print-quality inspection systems based on electronic imaging technology. Tim Lydell, CEO, says that most printing inspection systems are set up in sequential inspection stations. LVS offers print-quality turnkey inspection systems that can identify print defects, including those in all linear and Data Matrix codes, to less than 0.05 mm (0.002 in.). They meet print-quality standards of ISO 15426-1 and -2, ISO 15415, and ISO 15416.



System provides a complete inspection and closed loop data control system.

“This is an actual verification to these standards, not checking codes for readability,” Lydell says. “This is a very important distinction and critical in the quality of the codes and reliability of code tracking systems.”



You can't mention Data Matrix codes without bringing Microscan into the picture. The company invented the first laser diode bar code scanner and was involved in the development of the first Data Matrix symbology. Today, Microscan focuses on auto ID, machine vision, and illumination with application solutions ranging from basic bar code reading up to complex machine vision inspection, gauging, and measurement.

Microscan IPAK SE System

Randy Kemmerer, strategic accounts manager, says Microscan systems use cameras to take images of labels and packaging and have integral, proprietary software designed just to verify both correct information and human readability. "Other things have branched off this, such as making sure the label is straight and that the cap is on correctly. This winds up using multiple cameras looking at different parts of the package," he says. "Some companies only verify what is regulated: date and lot codes. Others go further just because they feel there is a need beyond what is regulated."

Microscan's latest offering is the I-PAK SE, which is a version that runs on a Hawkeye smart camera. It uses the exact software that is on its larger systems. "For companies that just want to do character verification, this does it all," Kemmerer says. "It feeds right into its main computer system. The smart camera brought a thousand-pound system down to something that fits into the palm of your hand."



Systemtech Senti Vision tools run on a CIP 13 Data Matrix and corresponding human readable text.

Unique Areas



Microscan IPAK system on stand.

Everything is possible for today's inspection technology. The unique metal detectors and x-ray inspection systems provided by Mettler-Toledo Safeline (Tampa, FL) and Thermo Fisher Scientific fall into this category as does the overall inspection software solutions provided by Systech International (Cranbury, NJ) that provides full closed-loop data for complete plant-level integrity.

Mettler-Toledo Safeline provides customized metal detectors and x-ray inspection systems for the ultimate in brand protection pertaining to contamination and quality control issues. Sarrina Crowley, marketing communications specialist for the company, says that contamination issues and basic package fill and integrity can be addressed totally by using multiple types of devices.

"With metal detection and x-ray inspection, every package—whether blister packs, tablets, capsules, plastic or glass bottles—or bulk product of any size can be inspected for all metals, including ferrous, nonferrous, and the difficult-to-detect stainless steel," she says. "X-ray inspection can also detect other dense contaminants such as stone, bone, and glass. They can inspect for overfill and underfill and make sure that all items in the package are present, and that the package is sealed correctly—even if packaged in metal foil," she adds.



Microscan IPAK inspection screen

Ries of Thermo Fisher says that while metal detectors tend to be more sensitive than x-ray systems, interest in x-ray is increasing. "It can do more than just find metal, and companies are becoming more comfortable with x-ray. Some potential users do have concerns about its effects on certain formulations. So to help them with feasibility studies, Thermo Fisher Scientific maintains a testing laboratory that will run products through x-ray multiple times and then analyze them using mass spectrometry."

Moving to full SPC tracking and analysis, Systech is an innovator of packaging execution systems (PES). The company offers a software suite that gives manufacturers complete control over packaging processes along with the actionable intelligence required to continuously improve performance. This includes vision, line management, performance metric, and serialization solutions.



The VeriSym provides a complete integrated system that does all the inspections in half the floor space of other bulk inspection systems with similar

The Systech Senti inspection product fits at the line level. There is a computer with a graphical user interface (GUI) integrated with cameras or scanners. This handles all visual inspections; bar code reading, character verification, and character recognition inspection at very high speeds. It is connected to, and receiving information from, all of the intelligent devices on the line like a hub.

"Many pharmaceutical lines are using older devices such as bar code scanners or devices that work with operator interfaces," says Len Valeo, director of product marketing. "We can integrate all stand-alone devices into our environment to help to handle regulatory needs. Senti can manage those devices for audit-trail functionality. If

throughput and resolution.

any changes are made to the interface, it then has to be done through our system; our system then audit trails who made inputs to the system, what they changed, and when they did it. This open architecture allows users to integrate strategically for maximum benefits.”

Valeo says that Systech has introduced new Ethernet camera technology for higher speed, resolution, and performance. These new systems are self-training and self-learning. “Once you put something in front of the camera, you can basically select the approach desired for the inspection, and the system will then automatically see, learn, and create the recipe needed,” he says.

Thoughts about the Future

The biggest issue in the area of inspection is the push toward e-pedigree. The goal is to stem counterfeit products, recycled products, or products repackaged for illegal resale. For many drug makers, e-pedigree is evolving into systems using unique Data Matrix coding on products, from the smallest dose level to that delivered to the shelf or end-user. Custody information could be added as the product moves from stage to stage and is tied into a database registration system.

While the concept may seem very simple, the implementation is very complicated. While FDA is still working on guidelines, in Europe it is in progress. Turkey will be the first to officially use e-pedigree and has already started. France is close behind. Vision inspection companies are all working to provide the best possible inspection solutions so pharmaceutical and medical device manufacturers can scale up fast in case there are U.S. or global mandates.

Pharma companies are running test and pilot programs to stay ahead of the game. Kemmerer says that many forward-thinking companies are currently working on inspection solutions.

LVS already has the LVS 7000 inspection system that can handle in-line inspection of these variable codes at the speed of a printing device and can verify the codes to ISO standards.

While e-pedigree is certainly at the forefront, other inspection issues are also prevalent. Some firms are putting forth ideas for inspection to ensure absolute validity of the product itself.

“Making sure that the right product being placed into the right packaging is just as important as tracking product movement via codes,” Valeo says. “Systech is working with customers on this area.”

Also today, few products are currently 100% inspected for actives. FDA’s interest in Process Analytical Technology (PAT) is moving in this direction.

One new technology that can take this to the finite level is infrared spectroscopy, which has been shown to be capable of measuring active ingredients in the dose as it is being inspected. Donovan says that this type of technology has the potential to be integrated with Symetix inspection systems.

Will increasing upstream product quality ever eliminate the need for downstream inspection? Ries responds with a resounding “no.” He says that “Companies will always need an insurance policy. They always have to be prepared to catch the random events that could contaminate products.”