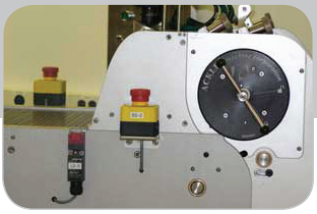
COGNEX vision

Expert Guide

Vision Ensuring Quality in Pharmaceuticals Production



Introduction

In no other industry are the incentives to guarantee product safety and packaging integrity as great as they are in the pharmaceutical industry. As a result, pharmaceutical product manufacturers have been "early adopters" in the successful deployment and use of machine vision technology. As the challenges become greater and the stakes higher, pharmaceutical product manufacturers need even more sophisticated machine vision hardware and tools to stay compliant with regulations, ensure customer confidence and mitigate risks. At the same time, these tools need to be easy to use and deliver even more reliable and repeatable results.

What are the major production challenges for the pharmaceutical industry?

Track and Trace

The Center for Medicine in the Public Interest (CMPI) estimates that there are more than 25,000 pharmaceutical packaging lines worldwide requiring modification to implement effective track and trace technologies. Devising and meeting industry-wide track and trace standards presents substantial challenges to both manufacturers and machine builders.

An effective track and trace solution requires implementing three levels of functionality: print and verify, serialization and track and trace. With this functionality in place, manufacturers can systematically print and verify marking numbers on all products, mark each product with a unique serial number and create a central database of this information. The central database allows manufacturers to track and store the location and status of each product as it travels through the supply chain until it is sold to the customer.

Serialization data can be extracted from four layers of supply chain operations following the path of an individual medicine from manufacturing through final delivery. In the production facility, each individual drug manufactured is marked with unique serialization data. Any hierarchy-level information appearing on packaging such as blisters, folder cartons, bundles, cartons, packages or containers also is recorded on the production floor.

Since pharmaceuticals manufacturing often occurs in several process stages, serialization information from each process stage is collected and administered throughout the manufacturing facility. Serialization information is collected at the internal supply chain level where data on product shipments between manufacturing facilities is recorded for further distribution. The process of delivering products to distributors, wholesalers, pharmacists and hospitals is recorded at the external supply chain level. This multi-level approach allows for an end-to-end product verification process.

Global serialization requirements present huge challenges to pharmaceutical manufacturers. With as many as 10 to 15 different country requirements, each with a different timeline and technology, compliance is becoming very complicated. Serialization solutions can be especially effective when quality requirements are high, when the product has an impact on consumer health and safety, when there is a threat of counterfeit products or when there is need for a full product history.

Counterfeiting

According to estimates from the World Health Organization, up to 15 percent of all medicinal products in the world are counterfeit. On a worldwide scale, perhaps millions of patients are not receiving the therapeutic benefit of the authentic product, and they run the risk of coming into contact with materials which may be hazardous or toxic. Counterfeit pharmaceuticals containing authentic active ingredient(s) at inefficacious levels or in undesirable chemical forms may lead to decreased levels of bio-availability and the development of resistant strains of disease. In other cases, unrelated pharmaceutical products have been altered or repackaged so they can be passed off as a more profitable product, costing manufacturers in lost revenue.

Recent CMPI research estimates that activities related to counterfeit drugs generate US$75 billion annually. CMPI expects that figure to grow by 20 percent annually in the coming years, giving drug counterfeiters comparable revenue to some of the world's largest health care companies.

There is no single tool capable of confirming complete authenticity of pharmaceutical products. Several verification and inspection methods need to be applied simultaneously in order to build complete confidence in the process.

Defect Detection and Quality Control

To control costs, ensure product safety and maintain consumer confidence it is essential that pharmaceutical manufacturers control quality and prevent defective products and packaging from entering the supply chain. Some of the quality checks performed on the production line include:


Cap/seal presence verification


Empty glass verification


Box/label inspection


Label placement


Particle inspection

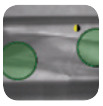

Final product inspection


Alphanumeric, 1-D, and 2-D code verification


Component inspection (stoppers/caps/glass)

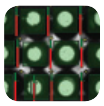

Liquid fill verification


Seal surface integrity


Product insert presence


Stopper position inspection


Presence of damaged product or packaging


Product quantity verification

21 CFR Part 11

Complying with the latest US Food and Drug administration (FDA) dictates on Electronic Records/Electronic Signatures—21 CFR Part 11 and comparable pharmaceutical inspection cooperation schemes enacted throughout the world have created significant challenges for pharmaceutical manufacturers.

21 CFR Part 11 requires that pharmaceutical manufacturers pay extra attention to security measures associated with computer-based systems. This includes fortifying access control measures as well as providing an electronic trail for all transactions. The traceability requirements have for all intents and purposes made the use of bar codes, including 2-D barcodes and lot and date code verifiers and readers mandatory.

Machine vision systems would fall under their definition of a "closed system:" an environment in which access is controlled by persons who are responsible for the content of electronic records that are on the system. In this case the FDA suggests that procedures and controls shall include:

A) Validation of systems to ensure accuracy, reliability, consistent intended performance and the ability to discern invalid or altered records.

B) The ability to generate accurate and complete copies of records in both human readable and electronic form.

C) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

D) Limiting system access to authorized individuals.

E) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify or delete electronic records.

F) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.

G) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

H) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.

I) Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training and experience to perform their assigned tasks.

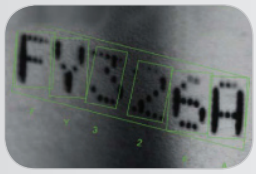
J) The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.

K) Use of appropriate controls over systems documentation including:

a. Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance.

b. Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

Four major environmental challenges on a pharmaceutical production line



Poor or variable lighting

Part changeovers

Tight spaces

Surface variation
(flat, curved, shiny, etc.)

Machine vision meeting the challenges of the pharmaceutical industry

Serialization and Tracking

Advanco: Ensuring product traceability with advanced 2-D code reading

Advanco, a major international integrator of item level serialization and tracking solutions deployed a complete traceability solution featuring Cognex In-Sight® ID readers to ensure product traceability for a global manufacturer that produces and distributes 60 million medicine boxes annually.

To achieve the required levels of traceability, Advanco chose Cognex In-Sight ID readers because it is the only system that can consistently deliver accurate and reliable code reading. The Cognex system is able to read multiple codes within one field of view and overcome the challenges of reading blurred or distorted codes on the production line.

In just 1.4 seconds, a Cognex In-Sight ID reader decodes all 2-D codes printed with inkjet onto the surface of each medicine package in a single action. Any defective products trigger an alarm and are removed. This procedure not only ensures all packages ready for shipment are fully traceable, but also improves production processes for both code marking and wrapping operations as defects are addressed immediately.

With the accurate and reliable read rates Cognex delivers, Advanco's customer is 100% satisfied that all 2-D codes are fully readable before leaving the facility.

Defect Detection

EISAI Machinery: 100% product quality entering the pharmaceutical wholesale chain

High speed pharmaceutical product testing company EISAI Machinery GmbH, has defined a machine that uses two Cognex In-Sight vision systems to inspect delicate glass vials in fractions of a second.

The Cognex-equipped machine can check approximately 6,000 packages and in its fastest version can even test up to 12,000 test units per hour.

In this application, a Cognex In-Sight vision system determines the cake height of the freeze-dried contents and detects the presence of any foreign objects on their surface. At the same time, it looks for "splashings"or splatters caused by unwanted boiling during the freeze-drying process. The In-Sight overcomes vibration stresses without sacrificing inspection speed.

An additional In-Sight system inspects the underside of the glass vials for cracks. For freeze-dried products, the vision system also checks the vials for unwanted particles and "meltbacks" (condensate residue that can arise during the freeze drying process of protein-containing substances).

An In-Sight color vision system checks both the vial cap and the flip-off seal, inspecting for the presence of the parts, the color of the cover and, for aluminum caps, the correct processing of the crimp. While the glass containers rotate 360°, the In-Sight system checks that the aluminum sleeves have been fitted completely around the edge of the glass and the stoppers are tightly inserted.

This system ensures that only the glass vials with 100% product quality are distributed to clinics, pharmacies, and medical practices worldwide.

Process Automation

Automated Systems of Tacoma: Vision-guided robots help automate vial and syringe filling

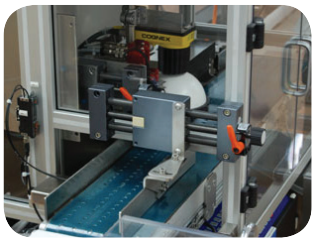
Automated Systems of Tacoma, Inc. (AST) used a Cognex vision system to develop an automated, single-platform machine to fill vials, syringes and other containers for pharmaceutical manufacturers. This machine features exact positioning functionally to address each product's unique size and type and eliminates the need to purchase multiple filling machines, or tolerate lengthy changeovers when switching between container types.

An In-Sight Micro vision system precisely locates each container and stopper and provides the robots these locations prior to processing. This approach allows for rapid changeover from one container type or size to another by loading a new robot program, replacing the products carriers, and instructing the robot to change out the end of arm tooling. The system's use of disposable materials is used on all process contacting parts which also reduces the changeover time, and eliminates the risk of cross contamination.

Thanks to the In-Sight Micro, the machine can handle all liquid packaging needs for many pharmaceutical companies, contract manufacturers and compounding pharmacies at hospitals at far less expense than comparable solutions.

Code Verification

Sanofi-aventis: Ensuring compliance for pharmaceutical products



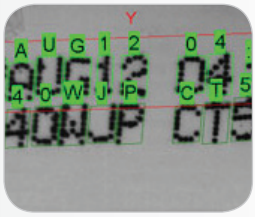
Pharmaceutical products manufacturer Sanofi-aventis worked with Cognex vision systems to design and implement a print and code verification solution to ensure compliance with GS1 codes readability regulations, completely eliminate operator errors caused by data input, reduce product waste, and improve coding quality.

This solution is designed as a mobile system, which can be adapted for packing lines and installed along the production process, as required. A Cognex In-Sight vision system with track and trace software provides information to a PC database to create an audit trail. As the products pass along the line, the required codes are printed onto the packaging.

A Cognex In-Sight vision system reads the printed data and verifies against the selected information camera at a speed of 300 parts per minute. The integrated track and trace software delivers a ready-to-deploy data capture and verification solution designed to help pharmaceutical manufacturers achieve unit-level product traceability. Incorrect codes are identified immediately and the offending product is removed from the line. After batch completion, a production report is created to ensure complete product traceability and maintain operational efficiency.

Machine vision tools for the pharmaceutical industry

PatMax® learns an object's geometry using a set of boundary curves that are not tied to a pixel grid, and then looks for similar shapes in the image without relying on specific gray levels. The result is a revolutionary improvement in the ability to accurately find objects despite changes in angle, size and shading.



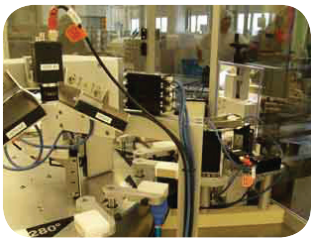
OCRMax™ powerful algorithm prevents misreads, handles process variations and provides easy font management. It's fast, easy to set up and simple to use across all platforms with minimal training being required.

TestRun helps you deliver continuous quality improvement. Any time the vision system fails to inspect a part properly, the quality manager can add that part to the TestRun database so the vision designer can make whatever modifications are required. In this way, the vision system constantly improves its performance.

Track and Trace software offers a data capture and verification solution designed to help achieve unit-level product traceability. Powerful Cognex code reading and verification software with a pre-configured job file and HMI interface make it easy to exchange data with third party systems for a full serialization solution.

Packaging Quality Control

Boehringer Ingelheim: Achieving perfect quality control



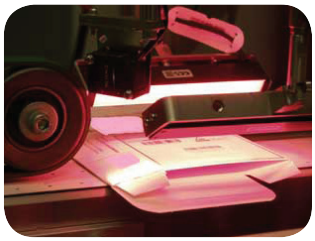
Boehringer Ingelheim relies on Cognex vision to achieve its quality control objectives: perfect printing quality inspection on a production line churning out around 300,000 blister packs and 100,000 folding packs every day.

The principal challenges facing Boehringer Ingelheim were the very high speeds at which the blister packs move on the production line, the variable accuracy of inkjet printing on foils with irregular surfaces and dirt, pressure, and sharp edges. In their production process, the inspection functionality provided by Cognex VisionPro® software overcame these challenges and ensured one hundred percent error-free blister pack printing quality.

Boehringer Ingelheim achieves perfect quality control by ensuring the detection of the printed undersides of the blister foils in fractions of a second. The information is transferred to the vision system so that it can perform a precise sample comparison. Depending on the product type, particular examination is made of varying details which are applied—including lot number and expiry date—in addition to looking at pre-printed information. The intelligent vision software knows and recognizes all the relevant symbols and letters and, on the basis of previously-taught parameters and tolerance limits, assesses the quality of a product.

Label Verification

Artur Theis GmbH: Pharmaceutical labels identification at 40,000 cartons per hour



Artur Theis GmbH has designed and deployed a machine that inspects high-quality labels with different identification and information carriers including 1-D codes, genuine lettering and holograms and bollinos. The machine features the Cognex In-Sight Micro vision system with PatMax pattern matching technology because it provides extremely high repeat inspection accuracy within specified tolerances and identifies possible defective products so they can be reliably removed.

The new Artur Theis machine can affix labels, stickers, and bollinos to up to 200 different types of folding cartons and check that they are in the correct position. If the labels and stickers are not perfectly aligned to the central features of the folding cartons, then additional information such as use-by date, product, and lot numbers cannot be applied correctly. The In-Sight vision system meets the pharmaceutical industry's increased level of automation demands by delivering far greater precision than the human eye can provide.

PatMax technology featured in the In-Sight Micro system helped the machine perform flawless inspections on a large variety of products with very different label shapes and colors by orient itself to certain predefined geometric features of the cartons in order to set and precisely determine the position of the labels and stickers in relation to it. PatMax pattern matching technology determines all of the important position values without errors—even under variable lighting and position conditions and despite changing angles, sizes, and shading.

The Cognex image processing library makes the machine usable for an extremely wide variety of image processing tasks. The calibration of new products is very simple and can be carried out with no specialized training.

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