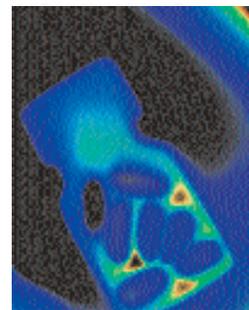


Interphex Delivers Packaging Solutions

Hallie Forcinio



Hallie Forcinio is *Pharmaceutical Technology's* Packaging Forum editor, 4708 Morningside Drive, Cleveland, OH 44109, tel. 216.351.5824, fax 216.351.5684, editorhal@cs.com.

Interphex remains one of the best places for pharmaceutical manufacturers to learn about the latest packaging solutions.

A blizzard that dumped several inches of snow on New York City on 15 March 2004, the first day of this year's Interphex show, couldn't slow traffic on the exhibit floor. Hot topics at the show included unit-dose bar coding, counterfeiting prevention, reproduction of reduced space symbology (RSS) bar codes, radio frequency identification (RFID), and, as always, quality control.

Bar coding

As the Food and Drug Administration looks for ways to prevent counterfeiting and mandates unit-dose marking on drug products used in hospitals and other healthcare settings to minimize the possibility of medication errors, bar coding is taking on new importance. Although thermal-transfer printing is commonly associated

with unit-dose marking, laser coding is another option to apply lot numbers and expiration dates directly onto plastic containers, films, or printed foils. In addition, there is potential to use a laser-based system to imprint two-dimensional matrix codes on tablets as an anticounterfeiting measure. The key here is to

apply a bar code to the tablets without slowing the packaging process (custom laser marking systems, Control Micro Systems Inc., Winter Park, FL).

A collaborative effort by a bar coding software specialist, a bar coding company, and a machine vision company has developed another laser coding system. The 21 CFR Part 11-compliant system combines a scribing laser coder with machine

vision verification and a validation package. Software enables etching of RSS codes, a format favored for marking unit-dose packages because of its ability to encode a sizable amount of data in a small space. A cleanroom-compatible system was shown printing human-readable information, and an RSS representing the product lot number and expiration date on labelstock that was preprinted with an RSS of the National Drug Code (model DSL laser coder, Domino Amjet, Inc., Gurnee, IL; vision system from Cognex Corp., Natick, MA; RSS software from Barcode Technology Inc., New York, NY).

Flexo printing can apply bar codes on lidstock to comply with unit-dose rules. Various styles of RSS can be printed with quickly cured ultraviolet (UV) ink. Installation typically requires approximately one week of downtime to remove the old printer, install the new one, and train personnel. Validation requires additional time but can be expedited with the use of an optional validation kit (Inprint UV-Flexo Web Printer, Grif-fin Rutgers Co., Inc., Ronkonkoma, NY).

RFID is a major topic at many meetings involving consumer products these days. Tags with frequencies of 13.56 MHz are commonly used for asset tracking, especially in closed-loop systems related to shipping, quality assurance, and inventory control. One turn-key RFID system includes a receiver and triggering photoeye as well as transponder-equipped smart labels. In action, the system verifies the transponder is functional before the system applies the smart label and writes data to it. (Sentient RFR002 13.56 Read/Write RFID system, Accu-Sort Systems, Inc., Telford, PA).

A line of vial coding and verification systems with single or twin printheads applies codes to container sides or tops in visible or invisible ink, verifies printing, and rejects any misprints. Some models also include a capper. Manual counters simplify height adjustment of the printhead(s) and camera(s). Capable of handling vial sizes from 2–500 mL at speeds as fast as 400 vials/min, the system can match the out-put of most fillers and is compatible with printheads and cameras from several vendors. Postfilling coding allows product

As FDA looks for ways to prevent counterfeiting, bar coding is taking on new importance.

traceability, discourages counterfeiting, and prevents product mixups between filling and labeling operations (KIV 1000, Bosch Packaging Technology, Minneapolis, MN).

Inspection

A first-time exhibitor and specialist in custom vision systems showed a system with high-speed lighting and camera(s) that provides 100% in-line inspection for items such as vials, plugs, seals, and oral dosage syringes. Custom software matches the system's speed to the packaging line's speed as items pass by or rotate beneath the camera. Because the software recognizes degrees of flaws, false rejects are minimized. A pattern recognition tool allows a check for features such as dosage lines (custom machine vision systems, RIS, formerly Ross Microsystems, Inc., Nanuet, NY).

An authentication system designed to foil counterfeiters is capable of ink-jetting covert patterns or codes within existing graphics. A lenticular lens reveals the hidden design, which can be authenticated by comparing it with a Web-based image (CounterProof Pro 3-D Inspection Suite, Complete Inspection Systems, Inc., Indialantic, FL).

Comparing two versions of labeling to confirm changes have been made accurately can take days. Automation by means of a high-speed personal computer, high-resolution scanner, and advanced visual comparison software can reduce this process to minutes. Compatible with virtually all desktop publishing and authoring tools, the proofing system can make comparisons even if a sample has been reformatted, exported to another application, or authored in a different operating system (AutoProof Pro Inspection Suite, Complete Inspection Systems).

Another proofreading solution checks a label, insert, carton, or press sheet sample against a master and automatically generates a list of defects. After operators accept or reject differences, images are then archived for future reference (TVS 2.0 PRO Software, Global Vision Inc., Montreal, QC).

A fiberoptic sensor capable of discerning minute changes can count very small tablets and can handle other challenging inspection tasks. An advanced liquid crystal display on the microprocessor-based

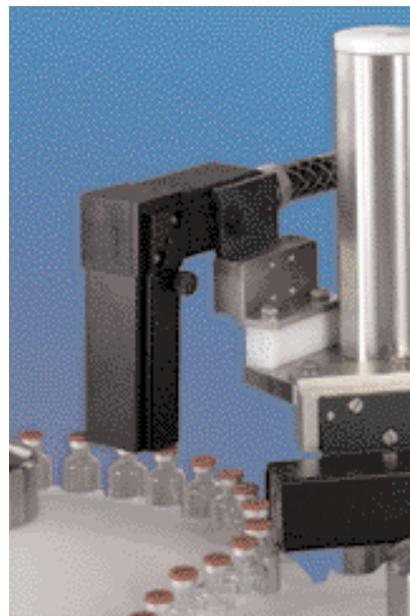
unit simplifies setup and operation by providing continuous configuration and performance data while a "teach" mode allows the user to set the sensitivity level so that it can differentiate between small differences in contrast (D10 Expert fiber optic sensors, Banner Engineering Corp., Minneapolis, MN).

Quality control

A mobile metal detector with powered height adjustment and positive-angle setting can be moved from one tablet press to another to check as many as 10,000 tablets/min for ferrous and nonferrous contaminants measuring <0.15 mm and stainless steel contaminants measuring <0.3 mm. A wireless Ethernet interface makes moving the unit simple because it eliminates the need to physically disconnect and reconnect the metal detector to the network (Phantom Pharmaceutical Metal Detector, Fortress Technology Inc., Scarborough, ON).

A new coil design boosts metal detector sensitivity 15–20%, thereby enabling smaller contaminants to be detected. Positioned at the outfeed of tablet presses or capsule-filling machines, the unit is available in four aperture sizes and quickly adjusts for infeed heights ranging from 760 to 960 mm. A hygienic design places all pneumatics and cables inside the stand and features an open frame, mirror-polished stainless steel mounting bars (with rounded profiles to eliminate debris and bacteria traps), and an easily removable reject system. A self-monitoring system alerts when recalibration is required and eliminates the need for manual performance checks (Goring Kerr DSP Rx metal detector, Thermo Electron Corp., Minneapolis, MN).

For moisture-sensitive products, desiccants can protect product quality and shelf life. Although desiccants are sometimes integrated directly into the packaging material, they are more likely to be in canister or packet form and inserted into the package separately. Desiccants in canister form enable a faster, more-reliable insertion method, but desiccants in packet form are less expensive and now claim similar reliability and insertion speeds with certain equipment. For example, the system provides 100% verification of packet placement and operates in excess of 300



A compact 28 × 40 in. footprint allows Bosch's KIV 1000 vial coding and verification system to slide over existing lines.

packets/min. A transition from desiccant canisters to desiccant packets can be made with submission of a CBE-0 or CBE-30 notification to FDA. The change also can be filed in an annual report to the agency as long as the appropriate equivalency data are included. A single-sourcing program for packets and insertion equipment simplifies the transition (Sorbent Savings Program, Multisorb Technologies, Inc., Buffalo, NY).

A new partnership has launched oxygen-absorbing canisters and packets designed especially for pharmaceutical applications. Although traditional oxygen absorbers need moisture to absorb oxygen, the new scavenger products work at low humidity levels to protect the shelf life of oxygen-sensitive pharmaceuticals and nutraceuticals. The canisters are compatible with automatic insertion at rates as fast as 1000 canisters/min. Both packets and canisters can be ordered in two-in-one versions that absorb moisture as well as oxygen (PharmaKeep canisters and packets, Süd-Chemie Performance Packaging, Belen, NM, and Mitsubishi Gas Chemical Co., Inc., New York, NY).

To make desiccants easily retrievable by pharmacists, an injection-molded polypropylene holder fits inside bottle necks, positioning the moisture absorber



Multisorb Technologies' Sorbent Savings Program provides a single source for rolls of StripPax desiccant packets and Active-Pak Automation insertion equipment.

in the headspace of the container just above the product. Although typically supported by a stem, the holder can rest on solid dosage forms and replace rayon or cotton wads. Various sizes accommodate 100-, 180-, and 270-mL bottles and neck finishes from 35 to 53 mm. The holders are compatible with most styles of closures and do not affect torque (Desiccant Basket, Healthcare Packaging Group, O. Berk Co., Union, NJ).

A starwheel on each side of the vial-filling area enables 100% in-line checkweighing. Empty containers pass through the first starwheel to capture tare weight, then they move through the filler, and then travel around a second starwheel that registers filled weight. Data can be recorded by nozzle, bottle number, or other parameters. If weights exceed preprogrammed tolerances, the system sounds an alarm or stops the machine. The checkweighing system can be installed on various fillers and is compatible with fills ranging from 1–40 mL (LF1240S-CWS Monoblock vial filler with 100% checkweighing, Cozzoli Machine Co., Somerset, NJ).

A compact checkweigher for small, light containers can check containers weighing <200 g at speeds as fast as 600 containers/min at an accuracy of ± 15 mg at 2σ . A force restoration weigh cell and dynamic weighing technology deliver tolerances tight enough to detect a missing tablet, component, or leaflet, as well as variations

in aerosol or fluid levels. A validation package can be provided to expedite the validation process (Rx1 pharmaceutical checkweigher, Hi-Speed Checkweigher Co., Inc., Ithaca, NY).

Counterfeiting/diversion prevention

To discourage counterfeiters, packages should carry more than one anticounterfeiting device. Fortunately, many anticounterfeiting tools are ink-related and relatively inexpensive. One converter handed out samples of a folding carton that demonstrated six different anticounterfeiting measures. Three features were visible only under UV light. When exposed to UV light, magenta phosphorescent ink, for example, glows terracotta or pink, a watermark simulating pearlescent varnish glows green, and invisible ink changes to a visible color. The other three options rely on special technology to produce barely visible microprint type, holographic stamping, or stochastic screening (N'Crypt Specialty Cartons, Alcan Packaging Contract Packaging and Specialty Cartons, Baie d'Urfé, QC).



The Goring Kerr DSP Rx metal detector diverts a suspect product into an integral lockable reject receptacle.

Hot-stamped holographic security stripes can be applied to cartons, inserts, and blister lidstock. The stripe can be combined with other overt and covert anticounterfeiting features, including strips that encode audible sounds such as music or speech, coin-reactive ink, microtext, temperature-sensitive ink, and UV-

sensitive ink (Medica Protec, Hueck Foils LLC, Wall, NJ).

A cap with a built-in RFID tag detects and records any opening of the container during transit or storage. The tag is programmed at the shipping point with information such as medication identification and certification code, tablet count, manufacturer, and intended destination, along with a disarm code. If the container is opened before reaching its destination, a light-emitting diode will blink to immediately indicate tampering. The tag may then be scanned to confirm the product information as well as any subsequent openings. In the pharmacy, the cap can discourage unauthorized access, theft, and poor recordkeeping. If the container is opened after store hours or if the tablet count is not updated after dispensing, an alarm sounds and is recorded. The next generation cap designs will be able to remind patients when to take their medication (eCAP/Secure, Information Mediary Corp., Ottawa, ON). **PT**

FYI

Review process participants

The Hydraulic Institute (HI) is seeking qualified individuals to participate in the review process of a newly completed standard for the definition, selection, application, operation, and maintenance of centrifugal slurry pumps. The scope of this standard includes types of slurries and slurry pumps, slurry limitations, slurry solids effect on pumps, pumping of froth, pump wear, and application. The standard provides requirements for wet-end and bearing housing shaft seals, establishes allowable nozzle loads, and provides a data sheet that can be used by purchasers and vendors to exchange information.

Interested parties may contact Karen Anderson, administrator, technical affairs, kanderson@pumps.org or tel. 973.267.9700, ext. 23.

To learn about membership in the Hydraulic Institute, contact HI Executive Director Bob Asdal at tel. 973.267.9700 or fax 973.267.9055. Requests may be mailed to Hydraulic Institute, 9 Sylvan Way, Parsippany, NJ 07054 or visit www.pumps.org and www.pumplearning.org.