Packaging Advances Showcased
Updated Equipment and Materials Displayed at Interphex

Hallie Forcinio

Now a part of the International Pharmaceutical Industry Congress, the 2002 Interphex pharmaceutical trade show was stronger than ever, both in attendance and in content. Dozens of innovative packaging machines, containers, materials, and components were displayed on location at the Jacob K. Javits Convention Center in New York City.

Blister packaging
A compact 4.2 × 1.45 m domestic-built machine has low positioning of coding equipment and film–foil reels. The machine’s nine servo drives and other components are contained in a pull-out rear cabinet, a configuration designed to improve hygienics, ergonomics, and maintenance accessibility. The 300-blower/min stainless steel unit has a maximum forming area of 244 × 154 mm. Capabilities include accommodating nearly any type of feeder, quickly changing over from cold to hot forming, and performing rotary-sealing, perforating, and cutting. The machine’s design includes space to mount vision and NIR inspection systems. The rotary sealing function minimizes heat transfer to the product, and rotary perforating and cutting reduce material usage and cost by narrowing the spacing between blisters to ≥2 mm. An integrated carteron responds to computer-based controls (B300, DT Packaging Systems, Leominster, MA).

A compact 2680 × 860 × 1630 mm blister packaging machine designed for clinical trials and low-volume production operates at 30 cycles/min whether it is running film or foil. The intermittent-motion machine features balcony construction and quick changeover without the need for tools. The maximum blister size measures 88 × 122 × 12 mm. However, the maximum pocket depth can be extended from 12 to 22 mm (P.G. Clinipack,IMA North America, Inc., Bristol, PA).

A blister card wallet production line generates ≤80 wallets/min with up to four blister cards each. Integrated with a blister machine or relying on manually loaded blister hoppers, the equipment creates a traditional paperboard wallet holder or child-resistant–senior-friendly style in various size and dose-count formats. Tool-free changeover takes ≤30 min (New-Wallet, Dividdella AG, Wareham, MA).

One established wallet pack has a broadened capability with the advent of a coating that allows the paperboard to seal to Aclar, a material commonly used for the forming web of blister packs. The wallet is child-resistant, senior-friendly, and compliance enhancing (Dosepak with Printkote EasySeal Plus paperboard, MeadWestvaco Packaging Resources Group, Stamford, CT).

Wallet formats also are available from at least one contract packager who can custom-design formats for compliance packs, starter kits, and physician-dispensed samples. Various paperboard and plastic material combinations, perforations, diecuts, and literature pockets also are available (Carded Blisters, Sharp Corp., Conshohocken, PA).

To enhance compliance, particularly in clinical-trial situations, an active radio frequency identification (RFID) tag that is built into a blister card wallet records the date and time as each dose is removed. This data is downloaded by a 13.56-MHz reader that is capable of scanning multiple tags simultaneously. Nearly one-half the size of a credit card, the 1.5-mm tag incorporates its own power source and a chip-and-sensor grid that adapts to any blister configuration. Alpha test trials for the tag were planned for July 2002 with beta testing scheduled for fall 2002. Inserting the RFID tag requires no special equipment and can be done by any pharmaceutical packaging converter (Med-ic Smart Package, Information Mediary Corp., Ottawa, ON). The choice of materials for blister packaging is expanding and includes a high-barrier alternative to foil consisting of polyvinyl chloride (PVC)–cyclo olefin copolymer (COC)–polyvinylidene chloride (Pentapharm COC SD/02, Klockner Pentaplast of America, Inc., Gordonsville, VA). For pharmaceutical packagers who prefer vinyl-free structures, the company offers a polypropylene/COC/polypropylene laminate.

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IMAs Sterifill F200 filling–sterilizing unit was shown as part of a complete aseptic line, which also included a washer and sterilization tunnel.

coding and embossing. One new machine with as many as four lanes creates four-side-seal pouches at a speed of 90 cycles/min. The unit can process pouches from 44–160 × 50–140 mm in size that contain products such as liquids, creams, powders, granules, tissues, and solid dosage forms (LA-160 Vertical Pouch Packer, Klockner Medipak, Clearwater, FL).

A compact tube filler with hot-air sealing jaws can process polyethylene, metal, or laminate tubes and is compatible with any style of product–feeding hopper. A balcony design positions the mechanical and electrical components in the same cabinet for improved accessibility and hygiene, and cam-controlled timing and programmable logic controllers (PLC) ensure accuracy and consistency. Depending on the height of the tube and how far the filling nozzles dive, the unit can fill and seal ≤80 tubes/min (Kalish K-80, DT Packaging Systems).

For conventional liquid filling, changeover is simplified and reduced to 5 min by a portable product-handling section with remote clean-in-place capability. To change over, nozzles slide out and are placed in temporary holders on the dockable filling system. One lever then releases the trolley, which is rolled away and replaced with another unit. Clean nozzles then are set in place, and the new batch can begin. Filling is governed by flow meters or lobe pumps that are arranged in pairs of 4, 6, 8, 10, 12, or more. Fill volumes currently range from 50 mL to liters, but eventually will be designed for volumes as low as 5 mL. A twelve-head machine fills ≤300 containers/min with 0.5%

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accuracy (Filamatic Series DFS Filler, National Instrument, Inc., Baltimore, MD).

Parenteral packaging
A small all-servo filling–stoppering machine designed especially for clinical trials relies on a peristaltic pump for filling and requires no change parts. Capable of simultaneously handling one, two, or four containers, the unit can output \( \leq 120 \) containers/min (model 1331, FP Developments, Inc., Williamstown, NJ). A sister machine that is integrated with a tray loader incorporates dual nested trays so the outer tray can be loaded while containers from the inner tray are being filled (Model 1377, FP Developments).

Another tray loader with dual trays is a servo-driven unit that requires no tools or change parts to change over. This machine is capable of processing \( > 400 \) vials/min. Loading patterns include straight, alternate, or N-1 (ATLJ-500S Servo-Driven Vial Tray Loader, Chase-Logeman Corp., Greensboro, NC).

A vial filler for volumes \( \leq 100 \) mL checkweighs parenteral products that are high-value or critical-dose and require extreme fill accuracy. Presented with piston pumps, but compatible with other filling mechanisms, this vial filler operates at 120 vials/min and checkweighs containers in pairs, checking both tare and fill weights without slowing down the filler. With 100% in-process weight measurement, the system can record fill data for each vial and provide documentation. The system accepts glass or plastic vials and can insert rubber stoppers or tip inserts and apply aluminum or screw caps (MLF 3002 Vial Filler, Bosch Packaging Technology, Minneapolis, MN).

A completely integrated parenteral line includes washing capability, a sterilization oven, filling and closing stations, and computer-based control and software for 21 CFR Part 11 compliance. Vials with 13-
Above: A metal 276 carousel outsert feeder from NJM/CLI provides at least a one-hour supply of and is easily adjustable to align the coding head for different containers.

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Top: Industrial Dynamics’s Lasetec Phase II coder can change serialized codes during production and is easily adjustable to align the coding head for different containers.

Above: A metal 276 carousel outsert feeder from NJM/CLI provides at least a one-hour supply of outserts, eliminates the need to dedicate an operator to the labeler, reduces labor costs, and improves worker ergonomics.

or 20-mm neck finishes begin at the washer, which can clean ≤300 vials/min (FAU6000 washer, Bausch & Stroebel, Clinton, CT). Next, vials pass through a sterilization tunnel with three sections: infeed and heating, a sterilization zone with temperatures 300–350 °C, and cooling (DHT3670 Laminar Flow Sterilization Tunnel, Bausch & Stroebel). Cooled containers move to the filling and stoppering unit, which features a rotary piston pump capable of a filling accuracy of ±0.1%, in-process checkweighing, and rotary stoppering (FFV6024 Vial Filler/Closer, Bausch & Stroebel). Carrier-type holders transport containers by the neck throughout the system. Because containers don’t slide, particulate generation is minimized. The carriers also enable seals to be accurately centered for filling and sealing.

Another complete aseptic line includes a washer and vapor hydrogen peroxide (VHP) sterilization tunnel integrated to an in-line filling and stoppering machine. The washer can be configured to handle various glass and plastic containers, including oval or elliptical shapes, and various infeed and outfeed options (Libra Hydra washing machine, IMA). From the washer, containers proceed to a VHP sterilization tunnel with a dry-heat chamber for depyrogenation (Libra Blue Galaxy VHP sterilization tunnel, IMA). Containers then transfer to the Class 100 filling area where they are processed four at a time. The system can accommodate fill volumes ≤500 mL at 320 vials/min (Sterfill F200 filling/stoppering unit, IMA). A filler for sterile vials exposes container openings for less than 8 in. of travel. Using presterilized containers and a Class 100 enclosure, this unit removes stoppers, fills vials, and then replaces the same stopper it removed. Final steps include application of a crimp or screw cap (model P1540, M&O Perry Industries, Inc., Corona, CA).

For large i.v.-solution bags, a filling module transports premade bags horizontally and centers the port for filling. After filling, the port is closed. The system is compatible with several filling methods and can be integrated with a bag-making module (BFV5060, Bausch & Stroebel).

Bags constructed of one ply of uncoated Tyvek and one ply of high-density polyethylene or other see-through sterilizable film protect presterilized supplies such as stoppers and vials as the component is transferred to an isolator-equipped filling line. The bags feature wrinkle-free, permanent seals and are compatible with ethylene oxide or steam sterilization methods (Isotech Bags, Tolas Health Care Packaging, Feasterville, PA).

Quality control Lines that require multiple inspection operations or that run at high speed often need multiple cameras to confirm quality. Typically, one vision system that supports up to two boards of four cameras each is mounted on a labeler or cartoner to ensure that all packaging components are present and correct. The inspection system includes computer-based control, a stainless steel enclosure, a flat-panel touch-screen operator interface, and an uninterruptable power supply (Visionemplace I-Pak Express, RVSI, Canton, MA). A lower cost two-camera system is available for less-stringent requirements. It requires only 35 microseconds to locate a randomly oriented eight-character code on a moving container and can check a two-dimensional code even faster, in slightly less than 15 microseconds. Because this system uses the same computer control and flat-panel touch-screen operator interface as the multi-camera unit, no retraining is needed for operators who switch from one system to the other. Optical character verification algorithms adjust to acceptable variations in preprinted or overprinted codes to reduce false rejects. The system supports a variety of camera models and offers onboard digital input/output for triggering, strobe control, and other interfacing functions (Visionemplace I-Pak Express, RVSI).

A vision system designed specifically for vial inspection relies on bright light from a multifiber-optic system and high-luminance light sources to examine the entire surface of the container. Comparing the captured image with a learned example, the unit detects glass defects; contamination in cake powder; level variations; and stoppers and cap position, position, and flaws. The system can process vials measuring 15–33 mm in diameter and 30–70 mm in height at speeds ≤180/min (Kanebo VVIS-SXX Vial Video Inspecting System, DJK-Global Group, Itasca, IL).

A digitally controlled photoelectric sensor monitors labels, rollstock, or other printed packaging materials for registration marks that will trigger labelers, form-fill-seal machines, or other packaging equipment. Internal controls store settings within the sensor, including automatic contrast tracking, which adjusts the unit as conditions change. An associated control panel allows an operator to adjust, configure, and monitor sensor operation by clicking on stored settings or feature icons (Smarteye DCS, Tri-Tronics Co., Inc., Tampa, FL).

A faster, more accurate checkweigher enables end-of-line quality control with in-motion weighing through starwheel indexing. Mounted above existing conveyors, the customizable system relies on electromagnetic forced compensation weighing technology and can be integrated with a reject system. The unit is equipped with 21 CFR Part 11–compliant software (HC-IS Indexing Checkweigher, OCS Checkweighers, Inc., Snellville, GA).

RFID technology that resides in a credit-card-size label is available for monitoring shipping conditions. Placed in the

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shipping container and activated as it leaves the manufacturing facility, the unit records as many as 64 temperature deviations beyond a preprogrammed range. These data are downloaded into a handheld RFID scanner when the shipment reaches its destination. The system is expected to be validated by the end of 2002 (TempLog Label, Schreiner Pharmaceuticals, Oberschleisheim, Germany).

Coding and marking
A hybrid printer combines a standard flatbed printer with a variable coder using inkjet, programmable hot stamp, or laser technology. The combination allows graphics and fixed text to be flexographically printed with conventional or UV light–cured ink and information such as lot codes, expiration dates, and bar codes to be variably printed. Variable printing simplifies tracking and tracing of individual packages and is a valuable tool in recall, diversion, or counterfeiting events (Platen Printer/Programmable Printer Hybrid, Adolph Gottscho, Inc., Union, NJ).

An enhanced continuous-motion thermal-transfer coder applies high-quality, 300-dot-per-inch dot and date codes at a rate of 1.5 m/s to moving webs such as those found on wrapping or bagging machines. Printing directly on bag or pouch surfaces can eliminate the cost and handling involved with preparing and inserting a separate instruction sheet. A 900-m ribbon minimizes downtime for roll changes (SmartDate 3, Markem Corp., Keene, NH).

Laser coders eliminate the need for ink and produce a permanent code on a variety of substrates. Compact electronic parts enable one unit to incorporate all of its electronics within the coding head. This design eliminates the need for a cabinet and only slightly increases the size of the head. Operators can change the font style and size from 1 to 30 mm without change parts. When various package sizes are run, an optional servo-controlled adjustment system automatically repositions the print head. The laser coder matches production line speeds while applying and verifying codes to passing packaging (Lasotec Phase II Laser Printer, Industrial Dynamics, Torrance, CA).

An enlarged aperture provides a large target area and fast throughput for a laser coder capable of printing as many as four lines of text or graphics in an 8.2-cm² area at a rate of ≈400 characters/s. Networking software allows this coder to be integrated into the packaging line without a separate computer (SmartLase SL, Markem).

Labels and labeling
Fast speed combined with small size describes a next-generation wipe-on label applicator capable of processing ≈181 mm-wide label stock at a speed of ≈6350 cm/min. The machine includes a streamlined interior with all-electronic components, a self-prompting display, a choice of five languages, and automatic setup (Model 3125 Wipe-on Labeler, Label-Aire, an Imppaxx company, Fullerton, CA).

Another label printer–applicator that is compatible with any printer on the market includes a rotatable operator interface with a two-line digital display and full error messaging. With all new electronics, the PLC-based machine’s interior component count has been reduced by 40%. Upgrades can be performed in ≈30 s from a Web site that enables a Flash download into onboard chips (Model 3038 Printer Applicator, Label-Aire).

A PLC-based 12-pocket carousel outsert literature feeder integrates with pressure-sensitive labels as part of a new line or as a retrofit. Changeover requires approximately one minute because no tools are needed and the hopper’s quick-change design allows 1219-mm trays of outserts to be slid into place even while the machine is running. During operation, the carousel indexes to empty each tray before moving to the next one, dispensing outserts at a rate of ≈250/min. Outserts range in size from 22 × 28 to 38 × 101 mm and may be applied to containers, caps, or under labels (Model 276 Carousal Outsert Literature Feeder, NJM/CLI, Pointe-Claire, QC).

Extended-text labels have been available for rigid containers for several years and now are offered for blister packages. Applying a multipage booklet or concertina-folded leaflet label to a blister’s foil lid stock reduces the packaging needed for clinical trials and samples and could eliminate the need for cartons. Because insert information is integral to the blister, blisters could simply be banded together for distribution. The leaflet covers the foil, making the yet-untested design potentially child resistant. The label may be produced in a two-part design, which includes a removable doctor’s leaflet in addition to the patient leaflet (Inseal Blister Pack Leaflet, Inprint USA, St. Charles, MO).

Interest in extended-text labels has surged as pharmaceutical manufacturers seek ways to meet requirements to include a “drug facts” box on over-the-counter products. One design boosts label real estate by approximately 70%. It features a single-ply label with print on both sides. Nearly two-thirds of the back is printed with ink and a pressure-sensitive, adhesive-deadening material so that section of the label can be lifted, read, and replaced repeatedly (Pharmalabel Text–A–Peel, R-Perfs Printing Alliance, Greensboro, NC).

Yet another extended-text design consists of a 40-page booklet with a glued spine. It can be applied with glue or combined with a pressure-sensitive label (40-Page Booklet Label, Pharmaceutical Litho & Label Co., Chatsworth, CA). A variation of the booklet label with integrated pages has 12 pages can be applied with a sling-style label made of heavy-duty 5-mL plastic. The integral hanger eliminates the need to add hanging hardware to containers intended to be suspended from i.v. poles or other devices (BPS 2000 combination booklet/sling label, Pharmaceutical Litho & Label).

Multilayer labels for the smallest ampuls and vials are available in several configurations. Options include labels with peelable sections for transfer to medical files and vaccination passports, detachable sections to provide information to both the caregiver and the patient, multiple pages printed in various languages, and integrated designs for clinical trials (Extended-text labels, Schreiner Pharmaceutical Labels).

Capping and closures
Skewed caps are eliminated with a rotary cap placer that sets the cap straight down on the bottle finish. With a processing speed of 300 caps/min, the unit can be integrated with a traditional spindle capper. The device can process most cap styles, including continuous thread, child resistant, and metal in container sizes 30–1500 cc (NERCAE Rotary Cap Placement System, New England Machinery, Inc., Bradenton, FL).

A press-and-turn, child-resistant metal cap with a translucent polypropylene overshell returns to the market following the acquisition of the patent holder. The steel undercap can be lithographed in various colors and embossed. Available finishes include 24–, 28–, 33–, 38–, and 45–400. Caps can be supplied with induction seal or pressure-sensitive liners to provide tamper evidence and child resistance (Saf-Lok CRC, Penn-Wheeling Closure, Glen Dale, WV).

Container innovations
An alternative to prefilled aluminum unit-dose cups for liquids is injection-molded amber polyethylene terephthalate. The current size accommodates fills of <1 oz, but a smaller cup for fills of 5–10 cc may be produced in the future (PET Unit-Dose Cup, Lyne Laboratories, Brockton, MA).

The impressive display of pharmaceutical processing and packaging equipment at the 2002 Interphex show isn’t the only opportunity to see pharmaceutical packaging equipment in action this year. A considerable range of pharmaceutical packaging equipment, including new product introductions, will be shown 3–7 November 2002 at Pack Expo International at McCormick Place (Chicago, IL). Meanwhile, it’s not too early to start planning budgets and goals for next year when Interphex returns to New York’s Javits Center, 31 March–2 April 2003.