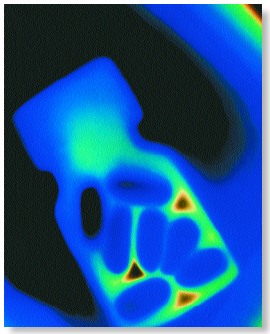
Bar Coding Deadline Looms



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We are now less than a year away from the April 24, 2006, deadline that requires bar coded labels on approximately 153,500 packaging units of prescription and over-the-counter (OTC) drugs dispensed in hospitals. Drug products approved for use after the rule's April 24, 2004, effective date must be bar coded within 60 days of approval.

FDA's final rule requires a linear bar code representing the product's national drug code (NDC) to be placed on the immediate container label and the outer wrapper that appears on most prescription and certain OTC drugs commonly used in hospitals, or about 75% of OTC products. The lot number and expiration date do not have to be included, but drug makers may do so, if desired. The rule applies to most drug manufacturers, as well as repackers, relabelers, private label distributors, and blood establishments (www.fda.gov/OHRMS/DOCKETS/98fr/04-4249.htm).

The goal is to reduce medication errors by providing an automated means to confirm the right dose is given to the right patient at the right time *via* the correct administration route. In use, the bar code on the unit dose pack is scanned at the time of administration. For a more complete record, bar codes on the patient's wrist band and caregiver's identification badge also could be scanned.

Compliance with the unit-dose bar coding rule requires integration of bar code technology, printing, quality control, data collection and transmission, and recordkeeping. If widely divergent packaging formats are involved, more than one solution may be required. Narrowing the choices can be a bewildering, time-consuming endeavor.

Further complicating the scenario, many technology providers, early adopters, and trade organizations recommend looking beyond simple compliance to use the information unit-dose coding makes available to gain internal benefits. This means encoding variable information such as the lot number and expiration data in addition to the NDC. "Many benefits can be gained through process changes that take advantage of information available on unit-of-use labels with little incremental labeling or equipment costs," notes a white paper entitled, "Beyond Point of Care: Benefiting from Unit-of-Use Bar Code Traceability in the Life Sciences Supply Chain" (**Zebra Technologies**, Vernon Hills, IL, www.zebra.com). In fact, the report notes, "variable-information labeling can improve regulatory compliance, recall management, distribution and returns, production control, product authentication, customer service, and other operations for manufacturers and distributors."

Many of these benefits relate to the increased visibility unit-of-use bar codes can provide. The ability to track product at the batch level throughout the supply chain increases efficiency and improves customer service while ensuring returns are authorized. In recall situations, this level of traceability makes it possible to pinpoint affected quantities and shipments and minimize the amount of product returned.

Unit-of-use data also can be valuable in production and inventory management. "Encoding lot numbers in the unit-of-use packaging and marrying that information with electronic production records can satisfy 21 *CFR* Part 11 [Electronic Records and Signatures Rule] reporting requirements and provide traceability by raw material batch, manufacturing equipment, time of production, equipment operator, and other variables," the report says.

Finally, unit-of-use data can work in conjunction with other overt and covert measures to authenticate products, minimize chances of counterfeiting, and help identify where diverted products went astray.

One of the first choices manufacturers must make when implementing unit-dose labeling is the bar code symbology. Any Uniform Code Council/European Article Number (UCC/EAN) linear bar code capable of accommodating the NDC is acceptable. Commonly used symbologies include Code 128, Code 39, and reduced space symbology (RSS). The latter is a family of codes specifically designed for reproduction in the limited space often found on blisters, vials, or other unit-of-use packaging formats. There are several variations of RSS, including a stacked configura-

tion that can encode an NDC, lot number, and expiration date into a single bar code measuring less than an inch wide.

Because various bar codes are acceptable and different customers may have different preferences, it's important for manufacturers to have a flexible printing system. Special attention should be paid to changeover time because runs of unit-dose formats may be relatively short.

The choice of printing method will be influenced by the type of package, existing equipment, and consumable costs. For example, thermal-transfer overprinters, flexographic platen printers, and ultraviolet printers can print lidstock for blister cards. Noncontact laser coding and inkjet also can be used.

For applications that require labels, thermal-transfer printers offer excellent print quality and frequently are integrated with label applicators in print–apply systems. Other options for coding labels include laser, inkjet, and hot stamping. Of course, labels can be preprinted if variable information isn't needed.

One specific software upgrade for a thermal-transfer overprinter has enhanced its ability to create bitmapped images of RSS codes. Mounted on a blister packaging or thermoform–fill–seal machine and compatible with either intermittent- or continuous-motion equipment, the printhead can print codes two-up. For bigger formats, printheads can be ganged to print more codes simultaneously. This unit features a clutchless, bidirectional ribbon drive to maintain proper ribbon tension and prevent breaks that cause downtime. The bidirectional feature also maximizes ribbon usage by backtracking after printing so that only 1-mm sections of ribbon remain unused. Based on a standard Windows operating system with Ethernet, the digital system can code in real time, making it possible for operators to automatically program date and time rollovers and offsets. A color touch screen with an intuitive graphical user interface makes the system easy to learn and simple to operate (**DataFlex** thermal-transfer overprinter, **Videojet Technologies Inc.,** Wood Dale, IL, www.videojet.com).

One application for prefilled syringes uses an off-line intermittent-motion thermal-transfer overprinter. To ensure 100% traceability of the 50,000 syringes filled each day, the overprinter can code preprinted labels with an RSS composite stacked bar code along with human-readable characters. The RSS code represents a lot number, date code, and a sequential production number. The image is sent to the printer as a bitmap, and 10 × 18 mm labels are printed off-line, respooled and applied to the syringe before filling. After filling, each syringe passes through a vision station. If the code is not readable, the line is stopped, and the label number is recorded. The unreadable label is removed, and a new label is applied.

Flexographic platen printers also deliver quality bar codes, alphanumerics, and graphics. Models are available to fit on virtually any blister packaging machine. The printers rely on flat rubber mats to transfer the image using solvent-based, water-based, or ultraviolet inks. Removable print-mat plates reduce plate changeover time to less than 60 seconds (800 Series In-line Platen Printers, **Adolph Gottscho, Inc.,** Union, NJ, www.gottscho.com/).

Noncontact inkjet systems, which form images with a dot pattern, are extremely flexible and can be ganged or mounted on a traversing mechanism to print across relatively wide expanses of lidstock. Standard industrial cartridges supply color, black, or ultraviolet/infrared inks (GottJet Series coders, **Adolph Gottscho, Inc.**).

Laser coders also are noncontact systems and etch high-resolution, permanent codes into substrates at high speeds using laser energy. The compact size of these coders simplifies integration with packaging or labeling equipment.

Most printing systems accept label data from a personal computer or an upstream system such as a manufacturing execution system. Printers also should be capable of recording and transmitting operational information to meet validation and 21 *CFR* Part 11 requirements.

Another critical component related to unit-dose bar code printing is quality control to ensure codes are scannable and correct. Typically, quality control is performed by a laser scanner or vision system mounted near the printing mechanism. On a platen printer, for example, a camera can be positioned after the printer to verify the human-readable information while a laser scanner grades the print quality of the bar code. Grades are assigned according to standards administered by the **American National Standards Institute** (Washington, DC, www.ansi.org).

To take full advantage of the track-and-trace capabilities offered by unit-dose bar coding, drug manufacturers also must study their product flow to identify locations where scanners can be positioned to collect data as product passes by. This information must then be stored and organized so that it can be retrieved as needed to document product transport.

Material handling also must be considered. For short runs, it may be practical to set up a manual or semiautomatic packing operation. One manual packing station designed for sample packaging, but also suitable for unit-dose applications, conveys blisters from the outfeed of the blister packager through a gap transporter to a stop where a preset number are automatically counted and dropped into waiting display trays. Once the count is complete, operators simply close the display trays, place them on an exit conveyor for case packing, and set up a new display tray. The stainless steel system can be configured with multiple stations (Blister Packaging Station, **Auto Pak Engineering Corp.,** San Juan, PR, www.autopak.com).

Perhaps most interesting is the potential for combining unit-dose bar coding with anticounterfeiting technologies and radio frequency identification (RFID). Future possibilities include ink with product-identifying DNA taggants and RFID labels read by reader-equipped cell phones. In the not too distant future, it will be possible to print codes directly on solid dosage forms. Whatever paths evolve, the security of the pharmaceutical supply chain will be greatly enhanced and medication errors should become much rarer than they are today. **PT**