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News

Adding Up the Numbers behind UDI

Achieving unique device identification (UDI) will be tough during a downturn economy. But that’s what FDA is hoping you will do.

Evidenced by the regulatory hints that FDA’s senior adviser for patient safety Jay Crowley gave at the February 12 UDI workshop, the agency is urging the medical device industry to step up to fight sluggish recalls, which endanger patients. (For more details on the two-part coding system FDA is considering for medical devices, see the Bar Code Supplement beginning on page 58 or visit www.fda.gov/cdrh/meetings/021209workshop/.)

Workshop panellists and attendees all acknowledged the need for a better way of identifying recalled medical devices. But the sticky issue of the downturn economy just couldn’t be ignored. Jean Sargent, supply-chain director for the University of Kentucky’s two-hospital system, explained that she has “C-Suite” support for better product identification. “Our pharmacy and clinical lab are moving toward bedside scanning,” she reported. “Our CFO is happy, and our CTO pointed out that by standardizing processes and nomenclature, we could reduce unnecessary variation.” But “we have to keep it simple—various standards would not work.”

Later, during an open discussion, Sargent pointed out that “we don’t need UDI on syringes or ‘doaldads,’” getting a chuckle. There are “economic issues—we don’t need to increase a 5 cent item to an 8 cent item.”

Separately, Gorwin Hee from Covidien suggested a “risk-based approach” to UDI as well as a “phased-in approach,” adding that “there is a finite limit on our resources so [let’s] use the most cost-efficient system.”

And costs could even be measured in terms of effort spent. Added Tom Werthwine from Johnson & Johnson: “We don’t need broadsweeping rules and then have exclusions—that’s a burden on manufacturers and on the agency.”

FDA has yet to release draft guidelines or rules on UDI. Crowley explained the workshop was industry’s chance to speak up about UDI. Written comments were accepted through February 27.

EPS Recycling

A company has joined forces with the Alliance of Foam Packaging Recyclers and increased its recycling efforts to include expanded polystyrene. ACH Foam Technologies (Denver) provides EPS packaging for the transportation of healthcare products, specifically pharmaceutical companies. Among the larger companies it provides packaging and recycling services for is ViraCor Laboratories.

“Basically the program is geared toward pharmaceutical or any temperate-sensitive customers who utilize EPS shipping containers,” says Keith Baechele, western regional manager for ACH. “Because EPS is recyclable, we encourage these customers to promote themselves as a collection center for their customers.”

Customers receive materials back, then store them for ACH to pick up when new product arrives. The company then transports the EPS back to its facility to recycle in one of two ways: grinding old material down and introducing it back into virgin block products to use for insulation or construction products, or densifying the ground material for ACH’s raw material supplier to remanufacture into raw goods.

Training is provided for customers that want to join in. ACH discusses material types and qualities that are suitable.

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“First, it has to be EPS,” Baechle says. Materials out there look similar, he adds, and they will contaminate the system if introduced, so customers are trained on what materials are recyclable or not.

“We have a secondary inspection process which ensures noncontamination as well at our facility level,” Baechle continues. The materials need to be free from labels, debris, dirt, or any foreign material. “For obvious reasons, we want the material to be ready for recycle as much as possible by the time it reaches our facility.”

A green sensibility lies at the core of the program, sometimes regardless of the original material’s source. ACH tries to accommodate other companies’ EPS product as well as its own, and Baechle ventures that the company collects as much product from other suppliers as its own. The primary goal is to serve its customers.

Different customers have different needs and participate on different levels of EPS recycling. ACH tries to accommodate each customer’s needs to the fullest extent possible to recycle EPS product, whether it was or is purchased from us or not.”

Allies in Image Systems

Vision software and tool provider Cognex (Natick, MA) has announced the launch of the Cognex Acquisition Alliance. This alliance aims to create technical and marketing relationships with camera manufacturers, for added value to the collective companies’ customers. Suppliers that have joined the Acquisition Alliance include Allied Vision Technologies, Dalsa Corp., and JAI.

Executive vice president and vision software business unit manager Markku Jaaskelainen said in a press release that discussions for expansion have already begun. The company’s ultimate goal with the collaboration is to quickly integrate and qualify new partner cameras with Cognex VisionPro software through vendor self-verification and enhanced customer service. Jaaskelainen anticipates more companies will join the alliance in the near future.

Michael Gibbons, product marketing manager at Point Grey Research, which joined the alliance, lauded the new group. “By providing a process for fast and easy delivery of Cognex Configuration Files [CCF] for all supported Point Grey cameras, we can maximize product compatibility and minimize integration issues.”

Industry Briefs

At its annual business conference in January, the Automated Imaging Association (AIA; Ann Arbor, MI) announced its new board of directors including president Michael Cyros, president of Allied Vision Technologies Inc. AIA is the world’s largest trade association for the global machine vision and imaging industry and supports events such as The Vision Show and the International Robots, Vision, and Motion Control Show. Newly elected to two-year terms on the AIA board include George Chamberlain, president and cofounder of Pleora Technologies Inc.; Gregory Hollows, director of machine vision solutions, Edmund Optics; and Peter Tang, VP innovation and technology, ATS Automation.

Medica Packaging (Cheshire, UK), part of folding packaging specialist Benson Group UK, has purchased a Gallus EM340S printing press for its pharmaceutical-focused business to begin work in the labels sector. The machine features a Scantech VisionTrack rewound the purchase and expansion into the new market. Medica has installed a press comparator system to compare the first-off print production pass to a customer-approved PDF, which the company believes could be a first in the pharmaceutical label market.

Cook Urological has for the third time designated Barger Packaging Inc. (Elkhart, IN) the “Dock to Stock” supplier. A representative from Cook cited Barger’s dedication to providing quality materials to safely supply effective medical devices as the quality it wished to recognize with the award.

The European Medicines Agency (EMEA) has granted license approval to Bayer Healthcare LLC for its new sterile filling facility on its Berkeley, CA, campus. Bayer Healthcare’s new facility can now supply the Bayer Kogene...