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Friday, January 11, 2008

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> **Pharmaceutical & Medical Packaging News**

**Pharmaceutical & Medical Packaging News** is a comprehensive resource for medical and pharmaceutical manufacturing professionals who need focused, reliable, and timely information to make intelligent packaging decisions.



**EDITOR'S PAGE**

**PMP News ePackage Newsletter**

**Executing Packaging Efficiency**  
-Daphne Allen

As drug makers begin to serialize every salable unit right on the packaging line, they may be adding new systems and processes to generate and handle a lot of data. In an era of lean manufacturing, however, companies may fear that serialization could add significant costs and burden.



**Silence Is Not Golden: California Seeking Data as It Considers Pedigree Delay**

A delay in California's Electronic Pedigree rule appears to be on many wish lists this year. Judging from the number of pharmaceutical companies and retail pharmacies asking for such a delay at the State Board of Pharmacy's Enforcement Committee meeting in December, most stakeholders do not appear poised to comply in 2009. While such reports disappointed the committee, it has not yet issued its final decision.

"Pharmaceutical companies are focusing on plant efficiencies these days," reports Joseph Ringwood, vice president of sales and operations for Systech (Cranbury, NJ). To do so, "many are trying to apply manufacturing execution systems (MES) to packaging lines with a server-level application. But the new complication is



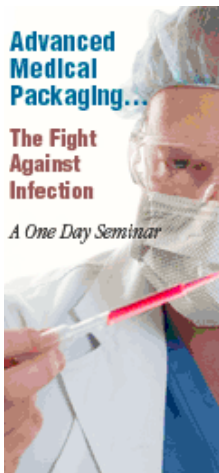
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#### THIS MONTH IN PMP NEWS

##### Order Up

The menu of services and supplies offered by contract packaging firms continues to grow.

##### Adding Up the Numbers

Managing the data from serialization initiatives demands dedicated software.

##### Assessing Options for OTCs

Marketers are considering green packaging alternatives.

##### Standardized Security for Security Products

A group tightens control over security graphics, with an eye on new risks.

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#### THIS WEEK'S WEB SIGHTING

##### Shorewood Packaging

Instead, the enforcement committee has provided a template for delay-seekers to follow as they provide written requests. All delay requests must follow this template. "A lot of companies have spoken to us that are ready to pass compliant product by 2009," said Joshua Room, California's deputy attorney general and the committee's lawyer, during the December meeting. "The board needs to decide whether extending the date is in support of its goal to protect patients."

All requests must be submitted to the committee for discussion at the January 23 meeting in San Diego. The board "will not consider any request not submitted in writing, and not received at least two weeks before a full Board meeting, e.g., by no later than January 9, 2008, to be timely for the January 23, 2008, meeting," writes the board in its template notice.

"My fear is that if we more forward with a delay, how will we know that we won't be sitting here in two years hearing the same comments?" asked committee member Stanley Goldenberg. "How will we know that [electronic pedigrees] won't fall off everyone's radar screen for another two years?"



A paper packaging producer has introduced an enhanced healthcare-solution Web site to provide customers with information about its packaging products and services for the healthcare industry. The site offers access to the company's range of healthcare packaging products, including over-the-counter and ethical folding cartons, blister cards, unit-dose-carded packaging, compliance packaging, child-resistant/senior-friendly packaging, physicians' sample packaging, promotional and new product packaging, and point-of-purchase displays. The site offers sections focusing on packaging solutions, safety and compliance, security, and branding, as well as an introduction to the Genesis online design collaboration tool.

Goldenberg expressed such concern after hearing from pharmaceutical companies and others that more time is needed. He had pressed four drug manufacturers (Amgen, Johnson & Johnson, Pfizer, and Roche) for impromptu progress reports, asking them to come forward from the audience to speak directly to the committee. He had asked them to respond to a presentation from Alien Technologies, whose Victor Vega reported that ultrahigh-frequency RFID is ready for item-level tagging.

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**EDITORIAL**

**Executing Packaging Efficiency**

As drug makers begin to serialize every salable unit right on the packaging line, they may be adding new systems and processes to generate and handle a lot of data. In an era of lean manufacturing, however, companies may fear that serialization could add significant costs and burden.

“Pharmaceutical companies are focusing on plant efficiencies these days,” reports Joseph Ringwood, vice president of sales and operations for Systech (Cranbury, NJ). To do so, “many are trying to apply manufacturing execution systems (MES) to packaging lines with a server-level application. But the new complication is serialization.”



Traditional MES solutions, however, were not specifically designed to handle packaging processes, let alone serialization efforts, Ringwood points out.

With its software platforms for managing different levels of packaging operations, Systech decided to integrate them all with what Ringwood calls the first end-to-end packaging execution system (PES).

“You cannot have serialization without a PES,” he says. “Giving items unique numbers and making associations demands that such information be managed and sent up into other business systems.”

Systech’s PES operates at three layers, bringing the following functions into a single infrastructure:

- Maintain safety and accuracy at the machine level using Systech Sentri during vision inspection.
- Manage all packaging and labeling devices at the line level using Systech Advisor. Systech’s Serialized Product Tracking (SPT) application, an application to Advisor, enables serialization.
- Collect all data—serialization or otherwise—to transmit to other plant levels like enterprise resource planning (ERP) systems using Systech Guardian.

“There is a tremendous amount of data generated by packaging operations that goes nowhere,” says Ringwood. “PES allows management to use that data.”

In October, The ARC Advisory Group (Dedham, MA) issued a white paper discussing how packaging execution systems can benefit lean manufacturing initiatives. The paper describes how a pharmaceutical manufacturer implementing 2-D Datamatrix bar codes for serialization selected Systech’s PES. The SPT application has enabled “serialization of products at the item, case, and pallet level.”

The manufacturer's next step is to extend the PES to include "plant-level management of EPC serial numbers and overall equipment effectiveness measurement using Systech Guardian," which "connects to ERP and EPCIS systems providing a single point interface to the enterprise and, ultimately, to the supply chain and customer." Currently involving 25 packaging lines across 12 worldwide sites, the project demonstrated "measurable performance improvements at the first plant."

With item serialization close to becoming law, pharmaceutical manufacturers are facing tremendous tasks.

But not impossible. The pharma company described in ARC's white paper was able to manage product serialization while realizing performance improvements, thanks to a packaging execution system. Your company could, too.

Daphne Allen  
Editor

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