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Business Strategies for Pharma/Bio Success



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## SPECIAL FOCUS REPORT

### Managed Care Contracts: The Struggle for Clarity

Changes in the industry landscape, the regulatory environment, and within manufacturers' organizations are continuously impacting the managed-care component of the pharmaceutical business. Model N recently conducted an industry survey of 53 pharmaceutical manufacturers that explored managed care and Medicare Part D trends

## PACKAGING/DRUG DELIVERY

### Packaging Execution Systems: A New Way of Thinking About Pharmaceutical Packaging

By Joe Ringwood, SYSTECH International

Date: 2007-04-30

*Using the right software can improve operational efficiency and pave the way for evolving serialization and tracking functions*

*The packaging line at a modern pharmaceutical manufacturer is the culmination of all the precise and highly regulated production activities that precede it. The packaging line is where carefully produced product is combined with labeling, trade dress and other packaging components. With margin pressures and regulatory demands mounting, pharmaceutical companies worldwide face an ongoing struggle to maximize productivity and performance at the machine, line and enterprise levels.*

Lately, the need to know what is happening on packaging lines has become more pressing. In addition to meeting myriad regulatory requirements governing product quality and patient safety, and emerging as a focal point for productivity and performance improvements, packaging lines are also considered a first line of defense against counterfeit and diverted products. Developments in serialization and authentication technologies are now being incorporated. RFID—a pivotal technology for improving both security and supply chain efficiency—will, by itself, greatly expand the data gathering and product tracking functions along the packaging line.

With mounting margin pressures and escalating regulatory demands, pharmaceutical companies face the need to integrate monitoring and control technologies on their packaging lines as never before. To efficiently address these new demands, pharmaceutical companies are investing in a new approach to automation and operations management: the Packaging Execution System or PES.

#### PES defined

A Packaging Execution System is composed of packaged software designed to capture performance and safety data from disparate automation and monitoring devices across a packaging line or lines. It then synthesizes that data into actionable intelligence and shares that information for real-time decisionmaking at the line, plant and enterprise levels. A PES is a modular, scalable, productized solution that is repeatable from line to line or plant to plant.

The PES concept borrows from a familiar data management scheme known as the Manufacturing Execution System (MES), a suite of software functions that reside between MRP/ERP (materials/enterprise resource planning) systems and manufacturing control systems. An MES makes it possible to share information between MRP/ERP systems, programmable logic controllers (PLCs), and distributed control systems on the manufacturing floor. Similarly, the PES can communicate directly with an organization's ERP system while providing real-time information critical to the plant personnel operating and overseeing packaging lines.



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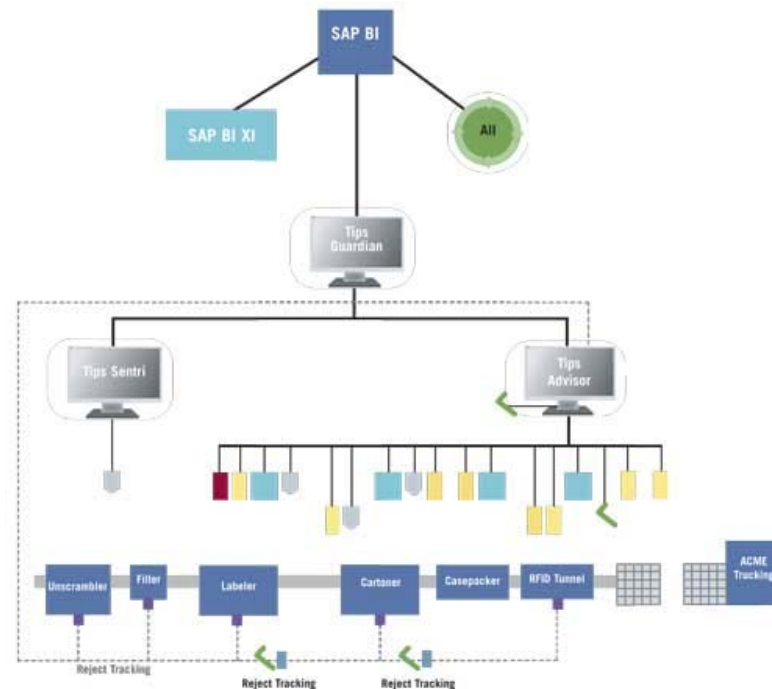
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The line infrastructure needed to collect essential packaging data for PES is generally already in place. Easily tailored to the requirements of any specific packaging line, software that is included in a PES is also meant to handle emerging requirements for product serialization, RFID or other product-tracking functions. The advent of productized software designed to function within a PES makes it possible to quickly and cost-effectively establish a completely integrated solution.

#### Complete visibility

Today, various segments or functions of the packaging line provide "real time" automated decisionmaking at high throughput rates. Consider machine vision, which guarantees that quality product is correctly packaged and helps reduce downtime and rejects by keeping an electronic eye on stations of the packaging line. Unfortunately, most vision tools do not provide analysis and visibility beyond the packaging line operator. With a properly designed PES, however, the capability now exists to gather the following types of information from the vision system and other intelligent devices on the line systems, integrate it with data from other parts of the line, and convey it to any part of the enterprise:

- \* Production run data
- \* Item-level serialization data
- \* Downtime/event reporting
- \* Line setup and changeover data
- \* Material usage
- \* Regulatory reports

In addition to making line intelligence available for decisions at the plant and enterprise level, a PES can seamlessly bring key information and instructions down to the line level from the ERP system, facilitating device management and set-up management such as:

- \* Lot Number
- \* Expiration Date
- \* Inventory and availability of packaging components
- \* Label commodity code
- \* Insert commodity code
- \* Carton commodity code
- \* Production line instructions

By managing information between the line and the enterprise, a PES architecture is uniquely able to streamline critical regulatory and business issues related to patient safety, counterfeiting and diversion. A key part of the emerging practices in product tracking capabilities is the adoption of the communication standards from EPCglobal, an international agency (U.S. operations in Princeton, NJ) that brings manufacturers and technology vendors together. EPCglobal has developed a communications architecture known as EPCglobal Information Services (EPCIS). As manufacturers activate item-level serialization solutions on the line, the PES communicates the vital serialization information seamlessly from the EPCIS data source to the line and gets the real-time tracking information, including rejects, back to the enterprise system for accurate, timely and convenient tracking.

As manufacturers put PES systems in place to meet regulatory requirements, business considerations such as enhanced line efficiency, predictability and more accurate projections can also be addressed. For instance, if a PES is adopted to streamline item-level serialization, Overall Equipment Effectiveness (OEE) can be easily added. Since a PES solution is in touch with all aspects of the packaging line, users can simply add OEE parameters into the PES. With a PES, when a line supervisor is notified of a real-time problem, the problem is addressed during the actual production run and the PES

automatically applies “on-time” information to the production schedule, preventing potential bottlenecks and improving line efficiency. While improving the communication between the enterprise and a packaging line, the PES provides the comprehensive visibility to identify global issues that are hindering efficiency—enabling best practices and enabling more accurate project production requirements.

Another benefit of PES software is scalability, both in terms of additional production capacity and broader functionality. No matter what functionality is installed on a line, a PES allows customers to incorporate new line capabilities as desired to help realize the full benefit. For example, when item-level serialization is installed on a line it is very easy for that manufacturer to add line optimization modules. Integrated PES solutions also enable customers to add new lines and new functionality immediately or over time. In essence with PES, each packaging line can be given time to evolve and adapt.

#### **PES in action**

Recently, a pharmaceutical manufacturer required a new packaging line including multiple verification points, recipe management, and device set-up and management. The complex nature of this particular line mandated a flexible approach that would include multiple line monitoring and control solutions and also allow for the addition of RFID serialized tracking in the future.

The company was introduced to SYSTECH's Packaging Execution System software solution. The integrated nature of the SYSTECH PES solution offered tight quality monitoring, machine vision inspection, reporting, and Overall Equipment Effectiveness (OEE) through software that eliminated the need for manual configuration of these capabilities.

All these systems—including the vision inspection solutions—were linked via one main data control center, which provides the company with automation and information management across their entire packaging line. The benefits of a single, highly configurable PES solution has proven so effective for the manufacturer that it is being implemented on three previously existing packaging lines.

#### **Making the case for PES**

The PES architecture integrates siloed packaging processes together into a cohesive packaging strategy—offering a dynamic packaging environment that enables manufactures to remain nimble in the face of market changes and prepares them for the next phase of business.

Packaging Execution Systems are scalable and modular in their design and execution. This allows pharmaceutical companies to add lines as needed and easily integrate functionality to the packaging process as required. For example, software modules can be added to the packaging system like item-level serialization alternatives for RFID or 2D barcoding or OEE that is integrated into line management.

Manufacturers are turning to PES providers to holistically address their machine, line and plant needs. SYSTECH offers Packaging Execution Systems that enable pharmaceutical companies to provide protection, clarity and optimization into their operations while allowing for expansion of product, modules and new features as regulatory demands arise and higher levels of efficiency is expected.

PES is an undeniable trend. Packaging efficiency, availability, performance and quality dictates whether or not products are delivered on time and in full, which directly impacts a company's bottom line. By adopting the PES approach, manufacturers can eliminate factors leading to loss of revenue, protect consumers, and rapidly realize positive business results.



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