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Security in Serialisation: Tracking Pharma Technology

The pharmaceutical packaging industry is experiencing a time of change and growth. We talk to technology provider Systech about how serialisation systems are helping to tackle some of the biggest challenges the industry faces today.

Date: 23 Sep 2010



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The pharmaceutical packaging sector is currently facing a number of challenges. One of the biggest is ensuring counterfeit drugs do not enter the supply chain. Estimates suggest that 10% of global drugs are counterfeit and 30% of product recall in the pharmaceutical industry is attributable to packaging.



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Estimates suggest that 10% of global drugs are counterfeit and 30% of product recall in the pharmaceutical industry is attributable to packaging.

The September 2010 Arena International Pharma Packaging and Labelling event in Munich, Germany, will tackle the subject of counterfeit drugs among other big issues affecting the industry. Addressing delegates on understanding serialisation practices within the context of an overall packaging executive system (PES) will be Frederic Menardo from international technology provider Systech International. Pharmaceutical Technology caught up with Frederic for an exclusive insight into Systech's technical expertise and lessons learned from deploying hundreds of serialised lines worldwide.



 Expand Image
Systech has over 150 packaging lines installed, and the Systech SPT is used to support track and trace, ePedigree, and product packaging authentication.



Pharmaceutical Technology: What are the biggest issues affecting the global pharma packaging and labelling industry today?

Frederic Menardo: Serialisation mandates in Europe and elsewhere have established the imperative for companies to consider their packaging information requirements. Due to progressive global regulatory expectations manufacturers need to promptly employ

serialisation solutions.

Current and pending regulatory requirements necessitate that manufacturers deploy track and trace, authentication and e-pedigree: an electronic record specifying the product's chain of custody, which is more efficient and accurate than paper records.

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Serialising products at the item level enables the above processes, allowing manufacturers to address global regulations as well as patient safety and anti-diversion initiatives.

"One of the biggest pharmaceutical challenges is ensuring counterfeit drugs do not enter the supply chain."

PT: Can you explain the part Systech technology plays in the serialisation process?

FM: Systech has over 150 packaging lines installed, and the Systech SPT is used to support track and trace, ePedigree, and product packaging authentication. SPT leverages Systech's productised packaging execution system (PES). Systech SPT maintains control over serialisation at the item, bundle, case and pallet levels and can be deployed over multiple lines in multiple sites. Systech SPT acts as a gateway between enterprise IT systems and packaging operations. The SPT gateway collects data from the entire on and offline packaging operation, ensuring the integrity of serialisation data before it is delivered back to the enterprise IT systems.

Regardless of the speed or availability of enterprise servers, the packaging operation can continue running at maximum throughput. Systech SPT is productised, configurable and expandable, allowing the solution to easily, quickly and inexpensively accommodate changing global demands. An expandable serialisation solution can easily grow to meet new requirements. Expandable serialisation software is modular because it allows manufacturers to increase capabilities as they need it, such as post-lot requirements for serialisation.

Manufacturers that invest in productised, configurable and expandable serialisation solutions that leverage a PES platform will be best positioned to deploy serialisation and take advantage of future opportunities, as well as be able to more quickly and cost-effectively respond to new demands. These solutions prepare manufacturers for the future while also controlling the total cost of ownership (TCO)



 Expand Image
Systech's packaging execution system.

PT: What are the benefits of mass serialisation and what are the main differences, if any, noted when rolling out this kind of system across US and other markets?

FM: It allows the tracking of unique items to fight counterfeiting and diversion, and improves the reimbursement payment processes in various countries.

The difference between a configurable system and a customisable solution lies in if the software needs to be recoded or customised to manage change. There are clear benefits to configurable software like Systech's packaging execution system.

Systech's serialisation software is designed with elements that can be assembled and realigned to quickly accommodate changing demands without requiring code rewrites.

In terms of addressing the US and other markets, Systech's configurable system is equipped to handle domestic and global requirements. Our configurable serialisation software is flexible, enabling it to support a wide variety of packaging line functions. For example, if serialisation requirements change, the line needs to perform new functions.

Configurable software already has the capabilities inside to create the instructions for these new functions, eliminating the need to write new code. Therefore, by investing in configurable serialisation software, manufacturers employ an adaptable and flexible solution that addresses current needs and can also meet changing demands as more complex regulatory requirements surface.

PT: What are the benefits of contract packaging? How can this process meet the demands of today's pharmaceutical packaging market? For example, in terms of saving time and money.

FM: Today's pharmaceutical packaging landscape is complex, with new requirements, products, and market demands surfacing continuously. Although manufacturers are meeting these challenges every day, they regularly turn to contract packagers to handle particular situations, such as specialised packaging, overflow and volume.

"Systech SPT acts as a gateway between



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Frederic Menardo of international technology provider Systech International.

market demands, increasing complexity. Although manufacturers are meeting these challenges every day, they regularly turn to contract packagers to handle particular situations, such as specialised packaging, overflow and volume.

As they look to contract packagers, some manufacturers' products also require serialisation to address regulations or to protect high-value products. Because contract packagers manage these responsibilities for numerous products on each line, they confront the toughest vision inspection, line management and serialisation in the pharmaceutical industry.

acts as a gateway between enterprise IT systems and packaging operations."

PT: What changes would you like to see the packaging industry make in the future and why?

FM: Delaying item-level serialisation can create future challenges. Changing from a model in which groups of items are packaged, labelled, identified and tracked identically to a model in which every item is unique transforms production processes and all subsequent recordkeeping. If companies delay too long in the hope of being given just one standard, they may not give themselves enough time for evaluation, testing and scale up on packaging lines.

Instead, manufacturers should develop an implementation plan that can meet current needs and regulations and evolve with ever-changing international standards. Their programmes should include use of configurable, scalable, global solutions that can be deployed companywide without requiring custom software coding for each product or packaging line.

Arena International's Pharma Packaging and Labelling Event will take place on 28 and 29 September in Munich, Germany.