

A win-win situation?

The introduction of UHF Gen2 RFID technology to the pharma supply chain promises to deliver the drug e-Pedigree that industry and government hanker, as well as welcome relief for both pharmaceutical companies and consumers



The pharmaceutical industry's look into the near future includes a major role for RFID, and for good reason. Improvements in the ability to track and trace pharmaceutical products (and their ingredients) throughout the supply chain have the potential to not only improve quality and production efficiencies, but also to contribute to the very real possibility of saving lives.

It is no secret that the pharmaceutical industry is a high-stakes business, with patient safety a primary concern. But the millions of research dollars poured into the development of new drugs also make them ripe tar-

gets for counterfeiters. The number of counterfeit drug cases investigated by the United States Federal Drug Administration (FDA) rose from an average of less than ten in the four years prior to 2001, to an average of 40 in the years between 2003 and 2005. In fact, it is estimated that as much as 10% of the world's pharmaceutical supply is counterfeit (1% in the US), and made with ingredients that range from inert to deadly. Although US pharmacies dispense billions of drugs every year, most of them safe, even a small fraction of counterfeit drugs in the supply can be disastrous. Efforts to thwart this escalating threat are consequently paramount.

Ensuring drug pedigree

To this end, the FDA, with input from industry, has mandated a means of ensuring drug pedigrees, and identified the key measures in this effort:

- Serialization - a unique identification number assigned to every product at the item level
- Authentication - the ability to verify that a drug product is genuine
- e-Pedigree - an electronic record detailing the product's chain of custody (more reliable, accurate, and cost-effective than

paper records)

- track and trace - the ability to track progress of the product along the supply chain

Recognizing that the application of RFID will render drug counterfeiting either extremely difficult or simply unprofitable, the FDA has also endorsed the technology as the most viable solution, and is urging more rapid and thorough adoption.

UHF Gen2 at the item level

One of the keys to more widespread deployment of RFID is the advent of UHF Gen2 RFID applied at the item level. This single breakthrough has enabled efficient, reliable, and low-cost solutions to satisfy the FDA's e-Pedigree mandate. Benefits of UHF Gen2 RFID technology to pharmaceutical companies include:

- High tag throughput rates with high read reliability, which allows manufacturing facilities to maintain and improve filling line speeds
- Item-level visibility at each step, allowing drug manufacturers to improve filling line efficiencies and optimize business processes to reduce inventory requirements
- Extensibility of a single UHF Gen 2 RFID system to support global supply chain applications from items to pallets and from the factory dock door to the pharmacy counter.

Benefits also flow through to distributors, wholesalers, and pharmacies in the form of improved labor efficiencies and more accurate return and expiry control.

Up until now, most pharmaceutical UHF RFID pilots have been exploratory in nature - "beta" tests, if you will. But last fall, Systech International and Impinj collaborated on an RFID packaging line project that has proven RFID is ready to perform in high-speed production filling lines.

RFID solutions to meet real world demands

Systech is a leading provider of Packaging Execution Systems for the pharmaceutical industry. The company's software solutions provide monitoring and management for the packaging line and collect and dis-



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tribute actionable packaging information across the plant and throughout the enterprise. Systech offers an RFID-enabling solution through its TIPS Serialized Product Tracking (SPT) solution - leveraging its TIPS Guardian and TIPS Advisor products, which have been deployed in multiple pilots worldwide.

Systech Guardian connects with the EPC Information Service (EPCIS), systematically bringing EPC data to Systech Advisor at the line level. Advisor assigns and verifies EPC codes at the item level and tracks items through the packaging process. In addition to documenting tag readability and identifying rejects, it also takes information from components on the packaging line to establish the parent-child relationships between the item, case and pallet. Finally, it collects and reports precise item-level data back to Guardian so it is ready to use in track and trace, and authentication applications.

Purdue Pharma selected Systech to provide the sustainable infrastructure needed to implement their Gen2 RFID solution and turned to Impinj for their UHF Gen2 RFID tagging and reader capability. Impinj used its RFID systems expertise to perfect application-specific tag and reader antennas. By coupling these with the standard Monza tag silicon and the Speedway reader, Imp-

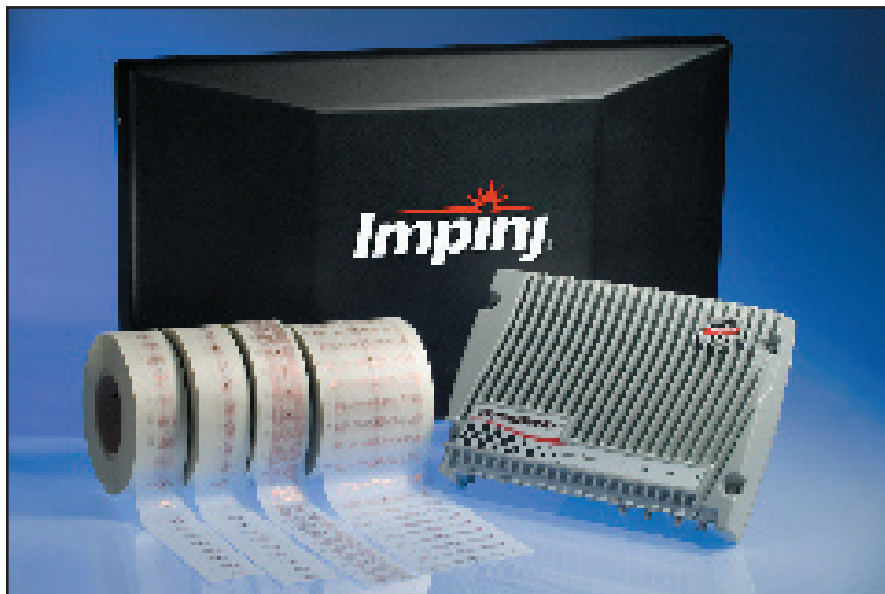
inj provided Purdue with a complete RFID tagging solution at the item, case, and pallet level.

As a key part of the solution, Impinj designed near-field antennas for the Speedway reader. These antennas, coupled with the Impinj Speedway reader's capability to selectively control antenna sensitivity (precisely constraining and controlling the read zone and thus facilitating the reading of RFID tags) made it easier for the Systech software to accomplish serialization.

The modular nature of Systech's software makes it easy to add management and tracking capabilities to the packaging operation. This scalability has hastened Systech deployment in multiple RFID pilots. Systech's solutions also replicate readily, allowing companies to move rapidly from pilot-level applications to full-scale implementations. This flexibility combined with Systech's line management capability and serialization functionality made it the perfect companion for Impinj UHF Gen2 RFID reader and tagging solutions.

Core RFID technology benefits

For years, Systech has been enabling companies to employ data matrix barcodes for



Purdue Pharma turned to Systech and Impinj to provide its packaging line with RFID capability, thus allowing it to trace its pharmaceutical products along the supply chain to the point of dispensing. Following advanced testing, the solution should deploy at production level during the 2nd quarter of 2007

serialization and authentication. Systech's RFID solutions allow pharmaceutical companies to attain serialization and authentication along with the added benefit of greater operational efficiency of their production line - all without detracting from their current performance. And eventually, the same RFID encoding will enable tracking throughout the entire supply and distribution chain.

Let's examine where RFID gives pharmaceutical companies an edge:

- Operational efficiency - The automation of packaging line tracing via RFID provides greater visibility into where problems might be occurring on the line. In addition to the machine vision inspection, the automatic recording of electronic data ties an item-level product to its track through a system, providing clues to problems or inefficiencies in the line much faster

- Item level - At the item level, RFID readers write EPC data to labels, cartons, vial caps, or bottles and can lock the tag. Later, data read from a tag that does not match a redundant barcode indicates a questionable item, subject to rework or scrapping

- Case level - At the case level, RFID readers check for questionable items (such as those indicated as scrapped or otherwise invalid). The software also establishes

parent-child relationships between the individual items and their accumulated position in the case, and downloads this information for appropriate case labeling

- Pallet level - Similar to the case level, the controlling software, using RFID readers, establishes relationships between accumulated cases and assigned pallets, and downloads this information for appropriate pallet labeling

- Initiation of the trail - RFID readers at the dock doors record the pallet tags as pallets exit the warehouse, establishing the source of the electronic pedigree and trail.

Future of the supply chain trail

As the database software develops and more RFID readers find their way into the supply chain, the data encoded on tags at the pallet-, case-, and item-levels will provide a means to trace pharmaceuticals all the way to the point of dispensing. Such tracing capability means counterfeit drugs have a harder time entering the system; shrinkage decreases as the tracing mechanism records the point of diversion of any product, down to the item level; recalls of pharmaceuticals for any reason are straightforward because the serial-

ization of product makes individual items identifiable.

Deployment success factors

The combined Systech/Impinj solution provided enhanced RFID capability in Purdue Pharma's packaging line. During advance testing, the Impinj RFID packaging line, which relies on tags powered by Impinj's Monza tag chips, surpassed tag read speed requirements with 100% read reliability. The combined solution is scheduled to deploy at production level within the second quarter of this year.

Impinj's tag chip and reader combination carry both EPCglobal's Gen2 Conformance Certification and Interoperability Certification marks, eliminating incompatibility concerns throughout the supply chain. EPCglobal-certified interoperability indicates RFID products (tags and readers) manufactured by different suppliers will work interchangeably, and are in fact, plug-and-play.

Benefits for all stakeholders

The Systech/Impinj collaboration for Purdue is just one example of how RFID is changing the landscape for pharmaceutical companies and ultimately, for consumers. E-pedigree, the electronic means of ensuring drug security, is no longer something for the future. The technology to support authentication is available and works now. Using the UHF Gen2 capability to operate well at the item-, case-, and pallet-levels, pharmaceutical companies have a proven means for tracking and tracing products from the production floor through the dock door and to the pharmacy counter. And that ability will not only improve the quality and production efficiencies for the pharmaceutical companies, but also will protect consumers from counterfeit pharmaceuticals - truly a win-win solution.

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