Product tracking and authentication for end-to-end pharmaceutical supply chain protection and efficiency

Counterfeit and diverted pharmaceutical merchandise represents an annual, worldwide revenue loss of between $24 and $49 billion[1], and the loss is growing by 6–8% per year. Liability issues are the responsibility of the original pharmaceutical manufacturer, adding substantial insurance, recall, and brand-erosion costs to direct revenue losses. Increasing public health concerns and international instability have compounded the urgency to adopt technologies to diminish the growing global problem of counterfeiting and product diversion. Several states have already legislated pedigree laws as a combative measure. The U.S. Food and Drug Administration (FDA) has published track-and-trace guidelines and is expected to introduce mandatory requirements soon. In addition to facing steep revenue losses from counterfeiting and product diversion, the pharmaceutical industry is under constant pressure to improve profitability margins and reduce costs.

This paper discusses several technological concepts that may be used to reduce the threat of counterfeiting and diversion, and which can also help to improve the efficiency of pharmaceutical supply chains. However, it should be made clear that isolated technologies are not an automatic salve; they must constantly evolve and be systematically linked in order to create a "moving target" that can effectively stay ahead of counterfeiters.

[1] IMS Health, 2003


hp

Public health concerns, liability issues, recall and insurance losses, brand erosion, and international instability present ongoing problems.

The industry's challenge: keeping products safe at a lower cost

In the past several years, known high-value products such as Vioxx, Procrit, Viagra, Epogen, and Neupogen have been targeted by counterfeiters. The types of counterfeits include accurate but unauthorized copies, diluted/reduced concentrations of the active ingredients, contaminated drugs, and those sold with fake labels containing inaccurate safety information. Those who consume any type of counterfeit drug subject themselves to great health and safety risks.

Worldwide pharmaceutical product sales in 2003 totaled nearly $490 billion, according to IMS Health. Counterfeit pharmaceuticals amounted to as much as a 10% lost revenue opportunity for manufacturers, and pharmaceutical counterfeiting is estimated to be increasing by 6–8% per year. Counterfeit activity costs manufacturers an order of magnitude more in liabilities, product recalls, and erosion of brand value than in product revenue loss itself.

Another growing problem is product diversion, also known as parallel trading. Product diversion occurs when a drug packaged and sold in one market is sold—sometimes illegally—to another market. Product diversion can cross international borders or occur within a specific country. As a result of major differences in prices set by regulators in neighboring countries, Europe has traditionally been the primary target for parallel trading, reaching levels of almost 20% of branded sales in the United Kingdom[2]. However, a burgeoning United States market has recently developed, with American consumers now spending approximately $650 million per year in cross-border purchases (equivalent to 1–2% of total pharmaceutical sales[3]). Spot checks in 2003 by the FDA and Customs Services at U.S. mail facilities confirmed significant drug imports from Canada (15.8%), India (14.3%), Thailand (13.8%), and the Philippines (8%)[4]. Product diversion—particularly involving prescription painkillers—also occurs with increasing frequency within health facilities such as hospitals and nursing homes.

Product diversion enables counterfeit products to be more easily passed off as genuine because a diverted drug is sold outside of the regulated supply chain, making the product difficult to track and authenticate. Diverted and repackaged products are also difficult to trace for recall purposes, and they can present significant health and safety risks if labeling information such as expiration date or lot number is inaccurate.

[2] Reuters Business Insight. *The Pharmaceutical Parallel Trade Outlook*. Datamonitor PLC. 2004.

[3] *Ibid.*

[4] *Ibid.*

The FDA, the U.S. Department of Defense, and the U.S. Department of Homeland Security have warned the industry about at-risk pharmaceuticals, and a growing number of states have legislated electronic pedigree (e-pedigree) laws; consequently, manufacturers are adopting vigorous approaches to counteract counterfeiting and diversion.

In addition to concerns about counterfeiting and product diversion, pharmaceutical companies face increasing pressure to reduce operating costs in order to improve profitability and to compete more effectively in the marketplace. Among the initiatives to achieve these goals are to identify cost-cutting opportunities within their supply chains and to gain better visibility of product inventory along the value chain—fostering faster and more efficient product recalls and returns.

Technological framework

- Define the technological concepts that have potential to solve the pharmaceutical industry's counterfeit and supply chain cost challenges.
- Define the technologies that are needed to make these concepts a reality.
- Identify any existing technologies that can be combined to offer an effective solution.

Two main concepts can help the pharmaceutical industry address its counterfeit and supply chain cost challenges: track-and-trace, and secure printing for authentication. Although the technologies have been used effectively in other applications, recent advances are creating new possibilities to apply them more effectively in the pharmaceutical industry. The technologies behind these concepts are discussed below.

Track-and-trace

Track-and-trace is the ability to track each product, beginning with the moment it is manufactured, through distribution, and to the end customer. To do this precisely, it is necessary to assign a unique serial number to each product at the individual package level, identifying the product type and its origin. Databases collect and store these e-pedigrees, enabling the tracing of every product from its originating manufacturer and throughout the supply chain.

Traditionally, bar codes printed on product packages have served the purpose of tracking and tracing. When both the product description (also known as product class) and the serial number exceed the practical limits of linear bar codes, two-dimensional (2D) matrix bar codes are often employed. A 2D bar code can contain up to 1.1 kilobytes (more than 1,000 characters) of machine-readable data in a space no larger than a standard bar code. The main weakness of printed bar codes is that 1) they must be scanned individually; 2) scanners must be within the bar code's line of sight; and 3) the bar code and the scanner must be in fairly close proximity to each other.

Radio Frequency Identification (RFID) technology has existed for decades, and it has been used with increasing frequency in recent years due to technological advancements that enable RFID to be more reliable and increasingly less expensive. Consisting of a small microchip attached to an antenna, RFID tags store the requisite product information, which can be read using radio waves. The information contained on the RFID tag can be accessed at various distances depending on the frequency of the tag and whether it's an active tag (attached to a power source) or a passive tag (no power source). The amount of information that can be stored on the tag varies depending on tag type and the encoding standard used. Typically, RFID tags are encoded based on an Electronic Product Code (EPC)—a compact "license plate" that uniquely identifies objects throughout the supply chain. EPCs are global data structure standards that measure either 64 or 96 bits in length.

RFID addresses the following shortcomings of bar codes: 1) It doesn't require line-of-sight to be read; 2) several tags can be read at once (up to 500 reads per minute, compared to fewer than 100 for bar codes); and 3) tags can be written and rewritten with greater ease. However, RFID technology has the following shortcomings of its own: 1) Cost of tags at the item level (depending on item value and size); 2) RFID infrastructure is not widespread; 3) environmental factors and product materials may impair the ability to read and write RFID tags (for example, certain liquids and metals may block radio waves); and 4) RF noise from other RF sources may affect the read quality.

Printed bar codes and RFID technologies are designed to complement each other to deliver track-and-trace functionality throughout the supply chain, but it is critical that both printed and RFID tagging be based on common standards. EPCglobal, a joint venture between European Article Numbering (EAN) International and the Uniform Code Council (UCC), has become the emerging creator of standards for identifying and encoding RFID data. The EPC identifier is based on the same EAN.UCC system of family product codes widely used for bar code identification.

Both EAN and UCC recommend using the Serialized Global Trade Identification Number (SGTIN) to track products in the supply chain. SGTIN is a new method of identifying unique items at the unit or retail level as well as at the case and carton level. It consists of a UCC-assigned company prefix and item reference combined with a serial number. Where UCC.EAN bar codes have traditionally been used, the SGTIN specification—combined with an RFID tag—can give visibility beyond the item reference (a description of the specific items contained within a unit) right down to the exact serial number of the item. For purposes of pallet identification, the Serial Shipping Container Code (SSCC) is used. The SSCC does not need to contain the item reference because pallets and shipping containers are not required to be item-specific. Both SGTIN and SSCC can be of various lengths. Examples of 96-bit SGTIN and SSCC codes are presented below.

Table 1. EPC SGTIN 96-bit encoding

	Header	Filter value	Partition	Company prefix	Item reference	Serial number
SGTIN-96	8	3	3	20–40	24–4	38
	0011 0000	8	8	999,999–999,999,999,999	999,999–9	284,877,906,943
	(Binary value)	(Decimal capacity)	(Decimal capacity)	(Decimal capacity*)	(Decimal capacity*)	(Decimal capacity)

* Capacity of company prefix and item reference fields vary according to the contents of the partition field.

Table 2. EPC SSCC 96-bit encoding

	Header	Filter value	Partition	Company prefix	Serial reference	Unallocated
SSCC-96	8	3	3	20–40	37–17	25
	0011 0001	8	8	999,999–999,999,999,999	99,999,999,999–99,999	Not used
	(Binary value)	(Decimal capacity)	(Decimal capacity)	(Decimal capacity*)	(Decimal capacity*)	

* Capacity of company prefix and item reference fields vary according to the contents of the partition field.

The e-pedigree database is another important track-and-trace technology. This database contains the history of each SGTIN as well as information regarding the relationships among items, such as the location of specific vials and the boxes in which they're packed. The database also contains each item's ingredients as well as the location and timestamps of all relevant actions performed on the item, including when it was produced, packed, shipped, received, and examined. All authorized users along the supply chain are able to electronically access information for a specific SGTIN from this database in a secure manner.

Another way that supply chain personnel can access information such as an item's SKU-level description is by leveraging the UCC-supported Global Data Synchronization Network (GDSN). Emerging standards and technologies may enable the EPCglobal Network to provide a standardized method of finding both history information and object-level information in the future.

Security printing for authentication

Many kinds of printed authentication techniques have been used as authentication features on various counterfeit-sensitive objects. For example, U.S. dollar bills use such features as color shifting inks, microprint, watermarks, and embedded magnetic particles to guard against counterfeiting. Most security-printing deterrents can be grouped into three categories: overt, covert, and forensic.

Overt. These features are easy to detect by sight, touch, or smell. Examples of overt security-printing deterrents include color-shifting inks, alignments that are difficult to replicate, microprinting, optically variable microstructures (OVMs)—also known as holograms—and visible watermarks.

Covert. These features can be detected by machines but are not visible to the naked eye. Examples of covert security-printing deterrents include invisible inks (such as those visible only when exposed to ultraviolet light), magnetic printing, encrypted codes, hidden overprints, micro-displacement of glyphs, and metal fibers.

Forensic. These features require laboratory testing in order to be detected. Examples of forensic security-printing deterrents include various embedded chemical compositions known as chemical taggants that are designed to uniquely identify an object.

In some security-printing techniques, users can authenticate the object without the need for additional information if they are aware of the type of features that are used. In these cases, authentication can occur at a basic, local level through what is known as a self-authenticating system. Covert and forensic features can provide additional authentication capabilities that may be required in the cases of very sensitive drugs or medical devices.

Sophisticated counterfeiters who are able to falsify some of these security-printing devices can be thwarted through the introduction of variability features. Today, variability can be introduced by leveraging variable digital printing (VDP) technologies that are capable of producing high-quality prints in commercial qualities—while at the same time printing each copy with different security features. In a production scenario, variability can be introduced for every lot of the product or changed regularly for larger lots.

Limitations of track-and-trace
Using only track-and-trace technology for product authentication has the following limitations:

- Information in pedigree databases may be flawed, so the user may not know with complete certainty in the authentication process if a problem exists in the information network or if a truly counterfeit product was identified.
- A track-and-trace network may not be widespread, and not all stakeholders may be able to take advantage of these technologies when needed.
- Tags themselves can be counterfeited, which could result in the introduction of erroneous information into the network.

Combining track-and-trace with secure printing
Pharmaceutical manufacturers are able to dramatically improve the safeguarding of their products from counterfeiting and diversion when using track-and-trace and secure printing together. By combining bar codes with RFID technology, track-and-trace could allow supply chain stakeholders to authenticate products by efficiently tracking products to their origin and verifying the history of even the smallest package.

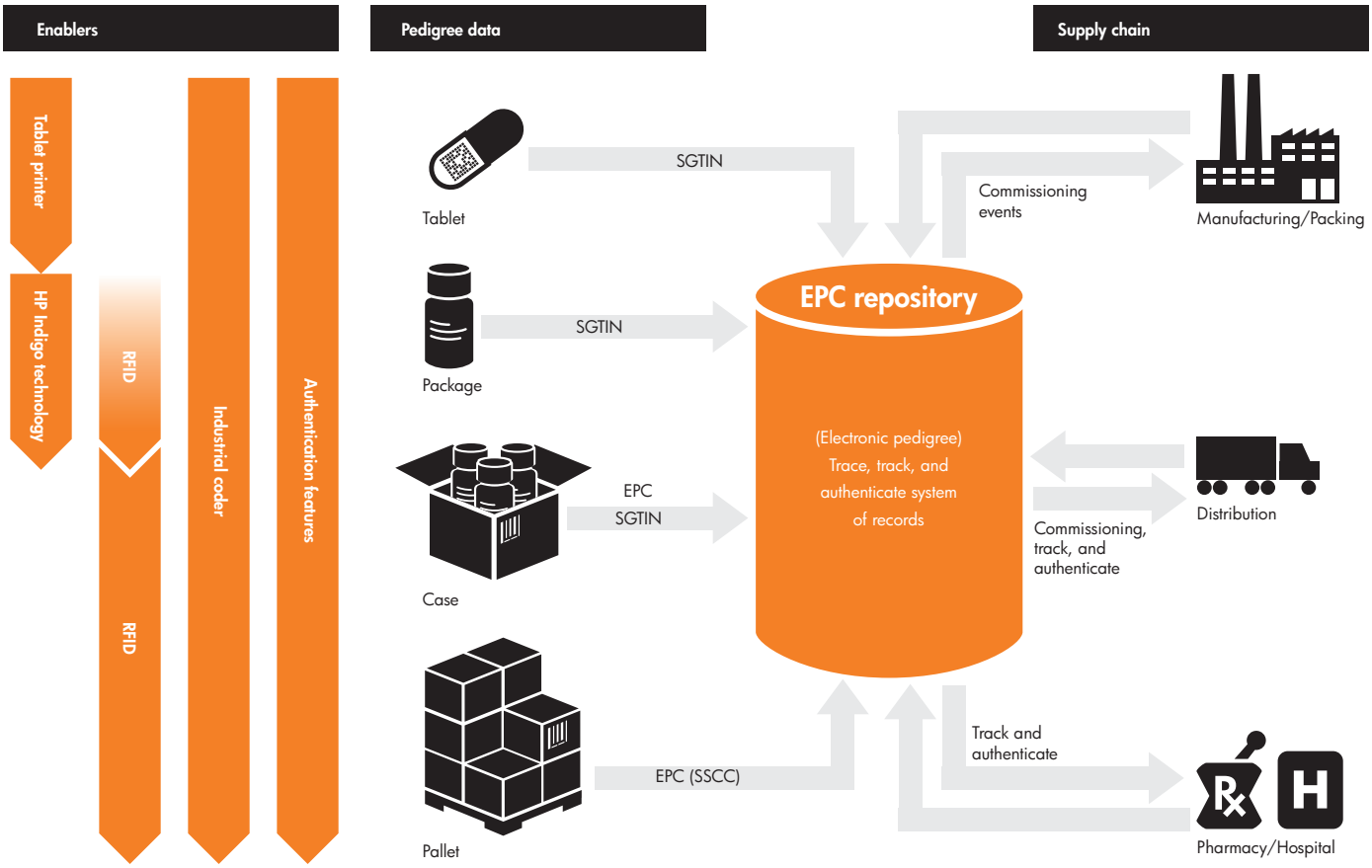
Secure printing can close the gaps in the track-and-trace network and complement track-and-trace information to provide more authentication capabilities to stakeholders. Variable authentication features can be stored in the pedigree databases, which adds another authentication dimension to each object's recorded history. When secure printing techniques are utilized in the printing of bar codes, counterfeiting becomes more difficult and costly.

Consider the following scenarios:

- If a box of bulk-packaged pills is stolen, how can you tell if the same pills were recovered?
- If you need to recall a batch of contaminated product, how do you know where it has gone before you finally locate it?
- If a patient suspects medication is not genuine, how can it be checked?

Combining track-and-trace with secure printing dramatically improves protection against counterfeiting and increases efficiencies in product recalls and other supply chain challenges.

Product tracking and authentication solution



Note that Serialized Global Trade Identification Numbers (SGTIN) are based on European Article Numbering International and the Uniform Code Council data structure standards.
EPC = Electronic Product Code
SSCC = Serial Shipping Container Code
RFID = Radio Frequency Identification

The HP Product Tracking and Authentication Solution

The previous section makes it clear that the industry must approach the implementation of anticounterfeiting and tracking measures by creating a system in which data is constantly linked from one stage of the packaging process to the next. By adding multiple layers of security, manufacturers will be better able to:

- Trace their products
- Verify their authenticity
- Allow third parties to verify their authenticity
- Make product diversion more difficult

HP has developed a comprehensive solution to provide traceability and secure product tracking and authentication (PT&A) capabilities for all product package levels from the unit dose (e.g., tablet) to the pallet level. HP's PT&A solution supports mass serialization of products and provides track-and-trace capabilities throughout the pharmaceutical value chain. Printed variable security features complement track-and-trace to provide additional authentication capabilities.

HP's solution leverages print technologies for tagging unit doses, blister packs, and bottles, as well as RFID for tagging boxes and pallets. Both printed and RFID tags provide standards-based product identification and mass serialization. HP combines track-and-trace tagging with secure printing technologies to provide sophisticated variable authentication on product labels.

Strong links are essential between the technologies that are implemented at each level. As these solutions are implemented throughout the supply chain, huge amounts of data will be created, processed, and stored. Without a strong architecture leveraging the relationships between security and tracking features, each technology would essentially be "flying blind"—receiving no input from its counterpart somewhere else along the anticounterfeiting system.

Print-on-tablet. HP has developed the innovative capability to print variable data on a single tablet—the smallest unit dose level. Tablet printing is also based on thermal inkjet (TIJ) technology, utilizing inks approved for human consumption. Tablet printing can either be integrated into the pharmaceutical production process or implemented as a separate machine.

This technology allows pharmaceutical manufacturers to place both track-and-trace as well as secure printing authentication features on even the smallest unit dose of the product. As a result, it provides important capabilities when products are sold in bulk and then repackaged throughout the pharmaceutical supply chain.

Secure variable printing. HP leverages its Indigo digital press technology to deliver this secure printing solution. As part of this solution, HP helps pharmaceutical manufacturers determine which secure printed features are most effective to protect specific products. HP provides secure printing algorithms and drivers, and then integrates the secure printing system into the overall PT&A environment as well as into manufacturer enterprise systems.

Indigo press technology has already been effectively integrated into pharmaceutical packaging by providing high-quality labeling of smaller lots without the high cost of print setup. Indigo printers can also be customized with finishing tools, allowing for mass customization of boxes and package inserts.

HP works with all parties to set up Indigo press operations either in-line with the packaging line, or "near-line" by either the manufacturer or a print shop. Stakeholders have the option to contract with HP as a managed service provider to maintain the secure printing algorithms and templates, or to host the entire computing environment.

In-line printing. In-line printing equipment with coders based on TIJ technology with 600 x 600 dpi resolution is available to print directly onto primary packages (paper-based substrates) and onto corrugated shipping boxes to facilitate identification, date coding, lot coding, production line efficiency, transportation, logistics, and inventory management. These coders are used in a wide variety of commercial and industrial environments.

This equipment can be efficiently used for printing 2D matrix bar codes, linear bar codes, or other variable labeling information on smaller packages such as blister packs. This information can also be printed by utilizing secure printing techniques such as invisible inks.

RFID technology. The PT&A solution uses RFID technology to tag cases and pallets, which provides efficient track-and-trace information from shipment at the manufacturing site, through the distribution network, to receipt at retailer sites. HP has leveraged its investment in research of RFID technologies at HP Labs as well as its internal and external experience implementing RFID solutions. As RFID technology develops and its cost decreases, PT&A will leverage RFID for tracking at package levels—and even at item levels. As part of the PT&A program, HP will test and customize the technology for pharmaceutical products and packages in its RFID centers of excellence as well as in its PT&A Solutions Center, which is discussed in the next section.

Electronic pedigree. Track-and-trace and other related authentication features are passed to an e-pedigree database for product authentication, tracking for safety and recalls, and supply chain optimization purposes.

Middleware software is used for passing SGTIN and EPC data to various RFID and printing devices for tagging products, collecting information from various reading devices, and then returning the information to enterprise systems and pedigree databases. HP works with best-in-class pedigree database software companies to integrate this emerging technology into its overall PT&A solution.

HP Product Tracking and Authentication Solutions Center

HP has successfully implemented a working prototype of its end-to-end solution in its new PT&A Solutions Center in Puerto Rico.

The HP PT&A solution is more than a collection of existing technologies. At the Puerto Rico center, HP will develop its prototype into a full-scale implementation of a pharmaceutical supply chain. Working with HP experts, participating companies will be able to test not only the various key technologies, but also to conduct proof-of-concept tests and plan full-scale pilot implementations. This will allow HP PT&A Solutions Center partners to gain expertise quickly at low cost and low risk.

In the RFID area, the Solutions Center will be capable of supporting the testing of pharmaceutical products in a prototype pharmaceutical packaging environment. The RFID solutions will be developed in support of PT&A clinical trials and research-and-development (R&D) processes as well as supply chain efficiency methodology.

The HP PT&A Solutions Center is intentionally located close to HP's state-of-the-art inkjet cartridge manufacturing lines. There, participants will be able to share HP's best practices in high-speed flexible manufacturing and packaging technologies that utilize excellent track-and-trace capabilities. Personnel experienced in pharmaceutical processes are part of the workforce at this HP site.

Why HP?

Recognized as a technological innovator and a provider of comprehensive solutions that meets unique industry needs, HP is the right choice to help the pharmaceutical industry combat counterfeiting while addressing supply-chain-related challenges. HP is renowned for its internal supply chain excellence, and the company's best practices have been successfully replicated by HP clients worldwide. In addition, HP has developed advanced track-and-trace capabilities in response to challenges in its own inkjet manufacturing operations and supply chain. HP was an early adopter of RFID technologies in its own manufacturing and distribution processes, and has also invested in research around RFID-related technologies through HP Labs and other R&D centers.

HP has technological expertise in printing technologies, RFID, mobility solutions, computing technologies, consulting, large systems integrations, and managed services. HP's investment in one of the most advanced product tracking and authentication solutions centers is a testimony to HP's commitment to working with the industry in this area.

In addition to HP's internal proven best practices, expertise in all of the technologies involved, and investment and innovation in the development of the PT&A solution, HP is in an ideal position to bring together other partners for client support. These partners include systems integrators, strategy consultants, middleware software makers, security experts, and a large variety of other best-in-class companies eager to work with HP and to complement HP capabilities and solutions.

For more information

For more information about the HP Product Tracking and Authentication solution, please visit **www.hp.com/go/manufacturing**.

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