



RFID in Life Sciences

Significant Pharmaceutical Supply Chain Value Using RFID for ePedigree, Patient Safety, and Anti-Counterfeiting

Global trade and e-commerce create a wealth of business opportunities, but they also create increased risk of product liabilities with channel diversion, counterfeit drugs and patient safety. Counterfeits result in lost sales opportunities and potential risk for products which can effect human health and safety. Where casualties are involved, it is often incumbent on the true manufacturer to prove the offending product was counterfeit.

Medicines purchased over the Internet from sites that conceal their physical address are counterfeit in over 50% of cases*. With estimated counterfeit drug sales soaring upwards to \$75B by 2010*, legislation is taking an active role towards securing the pharmaceutical supply chain.



The state of California accounts for up to 12-15% of the U.S. prescription drug volume, and as such, is leading the safe drug supply chain initiative by requiring an electronic pedigree and unique identification at the smallest individual distribution unit.

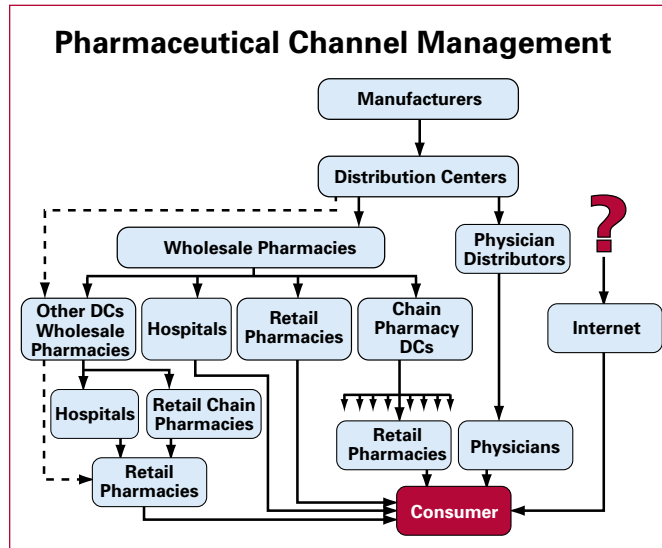
Accounting for individual distribution units can lead to supply chain inefficiencies. Fortunately, UHF RFID not only significantly contributes to the integrity of the drug supply chain, but it also substantially enhances the accuracy and efficiency of the inventory process.



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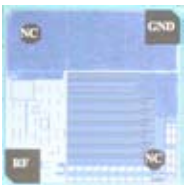
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Patient Safety



Value to Consumer:

- › With such a complex distribution system, and numerous ownership exchanges of product, it's easy to imagine how counterfeit drugs can infiltrate the pharmaceutical drug chain. And with mind-boggling counterfeit estimates up to \$75 Billion¹, patients – especially those relying on life enabling medication – can be at serious risk.
- › Legislative serialization options include the use of 2D Data Matrix or RFID technology. In contrast to an easily duplicated bar code, UHF RFID offers the manufacturer the option of a permanently locked, factory commissioned unique serial number (referred to as the UTID) embedded within the electronic RFID silicon chip.
- › The unique UTID signature, in addition to an optionally locked drug identification serial number, assigned by the manufacturer, provides the consumer with yet an additional level of authenticity.



ePedigree

Product Information	Lot Information	Product Serial Number	Pedigree Serial Number
AllergyMed Acme Pharmaceuticals 65 mg, 90 tablets NDC 0978-0324-01	Lot A231556 Expires: 15-Dec-2005	01.0000978.000324.1005536707	01.0000978.000324.1005536707
Drug Sales and Distributions			
AAA Pharmaceuticals sale to ZZZ Wholesaler Inc.			
Seller: AAA Pharmaceuticals Address: 123 Main St. Downtown, CA 99999 USA License Number: 00.00000 CA Date Released: 22-Jan-2005 Certified By: Michael Manufacturer Compliance Manager Michael@aaapharma.com 555-123-4567	Buyer: ZZZ Wholesaler Address: 5555 Center St. Uptown, CA 90009 USA License Number: 00.44444 CA Date Acquired: 23-Jan-2005 Certified By: Wendy Wholesaler Quality Manager Wendy@zzzwhole.com 555-789-4567	Invoice and Date: WHO-99999999 on 18-Jan-2005 Quantity: 1 Transaction: Sale	
ZZZ Wholesaler Inc. sale to Mom N Pop Pharmacy			
Seller: ZZZ Wholesaler Address: 5555 Center St. Uptown, CA 90009 USA License Number: 00.44444 CA Date Released: 22-Apr-2005	Buyer: Mom N Pop Pharmacy Address: 100 North St. Midtown, CA 90229 USA License Number: 00.55443 CA Ship to: Pop's Pharmacy Warehouse		

Sample e-Pedigree

The Application:

As drug manufacturers record the UTID and assign their unique product identifiers, shipment contents are aggregated and ePedigrees are used to record pertinent information, such as:

- › Product Information
- › Item Information
- › Transaction Information
- › Trading Partner Information
- › Signatures & Certifications
- › Additionally, an Advanced Shipping Notice (ASN) is electronically forwarded to the next recipient, in advance of the product receipt.
- › Serialized product is verified against the ASN, and the Pedigree certifies authenticity.
- › Without line-of-site restrictions, UHF RFID facilitates the confirmation process by enabling a quick scan of the individually tagged items without opening the case.



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Accuracy, Convenience, Efficiency



2D (Line-of-Sight)

(Pre-packaged Read Required)

RFID

(Post-Package Reads)

Value to Manufacturer/Distributor

- › As items are aggregated and prepared for shipment, it is important that the process integrity of the serialized contents are well maintained. When using line of sight technologies (e.g. 2D Data Matrix), process controls become especially critical and contents must be read individually, prior to case insertion. RFID enables case reads.
- › In production, it is common for the flow of product to be interrupted – in some situations this is for sample quality control, in others, for divergent product or exception handling. These production variances often result in secondary operations, requiring re-confirming aggregations, and often, re-packaging.



RFID Enabled

- › Inaccurately accounted serialization, received by downstream trading partners, can result in mandatory product containment until disposition is fully resolved, thus potentially resulting in additional validation

labor, and retail supply deficiencies. UHF RFID alleviates production flow restrictions and improves content accuracy by facilitating item reads within cases, without breaching the case seal.

- › RFID efficiencies are realized from the manufacturer to retailer at the item, case, and pallet level.

Applicable RFID Components

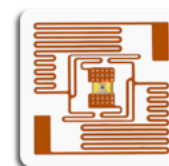
In Manufacturing/Distribution:

- › Readers: The Alien® ALR-9900 high performance enterprise reader, comes in a small, unobtrusive package and is well suited for multiple manufacturing applications, including packaging lines and pallet stretch-wrap turntable stations.
- › Handhelds: Vendors such as Psion Teklogix provide mobile scanners capable of reading UHF tags as well as 2D Data Matrix codes.
- › Tags: Alien offers UHF RFID tags in a variety of geometries with features available to enhance production efficiency, authenticity, brand protection, patient safety, containment, reverse logistics, and with optional read protected memory, even help curb charge-back fraud.



ALR-9900

Tags are available for optimization at the item, case and pallet level. Additional tag form factors are available. Smaller item-level tags (optimized for vials, blister packs & syringes) are currently under development.



Squiggle-SQ



Squiggle®



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In the Pharmacy:

- › Authenticity and simplicity are key within the pharmacy. Pharmacists need a solution which is virtually transparent to their day-to-day operations to enable them to concentrate on their customers. Today, aside from the ePedigree serialization legislation, pharmacists often find the process of confirming orders, and validating lot and expiration dates to be a labor intensive effort. Unfortunately this manual process can also result in errors.
- › With RFID enabled product, not only can the pharmacist quickly authenticate medication, but the once manual process of validating orders can be automated, dramatically improving operational efficiencies and accuracy.

Selected References:

- * World Health Organization, Fact Sheet No. 275

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- › Reader: Alien's newest addition to the reader family, the ALR-9650, is a nice compliment to the pharmacy application. This self contained product offering is especially attractive with an integrated antenna and reader within the same housing.
- › In addition to the compact size and high performance of the ALR-9650, is the added convenience of a single connection. Using the Power-Over-Ethernet (POE) option, a simple LAN cable serves dual functions: to communicate with the server and provide power to the reader.
- › Handhelds from vendors such as Psion Teklogix provide flexibility in mobility and can scan both UHF tags as well as 2D Data Matrix codes.

Alien Technology

Your Secure RFID Key to Authentication



For additional information,
 contact us today at
www.alientechnology.com



Alien Technology
 18220 Butterfield Blvd.
 Morgan Hill, CA 95037
 866-RFID NOW
www.alientechnology.com