

Technology options for RFID in pharma

How best to enable a cost-effective
electronic pedigree?



Comments to FDA Science Board

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Summary

- **RFID should provide tremendous benefits to the US pharmaceutical supply**
 - Provide electronic pedigree
 - Enable improved track-and-trace
 - Efficiencies in supply chain
- **HF RFID is a mature technology with several suppliers and products available today**
- **Tremendous investment is occurring in EPC UHF RFID, promising lower cost with equivalent or better performance compared to HF RFID**
- **Additional study is warranted before one type of RFID is selected for wide scale implementation for pharmaceutical items**

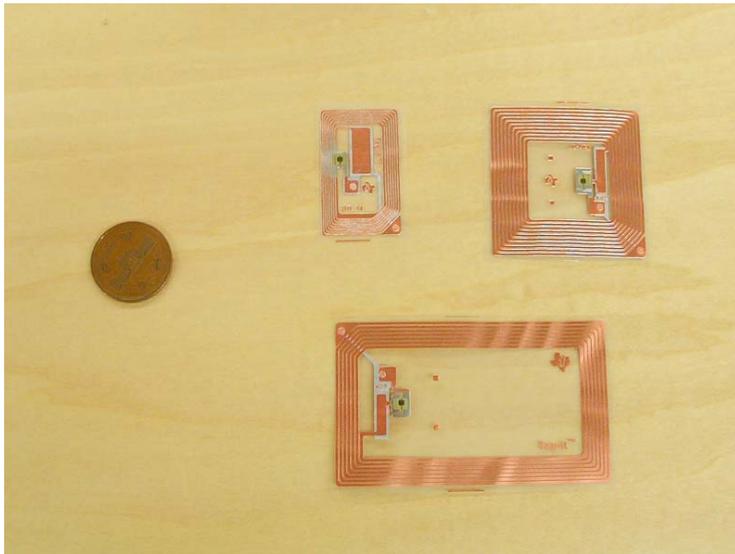
Passive Tag RFID Operation



HF and UHF RFID tag construction

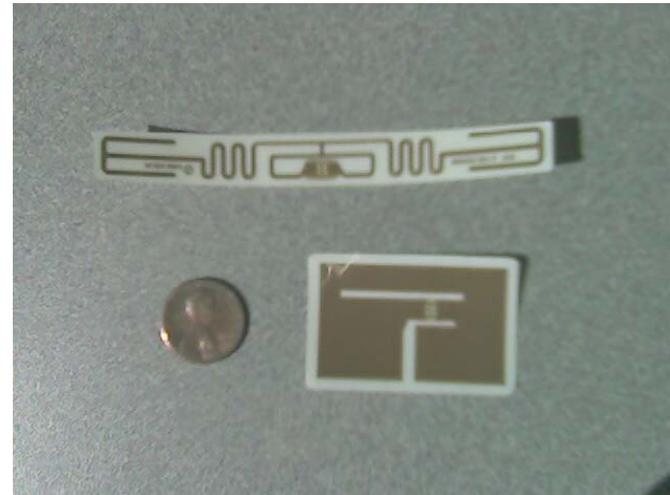
- **HF RFID tag**

- Metallic coil antenna
- Multi-layer due to loop crossover



- **UHF RFID tag**

- Dipole antenna
- Metal or printed conductor



EPC UHF RFID Market Drivers

- **Wal-Mart and U.S. Dept. of Defense mandates to suppliers: supply RFID tagged cases and pallets as of January 2005**
- **Others retailers following fast: Target, Tesco, Metro, Albertsons, BestBuy**
- **Enterprise software solutions with RFID capability from Microsoft, SAP, IBM, Manhattan Associates, and others**
- **Single global spec for UHF RFID: Gen 2**
- **Strong interest from other markets (transportation, for example)**
- **Readers are likely to become ubiquitous and available to consumers**



EPC UHF Global Product Availability

Country	Readers	Tags
U.S. (902-928MHz)	Production	Production
EU (866-868)	Production	Production
Australia (915-928)	Production	Production
Japan (950-956)*	Samples	Samples
Taiwan (922-928)*	Samples	Same as U.S.
Korea (910-914)*	Samples	Same as U.S.
China (TBD)	U.S. Samples	U.S. Samples

*Pending national regulations for UHF RFID

HF and UHF comparison table

	HF	UHF
Frequency	13.56 MHz	915 MHz (US) 860 MHz – 950 MHz (worldwide)
Baseline range	Range depends on reader; 1 m for tunnel, 5-20 cm for handheld	< 6 m for fixed reader antenna, < 2 m for handheld reader
Range degraded by metal	Yes	Yes
Range degraded by water	No	Yes
Technology/product status	>400 M shipped but technology is mature	>50 M shipped with continued development
Tag cost	Medium (> \$0.30)	Low (< \$0.10)

HF and UHF comparison table

	HF	EPC UHF
Anti-collision (read multiple tags)	Yes	Yes
Nonvolatile memory 96 bits or greater	Yes	Yes
Read rate > 500/sec	No	Yes
Small format possible (< 2 cm/side)	Yes (inches read range)	Yes (inches read range)
Security against code tamper	Yes (for some protocols)	Yes (32 bit lock code)
Worldwide usage	Yes	Yes (pending expected regulatory evaluation)

Value of market data is recognized



From *COMBATING COUNTERFEIT DRUGS*

A Report of the Food and Drug Administration (February 2004)

“In the long term, after there is significant market place experience with RFID, FDA plans to propose or clarify, as necessary and appropriate, policies and regulatory requirements relating to the use of RFID. Labeling, electronic records, product quality, and Current Good Manufacturing Practices (cGMP) requirements are issues that have arisen in connection with RFID. **However, regulatory or policy determinations regarding these, or other, issues should not be made until they can be informed by sufficient data and significant marketplace experience with RFID.**“

Establishment of UHF RFID

*EPC UHF RFID is the choice of Wal*Mart and the US Department of Defense*

- **These organizations examined HF RFID technology, and rejected it in favor of the developing EPC UHF technology**
- **HF RFID is mature, but difficult to innovate further to extend performance or lower cost**
- **There will be a massive infrastructure deployed to read EPC UHF RFID tags**
 - This infrastructure can be used to improve visibility of pharmaceutical items tagged with EPC UHF RFID
 - Not only manufacturers, but retailers and consumers as well, will have the capability of reading UHF EPC RFID, adding additional layers of security.

Recommendation

- While HF RFID technology is mature today, EPC UHF RFID promises at least equivalent performance **at lower tag cost**
- The reader infrastructure being developed for EPC UHF RFID will translate into the ability to provide **additional visibility** to pharmaceuticals as they travel through the worldwide supply chain
- The relative benefits of HF vs. UHF RFID have not been established

The FDA should encourage study to compare the relative advantages of HF and UHF RFID for pharmaceuticals and medical supplies

About Alien Technology Corporation



- ***Alien designs, manufactures, and deploys innovative RFID products to improve the efficiency, safety, and security of supply chain and logistics operations***
- **A leading producer of RFID tags and readers, in UHF band**
- **Products deployed in high-profile retail and DoD supply chain implementations currently underway**
- **Patented Fluidic Self-Assembly process delivers low-cost, high-volume tag manufacturing**
- **Operations in Morgan Hill CA, Fargo ND, and (soon) in Dayton OH**