Enhancing Patient Safety
Pfizer RFID Pilot

Rich Hollander
A Manufacturing Site in Latin America (GMP Compliant???)

TABLETING MACHINE
Manufacturing Site in Latin America

DRYING OVEN
Ponstan

Contains boric acid and no active ingredient

Tablets seized previously coated with leaded highway paint and floor wax
• In Sep 2004 the FDA stated they believe an RFID based authentication functionality will be available within the next year

AND

• “A business case could be made for deploying RFID based authentication now and track and trace later”
Topics Covered

• Overview of Pfizer Pilot Project
  – Why Pilot?
  – Goals
  – Project Team Structure
  – Pilot Schedule
  – EPC Numerology
  – Packaging: RFID Tags
  – Process: Manufacturing, Logistics Strategies and Authentication
• Adoption
• Authentication Session
• Lessons Learned
• Conclusion
Why Pilot?

• Patient Safety Initiative
  – Focus on Authentication of all Packaging Levels

• Gain hands-on experience with the technology
  – Understand the costs and benefits
  – Technical/Physical Limitations
  – Implications and challenges associated with widespread implementation

• Collaborate with our trading partners to define the necessary processes to support an RFID enabled pharmaceutical supply chain

• Accelerate the standards development process

• Develop and approach to write RFID tags on the packaging line and how to generate, associate and manage unique EPC’s for millions of units

• Viagra Selected
  – Most Frequently Counterfeited Product in World
  – One Site (Amboise, France), One Dedicated Line => Simplification and Focus
Project Goals

• Incorporate RFID tags into the packaging of all Viagra US trade product by year-end 2005.
  – Pallets, Cases and Units

• Provide a means to authenticate at the pharmacy level.
Pilot Schedule

Feb-Mar
- Plan/Analyze
  - Vision and objectives
  - Conceptual design
  - Work plan

Mar-April
- Design
  - Packaging line design specification
  - Tag performance testing
  - IT design specification
  - Logistics center design specification
  - Communication, training, and testing approaches developed

Jun-July
- Build
  - Packaging line mock-up and testing in US
  - Global and local IT infrastructure built
  - Tags designed and sourced
  - Authentication application built
  - Amboise IT interfaces built

Aug-Sept
- Test
  - End to End Test
  - Integration Test
  - Product Test
  - User Acceptance Test
  - Packaging line installed and tested in Amboise
  - Authentication application deployed and tested
  - Global and local IT infrastructure tested

Oct-Dec
- Deploy
  - Launch packaging line, IT systems, authentication application
  - Press release, web content
  - Collect metrics and document learnings

- Conceptual design complete
- Detailed design complete
- Packaging line shutdown
- Begin applying tags
- Logistics centers enabled
- Begin shipping to customers
- Packaging line mock-up and testing in US
- Global and local IT infrastructure built
- Tags designed and sourced
- Authentication application built
- Amboise IT interfaces built

Jun-July
- Build

Aug-Sept
- Test

Oct-Dec
- Deploy

Jan-Feb
- Monitor

Mar-Apr
- Revise

- Logistics centers enabled
- Begin applying tags
- Customers begin authenticating
- Begin shipping to customers

- Packaged line shutdown

- End to End Test
- Integration Test
- Product Test
- User Acceptance Test
- Packaging line installed and tested in Amboise
- Authentication application deployed and tested
- Global and local IT infrastructure tested

- Launch packaging line, IT systems, authentication application
- Press release, web content
- Collect metrics and document learning's
- RF Exposure Protocol & Test

- Manage inventories
- Begin gathering of metrics (internal & external)
- Assist with customer authentication builds
- Troubleshoot & resolve issues
- Watch for steady state

- Analyze metrics
- Analyze customer feedback
- Continue assisting customer authentication
- Plan for upgrade to UHF Gen 2 on cases & pallets
- Devise longer term HF strategy
- Initiate RFT projects

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EPC Numerology

- EPC Numerology
  - Currently there are two proposed number schemas under discussion within EPCglobal/GS1
    - Type I - Flexible Pharma Code with partial NDC
    - Type II - Flexible Pharma Code with full NDC
  - Pfizer Recommends:
    - Type I with partial NDC for patient privacy and supply chain security
    - The proposed flexible pharma code can provide a unique number Globally!
EPC Numerology

- **Unique within scope of their Name Issuing Authority**
- **Guaranteed unique by each Manufacturer**

- **Indicates length of the Manager ID and number of bits/digits available for serial number / product class id**

- **Identifies Product Class**

- **Partition Value**

- **Manager ID**

- **Product Class ID**

- **Serial Number**

- **Partition Value**

- **Manager ID**

- **Indicates**

- **Identifies**

- **Distinguish between Item, Inner Pack, Case, Pallet etc.** (4 bits = 16 values)

- **Indicates ‘Pharma’**

- **Header or URN Prefix**

- **Logistic Unit Filter**

- **Internal Header**

- **TYPE I**

- **TYPE II**
• EPC Numerology
  – Viagra Pilot Current:
    • 046.03.08.0069.00000000000000000001 (possible)
    • 046.03.08.0069.00000000001 (in use today @ Pfizer & GSK)
  – Future Proposal:
    • Includes additional Internal Header
    • 046.03.XX.08.0069.00000000000000000001
RFID Tag Frequency Selection

- **HF I-Code 1 (13.56 MHz) RFID item level tag**
  - Better read rates at short range
  - Better performance in proximity with liquids and metals
  - More proven and mature technology
  - Encode 96 bit Serialized EPC number
  - Non-Removable RFID Tag integrated into the primary bottle label
  - 100% Valid Reads on Packaging Line

- **UHF C1G1 (902-928 MHz) RFID case and pallet level tag**
  - Aptly suited for longer range case reads on conveyors
  - More cost effective for case and pallet where 100% read rates are not required
  - Encode same 96 bit serialized EPC number
  - 100% Valid Reads on Packaging Line
• **Process**
  - Labels with RFID tags are written to (EPC & 2D Barcode) and affixed to individual bottles at speed
  - Inspection and Rejection accomplished prior to case packing
  - Case is filled and sealed
  - UHF label is applied to case (EPC & Linear Barcode)
  - A read of all 48 bottle tags + the UHF Case tag is accomplished with a special RF Tunnel
  - A reject station handles no-reads at exit of tunnel
  - Acceptable cases are passed to palletization
  - Pallet is built with barcode scan and table top UHF printer for the pallet tag
Item Level Process Flow

- Label applied to bottle
- Lot & Expiry Inspection
- Outsert Applied & Inspection
- Bottle Exit, Outfeed Starwheel
- Krones Bottle Reject Station
- Rejected Bottles

Diagram showing the process flow with components such as RFID Readers, Labelers, Antennas, Inspectors, and Communication Links.
Amboise Packaging Line - Labeler

RFID Tag

RFID Antenna – Writes EPC code on tag
Item Level Label Tag

EPCglobal Logo and RFID Tag location (tag is under label)

EPC Data 2D Barcode

Color Shift
Case Level Process Flow
Case Level Label Tag

![Image of a boxed product on a conveyor belt with labels that read "Case Level Label Tag, Handle with Care, Fragile, S & T, S & T, T & S"]

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• **Shipping & Logistics**
  – Periodically the Packaging site (Amboise, France) sends EPC + Batch Data to the US
  – US Logistics centers receive goods and take EPC events during shipping to customers
  – EPC events are sent to the Authentication layer (EPCIS)

• **Authentication**
  – Customers wishing to authenticate are given access to the SupplyScape portal
  – Customers read RFID tags or scan barcodes and EPC events are logged into the EPCIS layer
  – Specific information and important messages are provided to customers using the portal at the time of reading/scanning
Authentication Demo

Electronic Product Code (EPC) Authentication

Product Information

VIAGRA® (sildenafil citrate)
50MG. 160 TABLETS
NDC 0063-4210-66

EPC Serial Number

33570832.1.702842 Anti-Counterfeit Measures

Authentication Summary

Status | Description
--- | ---
EPC Issued | EPC Issued By: Pfizer Inc. EPC Issue Date: 21-Feb-2005
Origin | Shipped From: 100 Jefferson Road Parsippany, NJ 07054 USA Shipment Date: 23-Feb-2005 Shipment Number: 12161971
Initial Destination | Shipped To: Rx Wholesaler 305 Wholesaler Place Greenville, MS 30701 USA
Adoption Status – Pilot Participation
- 1st Authentication, Morris & Dickson, 2D Barcode, January 2006
- Ongoing Authentications and Methods
  - McKesson – Case Level Tag association, Item Level soon
  - HD Smith – Mixed Tote Item Level RFID reads
  - Morris Dickson – strangely silent since January
- Customers Planning to Authenticate
  - ABC
  - Rite Aid
  - Cardinal Health
Lessons Learned

• Technology
  – We’ve demonstrated how it can be made to work
  – We understand how to scale it
  – We understand current technical limitations
  – We know how to communicate requirements to technology suppliers (Tags, Readers, etc)
  – We know what solutions integrators must bring to the table
  – We know what RFID standards must facilitate

• Industry Adoption
  – The verdict is not yet in on how well it works across the supply chain
  – 2006 will be a data gathering year
  – There are no guarantees
  – We must anticipate change
There is no substitute for doing your own pilot
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