

# Enhancing Patient Safety Pfizer RFID Pilot



Rich Hollander



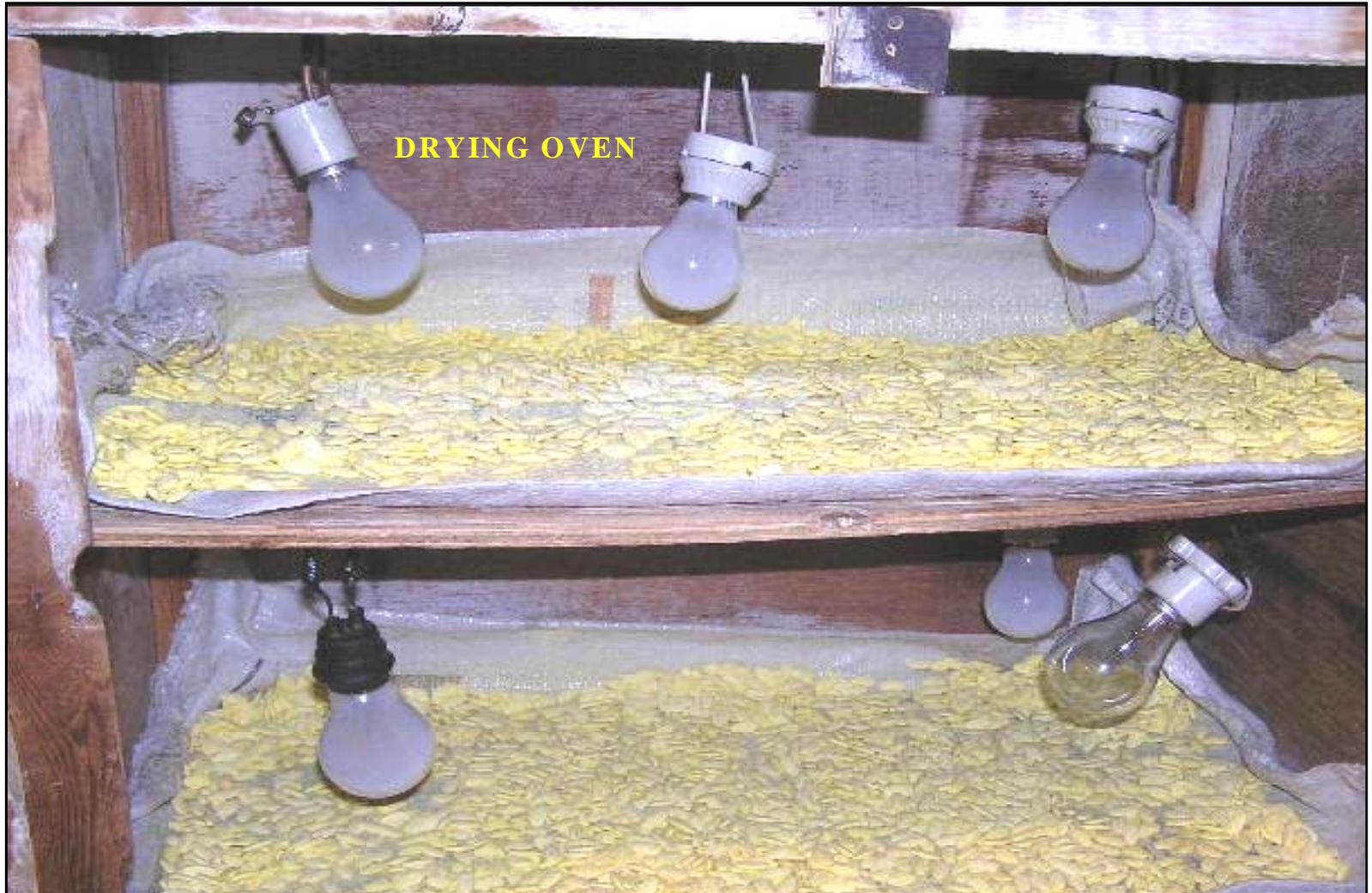
# A Manufacturing Site in Latin America (GMP Compliant???)



TABLETING MACHINE



# Manufacturing Site in Latin America





**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”



- 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

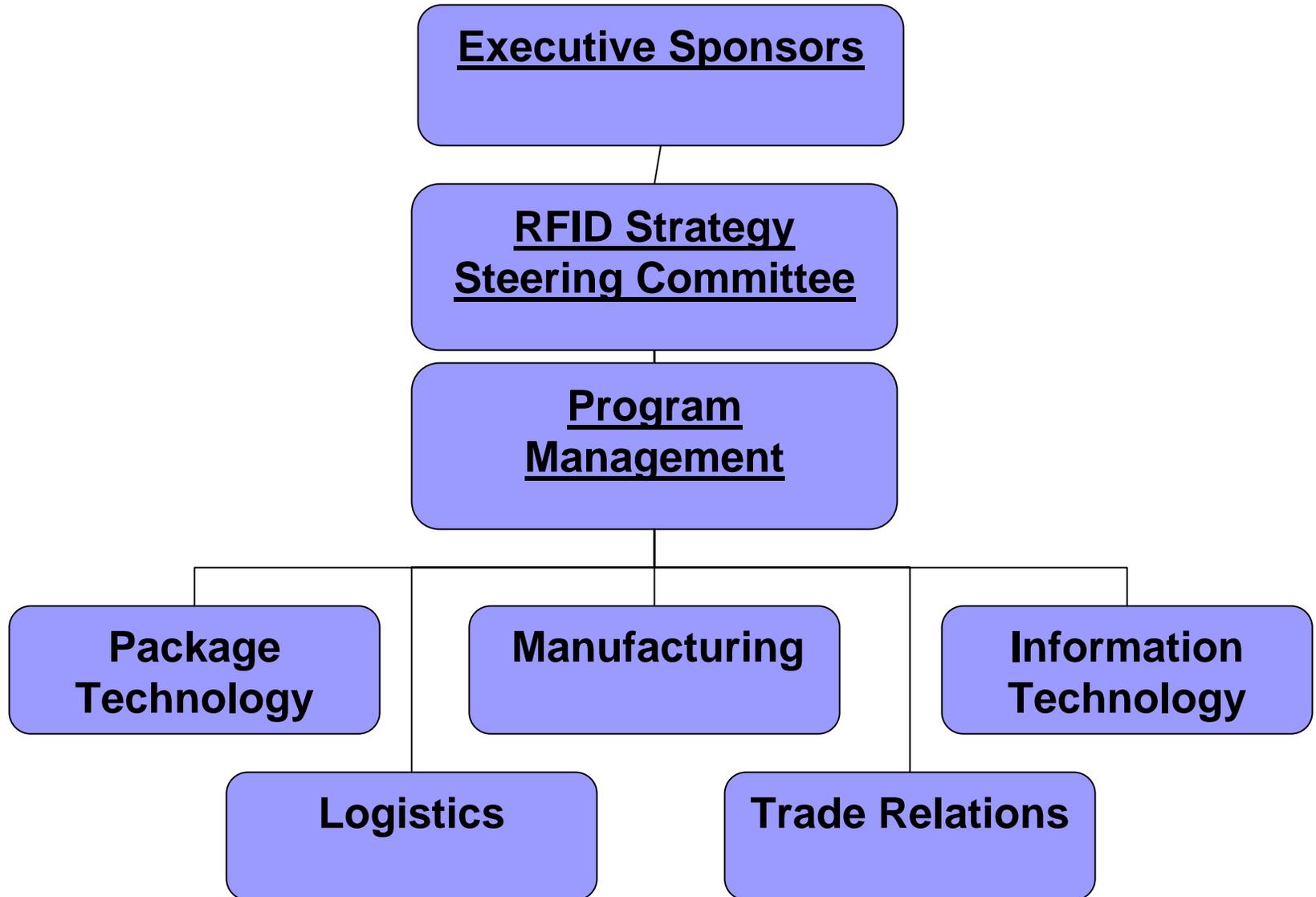


## Project Goals

- 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.

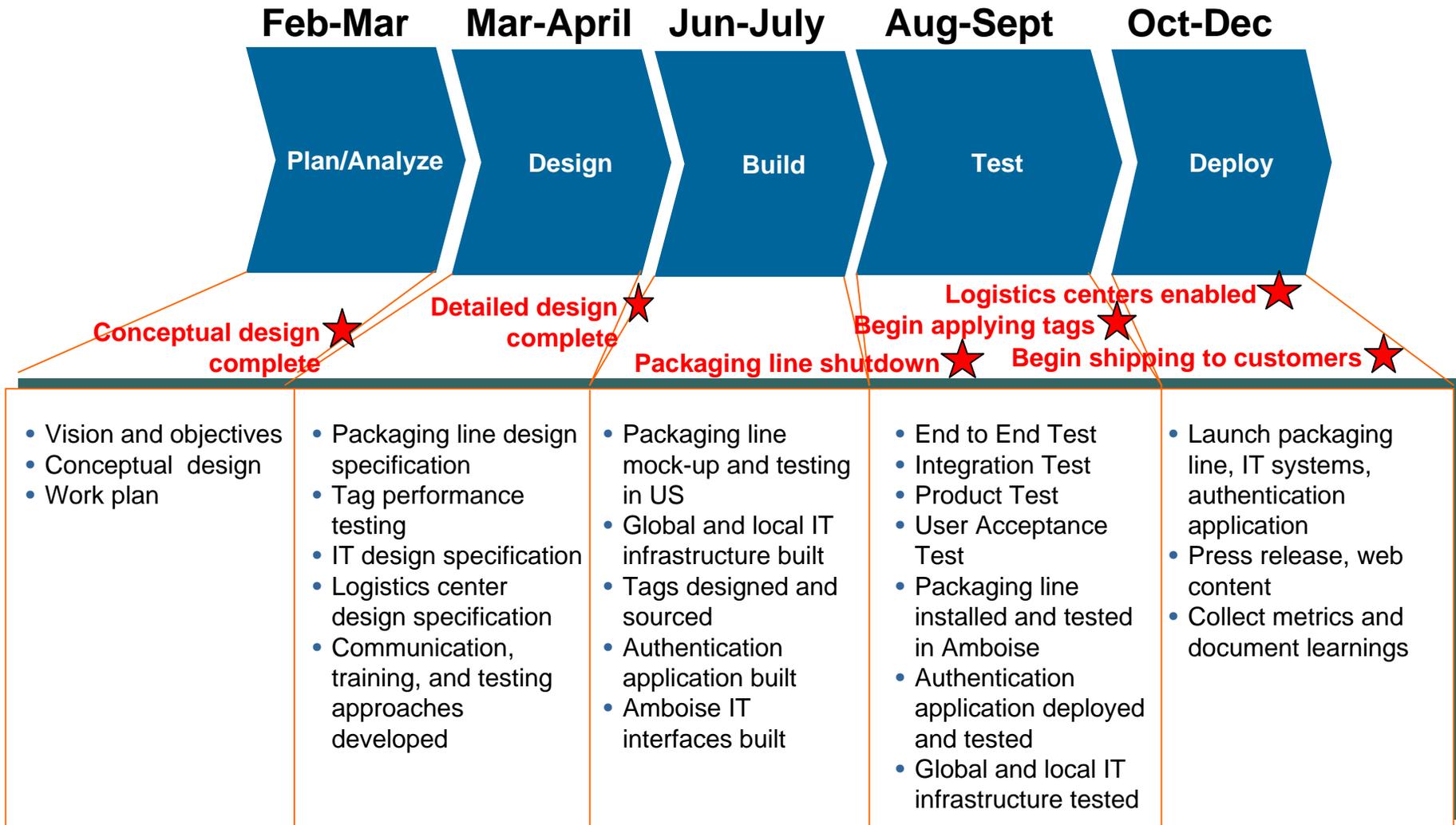


# Project Team Structure



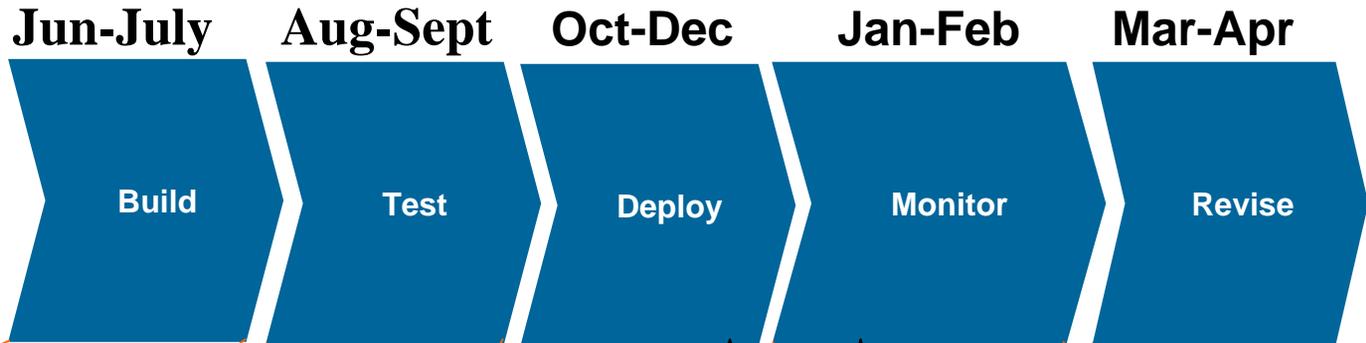


# Pilot Schedule





# Pilot Schedule



**Packaging line shutdown** ★  
**Begin applying tags** ★  
**Logistics centers enabled** ★  
**Begin shipping to customers** ★  
**Customers begin authenticating** ★

- 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

- 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

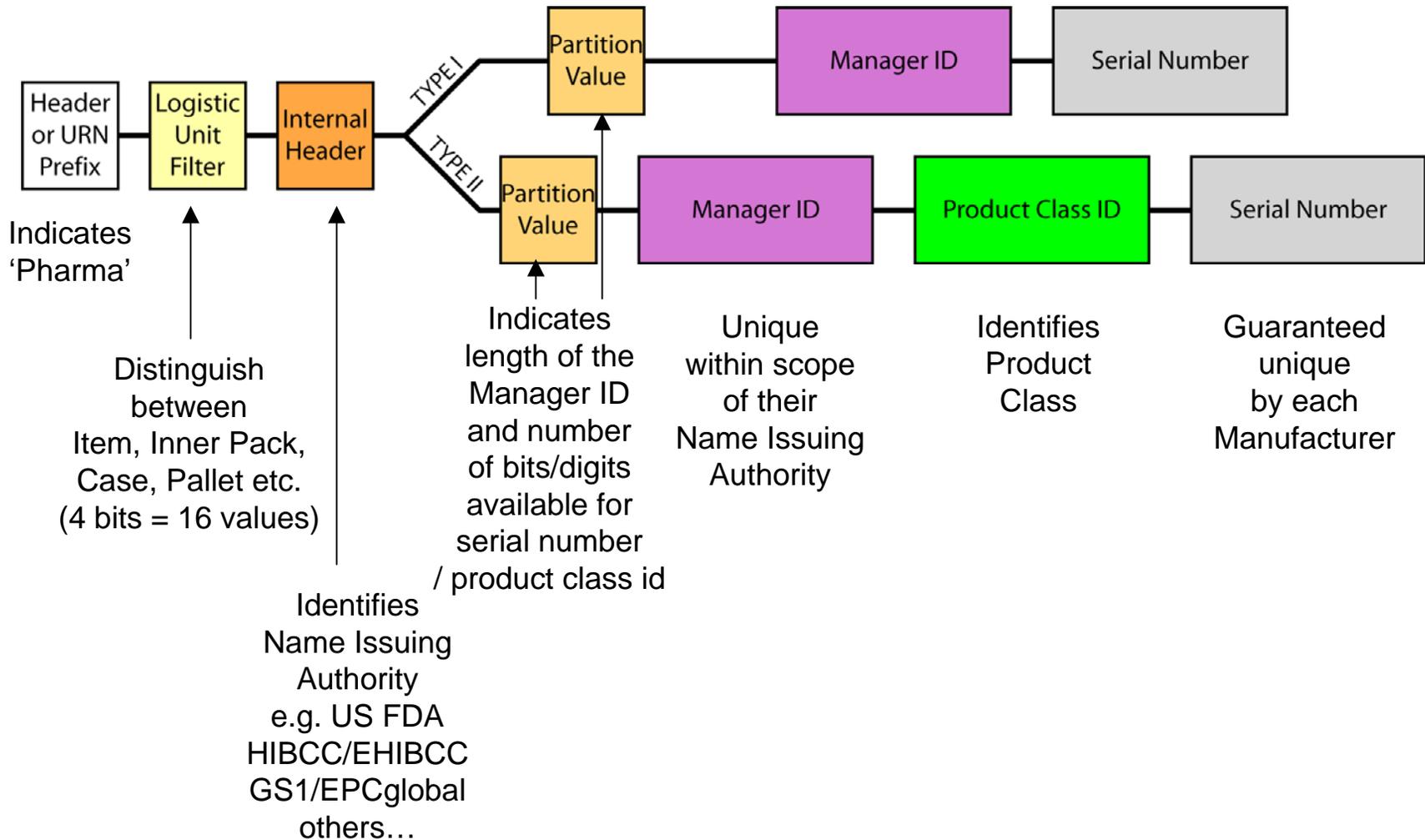
- Analyze metrics
- Analyze customer feedback
- Continue assisting customer authentication
- Plan for upgrade to UHF Gen 2 on cases & pallets
- Devise longer term HF strategy
- Initiate RFT projects



- **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

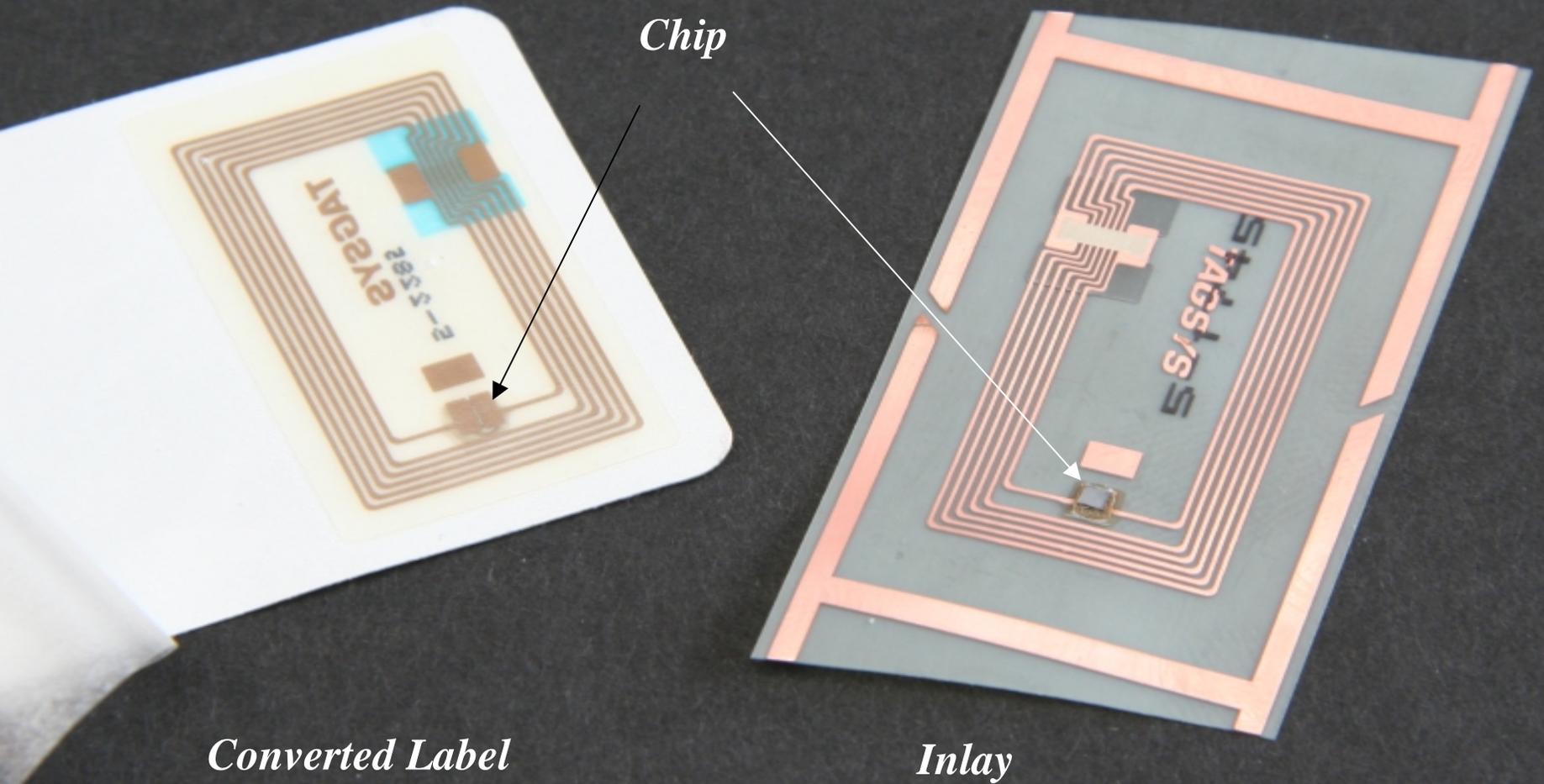




- **EPC Numerology**
  - **Viagra Pilot Current:**
    - 046.03.08.0069.00000000000000000001 (possible)
    - 046.03.08.0069.00000000001 (in use today @ Pfizer & GSK)
  - **Future Proposal:**
    - Includes additional **Internal Header**
    - 046.03.**XX**.08.0069.00000000000000000001



# RFID Label Tag Construction



*Chip*

*Converted Label*

*Inlay*

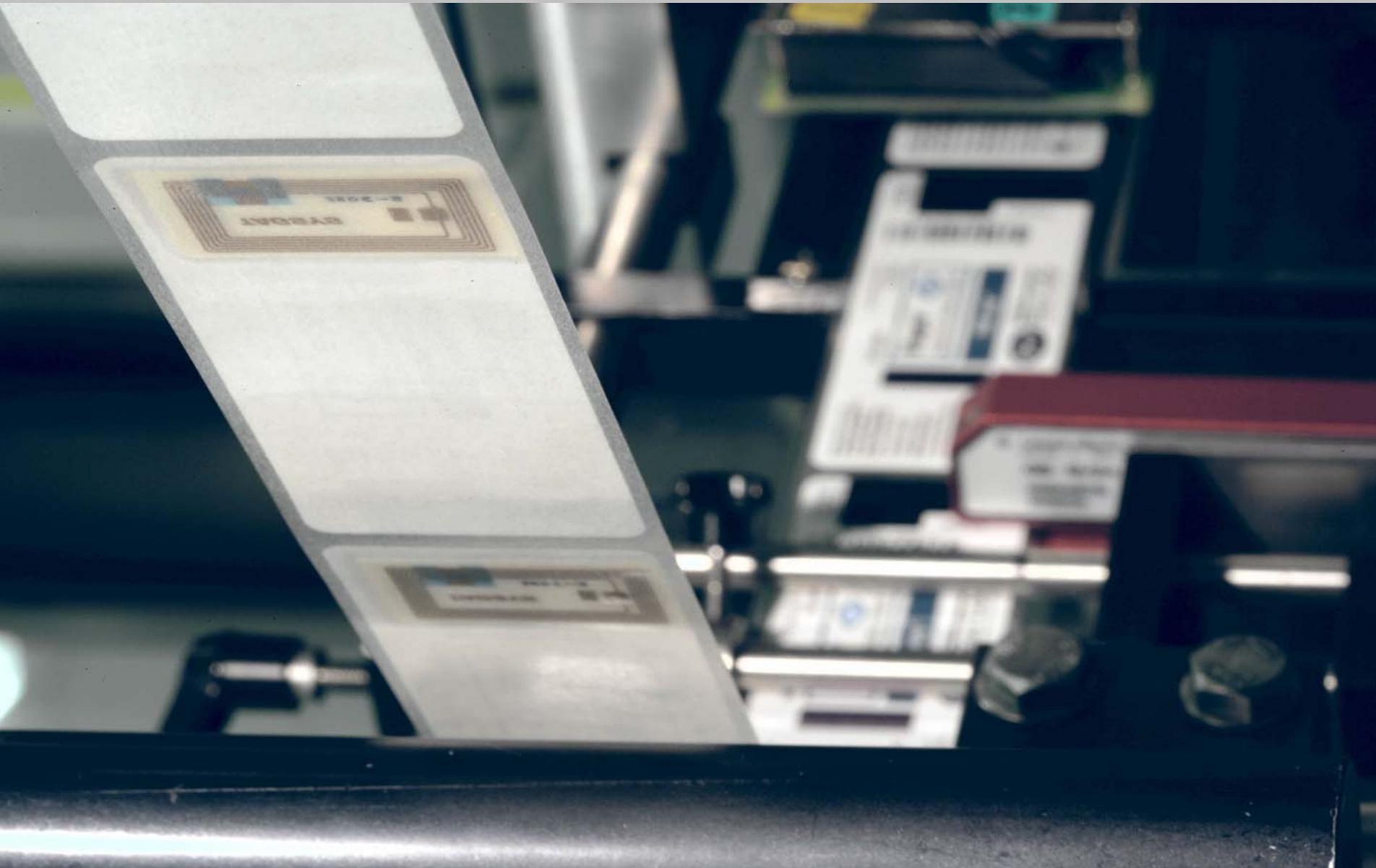


# RFID Tag Frequency Selection

- **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



# Packaging

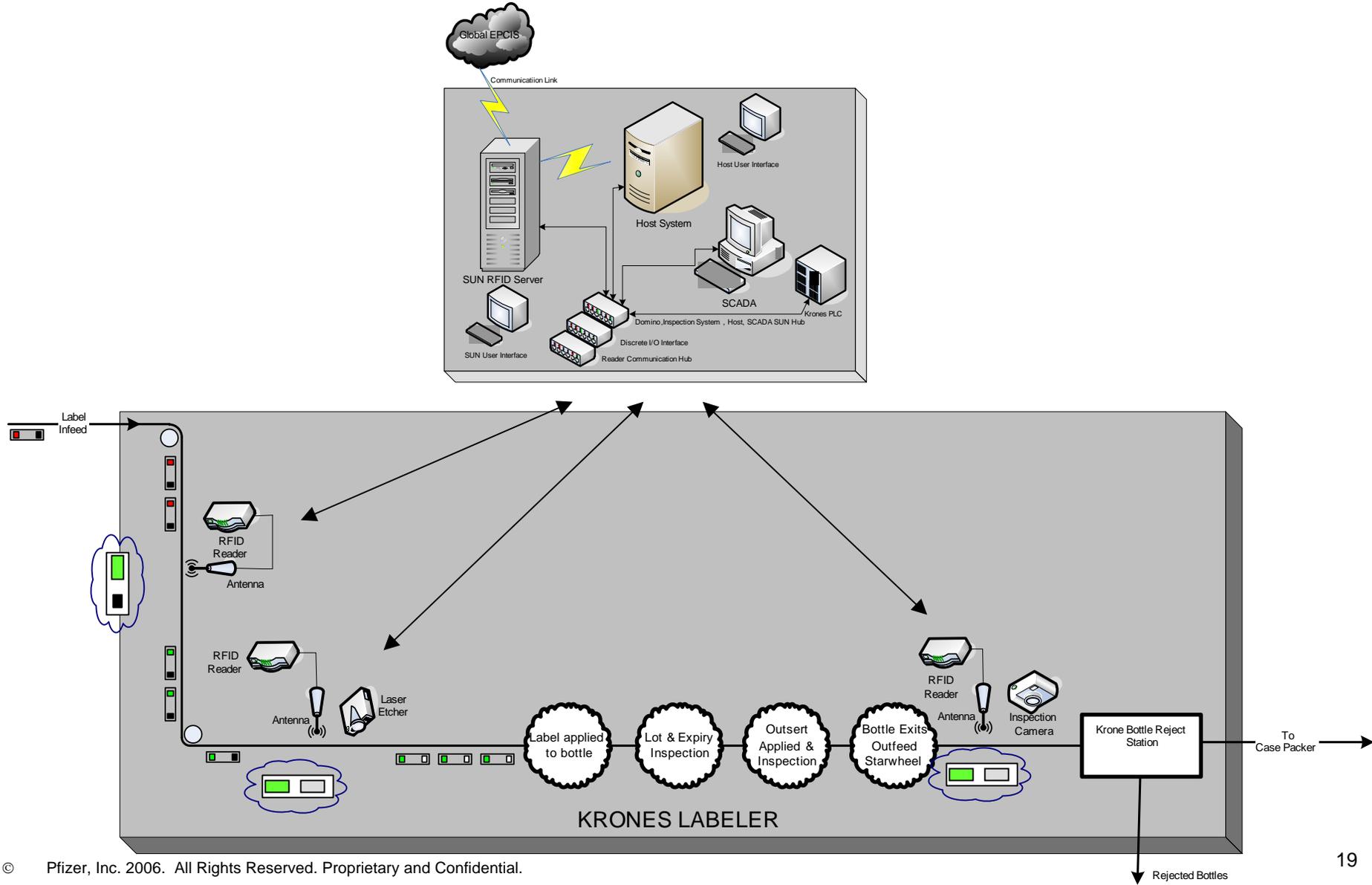




- **Process**
  - **Labels with RFID tags are written to (EPC & 2D Barcode) and affixed to individual bottles at speed**
  - **Inspection and Rejection accomplished prior to case packing**
  - **Case is filled and sealed**
  - **UHF label is applied to case (EPC & Linear Barcode)**
  - **A read of all 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**

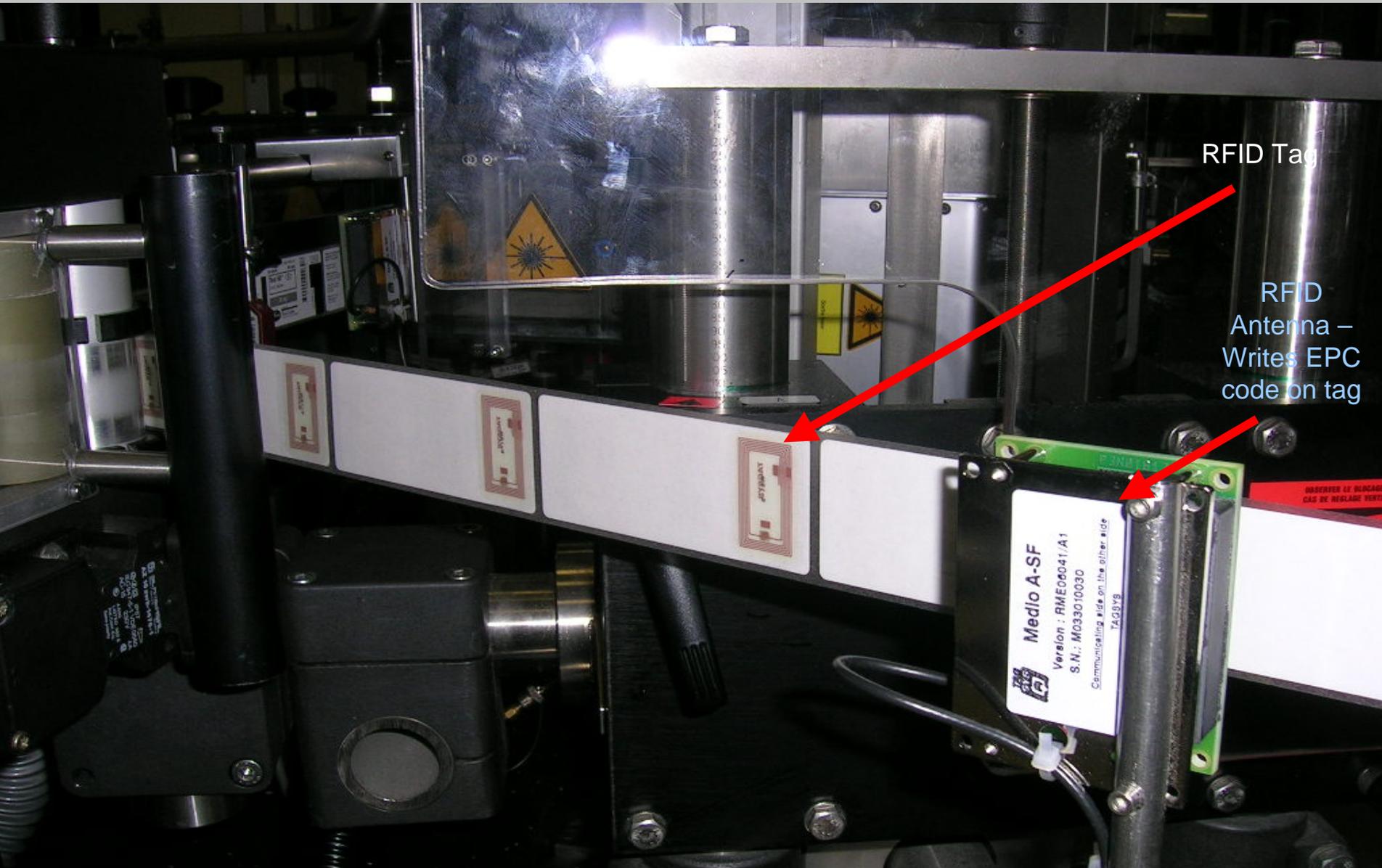


# Item Level Process Flow





# Amboise Packaging Line - Labeler



RFID Tag

RFID  
Antenna –  
Writes EPC  
code on tag

Medlo A-SF  
Version : RME00041/A1  
S.N. : M033010030  
Communicating side on the other side  
TAG978



# Labeler Feed





# Item Level Label Tag

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

The image shows a rectangular label for Viagra 100mg tablets. The label is divided into several sections. On the left, there is a white box with black text containing storage instructions, dispensing information, and dosage details. Below this box is a small EPC logo and text indicating the presence of an RFID tag. The central part of the label features the product name 'Viagra' in a large, bold font, followed by '(sildenafil citrate) tablets' and '100 mg\*' in a blue box. Above this, it says '30 Tablets' and 'Rx only'. The Pfizer logo and 'Pfizer Labs' are at the bottom. On the right side, there is a barcode, a small box with the number '4002', and a QR code. Below the QR code, there is a black box with white text: '8703245', 'PROD169', and '01 JUN-05'. A red line points from the text 'EPC Data 2D Barcode' to the QR code. Another red line points from the text 'Color Shift' to the black box. A red line also points from the text 'EPCglobal Logo and RFID Tag location (tag is under label)' to the EPC logo and text on the left.

store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].  
Dispense in tight containers (USP).  
**DOSAGE AND USE**  
See accompanying prescribing information.  
Each tablet contains sildenafil citrate equivalent to 100 mg sildenafil.

 This package contains a radio frequency device.  
05-5487-30-5

30 Tablets  
**Viagra**<sup>®</sup> 100  
(sildenafil citrate) tablets  
100 mg\*

NDC 0069-4220-30  
Rx only

 **Pfizer Labs**  
Division of Pfizer Inc, NY, NY 10017

Barcode: N3 0069-4220-30 3  
8703245

4002

PROD169  
01 JUN-05

EPC Data 2D Barcode

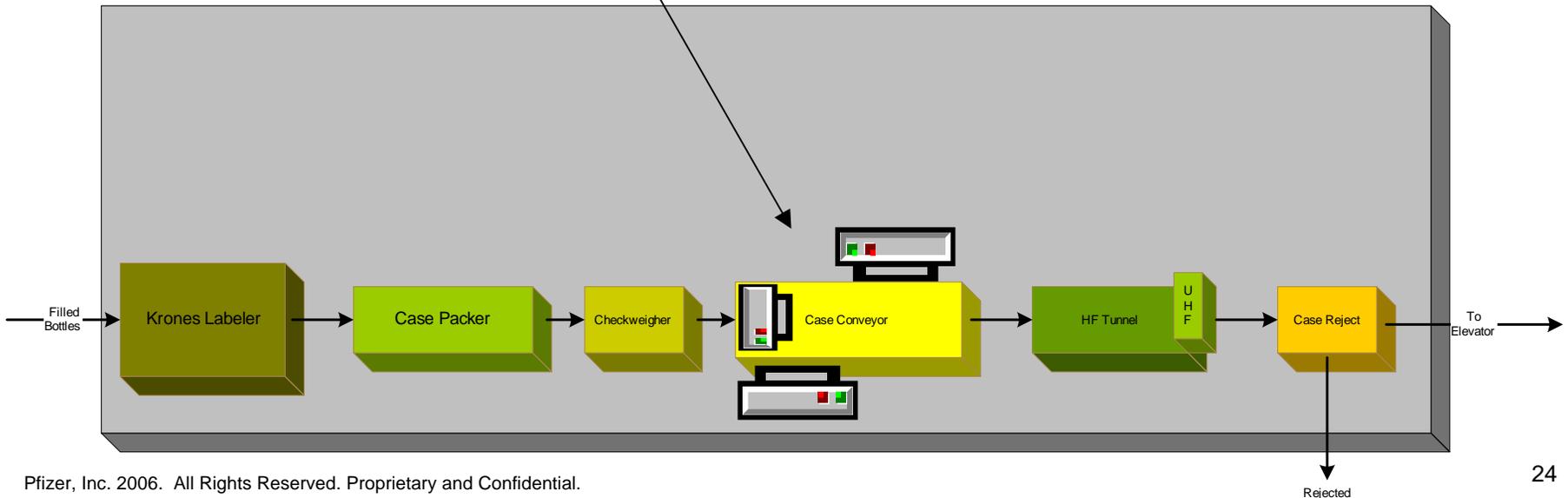
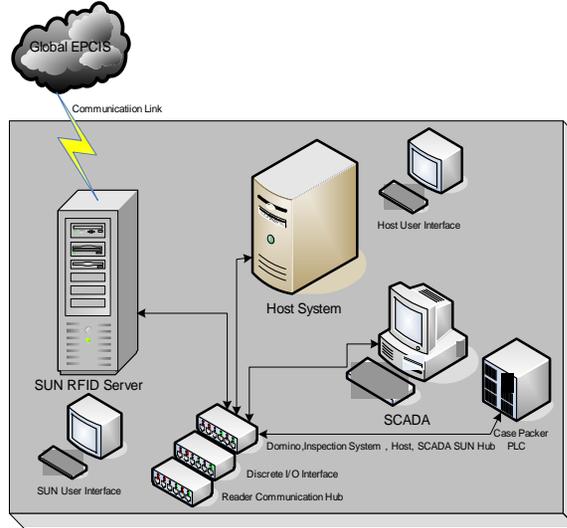
Color Shift

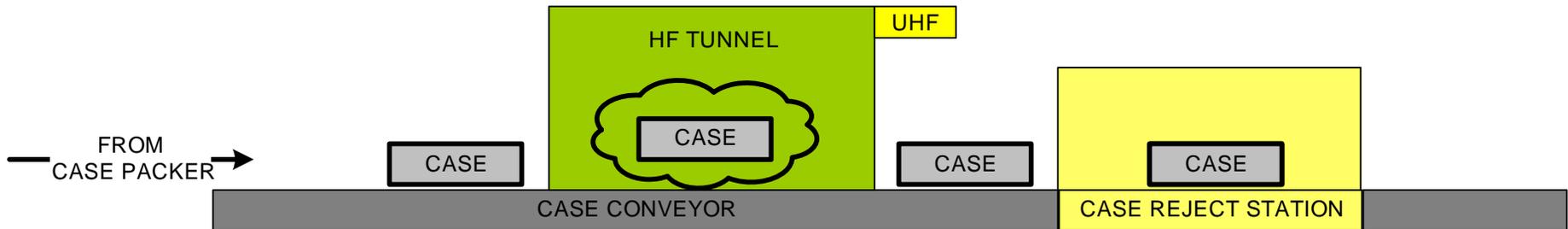
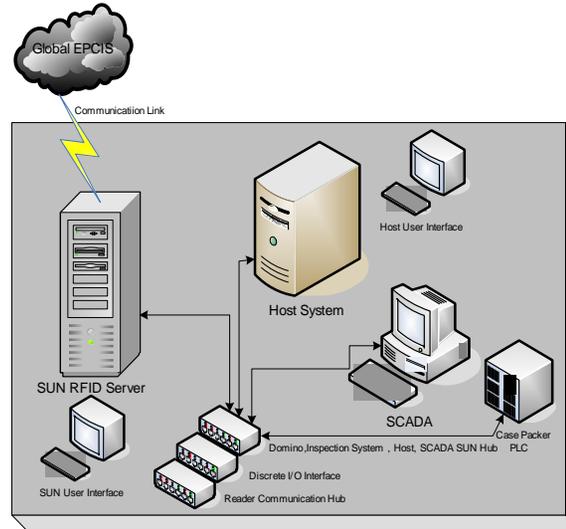


# Item Level Label Tag



# Case Level Process Flow



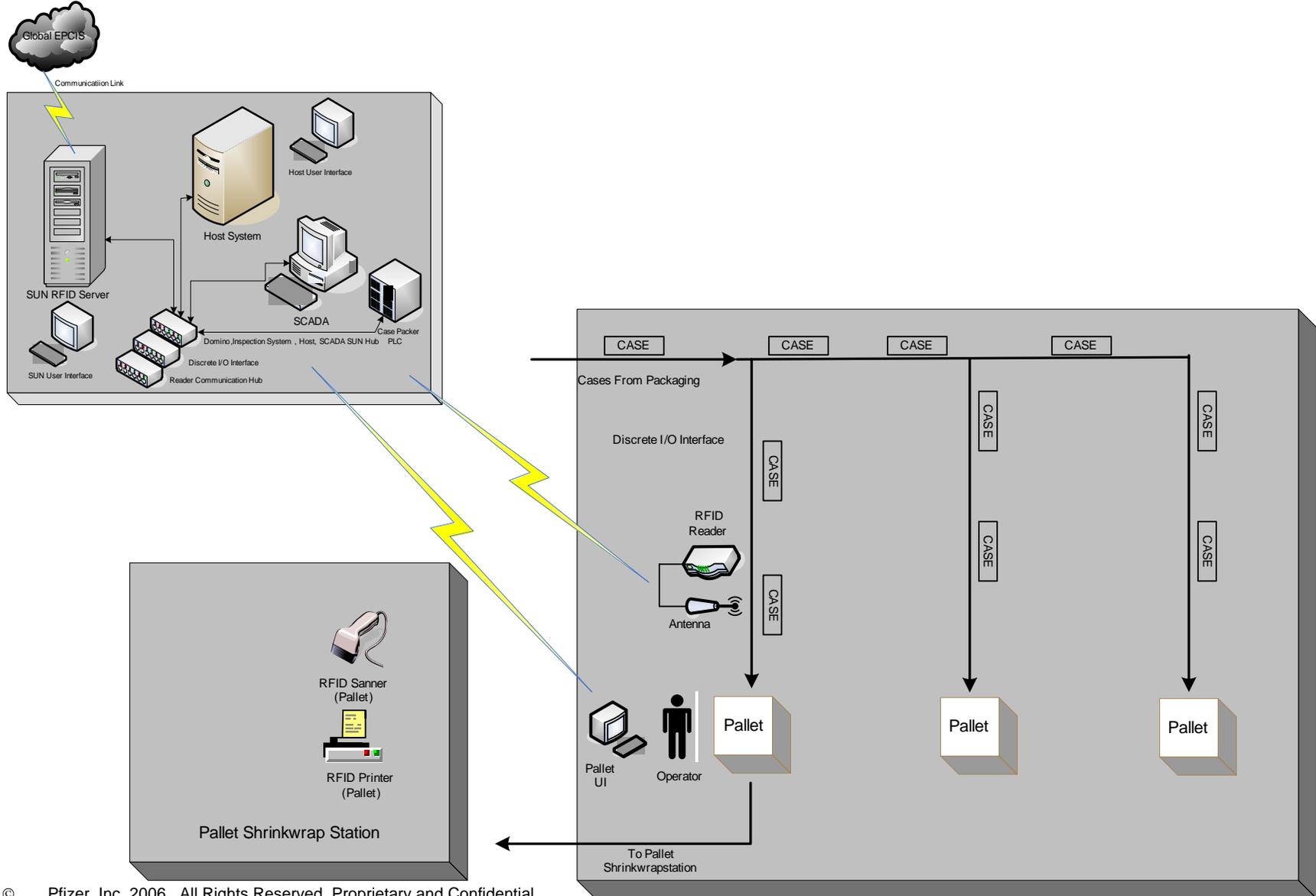


REJECTED CASES CASE



## Case Level Label Tag







# Logistics & Authentication

- **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

SupplyScape - Netscape

file:///C:/Documents%20and%20Settings/MarshTi/Desktop/V-Tag/SupplyScape%20Captures/single\_all\_good\_first

New Tab SupplyScape

**Pfizer** Electronic Product Code (EPC) Authentication

[Authenticate EPCs](#) [Logout](#)

You are logged in as **Neighborhood Pharmacy - Store #32**

Product Information	EPC Serial Number
 <p>VIAGRA® (sildenafil citrate) 50MG; 100 TABLETS NDC 0069-4210-66</p> <p><small>Product image is for illustration only and should not be used for authentication</small></p>	33570832.1.762842 <a href="#">Anti-Counterfeit Measures</a>

**Authentication Summary** [Authentication History 1](#)

Status	Description
EPC Issued	<b>EPC Issued By:</b> Pfizer Inc. <b>EPC Issue Date:</b> 21-Feb-2005
Origin	<b>Shipped From:</b> Pfizer Inc. 100 Jefferson Road Parsippany, NJ 07054 USA <b>Shipment Date:</b> 23-Feb-2005 <b>Shipment Number:</b> 12161971
Initial Destination	<b>Shipped To:</b> Rx Wholesaler 305 Wholesaler Place Greenville, MS 38701 USA



- **Adoption Status – Pilot Participation**
  - **1<sup>st</sup> 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**



- **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**

# Pfizer RFID Pilot Enhancing Patient Safety



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