

# Product Authentication and Getting Started With Track & Trace

# GS1 HEALTHCARE TORONTO

Merck & Co., Inc.





# **Product Integrity Strategy**

- Why?
  - Patient Safety
  - Compliance
  - Reduce Business Risks
  - Influence future efforts against counterfeits
- What could make up your strategy?
  - Technology (Mass Serialization / Anti-counterfeiting features)
  - Quality (case management / Investigation)
  - □ Legal (tougher penalties/enforcement)
  - □ Supply Chain (know trading partners)
  - □ Public Affairs (how to inform public)
  - □ Marketing / Sales (awareness / metrics)
  - □ Security (field Investigations)





### **Commercial Pilot Strategy**

WHAT **HOW** WHY **Identify Required Information Establish Data transfer process Demonstrate paper / Electronic Pedigree** Modify design for applicable systems to generate pedigree **Prepare for Demonstrate use of 2-D Bar Code** Identify Code print method(s) through supply chain Track code usability through supply Regulatory chain **Identify Readability of RFID** Requirements Identify points of reading RFID Through Supply Chain **Determine Hardware(s) and Tags to Test** & Improve **Demonstrate the electronic** Establish and monitor effectiveness **Patient Safety** communication of Pedigree / electronic data transfer **Authentication Increase Knowledge of Supply VOC of supply Chain Partners** Chain Validate Business Benefit **Identify opportunities of business Opportunities** benefit & Develop DOE to evaluate





#### **Merck Pilots**

Serialization
Data Repository

**Central Data Center** 

2D Pilot (Latin America)

**Mexico City, Mexico** 

**RFID Pilot (US)** 

Arecibo, PR Reno OFC

Item (Wallet) Level

HF RFID Tag
2D Data Matrix Code

Bundle Level
Virtual Inference

Shipper Level
UHF 2<sup>nd</sup> Gen RFID Tag
2D Data Matrix Code

**Local Data Server Systech Guardian** 

Serialized Data
Repository
SAP All

Messaging Exchange TIBCO

Item (Carton) Level
2D Data Matrix Code
Human Readable Serial
Number



# Items challenged in Pilot

- Equivalent inlays from manufacturers do not behave the same.
  - □ Inlays tuned to different frequencies
- Label converters do not convert the RFID labels the same way.
- Multiple brand readers reading the same tag.
- Readability of the 2D data matrix ECC200 code.
- Wallets make it through the complete supply chain.
- Business to Business exchange of data
- Gain experience with centralized serialization repository.





#### RFID/2D Wallet Label

- 49 x 22mm Removable Label
- Placed on front of wallet
  - □ Needs to be away from blister
- Pilot RFID/2D label
  - ☐ HF UID OTP Tag
    - SGTIN-96 (Item Reference masked)
      - **48.1.6.030006.1000000.123456789012**
    - UID (NXP Serialized Number)
      - **9876543210**
  - 2D Data matrix Barcode (Laser Inverse code)
    - AI(01)+AI(21)
      - □ (01)1<mark>0300060031448(21)</mark>123456789012
  - □ EPC Global Seal
  - "This label contains a radio frequency device" text





Rx or



#### FOSAMAX® RFID Case Label

- 4 x 4 Label on visible size of case near the current shipper end label.
- UHF 2<sup>nd</sup> Gen Tag
  - □ SGTIN-96
    - **48**.3.6.030006.3003144.123456789012
- 2D Data matrix Barcode
  - $\Box$  AI(01)+AI(21)
    - **•** (01)30300060031442(21)123456789012
- Linear GTIN Barcode 128
  - □ AI(01)
    - (01)30300060031442
- Linear Serialized Barcode 128
  - □ AI(21)
    - **(21)123456789012**
- Human Readable SGTIN-96
- EPC Global Seal
- "This label contains a radio frequency device" text







## **Pilot Findings To-Date**

- Serialization is not a turn key solution.
- Little changes can greatly effect RFID performance.
- Standards gaps & options allow for mixed practices.
  - □ Limited interoperability of reader brands
  - □ Data formats
  - □ Reader to tag readability
  - □ Alignment with supply chain partners
- Strong business practices are critical for success.
- Robustness of systems is still a concern.
- Key Suppliers in Industry have or could have capacity gaps.
- Integrity of Inference requires well designed systems.





### **Key Findings During Packaging**

- With a well designed system, similar line performance is possible.
- When a system goes off-line, everything stops!
- Process must be designed to detect manual errors/atypicals
  - □ Visuals and training to reduce mental stress of operators
  - □ Virtual Accountabilities vs. Physical Accountabilities differences.
  - □ Materials are found out-of-process, which causes discrepancies.
- Robustness of systems still needs improvement to sustain product supply.
  - Issues have been seen during production that caused discard of physically good material.
  - Maintaining communication with all the systems.
- As expected, not all RFID labels behaved the same way.
- Identified additional improvements to the line and processes for full scale serialization.





# **Packaging Line Read Rates**

#### **Read Metrics**



