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

WHY

- Prepare for Regulatory Requirements & Improve Patient Safety

WHAT

- Demonstrate paper / Electronic Pedigree
- Demonstrate use of 2-D Bar Code through supply chain
- Identify Readability of RFID Through Supply Chain
- Demonstrate the electronic communication of Pedigree / Authentication
- Increase Knowledge of Supply Chain
- Validate Business Benefit Opportunities

HOW

- Identify Required Information
  - Establish Data transfer process
  - Modify design for applicable systems to generate pedigree
- Identify Code print method(s)
  - Track code usability through supply chain
  - Identify points of reading RFID
  - Determine Hardware(s) and Tags to Test
- Establish and monitor effectiveness electronic data transfer
- VOC of supply Chain Partners
- Identify opportunities of business benefit & Develop DOE to evaluate

- Increase Knowledge of Supply Chain
- Validate Business Benefit Opportunities
Merck Pilots

Serialization Data Repository

RFID Pilot (US)
- Arecibo, PR
- Reno OFC

Item (Wallet) Level
- HF RFID Tag
- 2D Data Matrix Code

Bundle Level
- Virtual Inference

Shipper Level
- UHF 2nd Gen RFID Tag
- 2D Data Matrix Code

2D Pilot (Latin America)
- Mexico City, Mexico

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)10300060031448(21)123456789012
- EPC Global Seal
- “This label contains a radio frequency device” text
FOSAMAX® RFID Case Label

- 4 x 4 Label on visible size of case near the current shipper end label.
- UHF 2\textsuperscript{nd} Gen Tag
  - SGTIN-96
    - 48.3.6.030006.3003144.123456789012
- 2D Data matrix Barcode
  - Al(01)+Al(21)
    - (01)30300060031442(21)123456789012
- Linear GTIN Barcode 128
  - Al(01)
    - (01)30300060031442
- Linear Serialized Barcode 128
  - Al(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

Lot A
Lot B
Lot C
Lot D

% Loss Coding
% Item Not Commission
% Bundle Not Commission