AGENDA

- The Global Counterfeit Drug Problem
- The Potential Market – an International Focus!
- Industry Regulations
- Key Players in the Industry
- Cradle To Grave E-Pedigree
- Serialized Solution – Layered Model
- 3 Pieces to the Puzzle
- Serialization Reality
THE GLOBAL COUNTERFEIT DRUG PROBLEM

• A $200B Market

• Prompting massive demand for action: Patient Safety

• New & pending regulations

• Emerging requirement for product verification and authentication

• Much confusion & uncertainty

THE POTENTIAL MARKET – A INTERNATIONAL FOCUS!

A constant global theme that is emerging...
The Requirement for PRODUCT VERIFICATION based on CODIFICATION & MASS Serialization

This Global anti-counterfeit packaging market is expected to reach $82.2B by 2015
INDUSTRY REGULATIONS

USA
• California is the first and only state that has imposed serialization mandates
• The California law requires:
  – 50% of a manufacturer’s products must be distributed with electronic pedigrees by 2015
  – The remaining 50% of the manufacturer’s products must comply by 2016
  – Wholesalers and re-packagers must accept and pass ePedigrees by July 1, 2016
  – Pharmacies/pharmacy distribution centers must accept ePedigrees by July 1, 2017

EUROPE
– Turkey has been out in front
– France a close second
– Legislature is developing a sound strategy

REST-OF-THE-WORLD
• China - centralized pedigree and serialization
• Brazil – pilot unit serialization and scale up over the next few years

KEY PLAYERS IN INDUSTRY

• “The whole is more than the sum of its parts.”
  ARISTOTLE, FROM “METAPHYSICS.” 335-323 BCE

• There are no shortage of vendors offering technologies for new or retrofitted packaging lines
SERIALIZATION CHALLENGES

ORGANIZATIONAL CONSTRAINTS:
• Lack of resources
• Inertia
• Mergers & acquisitions
• Product/technology rationalizations
• Outsourcing
• Scheduling Time on the Line

GLOBAL INFRASTRUCTURE:
• The infrastructure to read the codes, etc. amongst the Supply Chain partners might not be in place to meet the deadlines

Responsible person A tosses looming T&T deadline memo B into wastebasket C which causes board D to become unbalanced raising tack E to pop balloon F startling cat G who jumps up, pushing bellows H, thus blowing fan blades I which winds and shortens cord J lifting trough K, causing baseball L to roll down and drop onto PLAY button of cassette player M which turns on specially recorded tape message N which has been embedded with the subliminal message CALL FOR HELP 610 427 3310

Additional hardware and software technology to Code, Read, Verify and Track the product through the line
CRADLE TO GRAVE E- PEDIGREE

Thinking “outside the box”

- Expand past the shop floor
- Address varying markets
- Integrate Coding, Serialization and Track & Trace solutions across the entire supply chain!

PRESENT: Pharmaceutical Manufacturers and Packagers Focus

PROPOSED: Full Implementation Requirement

SERIALIZATION SOLUTION – LAYERED MODEL

EPCIS: EPC Information Services to enable disparate applications to leverage Electronic Product Code (EPC) data via EPC-related data sharing, both within and across enterprises.
ERP: Enterprise Resource Planning
MES: Manufacturing Execution System
HMI: Human-Machine Interface of the Serialization application
1. M+W Life Sciences

Getting a serialized 2D bar code on a package achieves nothing if no one is equipped to read it.
To exit the shop floor you need to add a DATA MANAGEMENT PLATFORM + SYSTEMS INTEGRATION services

2. Serialization Platform

3. Information Technology

Project based & enterprise specific platform customization for:
- Track & Trace
- Anti-Counterfeiting
- Diversion Protection
- Recalls/ Returns
- Cold Chain
- Serialization e-Submissions

The Link To Full Implementation

SERIALIZATION REALITY

- The Global Counterfeit Drug Market is huge and affects Patient Safety
- Counterfeit drugs have Brand, Quality, and Regulatory implications as well.
- The inertia for Serialization Track & Trace is over – Pharma is implementing
- Implementation seems to stop with the pharmaceutical companies
- The market is disjointed & confused

Counterfeit Drugs
a very serious problem!

Patient Safety

Dispensing Errors
Reimbursement Fraud
Adulteration
Parallel Trade
Excessive Downtime

30% - 50% of drugs are counterfeits
US sales losses = $30B/year
Investments ↑15%/year

Made in USA
THE CASE FOR STRATEGIC CONSULTING SERVICES

- Overall Strategy & Implementation Planning
- Engineering assessments
  - Corporate
  - Site and/or
  - Line level
- Line Retrofit Evaluations
- URS and FRS development
- Serialization Awareness & Technology Training
- Proof-of-principle pilot and implementation plan management
- Serialization Technology Vendor Evaluations, Recommendation & Selection

THE CASE FOR TECHNOLOGY INTEGRATION SERVICES

- **Device Level:**
  - Encoding systems
  - Machine-vision
- **Packaging Line Level:**
  Configuring the Serialization software to manage the:
  - Data
  - Aggregation
  - Product and line recipes,
  - Business logistics
- **Enterprise Level:**
  - Providing access between critical data points from various packaging lines to ERP, EPCIS, and other IT business systems
  - Capturing the data and providing a data repository e.g. SAP Aii/OER
  - Establishing and allocating serial numbers, and
  - Managing the process, work orders, and e-pedigree
FAST FORWARD

ENFORCEMENT

• Push back from the Supply Chain stakeholders

• Will US implementation be delayed?

• Will the law be challenged?

• Is there some “middle of the road” alternative?

CRYSTAL BALL:

Time will tell...

THANK YOU

Q&A

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