

AGENDA

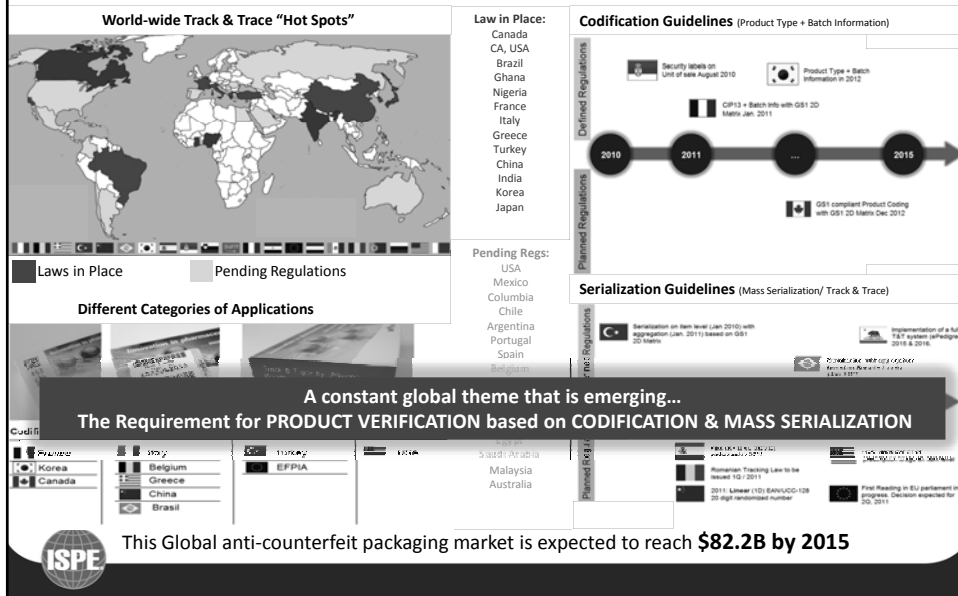
- The Global Counterfeit Drug Problem
- The Potential Market – an International Focus!
- Industry Regulations
- Key Players in the Industry
- Cradle To Grave E-Pedigree
- Serialized Solution – Layered Model
- 3 Pieces to the Puzzle
- Serialization Reality



- 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!



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

- Manufacturer's must submit an outline of the product % make-up by December 1, 2014
 - By unit volume
 - By product package (sku) type
 - By Drug Product family
- Nearly everyone in the U.S. pharmaceutical industry expects the FDA, with a congressional grant of authority or without, to require e-Pedigrees nationally--or even a more robust track-and-trace system -- so as to avert a patchwork of 50 state laws kicked off by California's action



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

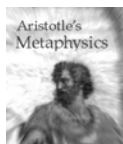


Approximately 50% of the industry now have at least one product line serialized

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



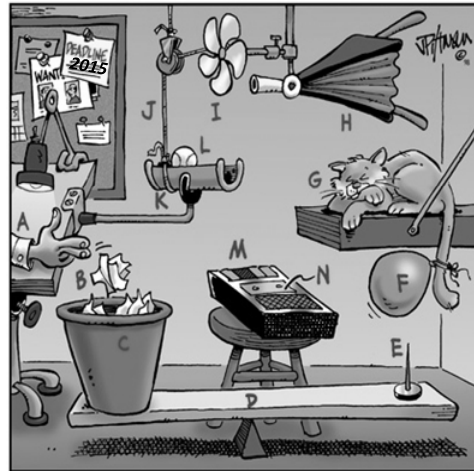
SERIALIZATION CHALLENGES

ORGANIZATIONAL CONSTRAINTS:

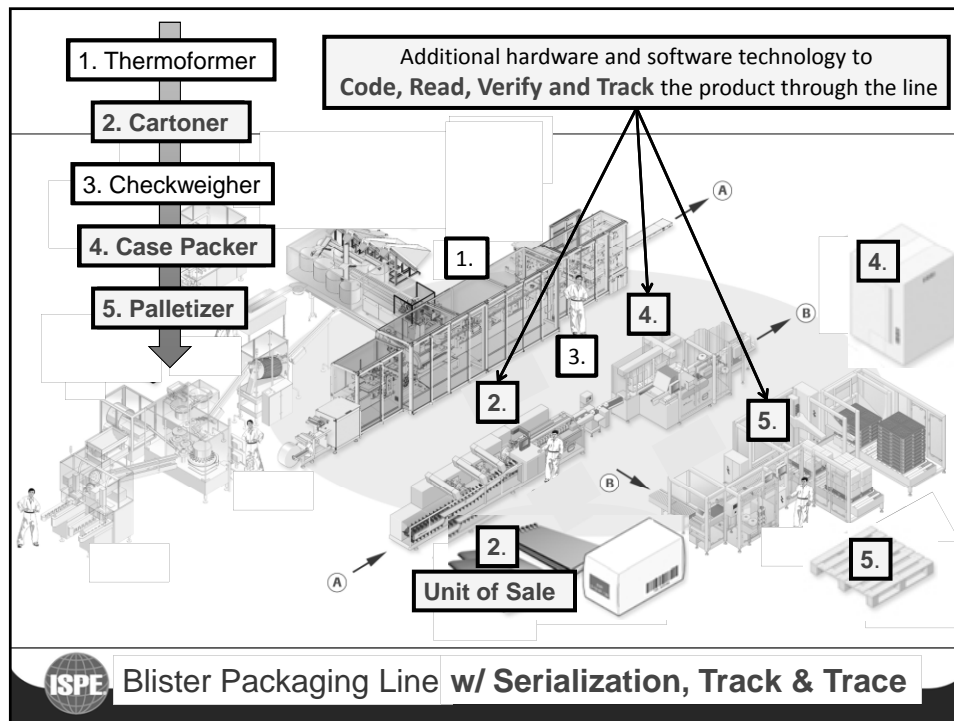
- Lack of resources
- Inertia
- Mergers & acquisitions
- Product/ technology rationalizations
- Outsourcing
- Scheduling Time on the Line

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 trash can **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**

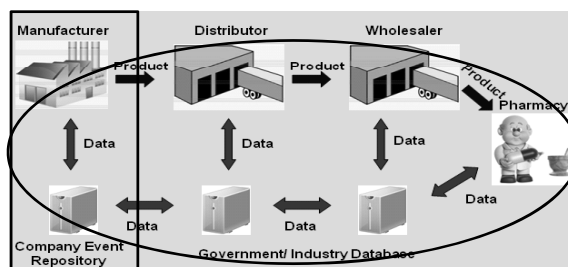


CRADLE TO GRAVE E- PEDIGREE

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

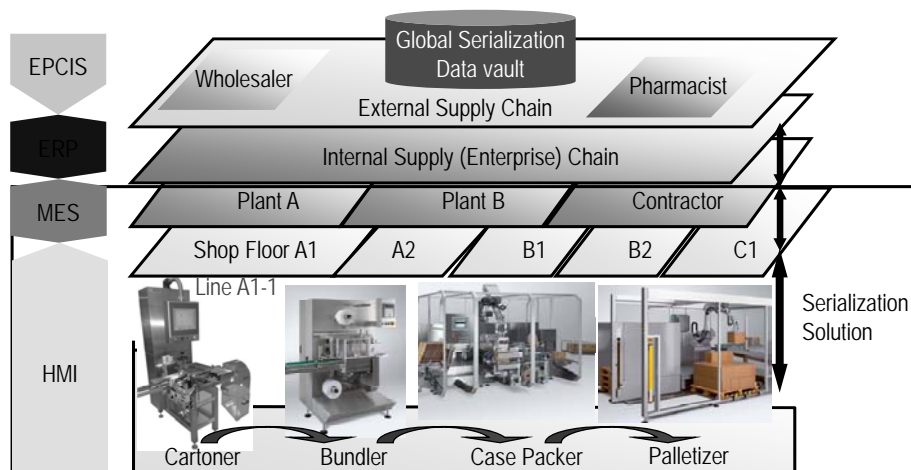


THE PHARMACEUTICAL SUPPLY CHAIN

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



3 PIECES TO THE PUZZLE:

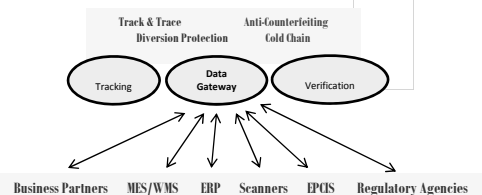
1. M+W Life Sciences



PLAN, DESIGN, CONSTRUCT, AND VALIDATE PRODUCTION FACILITIES

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



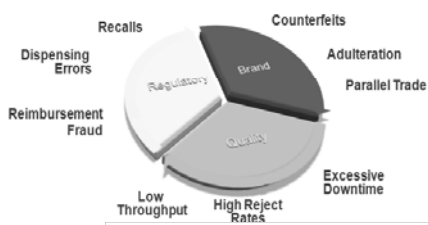
The Link To Full Implementation

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



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



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...



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