Serialization and Product Traceability

Serialization Preparedness – What You Must Know for Bullet-Proof Programs
Greg Cathcart CEO Excellis Health Solutions
Agenda

- Key Concepts
- Regulatory Monitoring
- Data Management and Governance
- Line Execution and Warehousing
- Contract Manufacturing
- Distribution / 3PLs / Reverse Logistics
- Program Structure
- Communications and Change Management
- Developing a Serialization Strategy
Serialization Concepts

Most serialization regulations require encoding a unique identifier at the unit of sale in a 2D datamatrix

<table>
<thead>
<tr>
<th>Application Identifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01)</td>
<td>GTIN</td>
</tr>
<tr>
<td>(17)</td>
<td>Expiration Date</td>
</tr>
<tr>
<td>(10)</td>
<td>Lot Number</td>
</tr>
<tr>
<td>(21)</td>
<td>Serial Number</td>
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</table>

GS1 standards prevail – exceptions exist!
## Serialization Concepts

<table>
<thead>
<tr>
<th>Configuration of Package / Shipping Container</th>
<th>Lowest Saleable Item</th>
<th>Homogeneous Case</th>
<th>Homogeneous Pallet</th>
<th>Container</th>
<th>Mixed Pallet</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest Saleable unit with a unique NDC</td>
<td>A case containing saleable items of all same NDC</td>
<td>A pallet containing cases of products of all same NDC</td>
<td>A case containing products of different NDC re-packed at the DC</td>
<td>A pallet containing cases of products of different NDC re-packed at the DC</td>
<td></td>
</tr>
</tbody>
</table>

### Primary Data Carrier & Encoded Data
- GTIN14
- Serial Number
- Expiration Date
- Batch Code

### Secondary Data Carrier & Encoded Data
- GTIN14
- Serial Number
- Expiration Date
- Batch Code
- Case Quantity

- SSCC18
- SSCC18
- SSCC18
Serialization Concepts

Aggregation / Inference / Hierarchy

- Assignment of child-level serial numbers to a unique serial number at the parent level
  - Sales units to bundles
  - Bundles to cases
  - Cases to pallets
- Electronic representation of grouped goods
- May travel through the supply chain with the product
- May be homogeneous or heterogeneous
Serialization Concepts

**Authentication** verification that the information appearing on the package is the same as what the manufacturer printed on a package.
Serialization Concepts

Track & Trace offers complete visibility of product as it moves through the supply chain.
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Regulatory Monitoring

Many countries either have regulations in place or are in the process of implementing them....

.... And each one has a different flavor
H.R. 3204 USA

1/15 Federal
- FDA to publish guidance for interoperable exchange of Tx info, hist, statement
- MFG to provide paper or electronic Tx hist, info, statement incl lot
- Investigation/Verification systems
- Whslr & Disp to receive same

1/16 CABoP
Mfr 100% SNI & e-Pedigree

1/17 CABoP
Retail/Pharmacies e-Pedigree

7/16 CABoP
Distributors/Repackers e-Pedigree

1/18 Federal
- Mfr. Product identifier
- Mfr. ability to verify SNI
- Mfr. Electronic Tx Hist, Info & Statement

1/19 Federal
Repackager product identifier
Repackager ability to verify SNI

1/20 Federal
Wholesaler and 3PL: Only receive product with identifier
Need ability to verify SNI at the package level

1/21 Federal
Dispenser: Only receive product with identifier
Need to verify SNI at the package level

1/24 Federal
Interoperable electronic system
Item level w/aggregation & inference
Regulatory Monitoring

Sources of regulatory information

- Internal in-country regulatory personnel
- Country MOH websites
- GS1 Public Policy Workgroup
- Trade Associations
- Conferences – Global Track and Trace
- Networking
- Service Providers
Regulatory Monitoring

Regulators are not supply chain professionals!

- Need to understand the implication of proposed regulations and get in front of them
  - Timing
  - Conformance to standards
  - Harmonization with other models
- Work with industry peers and trade associations to develop common positions
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Data Governance

Establish Enterprise Data Standards and Processes

• Global Trade Item Number (GTIN)
• Global Location Number (GLN)
• Serial number management
  ➢ Randomization
• Event data
• 3rd party data integration (CMOs, 3PLs, Customers)
• Analytics / KPIs
• Data archival
Data Governance

Global Trade Item Number (GTIN)

- GTIN is an 8, 12, 13 or 14 digit unique number assigned by a that uniquely identifies a product
- Assigned to any item that may be priced, or ordered, or invoiced at any point in the supply chain
- GTIN14
  - Compliance with generally accepted industry best practices thereby mitigating risk
  - Package level indicator allows for easy identification of packaging level
  - Algorithms for conversion of existing identifiers such as EAN, UPC, NDC, etc available
GTIN, like the USA regional NDC, is a product identifier valid and unique globally.
Data Governance

Global Location Number (GLN)

- A GLN is a unique identifier assigned to either a physical location or a legal entity of a trading partner.
- GLN’s act as a reference key to help identify key information about trading partners such as addresses, location types (headquarters, warehouse, etc.), contact information, etc.
- Provide a unique, unambiguous and efficient identification of all locations relevant to an electronic transaction.
Data Governance

Serialized Shipping Container Code (SSCC18)

- Extension Digit – Used to increase the capacity of the serial reference
- GS1 Company Prefix – assigned by the GS1 Member Organization
- Serial Reference – allocated by the company sequentially to a logistic unit
- Check Digit – calculated according to the standard algorithm

<table>
<thead>
<tr>
<th>SSCC (Serial Shipping Container Code)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extension Digit</td>
</tr>
<tr>
<td>N₁</td>
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Agenda

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3 New Pieces of the Puzzle

1. Serialization Line Execution System (Internal & CMO/CPO)
2. Corporate Serialization (EPCIS) Repository
3. Distribution Solution Capture Solution (Internal Capture & Third Party Logistics Partner)
Solution Architecture

There would have to be integration touch points between Enterprise systems and the corporate level repository. Multi-Tiered Architecture Site Level

Line Control system linking HMI

Line level

Integration Egate

Corporate Event Repository EPCIS

Note: EDI 856 ASN Advanced Shipment Notification
ASN XML Like File
EPCIS to EPCIS Event transfer of pedigree information

Integration Layer

Enterprise Systems ERP

Enterprise information about the shipment or transfer of goods

Serialization Information

Multi-Tiered Architecture Site Level

Company Trading Partners

Integration

Line level

Manufacturing

Distribution

Or

EPCIS ePedigree System

Corporated ASN Pedigree
Corporate Repository

- Manage serial numbers
- Record serial number statuses
- Record serial number events
- Receive / send serialization data to trading partners, regulatory bodies, supply chain partners
- Single solution for serialization information

Integration Touch Points
- Site / Line Systems
- Warehouse / Distribution System
- Business Events – ERP MES WMS
- External supply chain business partners
- Customers / Regulatory bodies
Line Execution

Serialization Process
High level View

Serialziation Information
Material Flow
Supporting MFG Operations

Corporate Serialization Repository

Corporate Level EPCIS Data Repository

Site Level Repository

Plant Level Serialization Facilitates Connectivity

Manufacturing Level Controls Printing & Vision Systems at the line level

Legend
Camera vision system
Line Printer for 2d data matrix bar code
Case level Pallet level printer
Hand held scanner For serial number capture
2d data matrix & Linear bar code

MFG Line Setup

Unit level Printing Capture of 2d Data matrix

Case/Pack level Printing & Capture of 2d Data matrix

Pallet Level Linear Bar Code Work Station

Serialization Reconciliation

inventory Put-Away

Quality Control
Manufacturing Warehouse
The distribution center will require the ability to pick/pack product. Re-label with a new serial number for the mixed products and then be able to capture the product and link to the downstream order or shipment confirmation.
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Serialization Planning

A large and complex undertaking

Markets
Regulatory
Government Affairs
Legal
Marketing
Business Development
Master Data
Package Development
Planning
Master Scheduling
Packaging

Purchasing
Contract Manufacturing
Warehousing
Distribution / 3PLs
Quality Assurance
Customer Service
Commercial
Contracts Chargebacks
IT
Finance
Customers
Licensing Partners
Reverse Distribution
Validation
Serialization Planning

**Weeks 1**
- Strategy Phase project planning
- Site visits scheduling
- Corporate visits scheduling
- Hold Kick-off meetings
- Distribute questionnaires to internal external groups

**Weeks 2-8**
- Hold on site interviews with groups impacted by serialization
- Packaging Line reviews
- Distribution center reviews
- Site visit summaries and analysis
- Reviews with corporate groups Enterprise Architecture, Integration

**Weeks 9-11**
- Develop serialization framework
- Definition of compliance road map
- Implementation phase project plan
- Serialization solution architecture development
- Data strategy
- Validation strategy definition
- Rollout plan development

**Week 12**
- Finalize serialization strategy recommendations
- Finalize budget estimates
- Core team strategy review
- Final strategy presentation
Serialization Planning

• Markets
  • Requirements
  • Timing
• Packaging Lines / Warehouses / CMOs
  • Products produced
  • Markets served
• Distribution Centers / 3PLs
• Corporate Infrastructure
  • Serial number provisioning
  • Serialization event capture
  • Statutory data transmission (authentication, T&T, ePedigree)
## Line Execution Status

<table>
<thead>
<tr>
<th>Site</th>
<th>Line</th>
<th>Start</th>
<th>Line Assessment</th>
<th>CAR Dev / Approved</th>
<th>Equipment Ordered</th>
<th>FAT</th>
<th>Installation</th>
<th>IQ / OQ</th>
<th>PQ</th>
<th>Cutover</th>
<th>Stabilization</th>
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<tr>
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<td>3Q14</td>
<td>07/11/14</td>
<td>07/14/14</td>
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<td>09/22/15</td>
<td>9/22/15</td>
<td>12/15/15</td>
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</tbody>
</table>
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Executive Sponsor/Steering Meeting* (Monthly)

IPP (Integrated Project Pl.) (Weekly)

Core Team Status Meeting (Weekly)

Work Stream Touch Point Meeting (Weekly)

**Meeting**

**Participants**
- Executive Sponsors
- Steering Committee
- Business Project leads
- PM
- PM
- Project Leads Business & IT
- Business Leads
- Project Leaders/Management
- Core Team
- PM & Project Leads Business & IT
- Team Members

**Agenda**
- Status Update
- Critical issues and risks
- Milestones
- Status Update
- Risks
- Key Issues resolution
- Milestones
- Status Update
- Deliverables
- Outstanding issues and risks
- Next steps and Milestones
- Recap of Last Week Status
- Business process issues
- Deliverables
- Status

*Additional meetings will be scheduled as needed for ‘Key Decisions’*
<table>
<thead>
<tr>
<th>Task Name</th>
<th>% Complete</th>
<th>Duration</th>
<th>Start</th>
<th>Finish</th>
<th>Predecessor</th>
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<td>VERT SERIALIZATION PROGRAM</td>
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<td></td>
<td>Wed 2/20/13</td>
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<td>Thu 3/21/13</td>
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## Stage Gate 2 Snap Shot - Enterprise Sol.

<table>
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<th>Task Name</th>
<th>% Complete</th>
<th>Duration</th>
<th>Start</th>
<th>Finish</th>
<th>Predecessor</th>
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### Stage Gate 4 Snap Shot - Line Execution

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<td>12 days</td>
<td>Wed 7/17/13</td>
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<td>95%</td>
<td>46 days</td>
<td>Thu 8/8/13</td>
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<td>Mon 6/3/13</td>
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<td>Mon 6/3/13</td>
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<td>Wed 7/17/13</td>
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<td>Mon 7/11/13</td>
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<td>Tue 8/6/13</td>
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<td>100%</td>
<td>10 days</td>
<td>Mon 8/9/13</td>
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<td>8 days</td>
<td>Mon 8/26/13</td>
<td>Wed 9/4/13</td>
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<td>Wed 10/2/13</td>
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<td>Mon 11/4/13</td>
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<td>Duration</td>
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<td>Finish</td>
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<td>Resource Names</td>
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<td>Mon 10/1/12</td>
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<td>1 day</td>
<td>Mon 10/1/12</td>
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<td>Wed 6/11/13</td>
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<td>Fri 10/11/13</td>
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<td>Duration</td>
<td>Start</td>
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<td>Predecessor</td>
<td>Resource Names</td>
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<td>31 days?</td>
<td>Fri 10/11/13</td>
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<td>14 days?</td>
<td>Mon 11/4/13</td>
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<td>Mon 11/4/13</td>
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<td>Fri 11/8/13</td>
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<td>1 day?</td>
<td>Mon 11/4/13</td>
<td>Mon 11/4/13</td>
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<td>Mon 11/4/13</td>
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<td>1 day?</td>
<td>Mon 11/4/13</td>
<td>Mon 11/4/13</td>
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<td>31 days?</td>
<td>Fri 10/11/13</td>
<td>Thu 11/21/13</td>
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<td>31 days?</td>
<td>Fri 10/11/13</td>
<td>Thu 11/21/13</td>
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<td>0%</td>
<td>1 day?</td>
<td>Mon 11/18/13</td>
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<td>Tue 10/22/13</td>
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Tenants for Success

• Build an Experienced Team (Internal & External)
• Conduct Site Visits (Internal & External)
• Meet with Solution Providers
• Develop an Overall Solution Strategy
• Identify Preliminary Requirements
• Pursue a Serialization Pilot
• Establish a Phased Approached
• Generate High Level Plans
• Engage Supply Chain Partners
• Determine How Much($)?
Questions
Thank you

Greg Cathcart - CEO
Excellis Health Solutions

www.excellishealth.com
Line Execution

Print and verify serialized data at sales unit
Print and verify serialized data at the bundle
Associate sales units with bundles
Print and verify serialized data at the case
Associate bundles with cases
Print and verify serialized data at the pallet
Associate cases with pallets

Manage reject / exception processes at
  –  Unit
  –  Bundle / Inner pack
  –  Case
  –  Pallet

Impact of product handling on the line
  –  How and when you can remove bottles, cases, from the line and place them back inline
Receive serialized finished goods
Receive associated serialization data
Ability to de-aggregate & re-aggregate serialized units
Ability to create serialized shipping containers
Ability to associate serial numbers with shipments
Ability to change serial number status
Ability to send serialized shipment data / changes in status or configuration to corporate repository

Movement of serial numbers within the four walls are generally not tracked