The Global Track and Trace Challenge

Six Key Issues to Master

Interphex 2015

Graham Clark, CMO/CPO Partnerships, TraceLink Inc.
1) Track and Trace is a Global Strategic Reality
40+ Countries and Over 75% of the Market by 2018

<table>
<thead>
<tr>
<th>2013 &amp; earlier</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
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</thead>
<tbody>
<tr>
<td><strong>N. &amp; S. America</strong></td>
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<tr>
<td>Argentina</td>
<td>Product Tracing Verification</td>
<td>Argentina</td>
<td>Brazil</td>
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<td>Chile</td>
<td>Coding, Traceability</td>
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<td><strong>Asia</strong></td>
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<td>China</td>
<td>Serialization, Reporting (2009 EDL)</td>
<td>India</td>
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<td>India</td>
<td>Serialization, Reporting (2012 EDL)</td>
<td>Serialization (MonoCarton)</td>
<td>Serialization, Report (All drugs)</td>
<td>QR, Report (Animal)?</td>
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<td><strong>EMEA</strong></td>
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<td>France</td>
<td>Denmark Coding (Injectables)</td>
<td>Saudi Arabia Coding</td>
<td>Ukrainian Serialization, Reporting (Mfg, Wholesaler)</td>
<td>Saudi Arabia Serialization</td>
<td>European Union Serialization, Verification, Reporting</td>
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<td>Turkey</td>
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<td>Jordan Serialization</td>
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<td>Slovenia Serialization</td>
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<td><strong>Draft Regulations in Development</strong></td>
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<td>Taiwan, Greece, Denmark, Mexico, Columbia, Libya, Algeria, South Africa, Albania, Cameroon, and more</td>
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2) Serialization is a Complex Business Issue
A Strategic Data Management Challenge, Not Putting Numbers on Bottles

- Serialization is both global and highly local, creating diversity you need to plan for in IT architectures and operational processes
  - Coding requirements: [2D vs. linear, GTIN vs. NTIN, different data ordering on package, etc.]
  - Serialization formats: [GS1, China EDMC, Brazil IUM, etc.]
  - Sources of serial numbers: [Pharmaceutical company, Government (China)]
  - Serial number generation attributes: [Randomized vs Sequential, 1 in 10,000 Uniqueness, Uniqueness Across All Products]
  - Packaging hierarchies, aggregation: [Unit, Bundle, Case/Transport Container]
  - Master data: [Company, Partner, Product]
  - Record retention: [6 yrs. past expiry, 1 yr. past expiry]
3) Your Supply and Trade Partner Networks Must Evolve


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4) Your Systems Face Unprecedented Scalability Challenges

Average Pharma Manufacturer Example

125M Products Shipped

24 Item per Case

120 Cases per Pallet

130,251,736 Serial Numbers Commissioned

Calendar Year

5 Generated
5 Reserved
5 Commissioned
5 Decommissioned
5 Destroyed

Average Serial Number Events

651,258,681

12 years

1,563,020,833 Serial Numbers Commissioned

7,815,104,167 Serial Number Events

Data

651 GB (1 KB per #)

7.815 TB (1 KB per #)
5) Serialization Fundamentally Changes How You and Your Network Does Business

- Serialization touches the entire organization
  - Managing unique product identity internally and externally creates data requirements and business process impacts

- Requires development of a common vocabulary and shared understanding of the impacts and tradeoffs
  - Cross-functional business process maps help you understand issues and evaluate prioritization
  - Early education on serialization system informs planning

- Serialization is a continuous transition over time
  - Systems, products, facilities, partners, markets evolve
  - Lot-level and serialized product co-exist for long periods

- A formal program enables necessary executive buy-in
  - Clarifies why this is strategically important to the business (compliance, competitive, opportunity)
  - Creates foundation to manage change in deadlines, regulatory requirements and supply network preferences
6) Timelines are **Always Longer Than They Appear**

**Strategy Development and Planning**
- Global Regulatory Analysis
- Supply & Trade Network Analysis
- Master Data Management Analysis
- Resource and Budget Planning

**Serialization and Compliance System**
- Network Analysis (Partner, Direct & Indirect Customer)
- Enterprise Serialisation Management Architecture
- Network Data Exchange Architecture
- CMO/CPO, Internal Site Integration and Testing

**Enterprise Systems and Integrations**
- Serialized Inventory Management Architecture
- Integration to Packaging Line
- Integration to ERP and WMS

**Packaging Sites**
- Packaging Line Blueprint Pilot
  - Design
  - Install & Build
- Packaging Line Deployment
  - Acquisition
  - Installation & Build
  - Integration & Test
  - Validation

**2015**
- 1H
- 2H

**2016**
- 1H
- 2H
- What about China?
- What about Brazil?

**2017**
- 1H
- 2H

**US DSCSA**

- 3PL Integration and Testing
- Trade Partner Network Integration and Upgrades

**Risk and Resource Constraint Buffer**

**Packaging Line Deployment**
- Acquisition
- Install & Build
- Integration & Test
- Validation

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TraceLink Provides Comprehensive Track and Trace Compliance Services with One Connection

- Trusted by 16 of the top-20 global pharmaceutical companies and leading businesses across the supply chain
- Integrated serialization and traceability solutions for US, EU, China, Brazil, and more on validated global cloud platform
- Live commercial network connecting over 130,000 global supply chain entities
- Designed to handle massive global serialization data and transaction event volume
- Over 10 years dedication to Life Sciences supply chain solutions; experience managing over 2 billion serialized events

Enable Your Secure Global Track and Trace Platform Today!

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