Holistic Serialization Solution

Rockwell Automation
Joe Whyte
Global Serialization Lead
Agenda

What is Serialization

Why Serialize

Serialization Implementation Challenges & Solutions

The Future of Serialization – Connected Enterprise

Why Rockwell Automation
### Serialization Requirements

<table>
<thead>
<tr>
<th>Blister Pack (Unit)</th>
<th>Bundle</th>
<th>Case</th>
<th>Pallet</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Blister Pack" /></td>
<td><img src="image2" alt="Bundle" /></td>
<td><img src="image3" alt="Case" /></td>
<td><img src="image4" alt="Pallet" /></td>
</tr>
</tbody>
</table>

| 8305254961 | 4693602591 8305254961 | 1112131415 4693602591 8305254961 | 1452267440 1112131415 4693602591 8305254961 |

**Human readable unique serial number**
- On each package (USA)
- On primary package (EU)

**Aggregation** of all primary package serial numbers to their lower level sub-package serial numbers in parent/child relationships
Serialization Requirements

**Track & Trace**
- Track & trace raw materials

**Generate**
- Acquire, Manage UID for each saleable item

**Aggregate**
- Package level serial numbers in Parent/Child Data relationships

**Store**
- Code information in a secure database

**Associate**
- Code information when dispatching products

**Scan**
- Codes to verify authenticity of product

**Validate**
- Serialization data matches the physical product received

**Track**
- Status of dispensed items to prevent re-use of serial numbers

**Confirm**
- That products have complete and accurate documentation

---

- **Supplier**
- **Manufacturer**
- **Distribution Center**
- **Pharmacy**
- **Central Database**

- Real world goods
- EPC / Barcode data

**Real world goods**
- **Raw Materials**
- **Finished Goods**
- **Vendor**
- **Customer**

**Track & Trace**
- Raw Materials
- Warehouse
- Manufacturer
- Finished Goods
- Distribution Center
- Pharmacy
- Central Database

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Market Trends:
Global Medicinal & Food Product Safety

The World Health Organization estimates counterfeit drug sales to range between $35 and 40 billion per year. Between 8 and 10% of the worldwide drug supply is estimated to be counterfeit.

- Growing health and safety risk with counterfeited drugs
- Growing involvement in the drug supply chain of under-regulated wholesalers and re-packagers
- Proliferation of Internet pharmacies, advancements in technology that make it easier to produce counterfeit drugs
- Increased importation of gray market medicines
- Ex: the 2008 contamination of Chinese infant formula
Regulations and industry standards specify what but not how to implement Serialization.

<table>
<thead>
<tr>
<th>European Medicines Agency</th>
<th>FDA</th>
<th>CFDA</th>
<th>ANVISA</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU Falsified Medicines Directive</td>
<td>Drug Supply Chain Security Act (U.S.)</td>
<td>China Food &amp; Drug Administration</td>
<td>Brazilian Health Surveillance Agency</td>
</tr>
</tbody>
</table>

- Other countries have begun instituting increased government regulations.
## Regulatory Timelines

<table>
<thead>
<tr>
<th>Status</th>
<th>Country</th>
<th>Codification</th>
<th>Serialization</th>
<th>Aggregation</th>
<th>Tamper Evident</th>
<th>Other Regulations</th>
<th>Deadline</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>China</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>December 2015</td>
<td>2012/13 EDL list*</td>
</tr>
<tr>
<td></td>
<td>India</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>July 2014</td>
<td>All Rx drugs - Exports</td>
</tr>
<tr>
<td></td>
<td>Nigeria</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td>October 2014</td>
<td>Anti-Infective drugs</td>
</tr>
<tr>
<td></td>
<td>Denmark</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>January 2014</td>
<td>All Pharmaceutical Products</td>
</tr>
<tr>
<td></td>
<td>Algeria</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>January 2015</td>
<td>All Pharmaceutical Products</td>
</tr>
<tr>
<td></td>
<td>Korea</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>January 2015</td>
<td>All Rx drugs</td>
</tr>
<tr>
<td></td>
<td>U.S. (Phase 1)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>January 2015</td>
<td>All Rx drugs</td>
</tr>
<tr>
<td></td>
<td>Slovenia</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>January 2015</td>
<td>All Rx drugs</td>
</tr>
<tr>
<td></td>
<td>Saudi Arabia (Phase 1)</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>May 2015</td>
<td>All Rx drugs</td>
</tr>
<tr>
<td></td>
<td>Japan</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>July 2015</td>
<td>All Rx drugs</td>
</tr>
<tr>
<td></td>
<td>Brazil (Phase 1)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>December 2015</td>
<td>All Pharmaceutical Drugs</td>
</tr>
</tbody>
</table>

- **Final Regulation**
- **Pending final approval**

*EDL: Essential Drug List
Brazil – 3 batches from plant to consumer by Dec 2015
– Full traceability of all products by Dec 2016

Rockwell Automation’s Proof of Principal Model for Brazil Dec 2015 Deadline

Manually packed
L0 – L2 modular solution
Deploy & Run in 2-3 Days

Cloud Serial number
generation management &
provisioning to packaging

Central communication hub
for Web portal data entry by
supply chain partners

Temporary Azure Cloud
database to track 3
batches from plant to retail

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## Why Serialize?

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<thead>
<tr>
<th>Business Category</th>
<th>Business Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONSUMER SAFETY/BRAND PROTECTION</td>
<td>• Regulatory compliance</td>
</tr>
<tr>
<td></td>
<td>• Product adulteration control</td>
</tr>
<tr>
<td></td>
<td>• Diversion source &amp; location control</td>
</tr>
<tr>
<td>CUSTOMER SERVICE &amp; RETURNS PROCESSING</td>
<td>• Authenticate transactions</td>
</tr>
<tr>
<td></td>
<td>• Improve chargeback payment accuracy</td>
</tr>
<tr>
<td>SUPPLY CHAIN INTEGRITY</td>
<td>• Complete Supply Chain Traceability</td>
</tr>
<tr>
<td></td>
<td>• Increase recall accuracy &amp; efficiency</td>
</tr>
<tr>
<td></td>
<td>• Direct to customer notifications</td>
</tr>
<tr>
<td>SUPPLY CHAIN OPTIMIZATION</td>
<td>• Improve forecasting</td>
</tr>
<tr>
<td></td>
<td>• Optimize inventory</td>
</tr>
<tr>
<td></td>
<td>• Improve supply chain planning</td>
</tr>
<tr>
<td>MARKETING &amp; BRAND LOYALTY PROGRAMS</td>
<td>• Real time consumer &amp; product market data</td>
</tr>
<tr>
<td></td>
<td>• Customer specific target marketing programs</td>
</tr>
<tr>
<td></td>
<td>• Consumer authentication via mobile device</td>
</tr>
<tr>
<td>BUSINESS OPTIMIZATION – CONNECTED ENTERPRISE</td>
<td>• Share data across departments: Sales, Marketing, Finance, Operations, Supply Chain, etc.</td>
</tr>
</tbody>
</table>
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**Serialization Implementation Challenges & Solutions**

The Future of Serialization – Connected Enterprise

Why Rockwell Automation
Scalability in Supply Chain
- Scalable serialization solution to support distributed operations: manufacturing, distribution, warehouse, pharmacy
- How to manage additional lines? Countries? Formats? Regulations?

Data Integration & Data Management
- High amount of data
- Printing and verification in a high speed environment

Data Accessibility & Management (Level 3)
- Data security
- Data exchange with external partners and interfaces between systems
- Data consistency, Data redundancy, Data Ownership, Master data

Operational Challenges for Data Generation & Acquisition
- Uniqueness of applied numbers (preferred randomized)
- Physical product limitations (limited space, different pack. materials)
- Wide range of products, formats, country requirements, packaging line types
Operational Challenges

IMPLEMENTATION CHALLENGES (LEVEL 0 – LEVEL 1)

Serialization Unit Controllers

LEVEL 1

PRIMARY PACKAGING AGGREGATION WORKSTATION

CASE PACKAGING AGGREGATION WORKSTATION

PALLETIZER PACKAGING AGGREGATION WORKSTATION

Line Integration Challenges
1. Different Controllers
2. Proprietary Platforms
3. Different Protocols
4. Proprietary Networks
5. Proprietary Communications
6. Custom Drivers Maintained by Users

Serialization Level 0 - OEM Machines, Printers & Vision Systems

OEM

LEVEL 0
IMPLEMENTATION SOLUTION (LEVEL 0 – LEVEL 1)

• Open Serialization platform to interface with existing packaging equipment
• PLC/PAC controllers for data management at Level 0 & Level 1
• Open Network & Communication Standards (Ethernet-IP)
• PLC/PAC Software in standard IEC 61131-3 programming languages
• Modular, Reusable & Scalable Solution
Implementation Challenges (Level 2 – Level 4)

Serialization-relevant data is widely distributed over different Automation and Information Systems at different ISA-95 levels!
Data Convergence (ISA-88 aligned data model)

IMPLEMENTATION SOLUTION (LEVEL 2 – LEVEL 4)

Delivering the right data to the right place at the right time!
Data Accessibility and Management

IMPLEMENTATION CHALLENGES (LEVEL 2 – LEVEL 4)

- How to integrate different external level 3/4 MES/ERP/EPCIS systems?
  - Do you have to customize for every external system?
  - Are you able to extend and adapt quickly?

- How to seamlessly integrate with Level 0/1/2 systems and equipment?
  - Can you cope with high-speed, real-time Serialization systems?

- Can your site server cope with the diversity of products, formats, country requirement, packaging line types?

- Is your site server CFR 21 Part 11-compliant?

- Is your site server pre-validated according to GAMP 5?
  - A risk-based approach to compliant good automated manufacturing practice computerized systems
Open Architecture

IMPLEMENTATION SOLUTION (LEVEL 2 – LEVEL 4)

- **J2EE** – proven technology for mission critical enterprise applications
  - Security and stability
  - Scalability without limits
- **Service Oriented Architecture (SOA)**
  - Feature rich business layer
  - Supports rich and thin (HTML) clients
- **Variety of supported software**
  - Operating Systems
  - Databases
- **Multi-tier data model**
- **Application development framework**
- **J2EE Strengths**
Integration with ERP Business Systems

IMPLEMENTATION SOLUTION (LEVEL 2 – LEVEL 4)
Supply Chain

IMPLEMENTATION CHALLENGES (LEVEL 5)

Product Flow
Data Flow
CDC – Central Distribution Center
RDC – Regional Distribution Center

EPCIS Certified Event Repository on Microsoft Azure

Brazil - Dec 2015

Consumers
Brasilia RDC
Sao Paulo CDC
RDC's
Consumers

Manufacturing

Consumers

Brazil

Sao Paulo CDC
Brasilia RDC
RDC's

EPCIS Certified Event Repository on Microsoft Azure

Product Flow
Data Flow
CDC – Central Distribution Center
RDC – Regional Distribution Center
ALL COUNTRIES WITH THE EXCEPTION OF CHINA ARE FOLLOWING THE GS1 STANDARDS

GS1 - An International not-for-profit association with over 100 country organizations

- Design and implement global standards and solutions that improve efficiency and visibility of supply and demand chains globally across sectors.

- Most widely used supply chain standards system in the world.

GS1 Standards

- Barcode Standards
- Data Accuracy Standards
- eCom Standards
- Electronic Product Code (EPC) Standards
- Global Data Synchronization Network (GDSN) Standards
- Global Data Dictionary
- Global Product Classification (GPC) Standards
- Extensible Markup Language (XML) Standards

EPCIS: Electronic Product Code Information Services

- Enables disparate applications to leverage EPC data via EPC-related data sharing, both within and across enterprises.
EDI or EPCIS for DSCSA

**EDI ... ASNs:**

- For 2015 requirements:
  - Extended version is working.

- For 2023 requirements:
  - We’re asking a lot from a message format that wasn’t created for this purpose.
  - It’s not global (Format: ANSI in US, GS1 elsewhere)
  - It’s not extensible without Standards action (multi-year process)
  - Carries more data than needed
  - No Exception Processes
  - No query mechanism
  - Needs Checking/Discovery process
  - Needs Certification process

**EPCIS:**

- For 2015 requirements:
  - Extended version is working.

- For 2023 requirements:
  - Purpose built for T&T
  - It’s global
  - It’s extensible without Standards action (multi-year process)
  - Carries minimum data
  - Exception Processes
  - Query mechanism
  - Needs Checking/Discovery process
  - Needs Certification Process
What is EPCIS?
Purpose built – Flexible - Extensible

EPCIS includes the ability to query or ask for information:

1. Commissioning Event
2. Packing Event
3. Shipping Event

EPCIS was purpose built for Track & Trace

1. Extensible "events" and "Dispositions"
2. May Extend Information for:
   - Geographies
   - Industries
   - Trading Partners
3. Includes Query functionality
Forward/Reverse Logistics

IMPLEMENTATION CHALLENGES (LEVEL 5)

Forward Logistics:
1. Distribution Center
2. Retailer
3. Customer

Reverse Logistics:
1. Customer Not Satisfied
2. Faulty Order
3. Overstock
4. End of Life
5. Recalls

Flow of Goods:
- Manufacturing to Distribution Center
- Distribution Center to Retail
- Reverse Logistic Partner to Retail
- Refund Awarded

Checking Service:
- Checking Service to EPCIS Event Repository
- Checking Service to Distribution Center
- Checking Service to Retail
- Checking Service to Reverse Logistic Partner
- Checking Service to Refund Awarded
Supply Chain Applications

IMPLEMENTATION SOLUTION (LEVEL 5)

- Configuration of supply chain partners to enable rework of pallets and cases while maintaining aggregation integrity
- Authentication by supply chain partners using smart scanners
- Track & Trace through downstream supply chain
- Detection of gray market diversion
- More efficient recall management
- More accurate returns management, including returns price verification
- Consumer authentication, communications and loyalty programs using mobile devices
Database is EPCIS certified by GS1 to support global exchange of data with supply chain partners

Generation of random or sequential serial numbers in GS1 format - prevents duplication across enterprise (multiple sites)

Hosted in Microsoft Azure Cloud
- Data centers located in 89 countries
- Compliance with SOC2 / SOC3 and ISO/IEC27001:2005 for security, routine backup, and disaster recovery

Includes event repository, which captures every event (e.g. commissioning, decommissioning, rework, authentication) of each package barcode. Event file is maintained for the life of the product.

Provisions serial numbers and downloads to the Level 3 site server at client’s facility. Receives serial numbers after completion of batch.
Scalable Supply Chain Connectivity Model

IMPLEMENTATION SOLUTION (LEVEL 5)

- Scalable Distribution Center Site Server Solution
  - Servers, Switches, Storage, Memory & Software
- Standard Solution for Long Term Support
- Tested, validated reference design
- Inclusive of all hardware, software and services
- Best choice of server, network & storage
- Lower total lifecycle cost
  - Reduced IT administration and support
  - Reduced server footprint
  - Enhanced security
  - Simplified backup
  - Simplified restore
Support & Maintainability Challenges

When serializing for regulatory compliance reasons -

- Serialization system failures in production sites = No Production
  - Network infrastructure
  - Site Server
  - Unit & line controllers
  - Equipment data interfaces
  - Operator interfaces
  - Printers & Vision systems

- Mission critical production assets require immediate attention
  - Single point of contact for the entire Level 0 – Level 3 system
  - Real-time Serialization Application-level support
  - Periodic performance analysis and reviews
  - Remote monitoring & diagnostics
  - Emergency dispatch
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Why Rockwell Automation
The Connected Enterprise

**Prediction** All manufacturers will serialize their products within 10 years

### BUSINESS BENEFITS
- Real time product consumption & demographic data
- Customer buying behavior information
- Brand protection, brand loyalty, compliance....

### BIG DATA
- Serialized products will optimize businesses by serving as a common thread across the connected enterprise
- Various departments will use the common data for their specific needs

### “INTERNET OF EVERYTHING”
- A company’s serialization data, when used to optimize the way a business operates, will become one of its most valuable assets
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Why Rockwell Automation
Why Rockwell Automation
Turnkey Serialization Solution

- Unique ability to provide all the key components of a complete serialization solution
  - EPCIS certified Cloud-based serial number generation, management & event repository
  - Expertize in Level 3 – 4 integration (serialization site server to MES & ERP systems)
  - Packaging line serialization solution for all package types using open architecture
  - Supply chain applications to provide business benefits and a potential Return on Investment

- Modular, reusable and scalable solutions

- Solution built with Commercial-off-the Shelf (COTS) products and software

- Proven technology & integration expertize with ERP & MES applications

- Capability to provide internal and external supply chain tracking

- Stable, global partner with global delivery and global support capabilities
Thank you for visiting the Rockwell Automation Center for Connected Enterprise.