

Setting the Standard for Automation™

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Serialization Implementation Challenges & Business ROI Opportunities

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- Joe Whyte is a 26 year LifeSciences & CPG Industry sales professional. Career highlights include regional, national and global sales and sales management roles, and periods as a digital automation technology entrepreneur. Technical expertise includes machine and process automation, robotics, packaging, vision, IT, data management, information systems, plant and supply chain optimization
- Joe joined Rockwell Automation in 2006 and is currently the company's Global Serialization Lead. His background at Rockwell Automation includes Strategic LifeSciences OEM Sales and Global Strategic LifeSciences Account Management.
- The Connected Enterprise Puts the Industrial Internet of Things to Work for You. It helps operations managers profitably manage and improve manufacturing and industrial processes. It helps IT executives reduce network complexities and exposure to information security risks. It shares productivity-improving information to workers across the organization in a context that is meaningful for each role.
- Accelerated by the emergence of the Industrial Internet of Things and advances in enabling technologies – including data analytics, remote monitoring and mobility – The Connected Enterprise opens new worlds of opportunity through greater connectivity and information sharing.







Serialization Implementation Challenges & Solutions

The Future of Serialization – ROI & The Connected Enterprise

Blister Pack (Unit)	Bundle	Case	Pallet
A CONTRACTOR OF			
			Pallet ID: Market ID: Market ID: Market ID: Darren
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

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



Level 0 – Level 5 Serialization Solution



GS1, EPCIS & Global Interoperability

ALL COUNTRIES WITH THE EXCEPTION OF CHINA ARE FOLLOWING THE GS1 STANDARDS

GSI - An International notfor-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 EPCrelated data sharing, both within and across enterprises.



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Implementation Challenges

Supply Chain Data	LEVEL 5	 Scalability in Supply Chain Scalable serialization solution to support distributed operations: manufacturing, distribution, warehouse, pharmacy EPCIS - How to manage additional lines? Countries? Formats? Regulations? 	
IT - OT Data	LEVEL 4	Data Integration & Data Management High amount of data Printing and verification in a high speed environment 	
	LEVEL 3 LEVEL 2	 Data Accessibility & Management (Level 3) Data security Data exchange with external partners and interfaces between systems Data consistency, Data redundancy, Data Ownership, Master data 	
Package Line Data	LEVEL 1	 Operational Challenges for Data Generation & Acquisition Uniqueness of applied numbers (preferred randomized) Product handling, product rejection, product rework, line modifications Physical product package limitations (space, materials, environment, etc.) Application & Inspection of printed codes 	
OEM Data	LEVEL 0	 Wide range of products, data formats, packaging line types Data Sequencing & Coordination of Material Handling, Printing & Inspection 	

ISA

Operational Challenges

IMPLEMENTATION CHALLENGES (LEVEL 0 – LEVEL 1)



Serialization Level 0 – Packaging Machinery, Printers, Labelers, Cameras & Barcode Readers



Printing Expertise Required

IMPLEMENTATION CHALLENGES (LEVEL 0 – LEVEL 1)



Selecting the right technology for the application is critical to success

- Thermal Ink Jet HP
- Laser
- Preprinted Label
- Drop on Demand
- Thermal Transfer
- Continuous Ink Jet
- Hybrid Flexo / Digital
- Inks Solvent, UV, Waterbased, Security
- Substrates Paper, Foil, PVC, Tyvek Metal, Direct part marking

Vision Expertise Required

IMPLEMENTATION CHALLENGES (LEVEL 0 – LEVEL 1)



Selecting the right technology for the application is critical to success

- Gray Scale & Color
- 3D Imaging, Line Scanners
- OCR / OCV
- Part Features
- Barcode Grading (ANSI Standards)
- Integration into HMI Packages
- High Speed Applications
 - High Speed Web Inspection
 - 2D Matrix Code Grading @ 400 PPM

Data Accessibility & Data 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?
 - Code of Federal Regulations Part 11 of Title 21: electronic records, electronic signatures
- Is your site server pre-validated according to GAMP 5?
 - A risk-based approach to compliant good automated manufacturing practice computerized systems

Data Convergence (ISA-88 aligned data model)

IMPLEMENTATION SOLUTION (LEVEL 2 – LEVEL 4)



ISA-88 aligned data model

IMPLEMENTATION SOLUTION (LEVEL 2 – LEVEL 4)



EPC data

EPC EPC event

Well structured data, ISA-88 and -95 aligned:

- Consistent
- Reusable
- Scalable
- No redundancies



Supply Chain Challenges

IMPLEMENTATION CHALLENGES (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





Forward/Reverse Logistics

IMPLEMENTATION CHALLENGES (LEVEL 5)



Support & Maintainability Challenges

SUPPORT CHALLENGES (LEVEL 0 – LEVEL 5)

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

Remote Serialization Application & Monitoring Support



ISA

Agenda

Serialization Requirements

Serialization Implementation Challenges & Solutions

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Why Serialize? - Business ROI Reasons

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

ISA

Serialization in the Connected Enterprise



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





Visit

http://www.rockwellautomation.com/rockwellsoftware/applications/product_serialization.page

to learn more