



# Healthcare Providers Drive Open-SCS Initiative: A Serialization Compliance Solution

[www.opcfoundation.org/open-scs-working-group](http://www.opcfoundation.org/open-scs-working-group)



# Open Serialization Communication Standard (Open-SCS)



(Formerly Open Architecture for T&T Group)

## Agenda

- Why Open-SCS is critical
- Who are We
- Progress Made
- Scope of Work Products 1.0
- Benefits to Healthcare Providers and Vendors

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## 'Counterfeit Industry' Estimated to Grow over 20% annually



Since 2012 Patent Cliff, generic products now make up 80% of global healthcare market and are the primary counterfeiting target:

- Counterfeit drugs generate ~\$75B USD Revenue annually and growing
- In many countries, counterfeit drugs constitute as 70% of total drug supply
- Large increases in thefts and reimbursement frauds
- **Authorities / Industry: Real-time plant-to-patient data for analysis and control of the drug supply chain**

McKinsey & Company makes the point,

- “Global standards could enable substantial patient safety benefits and enable total healthcare cost reductions of \$40-100 Billion USD.”

Insights into Pharmaceuticals and Medical Production, Building New  
Strengths in the Healthcare Supply Chain, McKinsey & Company,  
January 2013.

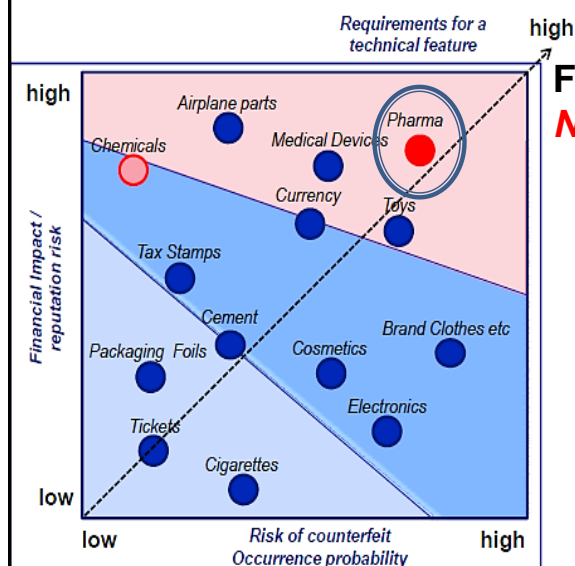




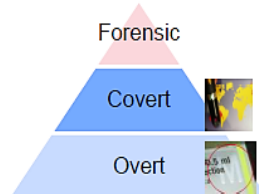
# Only 12 Percent Satisfied with Their Companies' Serialization Performance

Senior logistics executives polled at the Ninth Annual UPS Healthcare Forum in June 2014 reported an extremely low rate of success in addressing the challenge of regulatory compliance.

9th Annual (2014) Pain in the (Supply) Chain Survey, UPS Inc., 2014.



## Financial Risk vs. Risk of Counterfeit: *Need for Serialization Requirement*



Pharmaceutical Security Institute (PSI)  
2014 Industry Study, PSI, 2014



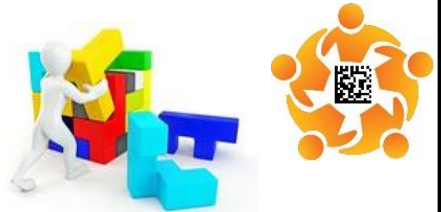
# Roundtable on Open Architecture for Packaging Line Integration



- First roundtable on Open Architecture for Track & Trace held on September 24, 2014 in Frankfurt, Germany
- Participants
  - Over 80 participants of 49 different companies
  - 18 Vendors of local systems
  - 12 Vendors of enterprise systems
  - 13 Consultancy
  - 24 Pharma and Healthcare companies



## Roundtable Conclusions: Voice of the Customer



- Lack of standardization in packaging line serialization / T&T
- Available solutions apply high-cost custom plant interfaces
- Users don't want / can't be locked in with 1 vendor or architectural landscape due to high M&A level in healthcare
- Current plant integration standards cover most but not all needs: ISA-95/88/B2MML, EPC-IS, OPC-UA, PackML
- A new standard set of specifications and guidelines are required to meet compliance deadlines
- Need a governing body to take global ownership
- Need funding to hire Experts SME and Leader



## Steering Committee was Formed

- |                        |                                     |
|------------------------|-------------------------------------|
| ■ Marcel de Grutter    | Abbott                              |
| ■ Michael Marrone      | Mylan Pharmaceutical                |
| ■ Nikolaou Spyros      | Famar Health Care Services          |
| ■ Ilan Eden            | Teva Pharmaceutical Industries Ltd. |
| ■ Dr. Oliver Nuernberg | SAP AG                              |
| ■ David DeJean         | Systech International               |
| ■ Jürgen Laskowski     | Werum IT Solutions GmbH             |
| ■ Jean-Pierre Allard   | Optel Vision Inc.                   |
| ■ Emidio Zorzella      | Antares Vision Srl                  |

### Executive Director

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## Progress was Made

### **Steering Committee has taken foundational steps:**

- Finalized Scope for 2016 Work Products v1.0
- Collaborative Partner of the OPC Foundation:
  - Host our website
  - Run the business of working group
  - Market and distribute work products
- New name: Open Serialization Communication Standard Working Group (Open-SCS)
- Launched Member Subscription Program
- Member: Global Traceability Co-ordination Forum (GTCF)
- Formation of an internationally recognized SME Architecture Team to rapidly develop 2016 Work Products (SMEs: GS1, OPC-UA, ISA)





# Open-SCS Work Products focus on 4 Main Functions of Line Serialization:



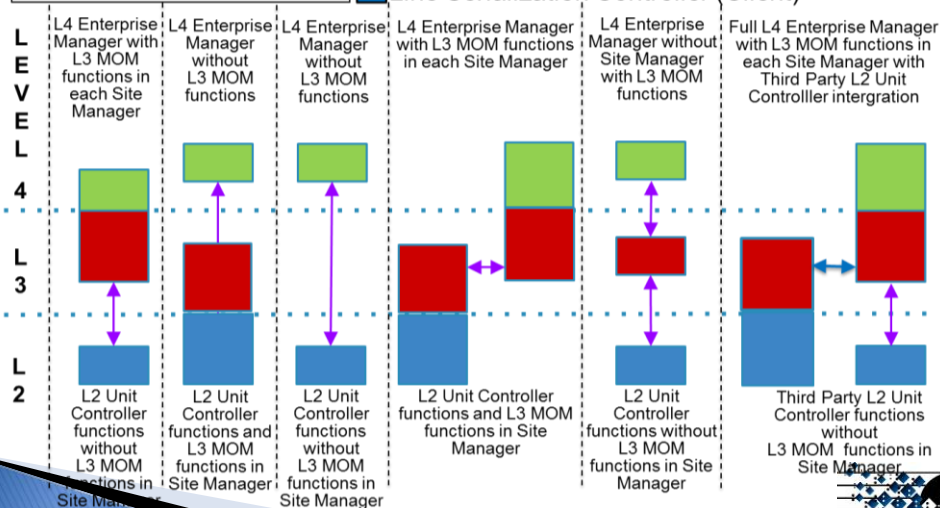
**Serialization Aggregation Data Management Interface Design**

➤ **Scope: Exchanges for 6 Packaging Line Serialization System Configurations**

➤ **8 Exchange Use Cases in Two Services Categories: Mandatory & Support Services**

Functionalities classified by ISA-95 Functional Level, Not Physical Location

- Enterprise Resource or Master Data Manager (Server)
- Site Serialization Manager (Server/Client)
- Line Serialization Controller (Client)





## Development Phases: Open-SCS Work Products

- **Phase 0 (2015): Fund Raising**
- *Phase 1 (2016):*  
Open Packaging Serialization Global Name Registry:
  - A Packaging Serialization Standard for specific set of line configurations and data exchange use cases
- *Phase 2 (Q2 2016):* Line-Plant-Supply Chain interoperability requirements specifications: Packaging Serialization URS/PQ and Two System FRS/OQs: EPCIS and OPC-UA/95/88/others
- *Phase 3 (Q3 2016):* Levels 2 & 3 packaging performance and equipment state data exchanges for Phase 1 use cases



# Cooperation



**To achieve our goals, we will work together with Supply Chain Groups:**

- OPC Foundation: Our host and specialist in OPC (UA)
- GS1: Global Standardization Organization (EPC-IS)
- Global Traceability Co-ordination Forum (GTCF)
  - Healthcare Distribution Management Association (HDMA)
  - APEC Business Advisory Council (ABAC)
  - Pharmaceutical Distribution Security Alliance (PDSA)
  - Global Supply Chain Strategy Group (GSCSG)
  - GS1 US RX Secure Supply Chain group (RXSSC)
  - GS1 Brazil Healthcare User Group
  - Rx-360: Traceability Data Exchange Architecture Working Group
- ISA: International Society of Automation (ISA-95/88)
- ISPE: International Society Pharmaceutical Engineers





## Benefits for Healthcare Provider - Reduce Cost

- Reduce scaling and deployment costs
- Reduce project delays on packaging line deployments
- Significantly reduce of validation costs and time
- Ensure competitive bids to standard specifications  
for the URS/FRS for specific use cases and exchanges
- Lower system development lifecycle costs
- Quantifiable obsolescence of product
- Stable definitions improve Level 2 Performance metrics

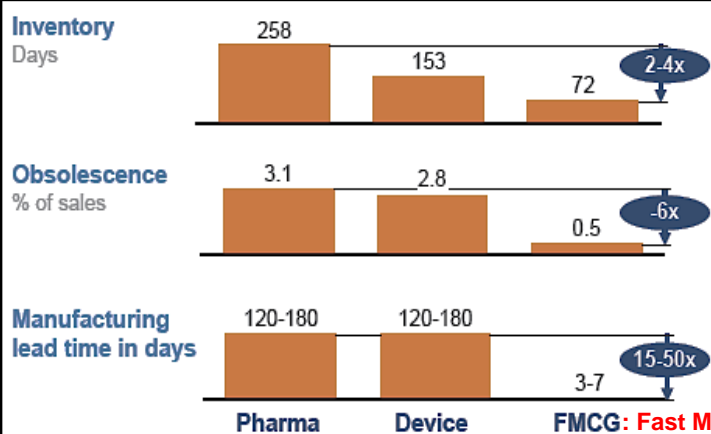


# Benefits for Healthcare Provider

## - Increase Agility

- Single Open Registry /Mapping for each country's compliance meta data
- Predictable integrations between legacy systems / equipment, new suppliers, new lines, and CMO partners
- Smoother M&A plant integrations and separation

### Healthcare Operations Metrics show Huge Improvements from Data Standardization and Business Process Re-Engineering (BPR)



Insights into Pharmaceuticals and Medical Production,  
Building New Strengths in the Healthcare Supply Chain,  
McKinsey & Company, January 2013.





## **Benefits for Healthcare Provider**

### **- Quality of Service Increased**

- Data Integrity /Robustness from a common operations and business language in an integration information model
- Suppliers innovate to stay competitive as opposed to focus on customized installation to short requirements
- Select best supplier by specialized activity & application type



## Benefits for Level 2 and Level 3 Vendors

- Broader understanding of customer's business processes
- Concentrated business focus on their core competencies:  
New innovations
- Low risk support for global demand of serialization compliance
- Increased confidence of customers, regulators, industry & patients
- Higher availability of rare resources for implementation



## Benefits for Level 2 and Level 3 Vendors

- More robust and stable software development lifecycle
- Common packaging serialization requirement templates for reduced documentation & validation efforts
- Proven seamless integration methods (EPCIS and OPC-UA/95/others) with existing/new equipment and systems
- Reduced risk & effects during system updates (re-designs)
- Long term business continuity and high value to customers through accelerated deployments





## How you can help? JOIN UP NOW!!!

### Membership by Subscription

1 Year Subscription	\$13,000.00 USD
2 Year Subscription	\$24,000.00 USD

Get your:

- ▶ Subscription Brochure
- ▶ Subscription Agreement

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# TODAY!



# Thank You for Your Attention



<https://opcfoundation.org/open-scs-working-group/>



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