

Open Serialization Communication Standard (Open-SCS) Working Group

MEMBER SUBSCRIPTION PROGRAM

Open-SCS OVERVIEW

Open Serialization Communication Standard Working Group's (Open-SCS) Work Products and Member Subscription are focused on standardizing packaging line serialization and aggregation data exchanges including supply chain packaging serialization activities (Distribution Center (DC), Warehouse, etc.).



The Open-SCS Initiative directly addresses the Healthcare Industry's Product Serialization Regulation Wave of the next decade.

Open-SCS is rapidly producing an open standard as the Open Packaging Serialization Global Name Registry. The Open-SCS work products are being co-developed with and based on the Open-SCS's Global Name Registry. Based on the primary names in the Object Registry, operation process and system specifications will be released in 2015 for the most critical packaging serialization uses cases and their data exchange interfaces. The exchange use cases are between the packaging line and their operations management in the plants, warehouses, and DCs and the enterprise manager for product serialization across the supply chain.

The Member Subscription provides the following Proposed 2015 Work Products and their updates as driven by rapidly evolving global serialization regulations by country:

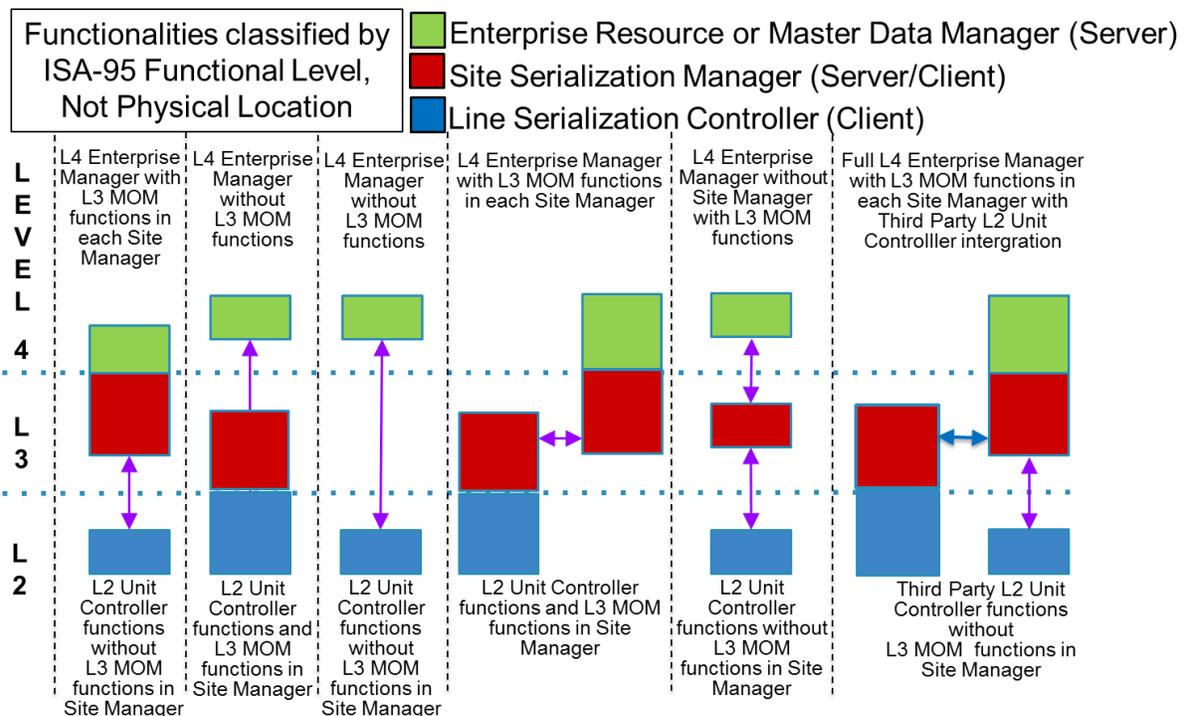
1. Packaging Serialization User Requirement Specification (URS)
2. Associated Performance Qualification Tests (PQ) Templates
3. Two System Functional Requirements Specifications (FRS) Templates for specific line configurations
 - a. An EPCIS Implementation with Standard Healthcare Packaging extensions to use cases
 - b. An OPC-UA / ISA-95 / ISA-88 Implementation
4. Associated Operations Qualification Tests (OQ) Templates

The Open-SCS Work Products focus on the 4 Main Functional Aspects of Line Serialization:

Serialization Aggregation Data Management IT Implementation

2015 Work Products*: Data Exchanges for 6 Packaging Line Serialization System Configurations

6 Proposed Use Cases in Two Data Exchange Categories: 1. Mandatory Services 2. Support Services



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“Global standards could enable substantial patient safety benefits and enable total healthcare cost reduction of \$40-100 Billion USD.” McKinsey & Company, January 2013

The Packaging Serialization URS establishes the Framework for Packaging Serialization System FRSS

6 Proposed Use Cases as Mandatory Services* are critical to the packaging line serialization process for Healthcare manufacturers to start compliance to globally evolving Healthcare product serialization regulations.

1. **Serial Number Provisioning:** Site or enterprise level authoritative service used to issue and track valid and unique serial number ranges or lists in sequential or random order to line serialization controllers.
2. **Electronic Product Code (EPC) Repository:** An enterprise central repository for the disposition and aggregation status of all EPCs produced by packaging line at each plant, warehouse and DC.
3. **Batch & Master Data Repository:** L3 MOM function in a site or enterprise level central repository for line level batch and master data required to configure packaging line equipment.
4. **Unused Serial Number Return:** A L3 MOM function for the authoritative service used to track and return unused serial numbers to the Serial Number Manager.
5. **Full Batch Import:** Plant & Line data collection with a high volume enterprise interface to obtain the disposition and aggregation status of all EPCs linked to a batch identifier.
6. **Serial Number Inquiry:** Plant & Line data collection with a high volume enterprise interface to obtain the disposition and aggregation status of a specific EPC.

Proposed Support Services* specified in the URS and defined in the System FRSS Templates:

1. Work and re-work tasks in the Supply Chain (warehouse and DC lines or work cells)
2. Packaging, rework, and shipping orders
3. Exception handling tasks
4. Re-work of closed batches tasks
5. Re-packing / re-labeling tasks
6. Re-aggregating closed batches tasks within the supply chain
7. Converting packaging orders into shipping orders
8. Re-working packaging orders at the packaging line
9. Check-out of damaged goods tasks
10. Re-print of existing pack labels SOPs must be defined for each of the above cases
11. Enable manual processes such as re-work and aggregation steps on the packaging line
12. Request by Product ID initiated by L3 system ('replenishment' of serial numbers)

Packaging Line Product Serialization Actors*

- Line Serialization Controller
- Site Serialization Manager
- Enterprise Serialization Master Data Manager and Resource Manager

****Proposed Use Cases, Manual Services, and Support Services may change in Work Product Approval Process***

For 2015 Work Products, the two System FRSS for the EPCIS and OPC-UA technical approaches map the Open-SCS standard's data objects and exchange use cases between the two approaches.

Last but far from least, the Open-SCS standard and specifications are heavily influenced by and maps directly into the rapidly evolving supply chain serialization regulations, their associated standards, and systems approaches. To facilitate this, the Open-SCS will have active representation in supply chain groups such as Rx360, GS1 US Healthcare, and ISPE for bi-direction channels between the standards' architects.

Proposed Important 2016 Work Products focus on selected data objects and exchanges for the Level 2 packaging equipment event data (performance metrics, state model, recipe and optimization) for the 2015 Version's set of packaging use cases using PackML and BatchML.

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PROGRAM SUMMARY

The Member Subscription Program delivers a high-value annual based plan that provide members unique business security and peace of mind in the rapidly changing Healthcare market.

The Open-SCS standard and specifications are designed to provide Healthcare manufacturers and suppliers with a low cost, scalable, secure and flexible integration platform for accelerating the deployment of packaging serialization solutions to meet the aggressive schedule of regulatory compliance through 2018.

For the small and large plants, Open-SCS establishes an expert network to develop rapid specification updates to regulatory changes to support the members' growing Healthcare business demands.

The Open-SCS Member Subscription Program Agreement and License: Member organization are entitled to utilize only those versions of Open-SCS specifications distributed under term of their Member Subscription for any purpose within the company paying for the invoice for the Member Subscription. Any distribution to non-member companies outside a member organization is strictly prohibited.

Subscription Periods: Agreement terms available for 12 and 24months. Long terms upon request.

Subscription Basis: Subscription terms are calculated based on day of invoice payment receipt and goes to the length of the subscription term.

RAPID REGULATORY RESPONSE AND VOTE ON SCOPE PRIORITIES

Purchasing the Member Subscription Program provides the member organization with continuous access to the Packaging Serialization URS and FRS templates for the subscription term. The Program ensures members have the rapid serialization regulation updates and direct input into future scope and work products, voting on scope priorities, and security updates for the duration of their Member Subscription Period.

EXPERT SUPPORT

Open-SCS expert services are there just when you need them. Open-SCS Members have access to expert members in GS1 EPCIS, OPC-UA, and Industrial Integration best practices and standards. Members receive discounted services rates directly from the member experts and contributors of the Open-SCS standards and specifications for their architectural design and implementation of the Packaging Serialization solutions.

SUBSCRIPTION TERMS AND PRICING

Member Subscription Program offers each member flexibility and choice with initial terms of one and two years. Upon request, three year or longer terms bring the additional benefits of deeper discounts and price predictability for the agreement term.

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

Open-SCS SPECIFICATIONS RIGHTS OF USE

Member Entitlement is limited to the use of versions of Open-SCS Specifications distribution available within the member's subscription period. The Rights-of-Use for those versions available within the term of the agreement for the Open-SCS Specifications remain with the subscriber thereafter.

STANDARD AND SPECIFICATION DISTRIBUTION

Members have continuous Member Access to the Open-SCS website and SharePoint sources for version distributions of the Open-SCS Specifications. Member are able to download new version releases, minor version and feature updates, and maintenance releases for the duration of their subscription period.

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OPEN STANDARD AND SPECIFICATION KEY BENEFITS and FEATURES

- Lowest Cost Single Packaging Serialization Integration Solution
- Rapid Development / Release
- GS1 EPCIS Alignment and Direct Liaisons
- OPC-UA Messaging Security
- Latest product releases
- Security and maintenance updates
- Expert technical support
- Online resources
- Process Flexibility
- Affordable Member Subscription Programs

Open-SCS Members' Serialization Mission:

- Protect the public
- Stop counterfeited product
- Stop reimbursement fraud and improve reimbursement processes
- Ensure quality of the product
- Ensure product availability on the market
- Ensure business longevity
- Keep delivering product in the market
- Understand risk
- Ensure profitability/Control cost

Table 1 shows the projected supply chain investments over the next 3-5 years with 4 of the Top 5 being in Serialization solutions. Consequently, manufacturers and downstream providers are aggressively requiring to their equipment, software, and solution vendors to focus on rapid deployment strategies to lower the cost and effectiveness compared to 1st wave of deployments during the past 5 years.

The Open-SCS Standardization effort requires ALL parties involved to work together to bring a working solution to the market in 2015 to accelerate system and equipment deployments of packaging lines and supply chain packaging serialization activities in significantly less time per line at a much lower cost. Healthcare manufacturers, downstream providers, and their partner providers must all come together to meet the requirements of market and regulations.

Table 1: Planned IT Investment by Healthcare Companies
7th Annual (2014) Pain in the (Supply) Chain Survey, UPS Inc., 2014
Globally Citing Planned Technology Investments by Type in the Next 3 to 5 Years

81%	Order Management Systems
66%	<i>Serialization and/or Track-and-Trace Technologies</i>
62%	Online Ordering Systems
53%	Cold Chain / Temperature-sensitive Technologies
50%	Security Technologies for High Value and/or High-Risk Shipments

Open-SCS end users and vendor members strongly agreed on the high business risk of today's market:

- ***Meeting regulation to the required time lines***
- ***Lack of knowledge (problem and solution)***
- ***Serialization validation as single point of failure***
- ***Potential price increase due to perceived loss of packaging line and supply chain efficiencies***
- ***What if products can't ship?***

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New and proposed serialization regulatory pressure are creating:

- **Highly complex challenges affecting all level of operation**
- **Poorly Solutions designed in a rush**
- **A “miracle” requirement for supplier**
- **Many custom made solutions**

Open-SCS Work Products enable manufacturers’ rapid response to aggressive compliance time lines:

- **Save money**
 - Significant reduction of validation cost
 - Significant reduction of scaling and deployment cost
 - Ensure competitive bidding
 - Lower cost and delay on new line acquisition
 - Improve OEE with stable solution
 - Lower cost of implementation
 - Obsolescence management
- **Increased agility**
 - Seamless integration of new supplier
 - Seamless integration of new lines
 - Seamless integration with CMO
 - Smoother integration /de-integration when in company merger /acquisition
 - Obsolescence management
- **Ensure quality**
 - Select best supplier by layer / application
 - Force supplier to innovate to stay competitive
 - Robustness through common operations and business language

Open-SCS Work Products enables vendors’ rapid response to aggressive compliance time lines:

- A more robust and stable development
- Common requirement templates and language to lower documentation and validation efforts
- Higher availability of resources
- Concentrated business focus on core competencies: Proven and new innovations
- Long term business continuity
- More trust of the regulators, industry and patients
- Quicker adaptation
- Seamless integration with existing equipment and systems
- Stronger basis and less effects of updates on the cores of the systems (re-designs)

ABOUT Open Serialization Communication Standard (Open-SCS) Working Group

Open-SCS is a commercial open source member subscription, combining the advantages of open source and the group membership allows members to efficiently and rapidly develop technology to deliver independent and open solutions. Open-SCS was founded with the mission of enabling member organizations to benefit from the open source ethos of a non-proprietary open standards and specifications built on innovation, independence and an open architecture.

TERMS AND CONDITIONS

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