Open-SCS Initiative:
A Serialization Compliance Solution

Feasibility Study
for the Rapid Development of
Open Serialization Communication Standard
for Healthcare Packaging Serialization Requirements
September 2015

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1. Executive Summary

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.

Only 12 percent reported they were satisfied with their companies' performance in this area.

Consequently, the Global and regional healthcare industries are at a critical juncture in human history. T**he current state of the Healthcare Industry** (and their primary challenges) is as follows:

1. **Regulatory compliance** remains the top business and supply chain issue. As shown in Figure 1, a murky legislative outlook and differing regulations by country make the issue more complex.
2. **Product protection from global counterfeiting**. As shown in Figure 2, both product integrity and product security has become a bigger challenge as products become more complex and companies expand into emerging markets. Concerns are particularly high in Asia-Pacific.
3. **Economic conditions** still weigh heavily on healthcare companies
   - Global Economic Crisis (GEC), particularly those in North America and Latin America
   - 2012 Patent Cliff (4)
     - Example: 8 major drugs went generic for a $33B USD loss and 12,000 jobs.
     - Generics now make up 80% of global market and are primary counterfeiting target.
4. **Cost management,** driven by regulatory reform and profit pressures, remains a top supply chain issue. Yet the level of concern is declining year over year.

This document presents the Feasibility Study for the Rapid Development of the Open SCS for Healthcare Packaging Serialization requirements. The main focus is on packaging line serialization and aggregation data exchanges including similar supply chain packaging serialization activities (Distribution Center, Warehouse, etc.). The study was the recommended first step from the First Roundtable on Open Architecture for Track & Trace held on September 24, 2014 in Frankfurt, Germany. For the Healthcare Industry, the study proposes the formation of the Open Serialization Communication Standard Working Group (Open-SCS) with the specific goal of rapidly developing a set of product serialization standards for the packaging line level and it interfaces to equipment and enterprise levels above the plants and warehouses. The initial three phases for work products are:

- 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. A set of Level 2 Packaging equipment event data for Phase 1 uses cases.

Layout transfer interface for various printer vendors and various label layout editors. This serialization investment has ROI potential for plants with large number of packaging lines with flexible dispatching options (means you can pack a product in one of several optional lines).

The basic Phase 1 scope of the proposed standard's work is a set of data exchanges and associated data objects or global registry of data objects for a specific set of common packaging use cases for use in:

1. Packaging Line User Requirement Specification (URS)
2. Performance Qualification Tests (PQ)
3. Set of System Functional Requirements Specifications (FRS)
4. Operations Qualification Tests (OQ)

The proposed Phase 2 work will use the URS as base to produce an implementation set of Packaging Serialization System Functional Requirements Specifications (FRS). To date, the draft scope defines six

common architectural approaches and two exchange protocols/technologies. The initial proposal is to develop the System FRSs for the EPCIS and OPC-UA technical approaches where the standard's data objects and exchange use cases are mapped between these two approaches. Last but far from least, the proposed standards for in-plant serialization data 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.

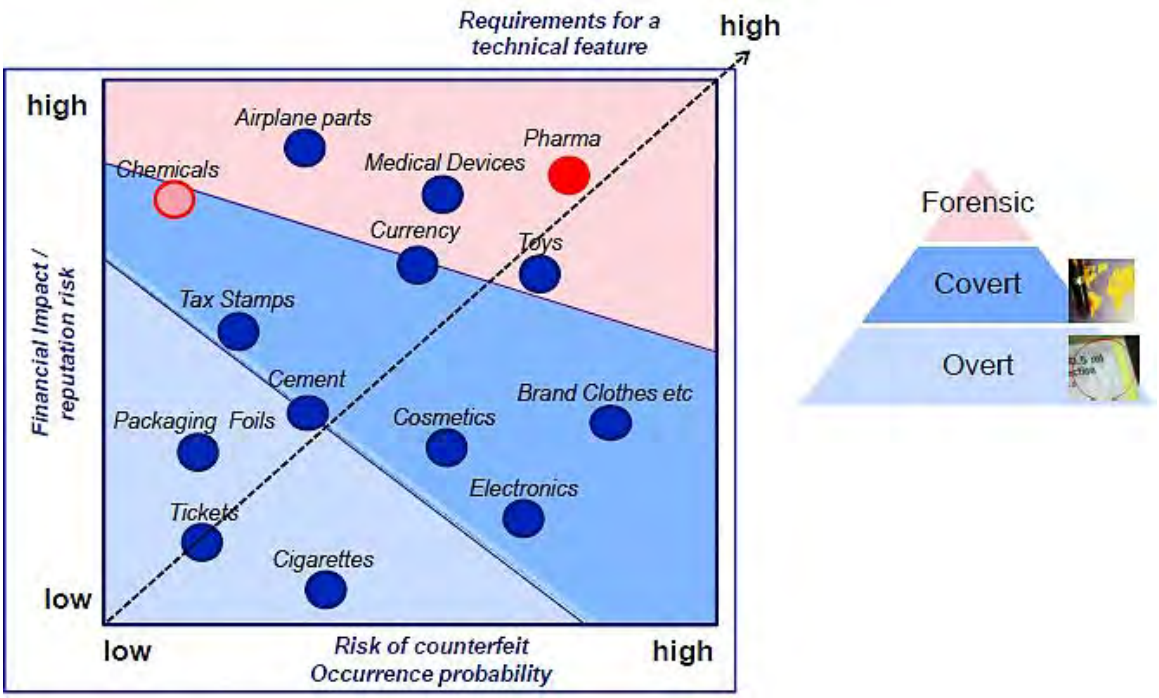
An important 3rd phase of OPEN-SCS work in 2016 proposes to do build out a selected set data objects and exchanges using PackML and BatchML for the Level 2 packaging equipment event data (state model, recipe and optimization) for the Phase 1 set of packaging use cases.

The importance of the OPEN-SCS work is centered on how healthcare manufacturers are struggling to meet the time line of the widely varying unclear global serialization regulations with a cost effective solution. While the supply chain T&T solutions based on GS1 standards are somewhat clearer, manufacturers currently see no clear solution path to packaging line and supply chain product serialization and aggregation activities due to many available approaches and applied technologies. A OPEN-SCS startup study of offerings for packaging line serialization systems of 10 leading vendors/solution providers found they all have similar adaptor/interface offerings for ISA-95 Level 2-3 and 3-4 data exchanges and cover over 80% common set of use cases and data exchanges for packaging line serialization; however, the data objects (syntax), structure (sematic form) and their transportation forms (connection/protocols) were varied greatly.

Note: The scope proposed in this OPEN-SCS Feasibility Study is subject to change based on review by Healthcare Industry.

Currently, the Healthcare supply chain systems are being deployed to meet the product track and trace (T&T) regulations by countries worldwide to address the widespread healthcare counterfeiting issues; unfortunately, their architectures and their data syntax vary greatly which is hindering scaling, effectiveness, flexibility and innovations. Within the current solutions footprints, those are only possible at a very high cost. Figure 1 shows how the Healthcare industry (Pharma and Med Devices) is carrying the highest risk and financial impact for manufactured products while having one of the highest occurrences of product counterfeiting.

Figure 1: Reputation Risk vs. Risk of Counterfeit, Need for Serialization Requirement (1)



The urgent need is shown in Table 1 for a global set of standards across all the layers of Open Systems Interconnection (OSI) Model (Appendix C) for product serialization and T&T across the Healthcare supply chain. McKinsey & Company states,

"Global standards could enable substantial patient safety benefits and enable total healthcare cost reduction of $40-100 Billion USD." (2)

T&T Standardization enables manufacturers' rapid response to aggressive regulation/compliance time lines by:

- Saving 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
- Ensuring quality
  - Select best supplier by layer / application
  - Force supplier to innovate to stay competitive
  - Robustness through common operations and business language

T&T Standardization enables vendors' rapid response to aggressive regulation/compliance time lines by:

- A more robust and stable development
- Common requirement templates and common 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)

Table 2 shows the projected supply chain investments over the next 3-5 years with 4 of the Top 5 being in Serialization and T&T 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 of the last 5 years (Refer to Table 4: Overview of Implementation Cost for Manufacturers). 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.

All parties must recognize that there is much more than only the legal requirements. Serialization is touching nearly all processes and activities across the manufacturing operations space and the supply chain processes.

Product design, packaging design and artwork, planning and scheduling processes, manufacturing physical processes, quality operations, etc. are all involved where serialization integrations with their supporting systems are a big benefit to workflow orchestrations and data management (batch, master, and meta data for L2, L3 and L4 processes).

A simple example are the Chinese requirements where the stocks of serial numbers must be manage to the product and then orchestrate the uploaded serializations data as part of the product release business process before the product may leave the plant. These processes require a number of seamless integrations with e.g. Enterprise, Manufacturing Operations Management, and Quality Management systems to effectively execute the release process. Consequently, serialization enables many new innovations like the use of E-Leaflets, E-Prescription and / or more commercial driven developments like applications for end users to find more information about the product. Also in clinical trial management and in laboratories, there are many possibilities to improve or combine processes and data. Unfortunately, the systems in place today make these opportunities very expensive and mostly cost prohibitive.

To formulate the proposed form and working process of the OPEN-SCS, the organizers of the Roundtable meeting appointed and retained an experienced subject matter expert (SME), Charlie Gifford, in manufacturing operations standards development and application. Charlie Gifford of 21st Century Manufacturing Solution LLC as the acting Executive Director of the OPEN-SCS conducted the discovery process for this study by interviewing and reviewing the members of the Roundtable (end users, equipment vendors, software vendors, system integrators, and SME consultants). The discovery showed that most of the vendors cover the same common set of use cases and data exchanges for packaging line serialization; however, the data objects (syntax) and their forms (connection/protocols) were varied greatly.

Table 1: Impact of Global Standard for Supply Chain Serialization and Track&Trace (2)

Table 2: Planned IT Investment by Healthcare Companies (3)

Percentage of Respondents

Globally Citing Planned Technology Investments by Type in the Next 3 to 5 Years

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

The real challenge and ultimate applied success of the serialization standard will be to get all the vendor members to agree on the global objects for a given set of exchanges for specific equipment types and product types/line layouts.

So the real question is how obtainable or feasible is this effort?

Recommendation:

The first step was the formation of theOPEN-SCS Steering Committee made up of the following Directors:

1. Marcel DeGrutter, Abbott Healthcare Products B.V.
2. Ilan Eden, Teva Pharmaceutical Industries Ltd.
3. Nikolaou Spyros, Famar Health Care Services
4. Michael Marrone, Mylan Pharmaceutical
5. Jean-Pierre Allard, OptelVision Inc.
6. Dr. Oliver Nuernberg, SAP AG

7. David DeJean, Systech International
8. Jürgen Laskowski, Werum IT Solutions GmbH
9. Emidio Zorzella, Antares Vision Srl

With 4 end users in a total of 9 voting members, the committee was formed to determine by simple majority vote the final reference data objects and technology FRSs for the formal draft development. The review and approval process for the formal draft data standard and best practices System FRSs will be written when the OPEN-SCS is formalized.

The second step is for the OPEN-SCS Steering Committee to immediately in March 2015 address the recommendation to collaborate with the OPC Foundation to host the OPEN-SCS. If approved, the OPEN-SCS will use the OPC working group processes as foundation adapted to the OPEN-SCS specific needs.

Ultimately once the OPEN-SCS standard and implementation System FRSs are approved, a super majority of vendors need to create a set of interface adaptors for their current object set, a set for the standard objects, and a documented mapping.

Note: A super majority of parties (vendors, EUs, and Sis) must openly acknowledge that the outcome of this effort is that no one vendor or end user's current data set will be the standard.

From the discovery discussions for this study with vendors, many were honestly skeptical about the group's ability to produce a standard in required regulation timelines with their concerns primarily coming from the very slow standard development/approval processes of the large internationals organizations such as GS1, ISO, IEC, ISA, etc. Mr. Gifford explained to the vendor members that this is the main reason that he and this study are recommending placing the OPEN-SCS in the OPC Foundation Inc. The OPEN-SCS Steering Committee is currently in exploratory discussions with the OPC Foundation. With primary purpose of accelerating the formal working group formation for accelerated standard development, the draft OPEN-SCS Charter is shown in Appendix E to be finalized and approved by the Steering Committee in March 2015. Once the relationship with the OPC Foundation is formally approved in Memorandum of Understanding (MOU) in March 2015, the fund raising effort will be conducted in 2015 to raise the $420K USD necessary to hire 2 SMEs in standardized integration practices to rapidly develop the drafts for serialization standard and implementation System FRSs as well as hire Mr. Gifford as the Executive Director to manage the OPEN-SCS and represent the OPEN-SCS in the supply chain serialization standards groups.

Note: If the OPEN-SCS is not a sponsored or funded group, the OPEN-SCS as a volunteer-driven group will simply not able to release an approved standard and implementation System FRSs in 2016 of the required detail and quality to adequately meet the end user demand and regulatory timelines. This is just the harsh reality; even in a funded effort per the Milestone Schedule below, the work will not be release until the end of Q1 2016.

Without this standard(s), the cost of regulatory compliance in the form of enterprise serialization T&T systems will increase by at least 2X due to custom plant integrations and cost of ownerships from change management.

From the study's discovery, there are a number of views on what the scope of the serialization standard should be. The four end users had a common view to that agreed with the proposed standard of the Roundtable with a few of additions outside of the proposed data objects. Some disagreement on scope will occur; however, strong conscious is required to raise sufficient sponsorship and subscription funding for accelerated development of the work products. There are definitely differences between the end users (e.g. Research based and Generic Pharma), equipment manufacturers and software vendors from process control, MES, and ERP. Each has a view that primarily focuses on their business's focus as would be expected and not the best way to address the regulatory and counterfeiting issues.

The proposed data standard as Phase 1 will address the ISA-95 Level 2-3 and 3-4 exchanges/interfaces with the common (as determined by Steering Committee) objects/elements required for supply chain integrations of plant data and events. Remark/re-label/rework stations in distribution centers can also be seen as Level 2-3

systems. The proposed Phase 1 needs to cover the primary scenarios/use cases/events for all the primary packaging line and rework/re-label/rework configurations for equipment and product types. Once formalized, the OPEN-SCS will conduct a rigorous survey and analysis to finalization the scope of the work products. As part of the OPEN-SCS's initial survey and finalizing of scope, detailed research is required on EPCIS (Level 3 and 4 data), OPC-UA's ISA-95 Services (Level 3 and 4 data), and PACKML Schema (Level 2 data). The PackML Schema address equipment process control, actual batch execution measure, and OEE data which are some of the additions required by manufacturers in the serialization data exchanges. These additions will not be addressed in the 2015 work as version 1 of Phase 1 standard.

Recommendation: In developing the proposed Phase 1 Standard, coupling OSI Transport Layer and the Data Presentation Layer (Refer to Appendix C) in the standard is not a recommended or common practice for integration standards. The proposed serialization standard focuses on the uses cases, data objects, and exchanges in a technology-agnostic way and then map the standard to a suitable communication technology examples.

Recommendation: The serialization system FRSs and associated implementation guidelines will define client and server agreements and what this communication technology approach is best for the requirement. This is exactly what OPC UA Part 6 explains (Refer to Appendix C and D).

Recommendation: Modelling the Data Presentation to process is recommended to be done by companion operations management standards such as ISA-88 (Batch and Recipe Execution) or ISA-95 (Enterprise-Control Integration and Manufacturing Operations Management (MOM) Activities).

Recommendation: The OPEN-SCS will be analyzing the use of the OPCUA ISA-95 Services and their use of the Business-to-manufacturing-markup-language (B2MML).

For instance, the Phase 1 Standard will address standard business case error responses for the packaging serialization use cases such as Serial Number Request, Batch Master Data Request, and Full Batch Import.

The Phase 1 Standard will not address the used of transaction error codes but the implementation System FRSs will since they specified as part of the code definitions in the Transport Layer, not the Data Layers. Transaction error code numbers are not relevant to the serialization exchange process and its data objects and use cases, only to the technical implementation of the communication method. This debate has occurred in other integrations standards efforts (ISA-95, OAGIS, OASIS, others) since ultimately end users' implementations drive a separation of Data and Transport Layers between any of the standards and the implementations. Also, the debate in other integration standards ultimately determined that interface security is both part of the data standard in the Data Session Layer and simultaneously in the Transport Layer for most architecture approaches. This will also be part of the scoping debate by the OPEN-SCS and the Steering Committee in March/April 2015.

Phase 1 work products must be completed and approved by Q3 2015 to meet the Healthcare Industry urgent regulatory compliance requirement. Consequently, the proposed OPEN-SCS approach is to accelerate the standards development through a funded development effort through a members' subscription model for the implementation FRSs documents.

Recommendation: The proposed Phase 2+ scope of the packaging line serialization standard will be determined until the research and draft of Phase 1 are completed in Q1 2015; As well, Phase 2 recommendations will be influenced by the evolving supply chain T&T standards being worked in 2015 by GS1 US Healthcare working groups, Rx360 group, and the final European EMS implementation.

Note: Mr. Gifford will represent the OPEN-SCS in these efforts once the group is officially established. New ERP and SCM solutions and other vendor approaches will also influence Phase 2 scope discussions as determined by the Steering Committee.

In summary, OPEN-SCS members must have an open mind during the standards development process. Members' positions on what "must" be in the working standard will have opposite relevant views on what is necessary for a working standard. The OPEN-SCS and Steering Committee discussions will have to agree on the direction through the use of a process where positions /approaches are presented, debated and voted on to move forward. Some "approved" directions will not be liked by all.

The minimum budget necessary to achieve the goal in 2016 of the Phase 1 Standard and System FRSs is $290K USD. The work by the standards architects will not begin until the fund raising has successfully reached this number. This number requires only 30 of the 80 companies of the Roundtable members to commit in February with $10K for a sponsorship or subscription products. If this commitment is not achieved in February, the Milestone Schedule below will be delayed until the funds available.

The following Feasibility Study provides for OPEN-SCS and Steering Committee discussions:

- Introduction and Business Requirement for Healthcare Product Serialization to explain the urgent market need to rapidly develop and release of a packaging line serialization standard
- The study proposes a basic scope to seed OPEN-SCS and Steering Committee discussions to finalize scope
- A preliminary set of primary serialization use cases and their exchanges are presented in the context of ISA-95 Activity Models and Functional Hierarchy
- The OPEN-SCS Milestone Time Line
- Operations Costs and funding methods for work products
- The proposed OPEN-SCS Charter

2015/2016 Operating and Revenue Cost Summary

The estimated budget for OPEN-SCS formation and labor required to develop, approve, and release standard and the System FRSs work products. The estimates are only best guesses since the final scope for the standard and the System FRSs work products is not established and the relationship discussions with the OPC Foundation are not complete. The numbers are based on the prior experience of Mr. Gifford from being a leading in standards committees for 20 years. The resources are required for OPEN-SCS to achieve the market penetration to adequate level in 2016 and to be profitable enough for reinvestment necessary to scale business model.

2015/2016 Revenue **$360K**
USD

Primary: OPEN-SCS Subscriptions for Open Source System FRSs $13K USD x 30 members = $390K USD

Operations Cost: $360K USD

Reserves for additional scope development, GS1/Rx360 Liaisons, marketing, and travel:

$390K - $254K = $136K USD

Schedule/Milestones for Formation of OPEN-SCS and Approval/Release of Standard

Milestones for the First Year Only:

- January 2015: Establish OPEN-SCS Steering Committee
- February 2015: Kickoff-Steering Committee Meeting
- March 2015: Final Draft of Feasibility Study to Steering Committee
- March 2015: Final Fund Raising Brochure and Send to all Open-SCS Members
- March 2015: Formalized OPC Working Group with signed MOU
- March 2015: Steering Committee Meeting
- May 2015: OPEN-SCS setup in OPC to manage revenue of sale of subscriptions for products
- June 2015: Finalize OPEN-SCS Website
- October 2015: Receive Product Subscriptions from Steering Committee members.
- November 2015: Final Business Case White Paper
- December 2015: Draft contracts agreed for Executive Director, and SME Architects
- December 2015: Send out Scoping Survey to members
- December 2015: Reach minimum required funding to start work: $260K USD. 20 members X $13K
- January 2016: Finalize contracts with OPEN-SCS SME Architect team
- January 2016: Begin work on URS and System FRSs V0.1
- January 2015: Send out final scope for Steering Committee vote
- February 2015: Final Scope
- March 2016: Release draft standard V0.1
- April 2016: OPEN-SCS User Group Face-to-Face Meeting to Finalize Standard and System FRSs.
- April 2016: Send out Final Drafts for vote and comment.
- April 2016: Comments due on Final Drafts
- May 2016: Send out second Final Drafts for vote and comment.
- May 2016: Comments due on Final Draft
- May 2016: Plan Phase 2 and 3 versions of work products
- June 2016: Release Final Standard and System FRSs

2. Introduction and Business Requirement for Healthcare Product Serialization

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.

Only 12 percent reported they were satisfied with their companies' performance in this area.

Consequently, the Global and regional healthcare industries are at a critical juncture in human history. T**he current state of the Healthcare Industry** (and their primary challenges) is as follows:

1. **Regulatory compliance** remains the top business and supply chain issue. As shown in Figure 1, a murky legislative outlook and differing regulations by country make the issue more complex.
2. **Product protection from global counterfeiting**. As shown in Figure 2, both product integrity and product security has become a bigger challenge as products become more complex and companies expand into emerging markets. Concerns are particularly high in Asia-Pacific.
3. **Economic conditions** still weigh heavily on healthcare companies
   - Global Economic Crisis (GEC), particularly those in North America and Latin America
   - 2012 Patent Cliff (4)
     - Example: 8 major drugs went generic for a $33B USD loss and 12,000 jobs.
     - Generics now make up 80% of global market and are primary counterfeiting target.
4. **Cost management,** driven by regulatory reform and profit pressures, remains a top supply chain issue. Yet the level of concern is declining year over year.

The urgent requirement for Healthcare companies to rapidly implement product serialization and track & trace systems and processes across their supply chain has a number of business drivers. This Feasibility Study for the Rapid Development of a Serialization Data Standard for Life Science Packaging Lines addresses these business drivers as outlined during the First Roundtable on Open Architecture for Track & Trace held on September 24, 2014 in Frankfurt, Germany. For the Healthcare Industry, the study proposes the formation of the OPEN-SCS with the specific goal of rapidly developing a set of product serialization standards for packaging line level in plants. The proposed standards for in-plant serialization data will be heavily influenced by and map directly into the supply chain serialization regulations, associated standards and systems approaches that are being deployed to meet the product track and trace regulations being released by countries worldwide to meet the widespread drug counterfeiting issues.

The members of the Open Architecture Track and Trace (T&T) **Roundtable agreed on their T&T Mission** as:

- Protect the public
- Stop counterfeited product
- Stop reimbursement fraud and or 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

The **Roundtable end users and vendor members strongly agreed on the high business risk** of the current market state in the following areas:

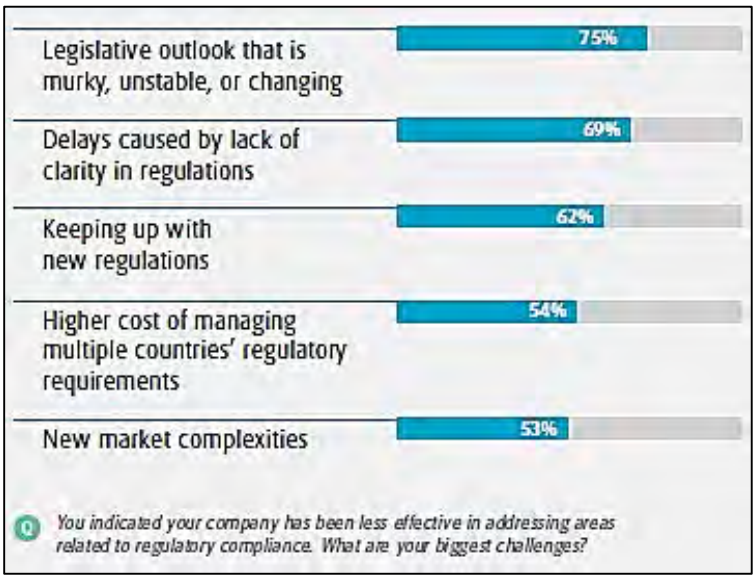
- Meeting regulation to the required time lines
- Lack of knowledge (problem and solution)
- Serialization validation as single point of failure
- Potential price increase due to perceived loss of packaging line and supply chain efficiencies
- What if you can't ship products…

The **Roundtable members** expressed that new and proposed T&T **regulatory pressure are creating**:

- A highly complex challenges affecting all level of operation
- Solution designed in a rush
- Asking miracle to supplier
- Many custom made solution
- Lack of time to step back

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.

Figure 2: Global Challenges to Regulatory Compliance (3)



At this critical juncture in human history, the global human population is growing (7 Billion+ at 10% per year) and the median age is rising (24.3 years at 10% per year). The middle class in emerging markets/nations is rapidly growing. Figure 3 shows that demand for healthcare services has never been greater or growing faster across the global marketplace.

Note: The middle class in emerging markets/nations are growing in some important 2nd world growth countries where the taxes are growing fast. Together, increased inflation, prices, etc. and the lifecycle cost of current solutions are forcing these healthcare markets to grow much slower than expected.

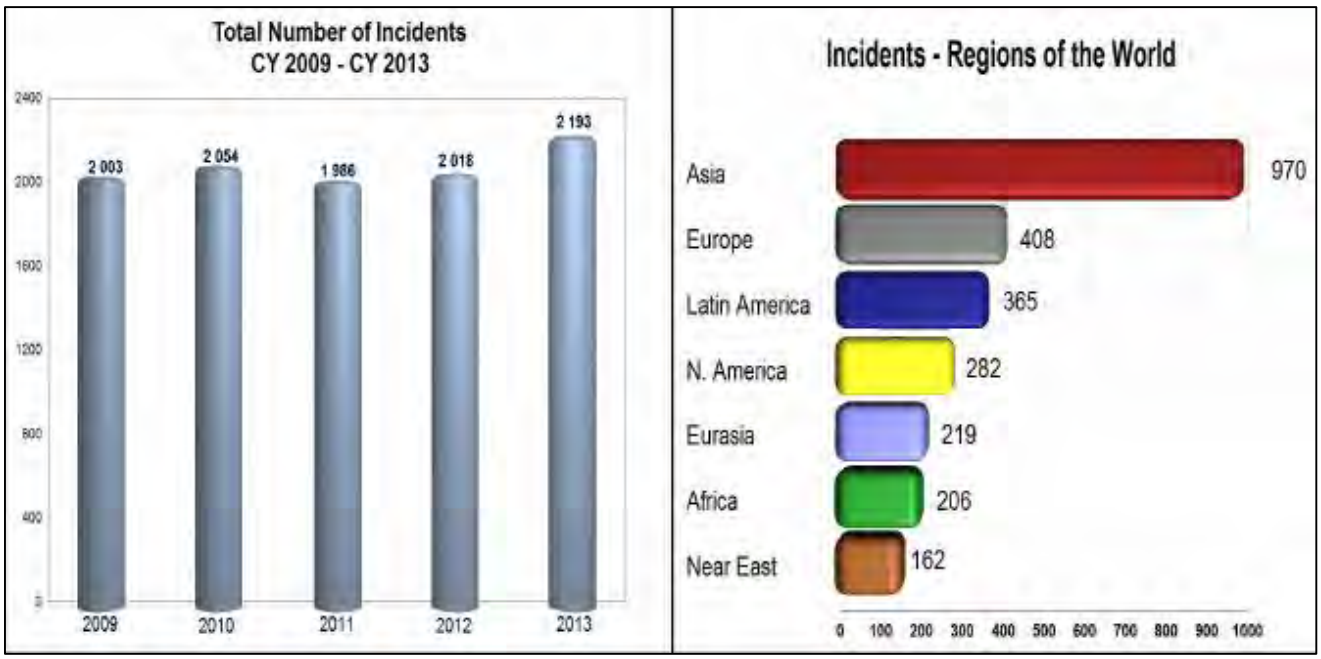
Figure 3: Healthcare Markets Targeted for Large Expansion (3)

Healthcare companies, some proactively and most reactively, are moving fast to make the strategic changes to their regional and global supply chains to meet the market demand; However, Figure 4 shows that #1 challenge and business driver for updated supply chain processes are rapidly evolving regulations for patient safety. Many companies attempting to capitalize on the new opportunities view the primarily challenge as their own outdated cultural resistance from paper-based processes to updated supply chain processes supported by secure electronic data transactions and rules-based decision making.

Figure 4: Top Challenges to Global Expansion (3)

The winners in tomorrow's Healthcare market must create agile, efficient, and flexible supply chains. 2015 is the time to take action to acquire new and available market share since re-engineering of business processes and supporting enterprise architectures has proven to be a 10+ year Strategic Transformation Journey. Unfortunately, investments for growth must first focus on the a widespread patient/product safety issue as shown in Figure 5 due to global large scale and growing drug counterfeiting. This has forced all the G20 and leading emerging nations to rapidly create strict product safety regulations in various forms of product T&T requirements. The cost and business re-engineering to comply with regulatory requirements on global scale is very difficult. The regulations and rules in each country are getting published, attempted by companies, and then changed based on the degree of effectiveness and/or compliance; all the while, they must keep changing to meet a growing high level of sophistication in product counterfeiting, safety and recall issues. Consequently, compliance is again the top business and supply chain issue for healthcare supply chain leaders.

Figure 5: Worldwide Counterfeiting, Illegal Diversion, and Theft Incidents (1)



Some facts about drug counterfeiting from PSI 20144 Industry Study (1) are as follows:

- Counterfeit drugs flood the market and generate **~$75B USD Revenue**
- The 'counterfeit industry' is estimated to **grow by 20% annually**
- In some countries, counterfeit drugs constitute as much as **70% of total drug supply**
- Most counterfeited drugs were in the genito-urinary category (37%), anti-infectives (12%) and central nervous system drugs (12%)
- Consumers often **purchase fake drugs online**
- Counterfeiters produce medicines with no regard for the health consequences of patients
- Counterfeit drugs look almost identical to genuine products
- Production of counterfeit pharmaceuticals is in most cases by Organized Crime on global basis.

Fortunately, the required supply chain T&T improvements to address regulations for patient safety and product protection are justifying the large system investments. Proactive manufacturers and their downstream providers are immediately capitalizing on huge untapped opportunities shown in Figure 6 with significant reductions in inventory, obsolescence, and lead time.

Lastly, Figure 7 demonstrates a strong part of the healthcare manufactures' business case in quantifying the "Impact on Profit of the Opportunities from Supply Chain Transformation".

Figure 6: Operations Metrics Show Huge Improvement Opportunities from Healthcare Business Process Re-Engineering (BPR) and Data Standardization (2)

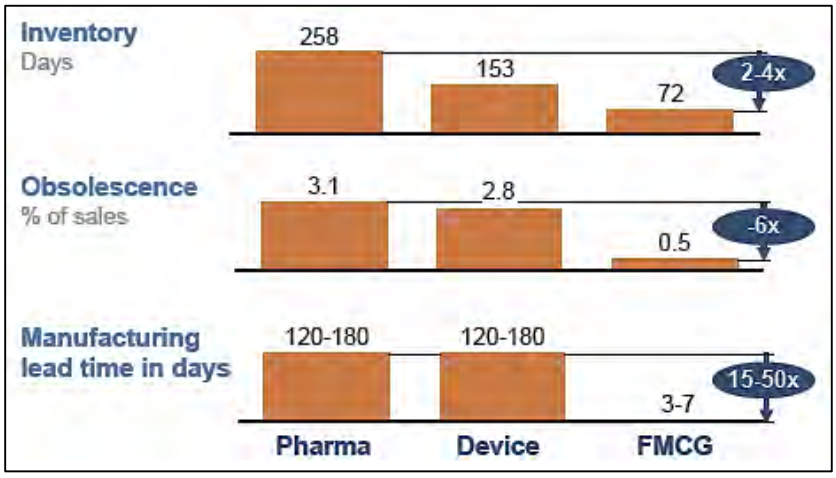
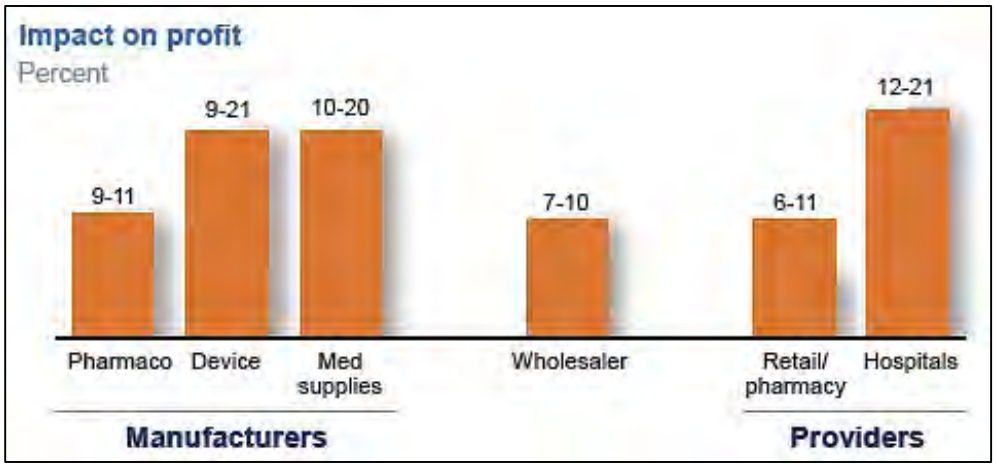


Figure 7: Impact on Profit from T&T Opportunities from Life Science Supply Chain Transformation (2)



The bottom line is there is balance to understand in forming investment strategies. The best practices for transformation strategies for profiting from untapped serialization opportunities are:

- **Contingency planning** is an area in which fewer than four in ten executives report success. Supply chain disruptions have had the greatest supply chain impacts in Asia-Pacific and Latin America.
- **Collaboration and partnerships** are top strategies to address challenges, such as complying with regulations, supply chain cost management, and global market access.
- **Technology investment** is the top strategy to improve competitiveness and efficiency. Planned technology investments enable better product protection, visibility, and easier patient access through online ordering.
- **Growth and global expansion** challenges include a complicated regulatory environment and inadequate infrastructure in emerging markets. Companies are leveraging partnerships to get ahead.
- **New channel and distribution strategies and business models** bring new opportunities for companies—particularly with anticipated growth in home healthcare. Yet shifts in channel mixes are slow to materialize.

Effective Supply Chain Processes Synchronized by L3 and L4 Master Data Management

Regulatory reporting by best-in-class manufacturers is slowly becoming much more efficient and effective through master data management within companies' enterprise T&T architectures as they roll-up and aggregate data across their divisions, regions and associated supply chains. The proactive manufacturers are gaining advantages with better decision making and planning from having faster data management across their supply chains. Complacent and laggard manufacturers and providers are still struggling with basic manual analysis and inaccurate data. Unfortunately, the laggards group is causing a widespread slowdown in other companies' regulatory transformation because they are part of a large integrated supply network.

The business process re-engineering (BPR) of the Healthcare Industry has a very high cost due to wide spread use of paper-based processes and/or standalone department-level applications; the high cost comes from BPR, manual data updates, data cleansing, and processing. A major driver of this cost is product catalog updates from suppliers which need to be incorporated manually into customers' systems, sometimes by dedicated vendors. The next generation serialization T&T system architectures are addressing these critical user requirements through master data synchronization for Level 2, 3, and 4 as a primary requirement/functionality to bring enormous process efficiencies and product accuracy. Innovative manufacturers and downstream providers are already receiving major benefits for their recall and supply chain processes effectiveness. Automated master data synchronization will greatly reduce customer (provider and patient) requests for product information, decreasing the manufacturers' burden.

Downstream Health Care Providers Require New Business Model

While manufacturers are positioning for growth, they must lower their product price points significantly to serve emerging and growth markets with lower cost products. However, many are complex products with complex packaging, storage and transportation requirements driven by temperature and humidity. Again, an effective digital supply chain is the key to profitably in the complexities of the markets.

McKinsey 2012 benchmarks illustrate key complexities of the Healthcare Industry (5):

- Healthcare manufacturers' SKU counts per packaging line increased by over 50% in the last 3-5 years
- Healthcare recalls grow even faster: 26% per year from 2005-2011 to more than 1000 per year now
- Regulatory scrutiny has increased along with safety issues: US FDA issued 18 Good Mfg. Practice (GMP) warning letters to manufacturers in 2005, and 53 in 2011 for a nearly 200% increase
- Regulators' response times also increased: FDA warning letters issued within 4 months of FDA inspection from 14% to 26%.

As of 2014, manufacturers have been slow to respond to their increase in recalls by improving their recall business processes and support systems. Most companies' recall processes fail to identify and remove all affected products from supply chain inventories and every exposed patient while applying hundreds of hours of expedited labor costs.

The market pressure to improve is increasing but downstream providers organizations (hospitals, pharmacies, and distributors) require new and very different reimbursement models for supply chains to change rapidly. Their revenue stream needs to change from fee-for-service to some type of new capitalized model based on risk-sharing agreements. Providers who can optimize safety and quality of care without raising costs may thrive under this type of business model –if they can show how their pharmaceutical, medical device and supply choices affect patient outcomes. This is a major influencer for standardized identification and automated tracking of healthcare products from plant to patient since it makes this business arrangement possible and highly desirable.

Net Benefit-to-Cost Ratio for Manufacturers

In Table 3, McKinsey & Company estimates investments, annual cost-to-benefits, and impact to patient safety for the three different types of barcoding for Healthcare manufacturers (3). This analysis shows:

- Significant returns to manufacturers from investments in adoption of global standards
- Benefits for each type of barcoding
- Accumulated benefits for both one-time and annual cost over 10 years
- Expected barcoding at the secondary packaging level to deliver about 20-25X more benefits vs. cost, while serialization would have a 4X benefit/cost ratio.

**McKinsey & Company did not quantify the benefits of the barcoding at the primary packaging level and the associated a 10-year benefit/cost ratio for this capability.
**Does not include a $90M one-time cash benefit from the inventory reduction.

In addition to the McKinsey & Company's Illustrative Business Case in Table 3, the reader should also consider Table A4 in Appendix A which is McKinsey & Company study on The Potential Product Serialization Benefits to Pharmaceutical Manufacturers (5). The study identifies the "Sources of Value" as:

- Reduce inventory assets
- Reduce inventory financing and holding cost
- Reduce produce waste due to obsolescence
- Reduce cost of recalls
- Reduction in counterfeits and recovery lost profit

The impact estimate and potential for case-by-case variation are estimated for each source of value.

For Table 4, McKinsey and Company created a hypothetical use case where estimated representative costs to upgrade enterprise IT, packaging line equipment and software, and project costs for a fictitious manufacturers with $4B in annual revenue and 25 packaging lines (5).

- These cost estimates are only illustrative and not intended as an investment case.
- The investment cost would roughly double if aggregation is also required (based on expert interviews).
- Actual costs vary for each company depending on existing capabilities and actual business conditions.

Table 3: Illustrative Business Case for Healthcare Manufacturer ($M USD) (5)

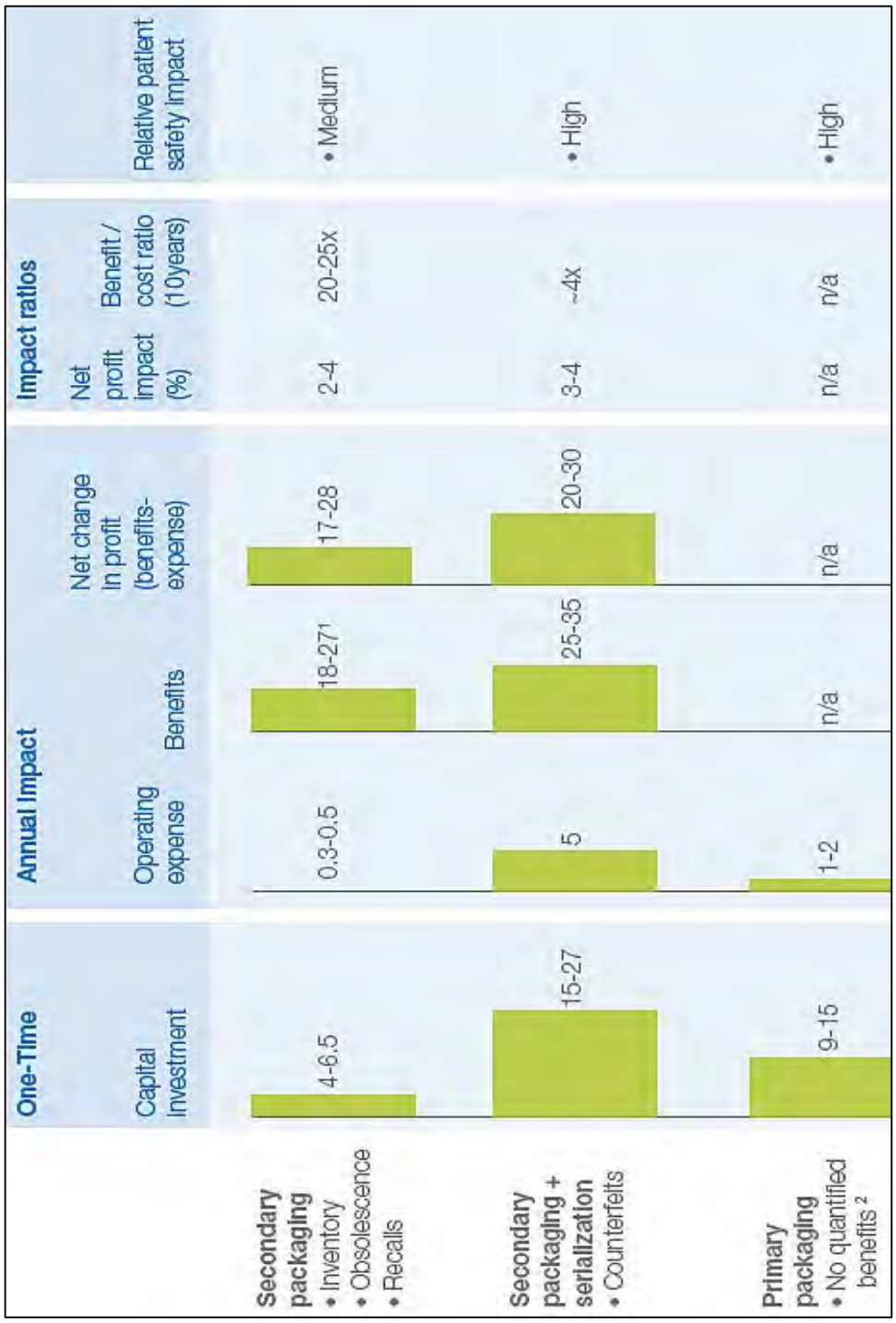


Table 4: Overview of Implementation Cost for Manufacturers (5)

Type of barcoding	Key assumptions	Major potential source of variability in actual cost
Product identification, lot number, and expiry date on secondary packaging	• $150-225,000 capital per each of 25 packaging lines • $1-2 million in licenses and integration cost for enterprise software • Annual expense 10-15% of invested capital (depreciation, maintenance, operating expense)	• Number of packaging lines • Existing packaging line equipment • State of enterprise software applications and interfaces
Product identification, lot number, expiry date, and serial number on secondary packaging	• $500,000 for equipment, line-level software, and project cost per packaging line[44] • $3-5 million in licenses and integration cost for enterprise software • Operating cost based on EFPIA estimate, scaled proportionally to revenue (EFPIA Individual Response to European Commission Concept Paper on the Delegated Acts for Coding & Serialisation, April 2012)	• Number of packaging lines • Extent of standardization across packaging lines and facilities • Equipment and software procurement effectiveness • Nature of existing enterprise software system serialization licenses already in-house
Product identificationon primary packaging	• $300-500,000 capital per each of 25 packaging lines • $1-2 million in licenses and integration cost for enterprise software • Annual expense 10-15% of invested capital (depreciation, maintenance, operating expense)	• Number of packaging lines • Existing packaging line equipment • State of enterprise software applications and interfaces

3. Scope of Open-SCS Working Group

On September 24, 2014, the founding First Round Table on Open Architecture for T&T was conducted.

- Over 80 industry suppliers and customers met in Frankfurt, Germany
- A Draft Set of Open Architecture Serialization/Aggregation Exchanges were presented as a starting point for discussion
- Very good technical scope discussions occurred in a collaborative approach
- Key outcome was a strong consensus that guidance should be developed and issued ASAP to support the industry in rapid deployment and cost reduction for the deployment of serialization systems to meet required dates of newly released regulations
- Recommendation to formalize an Open-SCS Working Group
- Recommendation to assemble team of SMEs to rapidly scope and develop of in-plant serialization standards
- Recommendation to search for home for working group by contacting standards organization (GS1, ISPE, OPC, etc.)
- An experienced leader was proposed, approached with offer and accepted the mandate to help formalize the working group
- Already 150+ members in the group (filtered)

Regulatory Requirements for Healthcare Industry's Operations and Supply Chain Processes

As mentioned above, the healthcare supply chain is functioning in a sub-optimal state now and was before the 2012 Patent Cliff which accelerated the global drug counterfeiting issue. Healthcare providers, distributors and manufacturers all struggle with a large error rate related to their procurement process. Inefficiencies or errors in the procurement process extend all the way to the patient, manifesting in ordering errors, not having enough product on hand to treat the patient, clinicians receiving the incorrect product, expired inventory and other scenarios.

There are many causes for the industry's inefficiencies. The industry has been challenged by their disparate proprietary data for products and for location information. The continuous translating of data and manual processes causes a multitude of errors and creates an insidious obstacle to achieving the desired future state of efficiency or implementing specific clinical systems and programs. The lack of common supply chain performance metrics creates further obstacles. Common shared metrics provide benchmarks which illuminate both good and bad supply chain performance. Something as basic as the true cost per transaction is largely a mystery to many manufacturers and healthcare providers.

New industry participants are often surprised to learn that many other industries have already implemented product tracking and recall processes that are decades ahead of the healthcare industry. A small number of proactive Healthcare manufacturers are already including GTINs and production data in barcodes on product labels to carefully track product from production to the point of delivery. However, the overall industry lags behind other industries in terms of product scanning, electronic ordering, order accuracy and other key processes. As shown in Figure 8, the industry's slow pace in collaborating and implementing best practices is perpetuating wasteful practices and sub-optimal processes. Despite significant investments by many companies (equipment, technology (firmware/software), product labeling, and attempts to automate processes), the healthcare industry is still burdened by their manual processes. A tremendous amount of business process re-engineering and cultural/organizational transformation is required from the packaging line to the pharmacy.

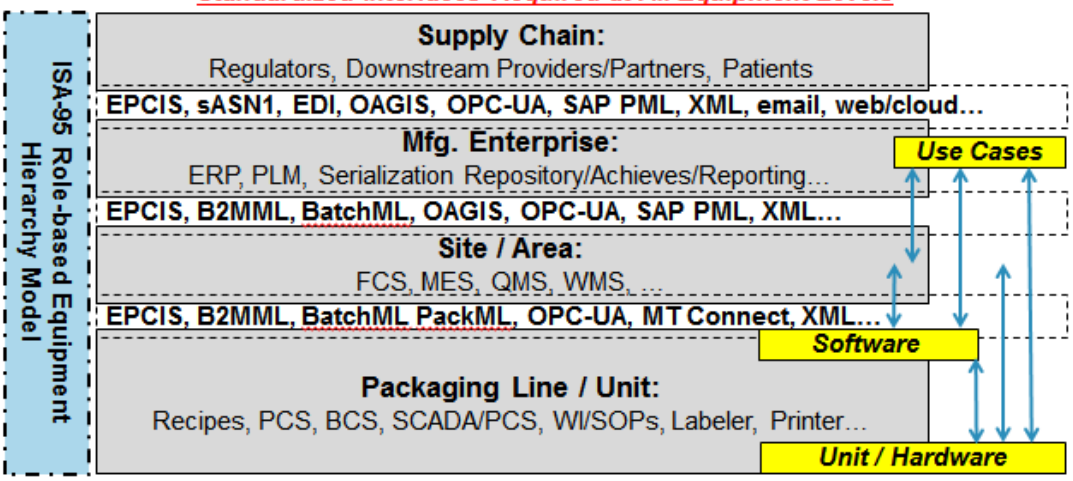
Figure 8: GS1 Germany, "Lack of standards in Healthcare is inefficient and adds risk…" (6)

- **Multiple bar codes on one package – which one to scan?**
- **Different types of non-standard bar codes – inconsistency; incompatibility**
- **No bar code – lost bar code, need to bar code: re-package; re-label**

Figure 9 shows the lack of standards at every ISA-95 Role-based Equipment Level (7):

- Inter-enterprise data exchange (Supply Chain)
  - Not standardized in OSI Data Layers -> Lot of interface adaptations required
  - Government reporting still varies / unknown
- Intra-entreprise data exchange (Enterprise/Site/Area/Packaging Line)
  - Enterprise IT <-> Site server interfacing
  - Not standardized in OSI Data Layers -> vendor specific implementations
- Inter-equipment data exchange (ex: bar code reader, labeler, case packer, printers)
  - Site server <–> Packaging controller interfacing (packaging execution)
  - Standardized interfaces in OSI Data Layers needed
    - Master data for L2, L3, and L3 artifacts
    - Process order data (batch variable data)
    - Serialization data provisioning and reporting
    - Status, reporting and error handling

Figure 9: Packaging Line Serialization System Use Cases and Interface (7)
(Mapped to the ISA-95 Role-based Equipment Hierarchy)



As seen Figure 10, many countries are currently developing and releasing serialization T&T regulations over the next 1-5 years. From country to country, there is a lot inconsistency in the T&T solution IT architecture and form of reporting; but there is limited, but random consistency in the use of the GS1 standards. The prevailing compliant with the latest Healthcare T&T regulations is that they remain a complex task for manufacturers and supply chain providers to accurately manage the varying regulations across the globe.

These disparate regulations are expected to cover over 70% of global medicines by 2017.

However, due to NO international set of data or exchange standards from plant to patient, the managing and implementing serialization requires not only financial investment but also a detailed understanding of local markets and regulations that must be correlated at the enterprise level.

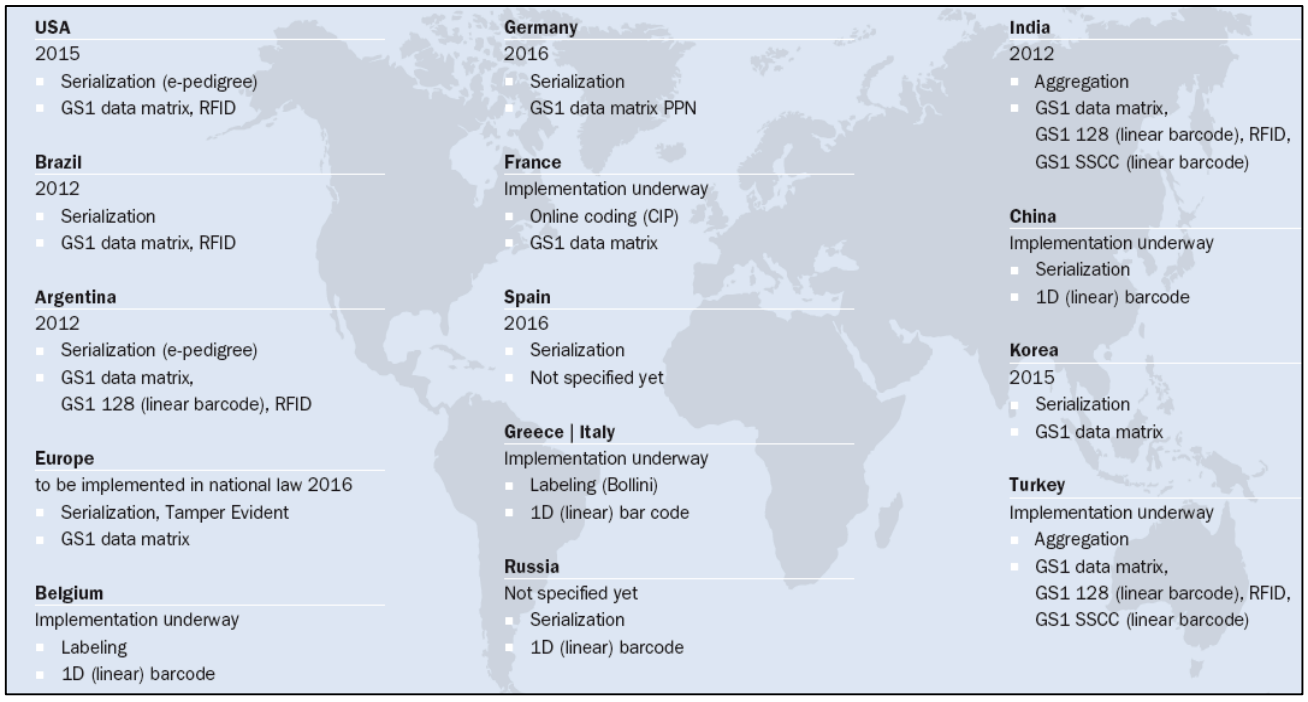
One common objective for Manufacturers and Providers: One Common serialization information model and IT architecture for all sites.

Whilst there are a couple of well-established markets in terms of regulations such as Turkey and China, many other markets are still in the process with their regulatory program (10):

- Serialization only: Korea (2015), Saudi Arabia (2017), EU &US (2018)
- Aggregation required: Turkey, China, Argentina, Brazil, India, US (2023)
- Regulatory Reporting: planned scope for July 2015
  - China, Turkey, Argentina
  - US Lot Level EPCIS & standard item Level EPCIS in pilot mode
  - EU in pilot mode only
  - India – no government reporting required so far
  - Korea – no government reporting required so far
  - Brazil planned but especially message orchestration goes way beyond classic regulatory reporting.

All requirements for serial number and barcode formatting, encoding / decoding, randomization etc. will be supported for the countries mentioned above!

Figure 10: Healthcare T&T Monitor – International Demands at a Glance (8)



EPCIS has become the primary integration standard for cross-supply-chain traceability

The serialization/aggregation regulations have brought about the formations of industry consortiums to address the serialization from the plant to the pharmacy through groups such as GS1's GS1 Healthcare US and Rx360 Working Group. GS1's electronic product code integration specification (EPCIS) has become the primary integration standard for cross-supply-chain traceability by most Healthcare companies. As shown in Figure 10, some limited combination of the following GS1 traceability standards have been written into or are proposed by most G20 and emerging countries' new healthcare traceability regulations:

- Global Location Number (GLN)
- GLN Registry
- Global Trade Item Number (GTIN)
- Serial Shipping Container Code (SSCC)
- GS1 Data Carriers
- GS1 Application Identifiers
- EPC Information Services (EPCIS)
- Core Business Vocabulary (CBV)
- Global Data Synchronization Network (GDSN)

As shown in Table 6, the GS Standards address the Who, What, Where, When, and Why of product traceability across the supply chain. In Table 7, the "Mission of the GS1" is to develop a comprehensive set of supply chain traceability standards for (Examples shown in Table 7):

1. Identify: GS1 Identification Numbers
2. Capture: GS1 System Data Carriers
3. Share: GS1 Interface Standards for Electronic Commerce

Consequently, Table 5 shows that GS1 is clearly going to be the standard at the package coding level, and from all evidence, at the information exchange layer as well.

Table 5: Plan to Use GS1 at the Package Level (9)

38%	**Don't Know**
55%	**Yes**
7%	**No**

Table 6: GS1 Standards at the Core of Track-and-Trace Using EPCIS (10)

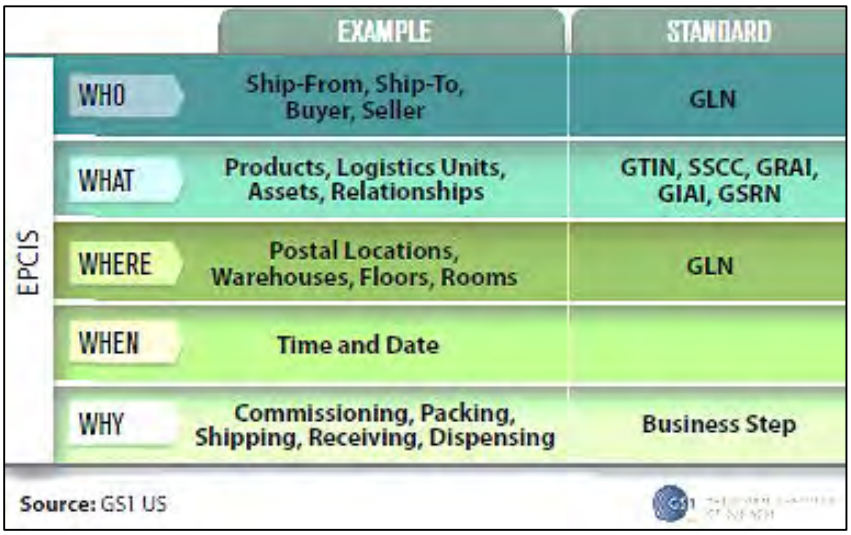


Table 7: The Mission of the GS1: Identify, Capture, and Share = Identification Numbers, Data Carriers, and Standards for Electronic Commerce (10)

Standardized Plant Serialization Data Aligned with Regulatory Supply Chain T&T Reporting

The Drug Quality and Security Act of 2013 (DQSA) from the United States and the European Stakeholder Model (ESM) have become a guideline for many other countries' regulation development.

The DQSA was signed into law on November 27, 2013 as Public Law 113-54. Title II of the legislation is referred to as the Drug Supply Chain Security Act (DSCSA) and establishes new federal requirements for traceability.

The ESM is based on the Point-of-Dispensing (PoD) Verification concept; its technical implementation is the European Medicines Verification System (EMVS).). There is put an organization in place called EMVO (European Medication Verification Organization) with a representation of Manufactures (Research and Generics), Parallel Traders, Wholesalers and Pharmacists to bring the EMVS in operation and manage the daily operation. The first National System will be connected to the European Hub soon.

The DSCSA is a very good example of the high level details and requirements that are required to ensure consistency throughout the drug supply chain with respect to serialization and traceability in the Healthcare supply chain; and subsequently, in-plant packaging line serialization T&T processes and systems must feed accurate and correctly structured product data into DSCSA's reporting artifacts. The OPEN-SCS focus must align the standardized plant serialization data with the form supply chain T&T data for regulatory T&T reporting.

The new U.S. federal law requires a transaction document (TD) beginning on January 1, 2015, and serialization of all prescription products by November 27, 2017. The TD is a document, initially in paper or electronic form, constructed by the entity selling the products and provided to the new owner. It contains transactional information and history and several statements to certify compliance with the law. The "transaction statement" (TS), part of the TD, certifies that the entity transferring ownership in a transaction:

A. is an authorized distributor of record as required under the Drug Supply Chain Security Act;
B. received product from an authorized person as required under the Drug Supply Chain Security Act;
C. received transaction information and a transaction statement from the prior owner of the product;
D. did not knowingly ship a suspect or illegitimate product;
E. had systems and processes in place to comply with verification requirements, including identification using U.S. National Drug Code (NDC) and packaging lot before December 2017 and using an serialized numeric identifier (SNI) after November 2017;
F. did not knowingly provide false transaction information; and
G. did not knowingly alter the transaction history.

Also under the law, "transaction information" (TI) must be exchanged and contains ten details, including:

A. The proprietary or established name or names of the product
B. The strength and dosage form of the product
C. The National Drug Code number of the product
D. The container size
E. The number of containers
F. The lot number of the product
G. The date of the transaction
H. The date of the shipment, if more than 24 hours after the date of the transaction
I. The business name and address of the person from whom ownership is being transferred, and
J. The business name and address of the person to whom ownership is being transferred.

Those entities in the supply chain who receive finished prescription drug or biologic products must include "transaction history" (TH), including the TI for each prior transaction going back to the manufacturer of the product.

After November 27, 2017, the TD, including the TS, TH and TI is required in electronic form and transaction information will include the SNI. The law requires all saleable items and their sealed standard homologous shipper case to be uniquely serialized for all prescription drugs traded in the U.S. after November 27, 2017.

A comprehensive system for the entire supply chain to fully secure the exchange of prescription drug and biologic products is expected by 2023 under the law. A full transaction pedigree will be defined by the U.S. Food and Drug Administration (FDA) prior to the required implementation in November 2023.

Packaging Line Serialization is the Focus of Open-SCS Working Group

There are many unsolved issues in supply chain T&T standardization (and the required enterprise IT architectures) for regulatory compliance that are actively being worked by GS1, Rx360, ISPE and other groups; However, no international working group is actively addressing the standardization within the plant of serialization and aggregation from the packaging line to enterprise to address regulatory compliance.

From the Healthcare business perspective, manufacturers are viewing the First Roundtable for Open Architecture for Track & Trace held on September 24, 2014 in Frankfurt, Germany as a very important and timely initiative. The group is forming the OPEN-SCS with the specific goal of rapidly developing a set of product serialization standards for the packaging line level Data Exchanges in plants.

The Open-SCS Working Group's proposed primary focus is to standardize the serialization data objects and required data exchanges for the primary product T&T use cases for inter-plant, packaging line, and equipment unit levels.

The basic Phase 1 scope of the proposed standard's work is a set of data exchanges and associated data objects or global registry of data objects for a specific set of common packaging use cases for use in Packaging Serialization Line User Requirement Specification (URS) and Performance Qualification Tests (PQ).

The resulting T&T standard(s) is the basis for system functional requirement specifications (FRS) for implementing standard integration method for serialization data between the packaging line and enterprise and supply chain T&T systems.

The proposed Phase 2 work will use the URS as base to produce an implementation set of Packaging Serialization System Functional Requirements Specifications (FRS) for six common architectural approaches and two exchange protocols/technologies. The initial proposal is to develop the System FRSs for the EPCIS and OPC-UA technical approaches where the standard's data objects and exchange use cases are mapped between these two approaches. Last but far from least, the proposed standards for in-plant serialization data 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.

The importance of the OPEN-SCS work is centered on how healthcare manufacturers are struggling to meet the time line of the widely varying unclear global serialization regulations with a cost effective solution. While the supply chain solutions based on GS1 standards are somewhat clearer, manufacturers currently see no clear solution path to in-plant packaging line serialization and aggregation of products due to many available approaches. A OPEN-SCS startup study of offerings for packaging line serialization systems of 10 leading vendors/solution providers found they all have similar adaptor/interface offerings for ISA-95 Level 2-3 and 3-4 data exchanges and cover over 80% common set of use cases and data exchanges for packaging line serialization; however, the data objects (syntax), structure (sematic form) and their transportation forms (connection/protocols) were varied greatly.

Most Healthcare companies drive batch packaging line operations directly out of ERP and/or MES order and recipe management routines; but these systems expects the "Serialization & Aggregation" data to be "automatically" reported back to these Business IT systems. Conversely, one of the most costly and

unpredictable aspects for companies in implementing a corporate wide serialization/aggregation systems and new business processes are the complex custom integrations to the packaging line level and equipment unit level. Currently, the majority of the equipment interfaces and Level-2-system-to-Level 3-system interfaces are custom mappings. These serialization mappings of vendor and/or company priority data objects and structures are for Product ID, Lot ID and aggregated IDs to the aggregated pallet level. Even using sematic structures of EPCIS from GS1, the custom syntax of master data are mapped at the line or plant level and re-mapped again to the plant operations management systems and then corporate supply chain data standards in the enterprise traceability systems. The plant level integrations are easily 50% the cost of implementing a serialization solution on packaging line.

The OPEN-SCS recognizes that the enterprise and supply chain traceability systems expect the data packages in all use case exchanges to be mapped to an EPCIS form so that they comply with the majority of the developing and new country regulations for supply chain traceability. However, the OPEN-SCS proposes to focus on the standardization of in-plant and plant-to-enterprise serialization data objects and primary exchange types/ user cases. In parallel, the OPEN-SCS proposes to align all their work products with the GS1 US Healthcare, RX360 working groups and any other relevant healthcare traceability standard working groups yet to be identified.

An important 3rd phase and secondary focus (2016) of OPEN-SCS work in 2016 proposes to do build out a selected set data objects and exchanges using PackML and BatchML for the Level 2 packaging equipment event data (state model, recipe and optimization) for the Phase 1 set of packaging use cases. These two additional areas of data exchanges are the additional product and process T&T data objects and exchange types that are required at packaging lines for:

1. Batch genealogy for product release per regulations. This data are NOT required by serialization regulations and/or EPCIS exchanges.
2. Continuous improvement to optimize the efficiency losses of the new packaging line configurations required for serialization regulations.

These additional data sets are proposed to be a secondary priority addressed in later parts of the standard. The priority of OPEN-SCS standard's work products will be determined once the formalized OPEN-SCS officially finalizes the scope of their work products in Q2 2016 and may include a portion of non-serialization L2 and L3 data such as detailed batch and master data, recipe execution data, batch release data, scheduling performance data, OEE performance, quality data, recall analysis, etc.

The OPEN-SCS proposed scope addresses the following customer user requirements for standardized in-plant product serialization data and exchange types:

1. **Brand protection:** Shine a light on cargo theft, pharmacy theft, counterfeiting, and diversion.
2. **Chargeback or discount reconciliation:** The specific unit price can be identified to establish margin for sales price. Duplicate requests for discount or chargeback are discovered.
3. **Reverse logistics:** Aid recalls, returns, withdrawals, and shrink/loss recovery.
4. **Inventory control:** Getter insight into raw materials ordering and process scheduling.
5. **Workflow processes:** Increased productivity through reduced physical handling and decreased errors.
6. **Marketing:** Build consumer trust through verification (authentication) via online portal or 800 number. It's not part of the U.S. law, though it could be part of the legal framework in other countries.
7. **Asset visibility:** Opens the door to the possibility of logistics transparency, including cold chain monitoring.
8. **Order-to-cash:** Increasing visibility of exactly what items were delivered to a specific customer and where the goods traveled, for proof of delivery and authorization of payment.
9. **Perfect order fulfillment:** Improving visibility of the exact item and quantities delivered and catching incorrect orders (caught when an attempt to authenticate an item shipped in error is made).
10. **Returns:** Ability to detect returns that were not originally.

The OPEN-SCS proposed scope for package line T&T systems is covering the following 3 main functional aspects:

- Serialization
- Aggregation
- Data Management
- Interface Design

The OPEN-SCS proposed scope addresses common packaging line configurations and associated industrial IT architectures from simple to most demanding / complex uses cases (not finalized and not limited to):

- Serialization at a single manual packaging line
- Small operation with only few products to be serialized and no IT Landscape in the production process
- From simple to most demanding / complex required architectures
  - "Stand alone" unit to serialize products
  - System that must run autonomous and generate/provide the serialized data
  - Extendable to Aggregation
- Serialization & Aggregation at multiple different packaging lines: Small, medium and larger operations
- Rework operation in a dedicated area or a standard packaging line of an already serialized batch
- Warehouse Extensions for packaging line in the finished good warehouse at plant (MES/ERP) or distribution center (ERP)
  - Re-Aggregation
  - Shipment
  - Goods Receiving
  - Re-Works
- Required exchanges and interfaces for centralized management architecture of (not limited to):
  - Serial numbers (Allocation, unused, authentication)
  - Product information (Product ID)
  - Batch data
  - Recipes
  - User information
  - Audit trail

Packaging Line Serialization Operations Activities and Systems Defined by ISA-95 Models

The ISA-95 is an international standard providing a proven framework for defining User Requirement Specification and Functional Requirement Specifications (URS / FSR) in compliant GAMP form for:

1. Manufacturing operations management (MOM, Level 3) work processes and support systems
   a. Production Operations Mgt. (ex. FCS, Historian, PLM, and MES)
   b. Quality Operations Mgt. (ex. QMS, SPC, and CAPA)
   c. Inventory Operations Mgt. (ex. WMS and Receipt and Inspection)
   d. Maintenance Operations Mgt. (ex. CMMS, Calibration, and EAM)
2. Inter-Level 3 Data exchanges between MOM functions and systems
3. Level 3 MOM data exchanges between Level 4 enterprise resource planning (ERP) and logistics systems

Note: Refer to Appendix B: ISA-95 Overview for the basic definitions of the Parts and Models addressed in this document. For a better understanding of how to apply ISA-95, refer to www.isa.org.

The ISA-95 standards have been widely adopted across manufacturing companies in continuous, batch and discrete industries and by system suppliers for defining the operations and associated systems of various Level 3 MOM processes and their data exchanges between Level 4 enterprise business processes and their associated systems.

The ISA-95 standards currently have approved 5 parts with Parts 1 and 2 defining the fundamental models and data objects for a framework for exchanging data between Enterprise (Level 4) and Manufacturing Operations Management (Level 3) systems. In 2010, updated versions of both Parts were released. The updates incorporate feedback from users of the standard gained over 10 years and the knowledge gained writing Parts 3, 4 and 5.

Part 3 specifically defines Level 3 of the Manufacturing Functional Hierarchy Model; MOM activities, functions defining each activity, tasks defining each function, and data exchanges between each functions for each activity model. Part 3 is widely used by manufacturing companies to describe their Level 3 MOM requirements and functions for their operations in URSs and supporting systems' FRSs.

Part 4 defines the Level 3 data objects for data exchange between each function within Level 3 (MOM) activity models.

Part 5 defines the transaction types for exchanging the data objects defined in Parts 2 and 4.

In developing a GAMP URS to healthcare regulations, transactions and manual data exchanges between business and operations processes are able to be clearly specified. In the context of the OPEN-SCS's serialization standards development, all the Parts of the ISA-95 framework will be used to define Level 2 and 3 data objects and exchanges between Levels 2, 3, and 4 for common packaging line configurations. Figure 11 shows the six proposed packaging line serialization system configurations with data exchanges from the September 2014 Roundtable. Process and work functions are classified in activity levels as a co-dependent functional hierarchy, not as a hierarchy of organization, systems, or physical location. The ISA-95 framework provides a single terminology for defining a packaging line in an Operations URS and the associated systems FRSs for defining the Levels 2 and 3 activities and exchanges for packaging line serialization and T&T functions, tasks, and exchanges.

One major issue is the widespread misinterpretation by end users, vendors and solution providers of their incorrect use of the ISA-95 Functional Hierarchy Model and the Role-based Equipment Hierarchy model. Most are incorrectly mapping an entire system to a role-based equipment hierarchy level as opposed to define the system across the Functional Hierarchy Levels. In the standard, the ISA-95 Levels are explicitly defined by functions, tasks, and data exchanges between functions and tasks.

Systems are mapped to the enterprise's role-based Equipment Hierarchy Model as a location or scope of use. For planning and finite capacity scheduling requirements, the Level 2 and 3 functions and tasks for the four MOM activity models are best mapped to each system by their location in an enterprise, site, area, or line within the Role-based Equipment Hierarchy model. The system and architectural requirement choices of what equipment-role level "should" contain what Level 2 and 3 functions and tasks depends on (but not limited to):

1. Timing requirements of data exchanges supporting operations and business processes per rule sets
2. The rate and type of expected change management per activity and function due to characterization/optimization of Make-to-order and new product introduction (NPI) work processes,
3. Operations order mix/type (% of Make-to-order to Make-to-stock and their changeover complexity)
4. Estimated amount of continuous improvement changes

This OPEN-SCS's packaging line serialization standard is aimed at serialization and aggregation of healthcare products on the packaging lines in the plant and warehouse equipment and then at exchanging serialization information with the enterprise business systems. This proposal serves as a blueprint on how each data exchange should be standardized and implemented to meet the following goals:

- Define and simplify the base roles for each actor
- Define the communication protocols used for each connection point
- Enable greater flexibility in terms of the serialization architecture available to the industry
- Reduce integration cost and delays of different products from different solution vendors

As shown in Figure 11, the OPEN-SCS proposed scope of serialization standards and implementation system URS/FRSs will focus on six different solution architectures for packaging line serialization and aggregation. These architectures will be characterized using the ISA-95 models to baseline and define the integrations covered by serialization standard.

Example of an explanation of the sample architectures:

1. A L2 serialization unit controller application has a site server with L3 MOM functionality as single application architecture co-exist in the packaging area with a L3 serialization manager vendor also has a site server with L3 MOM functionality as single application architecture. While this could be viewed as overlapping since both could be interpreted as an L3 system, each solution has its own distinct roles so this does not affect the overall workflow.
2. The L2 serialization unit controller is autonomous with no L3 MOM functionality on the L2 packaging lines in a plant and warehouse. The L2 unit controllers have a finite set of data exchanges as business process triggers to the enterprise-level enterprise resource manager that hosts L4 planning and logistics services and no L3 MOM functionality services in a serialization server. Even if there was a site serialization server in this scenario, the overall workflow is the same and again not affected as the L3 MOM functionality for serialization are supported by a MOM solution architecture such as an MES, PLM, Batch Execution System, Recipe Management, or manual MOM paper-based operations processes and activities.

This is why the proposed standard scope focuses on the roles of each serialization solution architecture (aka, actor) and how they are to communicate to the process mapped to the ISA-95 model.

As part of the implementation System FRS's, the L2, L3, and L4 functions and tasks of each solution's architecture will be mapped in detail to ISA-95 activity models by the function, tasks and data exchanges. The primary goal of this effort is to standardize the communication between 1) the L3 serialization manager and L2 the serialization controller and 2) the L3 serialization manager and L4 enterprise managers.

Packaging Line Product Serialization T&T Actors and Roles

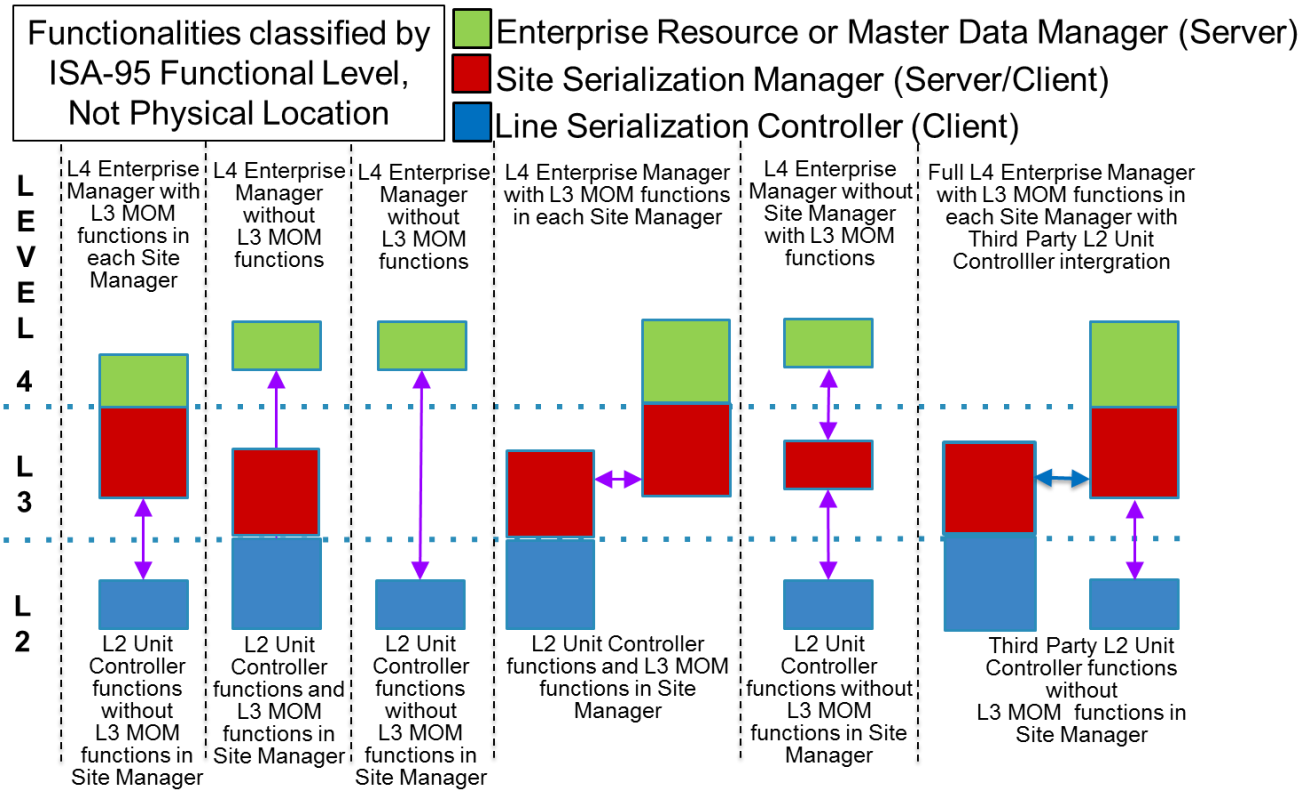
For the purpose of this document, four actors are defined (not limited to and will be further defined during standard development):

- **Line Serialization controller**
  - Equipment installed at the packaging line level with or without site L3 MOM functionality depending on the serialization solution architecture.
  - **Role:** Control equipment at the packaging line to apply serial numbers and record the events related to serialization to report to the serialization manager.

- **Site Serialization manager:**
  - L3 MOM architecture and functionality at the site and/or corporate level to manage the L2 and L3 serialization master data and L3 Serialization operations work processes.
  - **Role:** Provide to the serialization controller: 1) unique and valid serial numbers and 2) master recipe unit procedures and operations
  - **Role:** Serve as a master repository for L2 data and events collections from serialization controller
  - **Role:** Provide data exchanges for L2 and L3 data and events collections to enterprise resource manager
  - **Role:** Packaging order management: manage order header information (stand alone or received from L3/L4 System) and send order header together with recipes and serials to L2
  - **Role:** Centrally manage labels content (for pallets & shipper cases) and send label content to L2 as part of recipe
  - **Role:** Provide consolidated line status/monitoring

- **Enterprise Serialization Master Data Manager and Resource Manager:**
  - **Role:** Provide to the serialization manager and/or serialization controller:
    1. Unique and valid serial numbers
    2. Master recipe for serialization format
    3. Tracking used and unused released serial numbers
  - **Role:** L4 Enterprise architecture for product serialization T&T has functionality for planning, logistics and master repository (all batch, master data, and product T&T data from packaging line to patient) for Supply Chain operations and plant/warehouse packaging operations.
  - **Role:** Communicates serialization data to governmental database or to other trading partner (depending of the regulations).
  - **Role:** For a CMO scenario, manage serial numbers from the CMO customers' L4 Enterprise Resource Manager.
  - **Role:** For a CMO scenario, Send serialization for products in an L4/L4 exchange to CM) customers' L4 Enterprise Resource Manager.

Figure 11: Six Proposed Packaging Line Serialization System Configurations with Data Exchanges.
Functionalities are classified by the ISA-95 Functional Hierarchy Model by Level.



4. Proposed Packaging Product Serialization T&T Exchange Services for Actors

There are two categories of connection points covered in the proposed scope of the Open T&T Standard:

1. **Mandatory Services**
2. **Supporting Services**

Once the OPEN-SCS is formalized, the scope of Phase 1 and subsequent parts will be agreed upon.

1. **Mandatory Services** are the proposed bare minimum required for the packaging line serialization process by most end users and country regulations as of the September 2014 Round Table. Proposed Mandatory Services as the primary focus of Phase 1 in the Open Serialization T&T Standard are as follows (Subsequent Parts will be determine during the draft of Phase 1):
    1. **Serial Number Manager:** L4 Serial Number Provisioning function for 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 the L2 serialization unit controller.
    2. **Electronic Product Code (EPC) Repository:** An enterprise L4 central repository for the disposition and aggregation status of all EPCs produced by packaging line at plant or warehouse.
    3. **Batch and Master Data Repository:** L3 MOM function and its tasks in a site or enterprise level central repository for L2 and L3 batch and master data required to configure the 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:** L3 data collection and L3-L4 high volume interface to obtain the disposition and aggregation status of all EPCs linked to a batch identifier.
    6. **Serial Number Inquiry:** L3 data collection and L3-L4 high volume interface to obtain the disposition and aggregation status of a specific EPC.

2. **Supporting Services** are the proposed bare minimum required for the packaging line serialization process by most end users and country regulations as of the September 2014 Round Table. The proposed Supporting Services as the primary focus of Phase 1 Standard vs. the implementation System FRSs will be determined by the formalized OPEN-SCS's drafting of Part.
   The proposed Supporting Services are as follows:
    1. Work and re-work tasks in the Supply Chain (warehouse and distribution center line or work cell)
    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. Supports/enables 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)

Recommendation: The Phase 1 Standard will address standard business case error responses for the packaging serialization use cases such as Serial Number Request, Batch Master Data Request, and Full Batch Import.

Business Use Case Error Examples:

- Serial Number Request
  - Batch Number does not exist (in L3/L4)
  - GTIN does not exist (in L3/L4)
  - Company Prefix does not exist (in L3/L4)
  - Chinese Sub-Type does not exist (in L3/L4)
  - National registration e.g. Brazil ANVISA registration number does not exist (in L3/L4)
  - Batch Number not specified but mandatory (for a L3/L4 which would be configured to only accept request with a specified batch number)
  - Quantity not specified but mandatory (for a L3/L4 which would be configured to only accept request with a quantity)
- Batch Master Data Request
  - Batch Number does not exist
  - Process Order Number does not exist
- Full Batch Import
  - Batch Number does not exist
  - Batch Number in a status not allowing rework

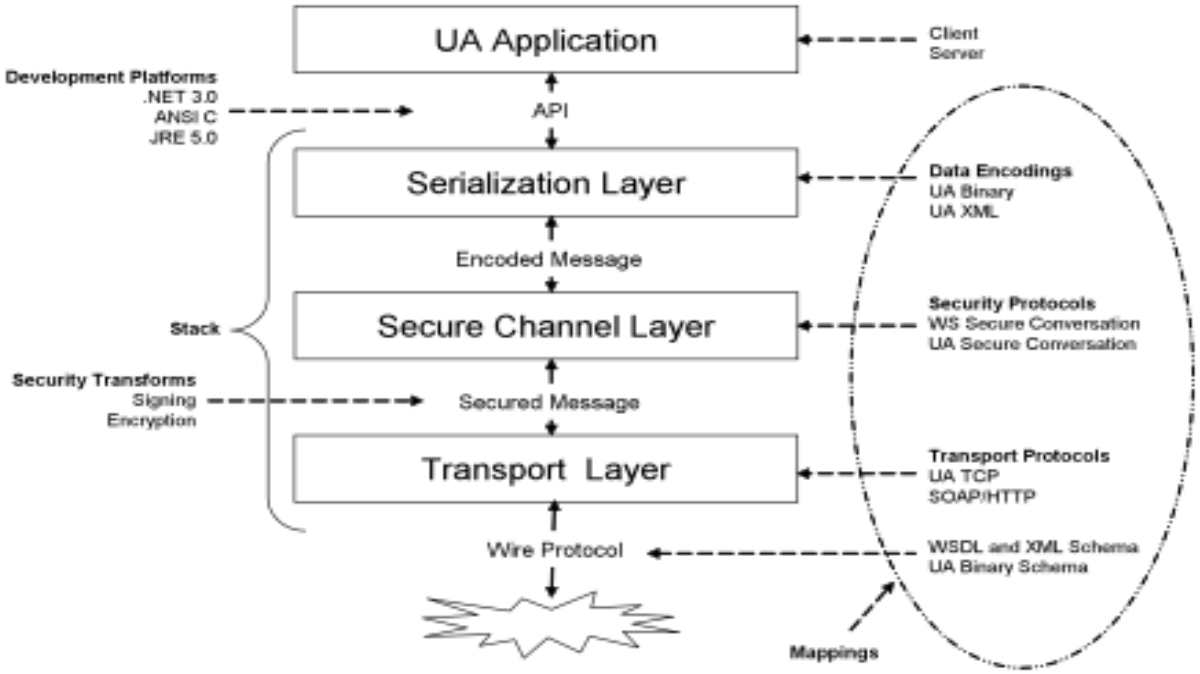
These business case errors will be determined by survey of the OPEN-SCS members.

Proposed Scope of Open Systems Interconnection model (OSI) in Serialization T&T Standard

Recommendation: In developing the proposed the Phase 1 Serialization T&T standard, coupling OSI Transport Layer and the Data Presentation Layer (Refer to Appendix C, (13)) in the standard is not a recommended or common practice for integration standards. The proposed Serialization T&T Standard focuses on the uses cases, data objects, and exchanges in a technology-agnostic way and then the standard data objects are mapped to suitable communication technology examples as shown in Figure D1 for serialization data presentation layer in the OPC UA Stack Overview.

The layers described in the OPC UA specification do not correspond to layers in the OSI 7 layer model in one-to-one mapping. Each OPC UA Stack Profile should be treated as a single OSI Layer 7 (Application) protocol that is built on an existing Layer 5, 6 or 7 protocols such as TCP/IP, TLS or HTTP. The Secure Channel layer is always present even if the Security Mode is None.

Figure D1: Serialization Data Presentation Layer in the OPC UA Stack Overview (11)



The serialization system FRSs and associated implementation guidelines will define client and server agreements and what this communication technology approach is best for the requirement. This is exactly what OPC UA Part 6 explains (Refer to Appendix D).

Recommendation: Modelling the data presentation to process is recommended to be done by companion operations management standards such as ISA-88 (Batch and Recipe Execution) or ISA-95 (Enterprise-Control Integration and Manufacturing Operations Management Activities).

Recommendation: The Data Presentation Layer for each service will be the *Normative* clauses in the Phase 1 standard; the Transport Layers technologies and methods for each solution architecture will be written as *Informative clauses* as sample System Function Requirements Specifications (FRS) for suggested company serialization implementation standards and design documents. Sample System FRS will be developed for the use of EPCIS and OPC-UA approaches for each solution architecture where each System FRS maps all the data objects into the XML schema and between schemas for reference and co-application.

The OPEN-SCS and Steering Committee will finalize scope for the implementation System FRSs as to which OSI Layers and technologies for each layer are to be addressed such the use of SOAP web services under the OPC-UA standard, Jason (with or without XML schema,) or RESTful services. While SOAP has broader support in the industry and is more explicit, Jason and REST are a more lightweight protocol. Also, these technologies have relatively the same advantages:

- Firewall friendly
- Platform agnostic
- Ease of support / troubleshoot

In the *Normative* clauses of Phase 1 standard, a strict separation of client and server roles will be defined. The serialization unit controller and the serialization manager have both the client device (requestor) and service host (server) roles depending service and its supported data exchanges. The proposed communication policy will be for synchronous transactions but can chain (trigger another synchronous request on the requestor). This allows a clear definition of the requestor vs. server roles of each actor.

Note: Using a synchronous call does not impose a uniform performance requirement on all calls such as required timings to support business processes and guaranteed delivery order. For example, the serial number inquiry is used in context of a user wanting to obtain the information of an EPC. It is therefore implied that the expected performance of such a call is limited by the patience and the expected work efficiency of the user making the call. It is understood that some solution architectures and their associated System FRSs may have more issues delivering the requested data in the expected delays; but such limitations do not change the fact that the user still need the data to be returned and has to wait for it. Rendering meaningless the fact, the connection needs to stay open while the user is waiting when using synchronous calls. As well, developing regulations could requirement security and transaction validation requirements.

Proposed Scope of the Mandatory Services for Phase 1 of Open Serialization T&T Standard

GS1 EPCIS protocol is primarily focused and applied on use cases between the enterprise (L4 functions) and the supply chain (L5 functions) platforms of the trading partners/providers across the supply chain. The proposed Mandatory Services for the Phase 1 Standard has a small set of data objects from the EPCIS standard for L2/L3 and L3/L4 data exchanges. Unfortunately, one of the most complex and costly parts of today's available serialization solution is end user and vendor custom specifications for packaging line serialization exchanges between L2 and L3 and between L3 and L4.

When selecting a vendor/partner, the capability and flexibility to implement T&T solutions into existing business IT architecture have become the #1 decision criteria. In particular:

- Interfacing with the existing IT infrastructure from Enterprise (L4 tasks) through to Packaging Line (L2 tasks)
- A validated, GAMP-compliant "Core Solution" with a reliable "Change Management Process"

The real challenge of this effort to develop a packaging line serialization standard is to get a majority of the vendor members of the Open Architectures T&T Roundtable to agree on global objects for a specific set of exchanges for specific equipment types, product types, and line configurations. So the real question is how obtainable is this effort? If so, as part of the OPEN-SCS's operating process (that will be written once formed), a OPEN-SCS Steering Committee of 4 end users in a total of 9 voting members will determine by simple majority vote the final reference data objects and communication technology approaches for System FRSs for the formal draft standard development. The review and approval process for the formal draft standard and implementation System FRSs will be written when the OPEN-SCS is formalized. If the OPEN-SCS Steering Committee accepts the recommendation for collaborating with the OPC Foundation to host the OPEN-SCS, the OPEN-SCS will use the OPC working group processes as foundation adapted to the OPEN-SCS specific needs.

Ultimately once the OPEN-SCS standard and implementation system FRSs are approved, industry adoption will be confirmed by a majority of vendors creating a set of interface adaptors for their current object set, a set for the standard data objects, and a documented mapping between the two.

Note: To drive rapid industry adoption, all parties (vendors, end users, and system integrators) must openly acknowledge that the outcome of this effort is that no one vendor or end user's current data set will be the standard.

Note: When "L3/L4" is indicated, it refers to the serialization server. Otherwise, ERP/MRP/MES are indicated which have various possible repository for the manufacturer master data (Batch #, Expiration, Product Name, Quantity per package, etc.)

Proposed Mandatory Services and Exchanges Specifics and Use Cases

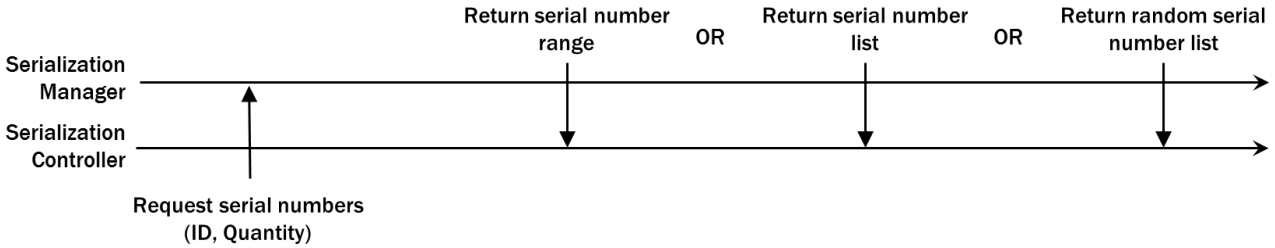
1. **Serial Number Provisioning**
   a. **Request Serial Numbers by Product ID, Batch ID, Quantity**
   b. **Return Serial Number Range**
   c. **Return Serial Number List**
   d. **Return Random Serial Number List**

Initiator: Serialization Controller

Host: Serialization Manager

Type: Synchronous

Process: The serialization controller provides a *Requestor ID* when requesting a specific number of *Serial ID*s for a specific *Product ID*.



Considerations:

- Exchange 1.1: L2 or L3 Request for serial numbers
  - Use Cases:
    1.1.1. L2 specifies the number of serial numbers for *Product ID*
    1.1.2. L2 specifies *Batch ID*
    1.1.3. L3 specifies *Product ID* for 'replenishment' of serial numbers
  - Serial Number ordering:
    - L2 makes a request specifying a sequential list
    - L2 makes a request specifying a randomized list
    - L2 makes a request specifying a range list
  - Serial Number types:
    - SGTIN (L2 makes a request based on a GTIN)
    - SSCC (L2 makes a request based on Company Prefix)
    - E-Code (L2 makes a request based on Chinese Sub-Type)
    - IUM (L2 makes a request based on a Brazil ANVISA registration number)
- Exchange 1.2: L3/L4 Response sends L2 a range of serial numbers
  - Use Cases: Serial Numbers)
    1.2.1. Only start and end numbers are sent
    1.2.2. A complete list
- Exchange 1.3: L3/L4 Response sends L2 a sequential list of serial numbers
  - Use Cases: Serial Numbers
    1.3.1. Only start and end numbers are sent
    1.3.2. A complete list
- Exchange 1.4: L3/L4 Response sends L2 a random list of serial numbers
  - Use Cases: Serial Numbers
    1.4.1. A complete list

- Exchange 1.2, 1.3. 1.4 Response Information includes:
  - Prefix
  - GTIN for SGTIN
  - Company Prefix for SSCC
  - Chinese Sub-Type and packaging ratio for E-Code
  - Brazil ANVISA Registration Number for IUM
  - (Optionally) Batch number (if it was specified in the request)
  - Also an "Acknowledge" standard message must be defined

As stated, the use of a specific and unique *Product ID* refers to a specific packaging level and product to identify the serial number pool the request is aimed at.

The Request as a single call for a given lot number, which can be traced back to an appropriate set of *Product ID*s and quantities, would be more efficient as opposed to making individual requests for *Serial ID*s; but the reality of the packaging process requires the support for individual requests to accommodate the need for extra serial numbers at the very least. To keep the set of connection points as simple as possible, the proposed suggestion is to prohibit overlapping services when possible and leverage a combination of the suggested services instead.

Recommendation: The use of a *Batch ID* and UOM to request serial numbers should be explained as optional even though it is presented in 2 use cases. In many implementations, the batch number is not specified when serial numbers are received from the Enterprise Master Data Manager so the Site Serialization Manager can apply downloaded numbers across large quantities for a number of Batch IDs. This insures that the packaging lines within plant are not down if the L3/L4 interface is lost. Therefore, it is important to keep this functionality for the batch number to be optional. The unknown to be discussed: How does this 3/4 interface process translate to a company's business or regulatory requirement?

A *Requestor ID* is also passed to enable a Serialization Manager to hold multiple pools for a given *Product ID*. This *Requestor ID* can be used to choose which pool to issue serial numbers from.

Note: The *Requestor ID* does not necessarily identify the requesting system, but the context in which the request is made (i.e.: for a given customer, from a given location, etc.)

Note: For serial number provisioning, the formalized Open T&T Working Group should consider if it would be better to use *Batch ID* and *Packaging Level* (optional) rather than the *Product ID* since some working group members may consider that the *Product ID* should be implicit from the *Batch ID*. This recommendation is not suitable for every L2 controller architecture configuration and so should be explained in the URS and System FRS Template as one or another.

Note: The proposed exchanges pass the serial number portion of the EPC and not receive the full EPC? The formalized Open T&T Working Group should consider the possibility for the disconnect between the serial number that is sent and the EPC that is finally generated. How is this validated? Secondly, this means a response file is more than 50% smaller. However, the standard and URS/FRS Templates must allow for the full EPC as well; especially, if the L2 is encoding in RFID. Thirdly, The OPEN-SCS should consider the expected response format should be indicated in the request message (e.g. S/N only, full RFID SGTIN-96 or SGTIN-198, etc.).

Note: When requesting serial numbers, the formalized Open T&T Working Group should consider additional information requirement:

1. Qualifier for Product ID? Is it GTIN, Internal, Country Specific code?
2. Location for which Serial Numbers are requested. This could determine the range/prefix of number.
3. Some sort of request ID.

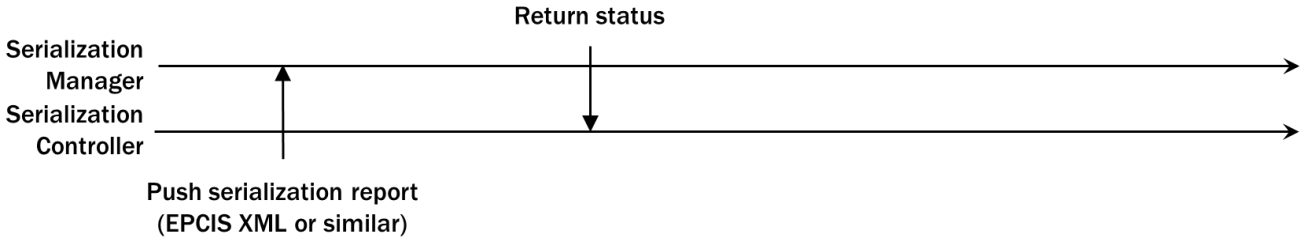
2. **EPC Repository**
   a. **Push Serialization Report**
   b. **Return Status**

Initiator: Serialization Controller

Host: Serialization Manager

Type: Synchronous

Process: The serialization controller will push the serialization report in the form of an EPCIS XML to the EPC repository. Some L2 Serialization Controller configurations store serial numbers for a few batches ahead. An EPCIS report or similar is sent after a batch (or container) is completed with no relationship to the serial number requests. Some country regulations such China requires L4 Enterprise Master Data Manager to send L2 Serialization controller and/or L3 Serialization Manager a range of serial numbers.



Considerations:

- Exchange 2.1: L2 Response pushes the serialization data report to L3/L4
  - Information include:
    - Report ID
    - Batch Number
    - Expiration Date
    - Other information required by a specific legislation (Plant Manager for example for the Chinese Reports)
    - Object Event **(EPCIS)**
      - **Commissioning Event**
      - **Decommissioning Event**
      - **Destroying Event**
      - **Deactivation Event**
      - **QA_Sampled (Quality Assurance Sampled)**
      - **Label_Sampled (Label Sampled)**
    - Aggregation Event **(EPCIS)**
      - **ADD (children added to a parent)**
      - **DELETE (children removed from a parent)**

Note: **BLUE** items handled by a standard EPCIS event. **RED** items could be part of an EPCIS message but not covered by the official EPCIS standard.

- Exchange 2.2: L3/L4 Response pushes the serialization data processing status
  - Information include:
    - Report ID
    - Report Processing Status
  - Use Cases
    - 2.2.1: Report processing started
    - 2.2.2: Report processing complete
    - 2.2.3: Report processing failed

Note: Exchange 2.2 would be asynchronous with Exchange 2.1. The reason being that the L3/L4 might "loose" the report and never process it. The other reason being that it can take hours until the L3/L4 is done with the processing part.

EPCIS Events:

- Requires support of only two event types
  - ObjectEvent
  - AggregationEvent
- Small subset of actions and disposition reported :
  - Commissioning (ObjectEvent, disposition Active, action ADD)
  - Aggregation (AggregationEvent, action ADD with epcList)
  - Destroy (ObjectEvent, disposition Destroyed, action DELETE)
  - Deaggregation (AggregationEvent, action DELETE, only used to send revisions to previously reported events)
- Reduced overhead / batch events
  - One commissioning events per packaging level (containing all the EPCs of that level)
  - All destroy events in one event
  - Final status only
- Commissioning events for all EPCs linked to a unique Batch ID, UOM and Master Data ID through EPCIS extensions
  - Non vendor specific namespace "epc_data"
  - EPCIS 1.0.1 extension model (compatible with EPCIS 1.1)
- Other industry requirements?

Implementation:

- Communication status in SOAP response:
  - Equivalent to standard HTTP status
  - Main statuses:
    - 200 = Success
    - 500 = Error

Note: Where the ISO Transport Layer should not be coupled with Data Presentation Layer in the Phase 1 Standard, the statuses should not be defined with a specific standardized number. Leave the definition of those codes to the Transport Layer specified in the URS/FRS templates for the use cases. These numbers are not relevant to the serialization process, only to the technical implementation of a (communication) part of it.

When the implementation FRS standard is considered by the formalized Open T&T Working Group, the code statuses of rejects (scrapped destroyed, print error, unused, etc.) should consider recommending this as an uploaded exchange in batch to avoid too many requests.

Note: The formalized Open T&T Working Group should consider uploading hierarchy in batch to make the protocol less chatty (Aggregation events in batch if using EPCIS compatibility).

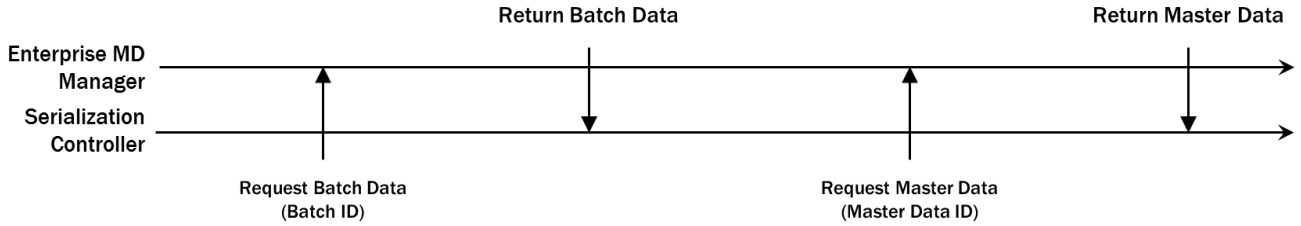
3. **L2 and L3 Batch and Master Data Repository**
   a. **Request Batch Data by Batch ID**
   b. **Return Batch Data by Batch ID, Product ID**
   c. **Request Master Data by Master Data ID, Product ID**
   d. **Return Master Data by Master Data ID, Product ID**

Initiator: Serialization Controller

Host: Enterprise Master Data Manager

Type: Synchronous, two distinct calls for L2 and L3 Batch Data and Master Data

Process: The serialization controller requests Batch and Master Data for a specific unique *Batch ID*



Considerations:

- Exchange 3.1:
  - L2 Request for Batch Data from L3 or L4 System
    - Batch Number or Production Order Number
  - L3 or L4 Response of Batch Data
    - *Batch ID*
    - Item expiration date
    - Quantity of items
    - *Master Data ID*
    - Packaging scenario (Used to refer to master data residing at the packaging line level)
    - Name-value pairs of custom elements (optional)
- Exchange 3.2:
  - L2 Request for Master Data from L3 or L4 System
    - Master Data ID or Product ID
  - L3/L4 Response of Master Data
    - Master Data ID
    - Unique *Product ID* (Ex.: GTIN)
    - Alternate *Product ID* (NDC, CNMC, custom…)
    - Product ID and/or Serial Number Prefix for each packaging level (E.g. Bottle, Carton, Bundle, Case, Pallet or simply Level 1, 2, 3, etc.)
    - Packaging level definition (one per packaging level)
    - Packaging level UOM
    - Child packaging level UOM
    - Number of children
    - Name-value pairs of custom elements (optional)
    - Production Order Number (Optional)
    - Batch Number (Optional)
    - Expiration Date
    - Manufactured Date (Optional)
    - Quantity of children in each packaging level (expect for the item level)
    - Quantity of item level to produce (Optional)

- Serialization ON/OFF for each packaging level
- Aggregation ON/OFF between for packaging level 2 and higher
- Print Layout Name for each packaging level
- Recipe ID (local set of parameters recorded at the packaging line controller)
- Recipe Description
- Any other packaging level specific information (Label Revision Number for example)
- Any other batch specification information (Manager Name for example is required for Chinese E-Code serialization report)

The process of initiating the request for L2 and L3 batch and master data from the Serialization Controller is as inclusive as possible for all architectures to define strict requestor-server roles for mapping the packaging process as closely as possible to keep the overall process as simple as possible (data is requested, data is provided).

The base of this type of request requires a key (usually a *Batch ID*/*Lot ID*). Consequently, one question is:

- How does the Serialization Controller obtain this information?
- Should OPEN-SCS support a use case for obtaining the batch key where the batch and associated numbers are dispatched to the line from L3 Scheduling to Serialization Manager? The plant floor user or L2 Controller requests the next batch and associated numbers which trigger a request from L2 to L3 to get the next batch data.

The possible use cases are:

1. User scans a barcode with the batch/lot number from a work order sheet (with the L2 controller scanner)
2. User enters manually the number on the L2 controller
3. ERP or other system pushes to the L2 the process order list (and the user chooses in it)
4. L2 requests from the ERP the currently pending batches and the user chooses it from a list

Since the serialization systems are part of larger operations supported by systems architecture, the information of what lot/batch needs to be produced is already available and required at the site/production floor level for many other tasks supported by other systems.

Second, in some circumstances, the moment at which batch and master data is set and would be pushed down may precede the moment when the selection of the packaging line is possible.

Architectural limitations aside, the only method that could have mapped to all processes encountered triggers the request from the Serialization Controller; hence, why this is the proposed method. Of course, feedback from the industry and working group members is required for consensus on the standard's direction.

Note: The formalized working group should consider having the Open T&T standard support a "subscription model" of L2 and L3 Batch and Master Data where the serialization controller is notified (with a *Batch ID* as the callback) of the existence of a new batch – as opposed to assuming that the *Batch ID* is always entered manually by an operator. With this subscription scheme, the serialization controller after being notified follow the sequence of retrieving L2 and L3 Batch and Master Data. This allows vendors to support only the protocol or extend it with the subscription scheme allowing also for "push" method.

Note: In line with the serial number provisioning consideration, based on *Batch ID*, the formalize Open T&T Working Group should consider the return using *Batch ID* and possibly packing level rather than *Product ID*.

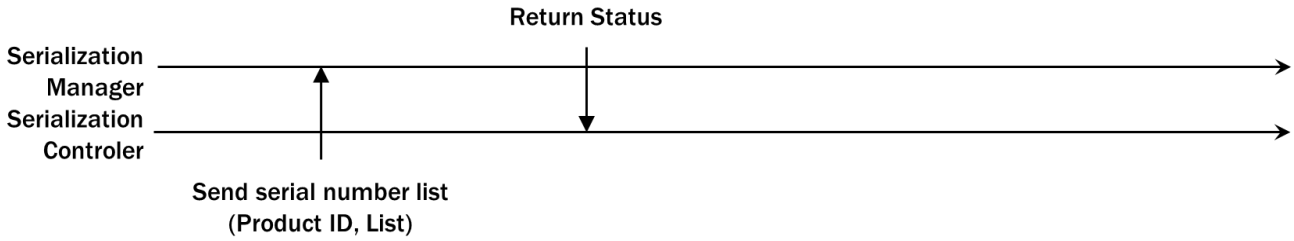
4. **Unused Serial Number Return**
   a. **Send serial number list by Product ID**
   b. **Return Status**

Initiator: Serialization Controller

Host: Serialization Manager

Type: Synchronous

Process: The serialization controller sends unused serial numbers in the form of a list



Considerations:

- Exchange 4.1: L2 Response pushes unused serial numbers to L3/L4
  - Information included:
    - Batch Number
    - Prefix (Product ID)
      - GTIN
      - Company Prefix
      - Country (Chinese) Sub-Type
      - Brazil ANVISA registration number
    - List of numbers OR “Start and End”
- Exchange 4.2: L3/L4 Response as an “Acknowledge” standard message must be defined

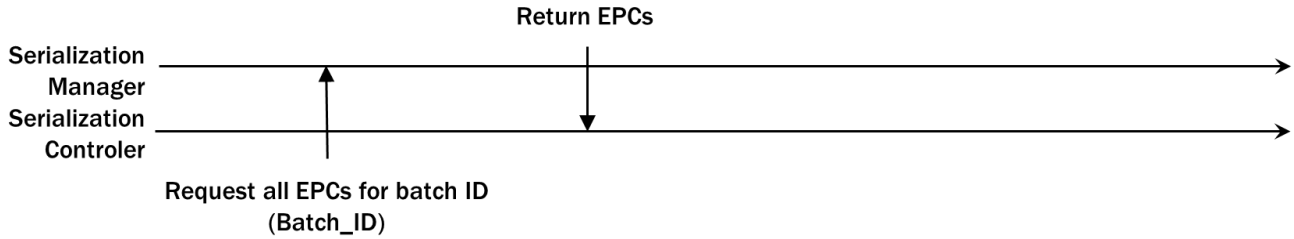
5. **Full Batch Import**
   a. **Request all EPCs for Batch ID**
   b. **Return EPCs**

Initiator: Serialization Controller

Host: Serialization Manager

Type: Synchronous

Process: The serialization controller requests all EPCs and their aggregation and disposition status.



Considerations:

- Exchange 5.1: L2 Requests the serialization data from L3/L4 (for rework purpose)
  - Based on a Batch Number

- Exchange 5.2: L3/L4 Response sends back the serialization data to L2 (for rework purpose)
  - Information to provide
    - Status of every serial number
      - Commissioned
      - Destroyed
      - Decommissioned
      - Deactivation Event
      - QA_Sampled
      - Label_Sampled
    - Parent of every serial number
      - Clear Indication if there is no parent

Information in the response:

- Iterations of EPC element:
  - EPC
  - Parent EPC
  - Disposition

6. Serial Number Inquiry (EPC Query)

a. Request information for EPC

i. Full Batch Rework

ii. Single Item

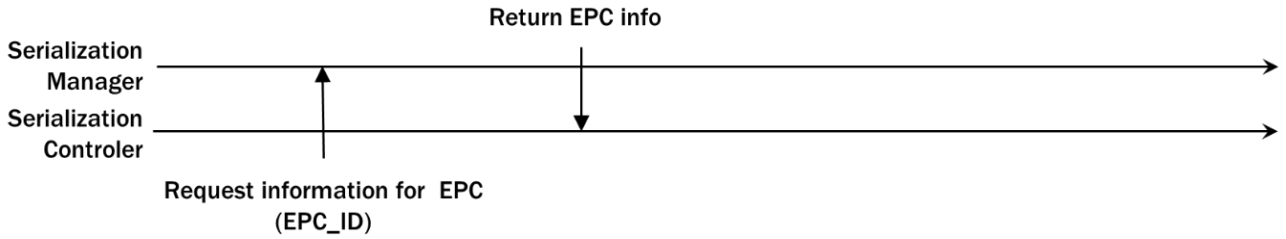
b. Return EPC info

Initiator: Serialization Controller

Host: Serialization Manager

Type: Synchronous

Process: The serialization controller request information for a specific EPC.



Considerations:

- Exchange 6.1: L2 requests the status of a serial number from L3/L4
  - Serial Number
- Exchange 6.2: L3/L4 sends back the status of a serial number
  - EPC (Serial Number)
  - Parent EPC (Serial Number)
  - Master Data ID (if available)
  - Batch ID
  - Disposition (Status: Commissioned, Decommissioned, etc.)
  - UOM (Unit of Measure: Name of the packaging level)
  - Child list

Note: Need address use case of “More than one lot number for a single EPC (or lack of a “master” lot number)”?

5. Milestones / Schedule for Formation of OPEN-SCS and Approval/Release of Standard

Milestones for the First Year Only:

- January 2015: Establish OPEN-SCS Steering Committee
- February 2015: Kickoff-Steering Committee Meeting
- March 2015: Final Draft of Feasibility Study to Steering Committee
- March 2015: Final Fund Raising Brochure and Send to all Open-SCS Members
- March 2015: Formalized OPC Working Group with signed MOU
- March 2015: Steering Committee Meeting
- May 2015: OPEN-SCS setup in OPC to manage revenue of sale of subscriptions for products
- June 2015: Finalize OPEN-SCS Website
- October 2015: Receive Product Subscriptions from Steering Committee members.
- November 2015: Final Business Case White Paper
- December 2015: Draft contracts agreed for Executive Director, and SME Architects
- December 2015: Send out Scoping Survey to members
- December 2015: Reach minimum required funding to start work: $260K USD. 20 members X $13K
- January 2016: Finalize contracts with OPEN-SCS SME Architect team
- January 2016: Begin work on URS and System FRSs V0.1
- January 2015: Send out final scope for Steering Committee vote
- February 2015: Final Scope
- March 2016: Release draft standard V0.1
- April 2016: OPEN-SCS User Group Face-to-Face Meeting to Finalize Standard and System FRSs.
- April 2016: Send out Final Drafts for vote and comment.
- April 2016: Comments due on Final Drafts
- May 2016: Send out second Final Drafts for vote and comment.
- May 2016: Comments due on Final Draft
- May 2016: Plan Phase 2 and 3 versions of work products
- June 2016: Release Final Standard and System FRSs

6. Estimated 2016 Budget for OPEN-SCS Formation and Standards Release

The estimated budget for OPEN-SCS formation and work required to develop, approve, and release standard and the System FRSs work products. The estimates are only best guesses since the final scope for the standard and the System FRSs work products is not established. The number based on the prior experience of Mr. Gifford from being a leading in standards committees for 20 years.

2016 Total Operating Cost Breakdown

Total Operations Cost:		**$360K USD**
Executive Director:	6 days per month x 9 months = 48 man/days x $1,200/day =	$57K USD
	Expenses = 4 trips x $5K =	$20K USD
Sales/Marketing Manager:	Covered in 2015 by Director and Steering Committee members	
SME Architects (2):	2 X 50 days = 100 man/days x $1,200/day =	$120K USD
OPC Operations Cost:		
Fee for services for the period March 30 to December 31, 2015. Includes BD Coordinator and Accounting services		$50K USD
OPC SharePoint and Web Site		$1K USD
Brochure and a subscription application form		$1K USD
OPC Total		$57K USD
Operating Cost SubTotal		$254K USD
Reserves for additional scope development, GS1/Rx360 Liaisons, marketing, and travel:		
	$390K - $254K =	$136K USD

The resources are required for OPEN-SCS to achieve the market penetration to adequate level in 2016 to be profitable enough for reinvestment necessary to scale business model.

2015 Revenue		**$390K USD**
Primary: OPEN-SCS Subscriptions for Open Source System FRSs	$13K USD x 30 members =	$390K USD

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12. OPC Unified Architecture Specification Part 2: Security Model, Release 1.02, OPC Foundation Inc., April 17, 2013
13. Open Systems Interconnection model (OSI), http://en.wikipedia.org/wiki/OSI_model

8. Abbreviation and Acronyms:

AI	Application Identifier
B2MML	Business-to-manufacturing-markup-language
BatchML	Batch-markup-language
BPR	Business Process Re-Engineering (BPR)
CBV	Core Business Vocabulary
CMO	Contract Manufacturing Organization
CMMS	Computerized Maintenance Management System
CNMC	
DQSA	Drug Quality and Security Act of 2013 (DQSA)
DSCSA	Drug Supply Chain Security Act (DSCSA)
EAM	Enterprise Asset Management
EMVS	European Medicines Verification System
EPC	Electronic Product Code
EPCIS	Electronic Product Code Information Services
ERP	Enterprise Resource Management
ESM	European Stakeholder Model
EU	European Union
FCS	Finite Capacity System
FDA	Food and Drug Administration
FRS	Functional Requirement Specification
GAMP	Good Automated Manufacturing Practices
GDSN	Global Data Synchronization Network
GEC	Global Economic Crisis
GLN	Global Location Number (GLN)
GMP	Good Mfg. Practice (GMP)
GTIN	Global Trade Item Number
IEC	International Electrotechnical Commission
ISA	International Society of Automation
ISO	International Organization for Standardization
ISPE	International Society for Pharmaceutical Engineering
IUM	
MES	Manufacturing Execution System
MOM	Manufacturing Operations Management

MOU	Memorandum of Understanding
NDC	U.S. National Drug Code (NDC)
OAGIS	Open Application Group Integration Specification
OASIS	Organization for the Advancement of Structured Information Standards,
OEE	Overall Equipment Effectiveness
OPC-UA	OPC Unified Architecture
OQ	Operations Qualification Test
OSI	Open Systems Interconnection Model
PackML	Packaging-markup-language
PLM	Product Lifecycle Management
PoD	Point-of-Dispensing (PoD)
PQ	Performance Qualification Test
QMS	Quality Management System
REST	Representational State Transfer
RFID	Radio Frequency Identification
SSCC	Serial Shipping Container Code
SGLN	Serialized Global Location Number (GLN)
SGTIN	Serialized Global Trade Item Number (GTIN)
SME	Subject Matter Expert
SNI	Serialized numeric identifier (SNI)
TD	Transaction document
TH	Transaction history
TI	Transaction information
TS	Transaction statement
OPEN-SCS	Open Serialization Communications Standard Working Group
UOM	Unit of Measure
U.P.C.	Universal Product Code
URI	Uniform Resource Identifier
URN	Uniform Resource Name
URS	User Requirement Specifications
WMS	Warehouse Management System
XML	eXtensible Markup Language

Appendix A: Supporting Research for Serialization T&T Standards Impact on Patient Safety

Product Integrity and Security

Counterfeit pharmaceuticals pose a significant threat to the viability of the Healthcare industry and patient safety. As supply chains become more complex and multidimensional the challenge of tracking products through the supply chain increases.

Pharmaceuticals consistently rank within the top ten categories for counterfeit goods and the risk to products can vary from country to country. In response Healthcare manufacturers are investing more in product security initiatives, such as serialization which involves coding products uniquely at the item level.

With so many solutions being presented, selecting the right technology or strategy can be its own challenge. There is great demand for standardized approaches to counterfeiting and solutions that can be rolled out globally, but this requires unity from Healthcare companies, vendors and trade associations.

"What is in common for everybody is once you lose direct control of your product it is very hard to, know where it goes to, how it is handled, how it is controlled," said Johannes Schoen, Senior Manager for Anti-Counterfeiting at Boehringer Ingelheim.

In addition to regulations, product integrity and product security are top issues. Concern about in-transit protection grows as products become more complex, often requiring temperature-sensitive transportation. As products travel further to new markets, the number of hand-offs increases, and supply chain visibility becomes even more important.

Among all supply chain executives, more in Asia-Pacific expressed concern about product damage and spoilage than in other regions. With China's projected 26%+ growth in Healthcare, their rapidly developed and release regulations are directed at securing product safety to eliminate a primary barrier.

Globally, product integrity remains a top supply chain concern for healthcare executives.

- 46% cite product security as a top supply chain concern
- 40% cite product damage or spoilage as a top supply chain concern

Figure A1: Top Global Challenges to Product Security (3)

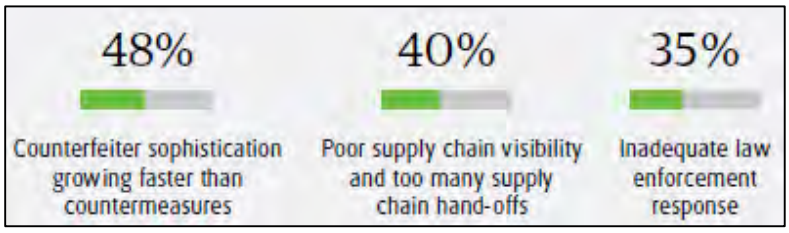


Figure A2: Top Global Challenges to Product Damage and Spoilage (3)

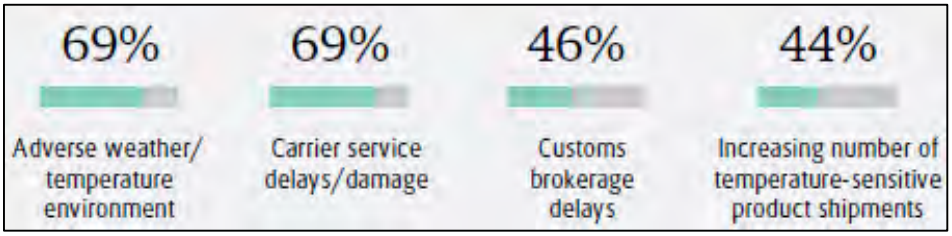


Figure A3: Serialization T&T Standards Impact on Patient Safety (5)

Table A4: The Potential Product Serialization Benefits to Pharmaceutical Manufacturers (5)

The potential benefits to pharmacuetical manufacturers

Source of value	Primary value drivers	Key assumptions	Impact estimate and potential for case-by-case variation
Reduce inventory assets	• Improve demand forecasting and inventory planning	• Inventory: 180 days • $600 million inventory assets (15% of revenue) •15% inventory reduction potential	• **$90 million one-time cash flow** • Base inventory holdings - does not vary drastically between companies
Reduce inventory financing and holding cost	• Reduce financing of working capital due to lower inventory assets • Reduce inventory management cost with more efficient and accurate processes	• $43 million inventory assets financing cost (cost of capital 7.1%) • $29 million inventory management cost (0.72% of revenue) • 15% financing cost and inventory management cost reduction	• **$11 million annual savings** • Base inventory holdings - does not vary drastically between companies
Reduce produce waste due to obsolescence	• Improve inventory management to shrink inventory levels and unused product	• $44 million obsolescence cost: 7.5% of inventory • 10% obsolescence reduction	• **$4 million annual** • Product portfolio - can vary supstantially for individual organizations
Reduce cost of recalls	• More efficient execution (increased supply chain visibility) • Reduce scope of recalls (better targeting)	• $1-2 milion cost per recall [41], not including product write-offs • 6-12 recalls per year[42] • 50% reduction in number of customers notified	• **$3-12 million annual** • Number and scope of recalls cost and savings could be signifigantly higher or a little lower
Reduction in counterfits and recovery lost profit	• Reduction in counterfit supply raises sales volume	• 6% of manufacturer's supply lost to counterfeiting • Ex-manufacturer price per pil of about $1.50 in developed countries, $0.20 in developing countries • 25-35% average reduction in lost sales • 70% gross margin	• **$25-35 million annual** • Highly dependent on extent of sales in high counterfeit markets and type of products sold, P&L impact estimate can vary substantially

[41] Typical "small" recalls – exceptional and large recalls can cost hundreds of millions of dollars or more
[42] Typical range of recalls by pharmaceutical manufacturer, from FDA Gold Sheet 2011

Appendix B: ISA-95 Overview

Appendix B is Chapter25 from the International Society of Automation's (ISA) book, Guide to Automation Body of Knowledge, 3rd and 4th addition. This chapter was authored by Charlie Gifford, 21st Century Manufacturing Solutions LLC., Chair and Founder of the ISA-95 Best Practices Working Group, Voting Member of the ISA95 Committee for 15 years.

Mastering the Activities of Manufacturing Operations Management

Understand the Functional Level 3 above automation and control and below the enterprise

B1. Introduction

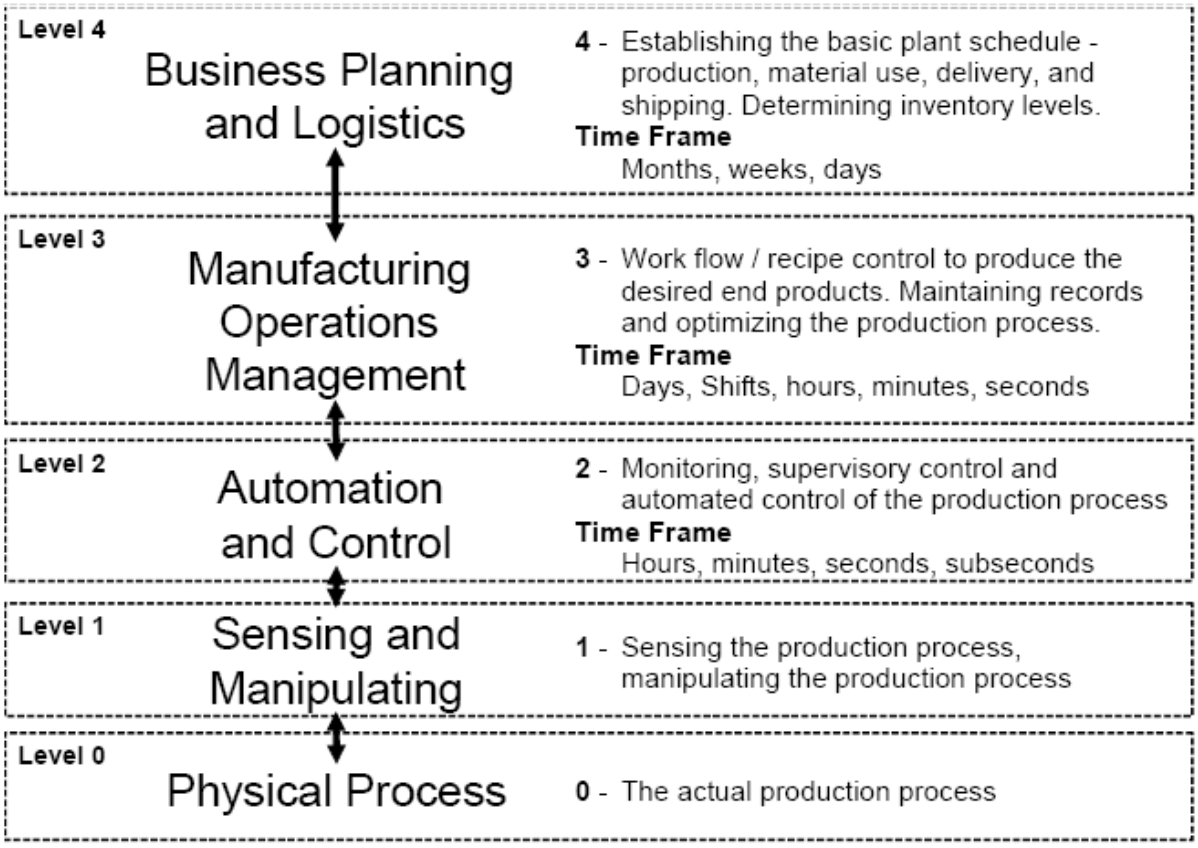
Automation only begins with equipment control on the plant floor; Automation also includes higher levels of control that manage production workflows, production orders and resources such as personnel, equipment, and materials across production areas. Effective manufacturing in the plant and across its supply chain is only partially based on equipment control capability. In an environment executing as little as 20% make-to-order orders (80% make-to-stock), resource optimization is critical to effective low cost order fulfillment. In the 21st Century global market, manufacturing companies must be efficient at coordinating and controlling resources (personnel, materials, and equipment) across different operations and control systems to reach their maximum potential. This is usually accomplished using industrialized manufacturing applications systems and documented execution and governance procedures. These systems are collectively called the "Manufacturing Operations Management" (MOM) functional level. MOM defines a diverse set of functions and tasks to execute production orders while effectively applying resources above automation control systems; these operations functions reside below the functional level of enterprise business systems; and they are typically local to a site or area. This chapter explains the functions of the MOM layer and how these functions integrate between each other for production optimization and within the context of other corporate business systems.

The term, MES (Manufacturing Execution Systems), described in earlier editions of this book was defined by AMR in the early 1990s was a high level explanation that did not describe the actual functionality set in general or in a vertical industry way. MES did not explain the inner MOM data exchanges (Level 3 in figure below) or the business Level 4 exchanges. MES for the most part has been a highly misunderstood term in manufacturing methods and systems. This term was primarily based on defining production management for a 20th century make-to-stock manufacturing environment. MES was focused on describing the execution and tracking of a production order route/sequence and associated material transitions; not on the execution of critical supporting operations such as quality, maintenance, and interplant inventory movement to effectively utilize available resource capabilities and capacity. This is key to cost effectiveness in operation manufacturing for make-to-order or lean pull supply chains. In ANSI/ISA-95.00.03-2005 - *Enterprise-Control System Integration, Part 3: Models of Manufacturing Operations Management (MOM)* standard, the basic MES definition was incorporated into the Production Operations Management (POM) activity model functions. The ISA-95 Part 3 Activity Models includes definition, which describes the actual functions, tasks within functions and data exchanges between functions. No MES definition does this. AMR Research currently updated their MES definition to use the term Manufacturing Operations System (MOS), which is a system abstraction from ISA 95 Part 3 instead of their own MES term. The ISA-95 Part 3 POM activity model is supported by activity models for Quality Operation Management (QOM), Inventory Operations Management (IOM) and Maintenance Operations Management (MaintOM); these four activity models define all the Manufacturing Operations Management (MOM) activities (functions, task, and data exchanges) for the *Purdue Enterprise Reference Architecture and Functional Model's* Level 3. Since 2006, ISA-95 Part 3 is the primary requirements definition template used by 80% of manufacturers worldwide to define their Level 3 MOM systems in their Requests for Proposals (RFPs).

The ISA-95 standard defines 5 levels of functions and activities of a manufacturing organization as originally described in the *Purdue Enterprise Reference Architecture (PERA).* Automation and control supports Level 1

and Level 2 while Level 3 Manufacturing Operations Management (MOM) supports Level 4 enterprise level to fulfill production and operations orders as shown in Figure B1.

Figure B1: Functional (Activity) Hierarchy in a Manufacturing Company



- ***Level 0*** defines the actual physical processes.
- ***Level 1*** defines the activities involved in sensing and manipulating the physical processes. Level 1 elements are the sensors and actuators attached to the control functions in automation systems.
- ***Level 2*** defines the activities of monitoring and controlling the physical processes and in automated systems this includes equipment control and equipment monitoring. Level 2 automation and control systems have real-time responses measured in subseconds and are typically implemented on programmable logic controllers (PLC), distributed control systems (DCS), and open control systems (OCS).
- ***Level 3*** defines the activities that coordinate production resources to produce the desired end products. It includes, work-flow "control" and procedural "control" through recipe execution. Level 3 typically operates on time frames of days, shifts, hours, minutes, and seconds. Level 3 functions also include maintenance functions, quality assurance and laboratory functions, and inventory movement functions, and are collectively called MOM. Level 3 functions directly related to production are usually automated using MOM.
- ***Level 4*** defines business-related activities that manage a manufacturing organization. Manufacturing-related activities include establishing the basic plant schedule (such as material use, delivery, and shipping), determining inventory levels, logistics "control," and material inventory "control" (making sure materials are delivered on time to the right place for production). Level 4 is called Business Planning and Logistics. Level 4 typically operates on time frames of months, weeks, and days. Enterprise resource planning (ERP) logistics systems are used to automate Level 4 functions.

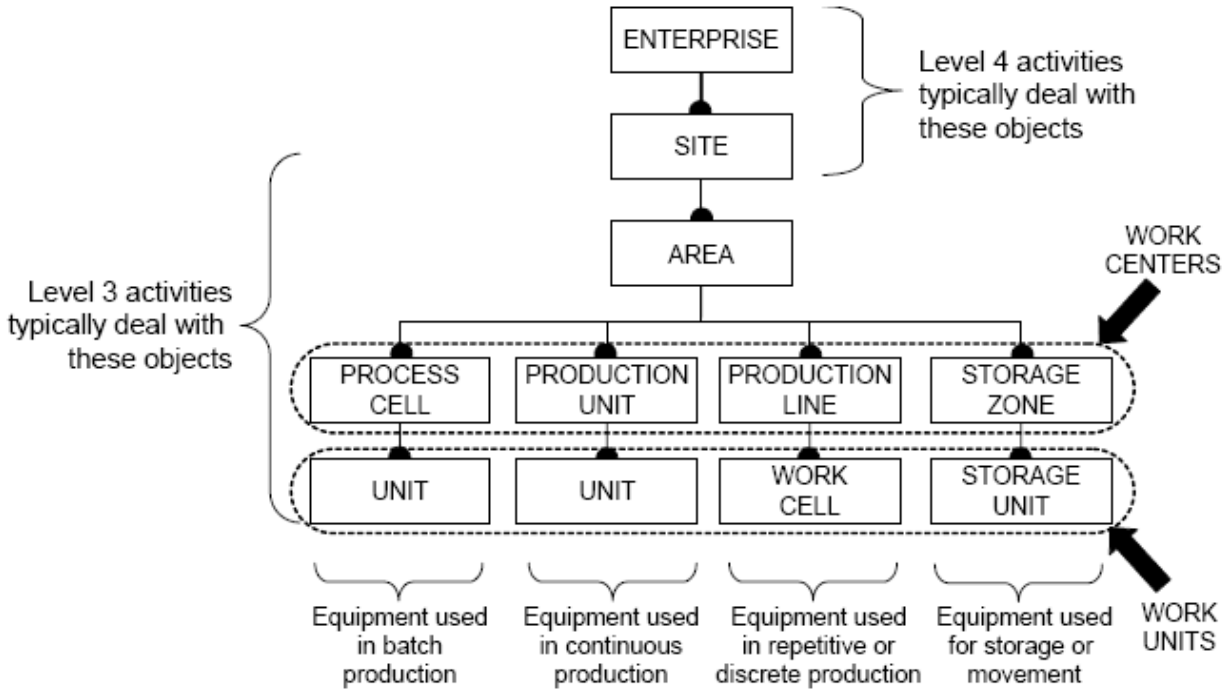
It is important to remember that each level has some form of control and each level has its own definition for real-time. Level 3 systems consider *real-time* to mean information available a few seconds after shop floor events occur. Level 4 systems consider *real-time* to mean logistics and material information is available daily or within a few hours after the end of a shift.

B2. Role-based Equipment Hierarchy Model

Figure B2 shows the role-based equipment and organizational hierarchy defined in the ANSI/ISA-95.00.03-2005 - *Enterprise-Control System Integration, Part 3: Models of Manufacturing Operations Management* standard.

Level 4 ERP and Logistics systems typically coordinate and manage the entire enterprise and sites within the enterprise, but it may also schedule to the area or work center level in less complex make-to-stock configurations. Level 3 MOM systems typically coordinate and schedule areas, work centers, and work units.

Figure B2: Role-based Equipment Hierarchy for Levels 2, 3 and 4 Functions



The role-based equipment hierarchy is an expansion of the equipment hierarchy defined in the ANSI/ISA-88.01-2010 batch control standard to include equipment types used in continuous production, discrete production, and inventory storage and movement. The role-based equipment hierarchy provides a standard naming convention for the organization of equipment, automation control, and manual control.

B3. MOM Integration with Business Planning and Logistics

- ANSI/ISA-95.00.01-2010 - Enterprise-Control System Integration Part 1: Models and Terminology (ISA-95 Part 1) and
- ANSI/ISA-95.00.02-2010 - Enterprise-Control System Integration Part 2: Object Model Attributes (ISA-95 Part 2)

These standards define terminology to be used for data exchanges and interfaces between Level 3 systems and Level 4 systems. This information is used to direct production activities and to report on production.

Formal data models for exchanged information include:

Four (4) MOM Resources Object Models

Personnel Class, Person, and Qualification Test Information: This is the definition of the persons and personnel classes (roles) involved in production. This information may be used to associate production with specific persons as part of a production record, or with personnel classes to allocate production costs.

Equipment Class, Equipment, and Capability Test Information: This is the definition of the equipment and equipment classes involved in production. This information may be used to associate production with specific equipment as part of a production record, or with equipment classes to schedule production and allocate costs.

Material Class, Material Definition, Material Lot, Material Sublot, and QA Test Information: This is the definition of the lots, sub-lots, material definitions, and material classes involved in production. This information allows Level 3 and Level 4 systems to unambiguously identify material specified in production schedules and consumed or produced in actual production.

Process Segment Information: This is the definition of the business views of production, based on Level 4 business processes that must send information to production, or receive information from production. Examples include: setup segments, inspection segments, production segments, and cleanup segments.

Four (4) MOM Information Categories Object Models

Product (or Operations) Definition Information: This is the definition of the materials, equipment, personnel, and instructions it takes to make a product. This includes the Manufacturing Bill (a subset of the Bill of Material [BOM] that contains the quantity and type of material required for producing a product). It also includes product segments, which define the routing and specific resources required at each segment of production.

Production (or Operations) Capability Information: This is the definition of the capability and capacities available from production for current and future periods of time. Capability and capacity information is required for both Level 4 scheduling and Level 3 detailed production scheduling.

Production (or Operations) Schedule Information: This specifies what products are to be made. It may include the definition of the specific personnel or roles to be used, equipment or equipment classes to be used, material lots or material classes to be produced, and material lots or material classes to be consumed for each segment of production.

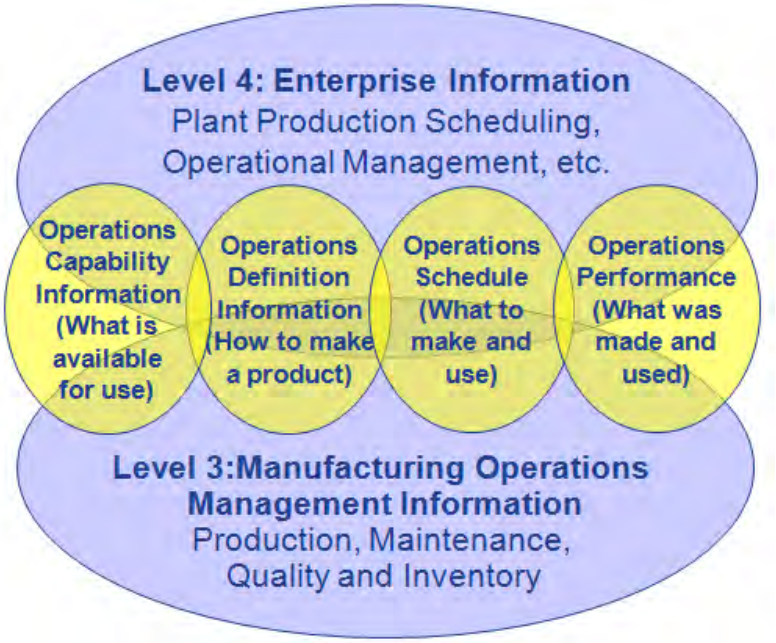
Production (or Operations) Performance Information: This specifies what was actually produced. It may include the definition of the actual personnel or personnel classes used, the actual equipment or equipment classes used, the actual material lots and quantities consumed, and the actual material lots and quantities produced for each segment of production.

B4. MOM Execution of the Production Order through Coordinated Operations

The above ISA-95 Part 2 resource object models of the four (4) manufacturing resources (Personnel, Material, Equipment, and Process Segment) are used to construct the 4 MOM Information Category object models (Operations Definition, Operations Capability, Operations Schedule, and Operations Performance).

The resource object models construct a "segment" or unit of work, which is the ISA-95 generic term for an operation, step or phase. The Process Segment is the foundation concept of the ISA-95 data model that allows Level 2 real-time data to be contextualized and aggregated for business process activities. This architectural consideration allows data collection, analytics, reporting and interfaces to be configurable and much less costly. Level 2 data is aggregated by resource objects to and from the Information Category objects shown in Figure B3.

Figure B3: ISA-95 Information Categories (objects) Handled by Manufacturing Operations Management and Exchanged between Levels 3 and 4



The derived Operations Definition and Operations Schedule object models use this data structure for detailed scheduling, dispatching and execution applications to contextualize Level 4 business process information into a form required for Level 2 and Level 3 MOM (Part 3) applications. The derived Operations Performance and Capability object models use this data structure to contextualize real-time data in data collection applications so that analytics, tracking, reporting and Level 3-4 interface applications are easily able to aggregate Level 2 and Level 3 applications into a form required for Level 4 applications.

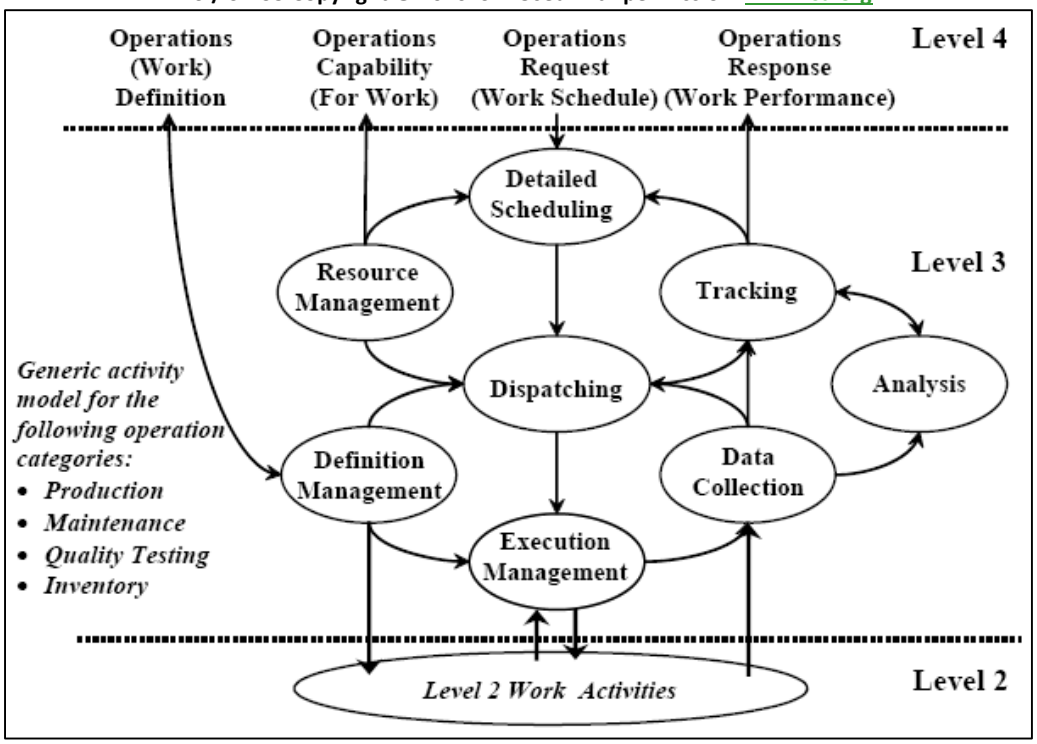
A segment in a recipe (batch) or production route (discrete) is constructed by using the combined resource models (personnel, equipment, and materials) in unison to describe the unit of work in terms of resources and resource test requirements. For example, each person in a plant gets identification (ID) and a set of personnel classes whose specifications are tested prior to permitting the person to being scheduled, dispatched, or executed as a resource in a segment or operation. Personnel are tracked from Level 2 and analyzed at Level 3 based on this ID and property class within the segment.

In a business planning and logistics form, process segments are used to construct a library of plant capabilities that are used to generate "Operations Segments" for actual products, which have the form of production routes in discrete hybrid environments or recipes in batch-process hybrid environments.

For the actual MOM form of a defining the executable units of work unit, ISA-95 operations segments are recursive with increased levels of nested granularity for the "operations segment" definition for each Level 3 activity function (Schedule, Dispatch, & Execution). The benefit is that the actual application outputs are contextualized in a form needed for each function's specific interface. When each Level 3 application's results and Level 2 process control work data are fed back to Level 3 Data Collection applications in the contextualized form, the Operations Performance applications (analysis, tracking, reporting and interfacing) can readily aggregate the information for the Production Order and operation order as facilitated by the ISA-95 data model and segment concept. This segment construction is the basis for the four information categories of Operations Performance.

Part 3 defines the detailed activities of several MOM application categories and their interrelations (work flow) within Level 3 and as well as interactions with Level 4 applications. As shown in Figure B4, a generic operations detailed activity model is defined and used to elaborate four (4) key MOM activities: Production, Maintenance, Quality Testing, and Inventory handling. Functions and high level data exchanges are defined for each MOM activity.

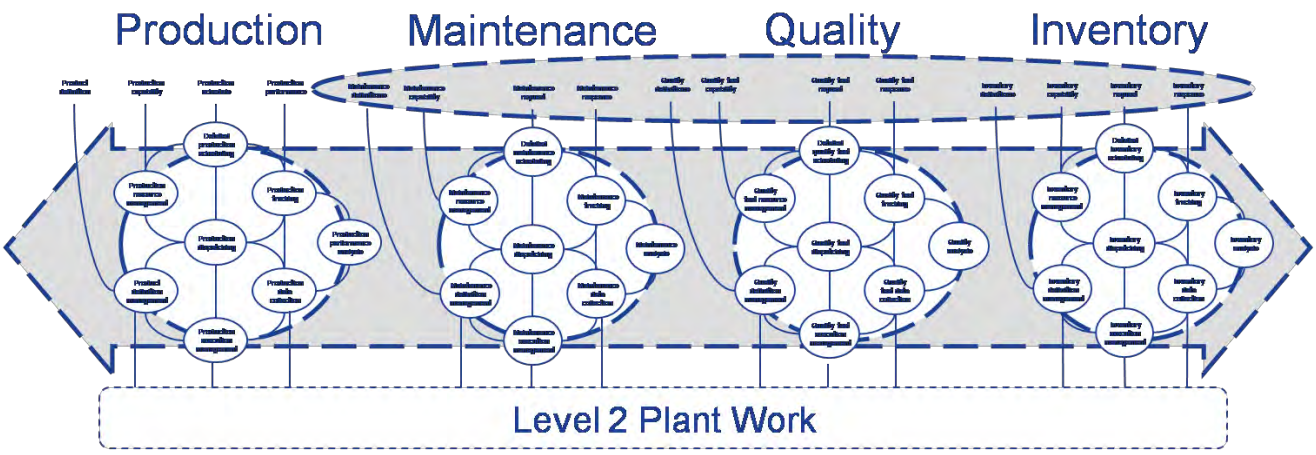
Figure B4: ISA-95 Generic Detailed Work Activity Model (Part 3) for MOM



In Figure B5, the shaded elements define the information flows for supporting operations within Level 3 areas to support Production Operations in the execution of a Production Order. The Production Operations cycle time is dependent on the other operations activities response. As a make-to-stock (MTS) manufacturing environment is adapted to a higher percentage of make-to-order (MTO) or engineer-to-order (ETO), the constraints or barriers to production workflow move from equipment constraints to the supporting operations. In MTO and ETO production orders and their associated workflows, the production rules, parameters, workflow dependency, work instructions, bill-of-materials, and quality specifications are still being defined and stabilized in production.

Note: Some supporting operations information may flow to other Level 4 systems.

Figure B5: Production Operations Cycle Time Dependent on Other Activities Response



B5. MOM and Production Operations Management

Figure B4 illustrates the different Level 3 operations-oriented functions that take place in sites and areas. Each bubble in the figure represents a function which is collection of tasks that occur in a production facility as an operations schedule is converted into actual production. It illustrates how production requirements from the business are used to coordinate and control plant floor activity. The top four arrows identify previously defined information that is exchanged with business logistics systems.

The MOM model is driven by operations *schedules* developed by the business and sent to production. The *operations schedules* are used by detailed production and operations scheduling activities that define *detailed production and operations schedules* containing *production and operations work orders*. The *production and operations work orders* are dispatched to work centers and work units based on time, events and real-time resource availability. The *production and operations work order* is executed and data is collected in an operations data collection activity.

Note: In batch systems a *control recipe* is the equivalent of a *production work order*.

The collected data is used in production and operations tracking activities that relate the time-series information to the work order information to generate a report on *operations performance* and tracing and tracking information. The collected data and the data from tracing and tracking are used in production an operations analysis functions to generate reports and KPIs (Key Performance Indicators). *Operations capability* information about the current and future availability is provided to business scheduling systems by production resource management activities. *Operations definition* information about the recipe, procedures, Bill of Material (BOM), and work routing needed for production is managed by product definition management activities.

B6. Detailed Scheduling (*Production and Operations*)

These are the activities in a facility that take a business master production schedule and use information about local resources to generate a detailed operations schedule. This can be an automated process, but in many plants scheduling is done manually by expert production planners or production planning staff. Automated systems are sometime referred to as plant level advanced planning and optimization systems.

The key element of this activity is detailed scheduling of work assignments and material flows to a finer level of granularity than the business schedule. While Level 4 master schedules may schedule work assignments to areas and work centers, detailed operations scheduling will schedule work assignments to work centers and

work units. Additionally, many business systems schedule based on unlimited capacity while detailed (or finite capacity) scheduling takes into account the constraints around personnel, material, and equipment.

B6.1. Dispatching (*Production and Operations*)

Once a detailed operations schedule is available, that schedule is dispatched to production lines, process cells, production units, and storage zones. This can take the form of supervisors receiving daily schedules and dispatching work to technicians, or automated systems performing campaign management of batches and production runs. Operations dispatching includes handling conditions not anticipated in the detailed operations schedule. This may involve judgment in managing workflow and buffers. Unanticipated conditions may have to be communicated to maintenance operations management, quality operations management, and/or inventory operations management. This is one of the core functions of an MOM.

B6.2. Execution Management *(Production and Operations)*

Production and operations execution management activities receive the dispatched work requests and, using paper-based systems, MOM systems, or recipe execution systems, coordinate and control the actual work execution.

This may include the execution of procedural logic in recipes and display of work flow instructions to operators. The activities include selecting, starting, and moving units of work (such as a batch or production run) through the appropriate sequence of operations to physically produce the product.

The actual equipment control is part of the Level 2 functions. Production and operations execution management is one of the core functions of an MOM system, but it may also be performed by recipe or manual workflow instruction systems in DCS systems or batch execution systems. The standards for information flows from Level 3 to Level 2 are defined in the ANSI/ISA-88.01-1995, OPC, and Fieldbus standards.

B6.3 Data Collection (*Production and Operations*)

Production and operations data collection is the activities that gather, compile, and manage production data for specific units of work (batches or production runs). Manufacturing control systems generally deal with process information such as quantities (weight, units, etc.), properties (rates, temperatures, etc.), and equipment information such as controller, sensor, and actuator statuses. Collected production and operations data includes sensor readings, equipment states, event data, operator-entered data, transaction data, operator actions, messages, calculation results from models, and other data of importance in the making of a product. The collected data is inherently time or event based, with time or event data added to give context to the collected information. This information is usually made available to various analysis activities, including product analysis, production and operations analysis, and process analysis. Real-time data historians and automated batch record logging systems support this activity.

B6.4 Tracking (*Production and Operations*)

The production and operations tracking activities convert sensor and equipment data into information related to assigned work (batches and production runs), and into tracking information about equipment, material, and personnel used in production. Production and operations tracking also merges and summarizes information that is reported back to the business activities. This is one of the core functions of an MOM. When automated systems are used they usually link to data historians and batch record logging systems.

B6.5 Resource Management (*Production and Operations)*

The resource management activities monitor the availability of personnel, material, and equipment production and operations resources. This information is used by detailed operations scheduling and business logistics planning. These activities take into account the current and future predicted availability, using information such as planned maintenance and vacation schedules, in addition to material order status and delivery dates. This activity may also include material reordering functions, such as Kanban. Kanban is a material management system used as part of just-in-time production operations where components and sub-assemblies are

produced, based upon notification of demand from a subsequent operation. A Japanese word for "sign," Kanbans is a signaling system to trigger action. As its name suggests, Kanban historically uses cards to signal the need for an item. However, other devices such as plastic markers (Kanban squares) or balls (often golf balls) or an empty part-transport trolley or floor location can also be used to trigger the movement, production, or supply of a unit in a factory. (http://en.wikipedia.org/wiki/Kanban).

Resource management is usually a mixed operation, with manual work, automation, and database management. Management of the resources may include local resource reservation systems, and there may be separate reservation systems for each type of managed resource (personnel, equipment, and material). This is one of the core functions of an MOM.

B6.6 Definition Management *(Production and Operations)*

Operations definition management includes activities associated with the management of product and operations definitions. These may be recipes, work instructions, assembly instructions, standard operating procedures, and other information used by production to make or assemble products. This is one of the core functions of an MOM.

B6.7 Performance Analysis (*Production and Operations)*

The activities associated with the analysis of production, operations, process, and product are defined as operations performance analysis. These are usually off-line activities that look for ways to improve processes through chemical or physical simulation, analysis of good and bad production runs, and analysis of delays and bottlenecks in production. Operations performance analysis also includes calculating performance indicators, leading, and trailing predictors of behavior. These activities generally are major users of information collected in plant data historians. There are often separate tools for production, operations, process, and product analysis, and the tool sets vary based on the type of production (continuous, discrete, or batch).

B7 Other Supporting Operations Activities

The above list does not define all of the activities of a production facility. There are also maintenance operations management activities, quality operations management activities, and inventory operations management activities.

Maintenance Operations Management: The activities that coordinate, direct, and track the functions that maintain the equipment, tools and related assets to ensure their availability for manufacturing.

Quality Operations Management: The activities that coordinate, direct, and track the functions that measure and report on quality. The broad scope of quality operations management includes both quality operations and the management of those operations to ensure the quality of intermediate and final products.

Inventory Operations Management: The activities that coordinate, direct, and track the functions that transfer of materials between and within work centers and manage information about material locations and statuses.

Manufacturing Operations Infrastructure Activities: Manufacturing operations also require infrastructure activities that may be specific to manufacturing, but which are often elements also required by other parts of a manufacturing company. The infrastructure activities include:

- Managing security within manufacturing operations
- Managing information within manufacturing operations
- Managing configurations within manufacturing operations
- Managing documents within manufacturing operations
- Managing regulatory compliance within manufacturing operations
- Managing incidents and deviations

B8. Level 3-4 Boundary

There are four rules which can be applied to determine if an activity should be managed as part of Level 4 or as part of Levels 3, 2, or 1. An activity should be managed at a Level 3 or below if the activity is directly involved in manufacturing, includes information about personnel, equipment, or material, and meets any of the following conditions:

a) The activity is critical to plant safety
b) The activity is critical to plant reliability
c) The activity is critical to plant efficiency
d) The activity is critical to product quality
e) The activity is critical to maintaining product or environmental regulatory compliance.

Note: This includes such factors as safety, environmental, and cGMP (current good manufacturing practices) compliance.

This means, in some cases, the Level 3 activities defined above may be performed as part of logistics instead of operations. Typically, this involves detailed production scheduling and production dispatching.

The scope of an MOM system is determined by applying the above rules to each site or area within a site.

B9. References

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7. Bianca Scholten, The Road to Integration: A Guide to Applying the ISA-95 Standard in Manufacturing. ISA 2007.
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B9.1 Practical References

1. Brown, Mark Graham. Baldrige Award Winning Quality: How to Interpret the Malcolm Baldrige Award Criteria. ASQC Quality Press, 1995 and 1996.
2. Goldratt, Eliyahu M. and Jeff Cox. The Goal: A Process of Ongoing Improvement. North River Press, 1992.

Appendix C: Open Systems Interconnection (OSI) Model

Figure C1: Open Systems Interconnection (OSI) Model (13)

OSI Model				
	Layer	Data unit	Function[3]	Examples
Host layers	7. Application	Data	High-level APIs, including resource sharing, remote file access, directory services and virtual terminals	HTTP, FTP, SMTP
	6. Presentation		Translation of data between a networking service and an application; including character encoding, data compression and encryption/decryption	
	5. Session		Managing communication sessions, i.e. continuous exchange of information in the form of multiple back-and-forth transmissions between two nodes	
	4. Transport	Segments	Reliable transmission of data segments between points on a network, including segmentation, acknowledgement and multiplexing	TCP, UDP, L2TP
Media layers	3. Network	Packet/Datagram	Structuring and managing a multi-node network, including addressing, routing and traffic control	IPv4, IPv6, IPsec, AppleTalk
	2. Data link	Bit/Frame	Reliable transmission of data frames between two nodes connected by a physical layer	PPP, IEEE 802.2
	1. Physical	Bit	Transmission and reception of raw bit streams over a physical medium	DSL, USB

Open Systems Interconnection model (OSI) is a conceptual model that characterizes and standardizes the internal functions of a communication system by partitioning it into abstraction layers. The model is a product of the Open Systems Interconnection project at the International Organization for Standardization (ISO), maintained by the identification ISO/IEC 7498-1.

The model groups communication functions into seven logical layers. A layer serves the layer above it and is served by the layer below it. For example, a layer that provides error-free communications across a network provides the path needed by applications above it, while it calls the next lower layer to send and receive packets that make up the contents of that path.

Appendix D: OPC UA Communication Stack and Security Architecture

Communication Stack

This standard defines Mappings between the abstract specifications and technologies that can be used to implement them. The Mappings are organized into three groups: Data Encodings, Security Protocols and Transport Protocols. Different Mappings are combined together to create Stack Profiles. All OPC UA Applications shall implement at least one Stack Profile and can only communicate with other OPC UA Applications that implement the same Stack Profile.

This standard defines the Data Encodings in Clause 5, the Security Protocols in Clause 6 and the Transport Protocols in 6.7.6. The Stack Profiles are defined in Part 7.

All communication between OPC UA Applications is based on the exchange of Messages. The parameters contained in the Messages are defined in Part 4; however, their format is specified by the Data Encoding and Transport Protocol. For this reason, each Message defined in Part 4 shall have a normative description which specifies exactly what shall be put on the wire. The normative descriptions are defined in the appendices.

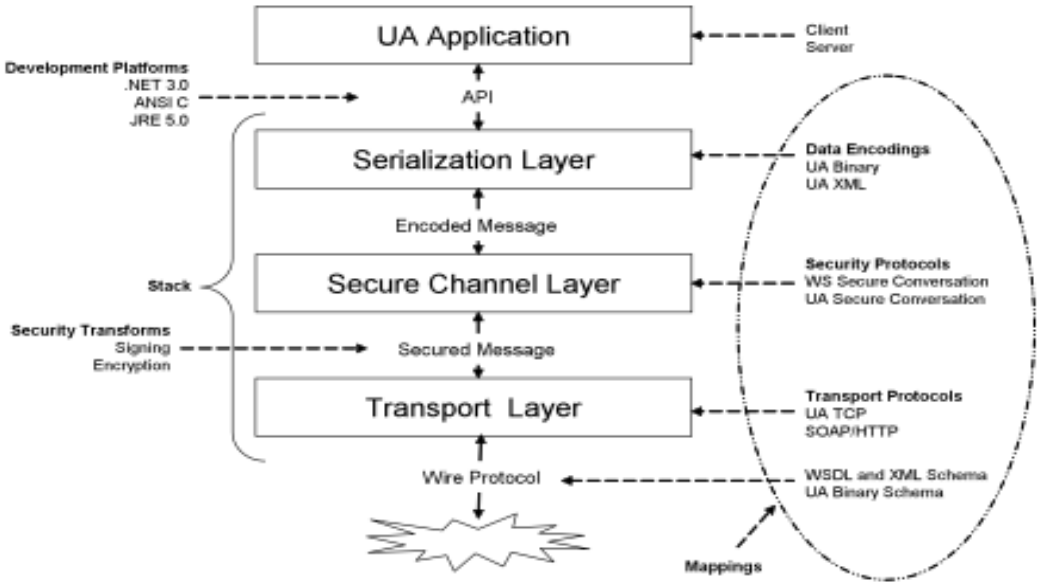
A Stack is a collection of software libraries that implement one or more Stack Profiles. The interface between an OPC UA Application and the Stack is a non-normative API which hides the details of the Stack implementation. An API depends on a specific Development Platform.

Note: The datatypes exposed in the API for a Development Platform may not match the datatypes defined by the specification because of limitations of the Development Platform. For example, Java does not support unsigned integers which means that any Java API will need to map unsigned integers onto a signed integer type.

Figure D1 illustrates the relationships between the different concepts defined in this standard. The layers described in this specification do not correspond to layers in the OSI 7 layer model. Each OPC UA Stack Profile should be treated as a single Layer 7 (Application) protocol that is built on an existing Layer 5, 6 or 7 protocol such as TCP/IP, TLS or HTTP. The Secure Channel layer is always present even if the Security Mode is None. In this situation, no security is applied but the Security Protocol implementation shall maintain a logical channel with a unique identifier.

Users and administrators are expected to understand that a Secure Channel with Security Mode set to None cannot be trusted unless the Application is operating on a physically secure network or a low level protocol such as IP Sec is being used.

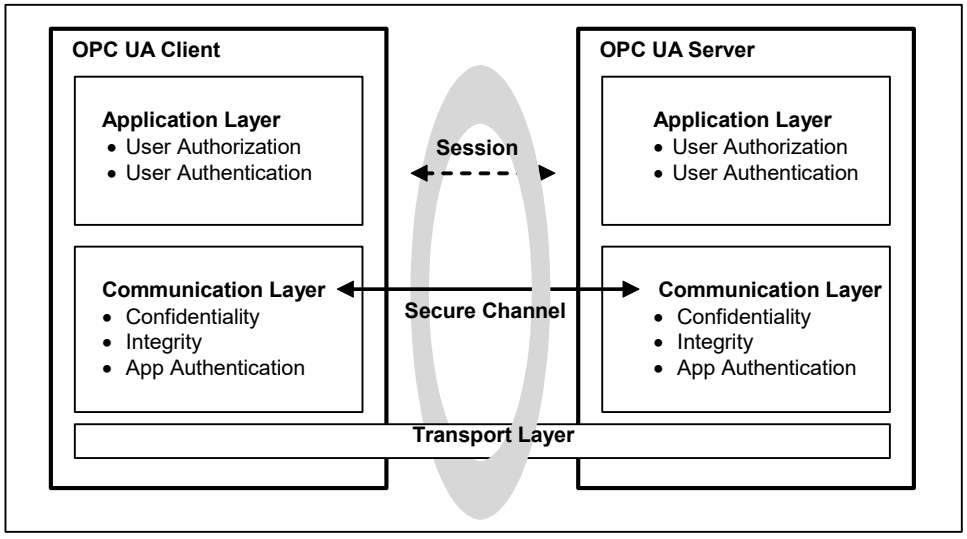
Figure D1: Serialization Data Presentation Layer in the OPC UA Stack Overview (11)



OPC UA Security Architecture (12)

The OPC UA security architecture is a generic solution that allows implementation of the required security features at various places in the *OPC UA Application* architecture. Depending on the different mappings described in **Error! Reference source not found.**, the security objectives are addressed at different levels. The PC UA Security Architecture is structured in an Application Layer and a Communication Layer atop the Transport Layer as shown in **Error! Reference source not found.**.

Figure D2: OPC UA Security Architecture (12)



The routine work of a client application and a server application to transmit plant information, settings, and commands is done in a session in the Application Layer. The Application Layer also manages the security objectives user Authentication and user Authorization. The security objectives that are managed by the Application Layer are addressed by the Session Services that are specified in **Error! Reference source not ound.**. A session in the Application Layer communicates over a Secure Channel that is created in the Communication Layer and relies upon it for secure communication. All of the session data is passed to the Communication Layer for further processing.

Although a session communicates over a Secure Channel and has to be activated before it can be used, the binding of users, sessions, and Secure Channels is flexible.

Impersonation allows the user of the session to change. A session can have a different user than the user that activated the session for the first time, since user credentials are not validated before activating a session.

When a Secure Channel breaks, the session will still be valid to be able to re-establish the Secure Channel otherwise the session closes after its lifetime expires.

The Communication Layer provides security mechanisms to meet Confidentiality, Integrity and application Authentication as security objectives.

One essential mechanism to meet the above mentioned security objectives are to establish a Secure Channel that is used to secure the communication between a client and a server. The Secure Channel provides encryption to maintain Confidentiality, Message Signatures to maintain Integrity and Digital Certificates to provide application Authentication for data that comes from the Application Layer and passes the “secured” data to the Transport Layer. The security mechanisms that are managed by the Communication Layer are provided by the Secure Channel Services that are specified in **Error! Reference source not found.**.

The security mechanisms provided by the Secure Channel services are implemented by a protocol stack that is chosen for the implementation. Mappings of the services to some of the protocol stack options are specified in **Error! Reference source not found.** which details how the functions of the protocol stack are used to meet the PC UA security objectives.

The Communication Layer can represent an OPC UA protocol stack. OPC UA specifies two alternative stack mappings that can be used as the Communication Layer. These mappings are UA Native mapping and Web Services mapping.

If the UA Native mapping is used, then functionalities for Confidentiality, Integrity, application Authentication, and the Secure Channel are similar to the **Error! Reference source not found.** specifications, as described in etail in **Error! Reference source not found.**.

If the Web Services mapping is used, then **Error! Reference source not found.**, **Error! Reference source not und.** and **Error! Reference source not found.** as well as **Error! Reference source not found.** are used to implement the mechanisms for Confidentiality, Integrity, application Authentication as well as for implementing a Secure Channel. For more specific information, see **Error! Reference source not found.**.

The Transport Layer handles the transmission, reception and the transport of data that is provided by the Communication Layer.

To survive the loss of the Transport Layer connections (e.g. TCP connections) and resume with another, the implementation of the Communication Layer is responsible to re-establish the Transport Layer connection without interrupting the logical Secure Channel.

Appendix E: Track and Trace Working Group (OPEN-SCS) Charter / Draft

Working Group (WG) Charter

WG Name:	Open Serialization Communication Standard Working Group (OPEN-SCS)
Section I: Working Group Identification	
Charter Approval Date:	February 2015
Name of WG Executive Director:	Charlie Gifford
Name(s) of Appointed Liaison(s):	
WG Workspace URL:	
WG Mailing List:	Open Architecture T&T Roundtable Group and OPEN-SCS members
Important Document Links:	• {Doc1} • {Doc2} • {Doc3} • {Doc4}

Section II: Mission, Purpose, and Deliverables

Mission & Scope:

From the First Roundtable on Open Architecture for Track & Trace held on September 24, 2014 in Frankfurt, Germany. OPEN-SCS was formed with the specific goal of rapidly developing a set of product serialization standards for packaging line level in plants.

The proposed standards for in-plant serialization data will be heavily influenced by and map directly into the supply chain serialization regulations, associated standards and systems approaches that are being deployed to meet the product track and trace regulations being released by countries worldwide to meet the widespread drug counterfeiting issues. The members of the Open Architecture Track and Trace (T&T) **Roundtable agreed on their T&T Mission** as:

- Protect the public
- Stop counterfeited product
- 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

The **Roundtable end users and vendor members strongly agreed on the high business risk** of the current market state in the following areas:

- 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 you can't ship products…

The **Roundtable members** expressed that new and proposed T&T **regulatory pressure have created**:

- A highly complex challenges affecting all level of operation
- Solution designed in a rush
- Asking miracle to supplier
- Many custom made solution
- Lack of time to step back

Deliverables:

1. The basic scope of the OPEN-SCS standards is proposed as a set of data objects and exchanges for a given set of common packaging use cases typically used in a Healthcare Packaging Line User Requirement Specification.
2. Best practices implementation set of Packaging Line System Functional Requirements Specifications (FRSs) for 6 common architectural approaches and exchange technologies. The initial proposal is to develop System FRSs for an EPCIS and OPC-UA technical approaches where the same standard data objects and exchange use cases are mapped into and then between these approaches.

The proposed standards for in-plant serialization data is heavily influenced by and maps directly into the rapidly evolving supply chain serialization regulations, associated standards and systems approaches. Healthcare supply chain systems are being deployed to meet the product track and trace (T&T) regulations by countries worldwide to address the widespread healthcare counterfeiting issues.

The OPEN-SCS as a first step shall request public input to have a clear understanding of the exact nature and scope of each packaging line process. Based on this information, and its own views, and any additional information gathered by the Working Group, the Working Group is expected to make recommendations for final scope of the standard and implementation System FRSs.

The sponsored work products will be funded by soliciting Healthcare industry for producers, vendors, and SIs. In order to meet the regulation time line, this standard must be accelerated over 6 months; the OPEN-SCS must raise a significant amount money to pay for my time and two standards SME authors to drive the accelerated process over months and not years. A volunteer model will simply not work. So I am proposing a business model for this where the OPEN-SCS standards are data objects standards and then the OPEN-SCS sells:
1. Contribution sponsorships for those members who are able to get this through their company easily
2. A product as subscription model to an open source a System FRS for each OPCUA-95 and EPCIS implementations. Each System Functional Requirement Specifications (FRS) is for a specific life sciences packaging line configuration with specific exchange use cases. For these deliverables, the OPEN-SCS members would pay up front in Q1 2016 so we can start work with contract guarantee of a FRSs deliverable by end of Q2/Q3. The FRSs and implementation guideline documents would continually be updated over the years. Especially over the next 2 years. So companies should pay at least for the next 2 years.

3. For an additional $10-20K, onsite and online training or design review credits for use of the standard, OPCUA, and the FRSs. The training content will have to be paid development but IP owned by OPC.

The OPEN-SCS will establish a group of subject matter experts for each production process to provide the consultant developing deliverables with the technical inputs and deliverable review and approval.

Recommendations may take different forms including, for example, recommendations for consensus policies, best practices and/or implementation guidelines. The OPEN-SCS shall use the W3C Working Group Guidelines to develop a set of OPEN-SCS Guidelines to govern the working group and their deliverables.

Objectives & Goals:

- To form the OPEN-SCS.
- To setup OPEN-SCS as part of an international standard group.
- To develop and release the Serialization T&T standard for Healthcare packaging line in 2014.
- To fully fund the OPEN-SCS develop effort to accelerate the development of the work products.

Success Criteria

The main criterion of success for the OPEN-SCS is that recommendations and deliverables released during the operation of the Working Group provide much improved methods for defining user and functional requirements for operations management systems for Healthcare packaging line. Timely delivery of the materials mentioned above (including our own quality commitments) is a criterion for judging the quality of the work of the group.

Deliverables & Timeframes:

The WG shall respect the timelines and deliverables as outlined by the OPEN-SCS. The OPEN-SCS shall develop a work plan for each work project once the scope is finalized with an assigned work breakdown structure that outlines the necessary committed resources, steps, and expected timing in order to achieve the milestones and deliverables for each sponsored project.

Duration

This Working Group is scheduled to begin in Q1 2016. The first draft of the data object standards and System FRSs are to be released in Q2 2016 with a short comment period so a final version can be voted, approved and released by June 2016.

Section III: Formation, Staffing, and Organization

Membership Criteria:

The Working Group will be open to all interested in participating. New members who join after work has been completed will need to review previous documents and meeting transcripts. All members are required to commit to 10 man-days per year of volunteer time for delivery of OPEN-SCS assignments.

Group Formation, Dependencies, & Dissolution:

This WG shall be an OPC Foundation Working Group.
A OPEN-SCS Steering Committee was formed to setup and approve the operations process, administration process, staffing and work product scope/schedule/approval. The Executive Director will circulate a 'Call For Volunteers' as widely as possible in order to ensure broad representation and participation in the Working Group, including:

- Publication of announcement on the OPCF web site; and
- Distribution of the announcement to Open-SCS Membership

Milestones for the First Year Only:

- January 2015: Establish OPEN-SCS Steering Committee
- February 2015: Kickoff-Steering Committee Meeting
- March 2015: Final Draft of Feasibility Study to Steering Committee
- March 2015: Final Fund Raising Brochure and Send to all Open-SCS Members
- March 2015: Formalized OPCF Working Group with signed MOU
- March 2015: Steering Committee Meeting
- May 2015: OPEN-SCS setup in OPC to manage revenue of sale of subscriptions for products
- June 2015: Finalize OPEN-SCS Website
- October 2015: Receive Product Subscriptions from Steering Committee members.
- November 2015: Final Business Case White Paper
- December 2015: Draft contracts agreed for Executive Director, and SME Architects
- December 2015: Send out Scoping Survey to members
- December 2015: Reach minimum required funding to start work: $260K USD. 20 members X $13K
- January 2016: Finalize contracts with OPEN-SCS SME Architect team
- January 2016: Begin work on URS and System FRSs V0.1
- January 2015: Send out final scope for Steering Committee vote
- February 2015: Final Scope
- March 2016: Release draft standard V0.1
- April 2016: OPEN-SCS User Group Face-to-Face Meeting to Finalize Standard and System FRSs.
- April 2016: Send out Final Drafts for vote and comment.
- April 2016: Comments due on Final Drafts
- May 2016: Send out second Final Drafts for vote and comment.
- May 2016: Comments due on Final Draft
- May 2016: Plan Phase 2 and 3 versions of work products
- June 2016: Release Final Standard and System FRSs

Patent Disclosures

This Working Group operates under the OPCF IP Policy (5 February 2004 Version). To promote the widest adoption of Web standards, OPEN-SCS and OPC seeks to issue deliverables and recommendations that can be implemented, according to this policy, on a Royalty-Free basis.

Working Group Roles, Functions, & Duties:

The OPEN-SCS/OPC Staff assigned to the WG will fully support the work of the Working Group as requested by the Executive Director including meeting support, document drafting, editing and distribution and other substantive contributions when deemed appropriate.

Staff assignments to the Working Group:

- OPC staff assistant
- OPEN-SCS Executive Director
- OPEN-SCS Standard Architect(s)

The standard WG roles, functions & duties shall be applicable as specified by the OPEN-SCS Guidelines which shall be developed based on the W3C Working Group Guidelines.

Communication Mechanisms

- Email

The archived mailing list is the primary means of discussion within the group.

- Web

The group maintains a public Working Group page.

- Phone Meeting

OPEN-SCS meets monthly by GoTo Meeting on Friday at 10am EST time for one hour and a half.

- Face-to-face Meetings

Face-to-face meetings will be arranged 2 times a year, rotating location between USA west coast, east coast, Europe, and occasionally Asia/Pacific/Australia. Meeting details are made available on the OPC Calendar and on the OPC home page.

- Communication with the Public

The OPC home page is the primary way of communicating the group's progress to the public.

Participation

Good Standing in the OPEN-SCS

Participation on an ongoing basis implies a serious commitment to the OPEN-SCS charter, including:

- Attending most meetings of the Working Group
- Providing deliverables or drafts of deliverables in a timely fashion
- Being familiar with the relevant documents of the Working Group, including minutes of past meetings
- Following discussions on relevant mailing list(s)

When the Executive Director and the participating team agree, the Executive Director may declare a participant in bad standing. If there is disagreement between the Executive Director and the participating team about standing, the OPEN-SCS Executive Director determines the participant's standing.

A participant may be declared in bad standing in any of the following circumstances:

1. The individual has missed more than one of the last three distributed meetings
2. The individual has missed more than one of the last three face-to-face meetings
3. The individual has not provided deliverables in a timely fashion twice in sequence

The above criteria may be relaxed if the Executive Director and participating team agree that doing so will not set back the Working Group. For example, the attendance requirement may be relaxed for reasons of expense (e.g., cost of travel) or scheduling (for example, an exceptional teleconference is scheduled at 3:00 a.m. local time for the participant). The Executive Director and participating team should apply criteria for good standing consistently as determined by the OPC President.

When a participant risks losing good standing, the Executive Director and participating team must discuss the matter with the participant and the OPC President before declaring the participant in bad standing.

The Executive Director declares a participant in bad standing by informing the OPC President and the participant of the decision. If the OPC President and Executive Director differ in opinion, the OPC President may ask the Executive Director of the International BOD to confirm or deny the decision.

In order for a participant to regain good standing, the participant must meet the participation requirements for two consecutive meetings. The Executive Director must inform the OPC President of any change in standing.

OPEN-SCS group participants should realize that QA is to be considered a natural overhead of any Working Group. QA will succeed only if every person inside OPEN-SCS participates in it.

OPEN-SCS participation (attending meetings, reviewing documents, preparing drafts or tools) is expected to consume between one man-day per month.

OPEN-SCS expects and will be welcoming different communities to contribute to the Activity:

- OPEN-SCS participants (OPEN-SCS Team or not) developing specifications
- End-user advocacy groups tracking and lobbying content and/or product compliance

As this Activity has a clear multi-stakeholder approach, we expect to use multiple approaches to reach our goals, and not a fixed set of rules that would not be applicable to all participants.

How to Join the Working Group

Information about how to join the Working Group is available on a separate OPEN-SCS How-to-Join web page.

Preparation

1. Read the OPEN-SCS home page as appropriate
2. Read the OPEN-SCS Charter. In particular, read the section on requirements for participation in the Working Group.

Note: Expected duration of the group and the amount of time and travel expected.

Request to Join

Get in touch with the Executive Director and Staff Contact of the group to apply.

Approval

Each member of the Working Group is required to submit an SOC.

Statements of Commitment (SOC) Guidelines:

Each member of the Working Group is required to submit an SOC.

Section IV: Rules of Engagement

Decision-Making Methodologies:

Confidentiality

The Working Group and the Activity resources in general are publicly accessible.

All documentation, test suites, and validating tools produced inside this Activity will have to be defined under a license. There are still questions about the kind of license to use (for instance, working groups have two licenses: one for document and one for software, the document license being more restrictive for the change control, which may be of interest to ensure the integrity of QA tools). This will be discussed in the QA Activity. In any case, we expect the tools to be freely usable, runnable, and downloadable and that the group will operate under a royalty-free licensing mode (RF).

Decision-Making

The Executive Director is responsible for designating each position as having one of the following designations:

- **Full consensus** - when no one in the group speaks against the recommendation in its last readings. This is also sometimes referred to as **Unanimous Consensus.**
- **Consensus** - a position where only a small minority disagrees, but most agree.
- **Strong support but significant opposition** - a position where, while most of the group supports a recommendation, there are a significant number of those who do not support it.
- **Divergence** (also referred to as **No Consensus**) - a position where there isn't strong support for any particular position, but many different points of view. Sometimes this is due to irreconcilable differences of opinion and sometimes it is due to the fact that no one has a particularly strong or

convincing viewpoint, but the members of the group agree that it is worth listing the issue in the report nonetheless.

- **Minority View** - refers to a proposal where a small number of people support the recommendation. This can happen in response to a **Consensus**, **Strong support but significant opposition**, and **No Consensus;** or, it can happen in cases where there is neither support nor opposition to a suggestion made by a small number of individuals.

In cases of **Consensus**, **Strong support but significant opposition**, and **No Consensus**, an effort should be made to document that variance in viewpoint and to present any **Minority View** recommendations that may have been made. Documentation of **Minority View** recommendations normally depends on text offered by the proponent(s). In all cases of **Divergence,** the WG Executive Director should encourage the submission of minority viewpoint(s). The recommended method for discovering the consensus level designation on recommendations should work as follows:

i. After the group has discussed an issue long enough for all issues to have been raised, understood and discussed, the Executive Director, or Co-Chairs, make an evaluation of the designation and publish it for the group to review.
ii. After the group has discussed the Executive Director's estimation of designation, the Executive Director, or Co-Chairs, should reevaluate and publish an updated evaluation.
iii. Steps (i) and (ii) should continue until the Executive Director/Co-Chairs make an evaluation that is accepted by the group.
iv. In rare case, an Executive Director may decide that the use of polls is reasonable. Some of the reasons for this might be:
    - A decision needs to be made within a time frame that does not allow for the natural process of iteration and settling on a designation to occur.
    - It becomes obvious after several iterations that it is impossible to arrive at a designation. This will happen most often when trying to discriminate between **Consensus** and **Strong support but Significant Opposition** or between **Strong support but Significant Opposition** and **Divergence.**

Care should be taken in using polls that they do not become votes. A liability with the use of polls is that, in situations where there is **Divergence** or **Strong Opposition**, there are often disagreements about the meanings of the poll questions or of the poll results.
Based upon the WG's needs, the Executive Director may direct that WG participants do not have to have their name explicitly associated with any Full Consensus or Consensus view/position. However, in all other cases and in those cases where a group member represents the minority viewpoint, their name must be explicitly linked, especially in those cases where polls where taken.
Consensus calls should always involve the entire Working Group and, for this reason, should take place on the designated mailing list to ensure that all Working Group members have the opportunity to fully participate in the consensus process. It is the role of the Executive Director to designate which level of consensus is reached and announce this designation to the Working Group. Member(s) of the Working Group should be able to challenge the designation of the Executive Director as part of the Working Group discussion. However, if disagreement persists, members of the WG may use the process set forth below to challenge the designation. If several participants (see Note 1 below) in a WG disagree with the designation given to a position by the Executive Director or any other consensus call, they may follow these steps sequentially:

1. Send email to the Executive Director, copying the WG explaining why the decision is believed to be in error.

2. If the Executive Director still disagrees with the complainants, the Executive Director will forward the appeal to the OPEN-SCS Steering. The Executive Director must explain his or her reasoning in the response to the complainants and in the submission to the liaison. If the OPEN-SCS Steering Committee supports the Executive Director's position, the OPEN-SCS Steering Committee will provide their response to the complainants. The OPEN-SCS Steering Committee must explain their reasoning in the response. If the OPEN-SCS Steering Committee disagrees with the Executive Director, the OPEN-SCS Steering Committee will resolve with compliant with complainant directly. Should the complainants disagree with the OPEN-SCS Steering Committee support of the Executive Director's determination, the complainants may appeal to the OPC Foundation or their designated representative? If the OPCF agrees with the complainants' position, the OPCF recommends remedial action to the Executive Director.
3. In the event of any appeal, the OPCF will attach a statement of the appeal to the WG and/or Board report. This statement should include all of the documentation from all steps in the appeals process and should include a statement from the OPCF (see Note 2 below).

Note 1: Any Working Group member may raise an issue for reconsideration; however, a formal appeal will require that that a single member demonstrates a sufficient amount of support before a formal appeal process can be invoked. In those cases where a single Working Group member is seeking reconsideration, the member will advise the Executive Director and/or Liaison of their issue and the Executive Director and/or Liaison will work with the dissenting member to investigate the issue and to determine if there is sufficient support for the reconsideration to initial a formal appeal process.
Note 2: It should be noted that ICANN also has other conflict resolution mechanisms available that could be considered in case any of the parties are dissatisfied with the outcome of this process.

Status Reporting:

Minutes for all meeting shall be taking and distributed by the OPCF staff assistant.
An OPEN-SCS sponsored projects shall have monthly status reports submitted to the working group.

Problem/Issue Escalation & Resolution Processes:

The WG will adhere to OPCF's Expected Standards of Behavior as documented.
If a WG member feels that these standards are being abused, the affected party should appeal first to the Executive Director and Liaison and, if unsatisfactorily resolved, to the Executive Director of the Chartering Organization or their designated representative. It is important to emphasize that expressed disagreement is not, by itself, grounds for abusive behavior. It should also be taken into account that as a result of cultural differences and language barriers, statements may appear disrespectful or inappropriate to some but are not necessarily intended as such. However, it is expected that WG members make every effort to respect the principles outlined in OPCF's Expected Standards of Behavior.
The Executive Director, in consultation with the Chartering Organization liaison(s), is empowered to restrict the participation of someone who seriously disrupts the Working Group. Any such restriction will be reviewed by the Chartering Organization. Generally, the participant should first be warned privately, and then warned publicly before such a restriction is put into place. In extreme circumstances, this requirement may be bypassed.
Any WG member that believes that his/her contributions are being systematically ignored or discounted or wants to appeal a decision of the WG should first discuss the circumstances with the WG Executive Director. In the event that the matter cannot be resolved satisfactorily, the WG member should request an opportunity to discuss the situation with the Executive Director of the Chartering Organization or their designated representative.

In addition, if any member of the WG is of the opinion that someone is not performing their role according to the criteria outlined in this Charter, the same appeals process may be invoked.

Closure & Working Group Self-Assessment:

The OPEN-SCS will do a formal year assessment with the Steering Committee.

Section V: Charter Document History

Version	Date	Description
0.1	9 January 2015	First draft developed by C. Gifford
1.0	03 January 2015	C. Gifford

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Translations: If translations will be provided please indicate the languages below: