

COOPERATION OPC Foundation and OPEN-SCS

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Track and Trace: OPC UA in the Pharmaceutical Industry

4 OPEN-SCS: INDUSTRY REQUIREMENTS

Healthcare supply chains need to be safe and ensure that counterfeit products are not introduced into the supply chain and to users.

6 OPEN-SCS: AT A GLANCE

8 QUOTES

- Verifarma
- Uhlmann
- TraceLink
- SEA Vision
- Abbott
- Körber
- Mettler Toledo
- WIPOTEC-OCS

12 OPEN-SCS: TECHNOLOGY

- 12 Technical Overview
- 14 OPC UA based solution
- 18 Security

20 OPEN-SCS: ORGANIZATIONS

- Working Group
- Membership

22 OPEN-SCS: RESOURCES

- Specifications
- Training Material
- Implementation Guidelines
- Certification overview

24 OPEN-SCS: SUCCESS STORIES

- 24 ADVANCO
- 26 Rotzinger
- 28 WIPOTEC-OCS
- 30 Körber





WELCOME TO THE OPEN-SCS WORKING GROUP

Welcome to the OPEN-SCS working group, which, over the past 4–5 years, has created the OPEN SERIALIZATION COMMUNICATION STANDARD (SCS) for the integration of serialization and track and trace systems.

Serialization systems provide unique serial numbers – increasingly required by regulators – used to detect counterfeit products and to support and track products through the supply chain. This functionality is of vital importance in the healthcare industry, and is becoming increasingly required in food & beverage, consumer goods, electronics, and other regulated and high value industries.

I am extremely happy to report that we have a comprehensive set of specification documents, which allow vendors to develop, test and implement OPEN-SCS in their products. We also have a test environment to help vendors test and validate their products. This was our goal, and now a select group of vendors have taken the lead and are soon to release products to the market.

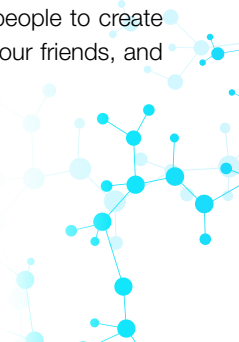
The OPEN-SCS does not replace current standards but combines them with OPC UA Companion Specifications to provide secure, interoperable, reliable, vendor independent and platform-independent communications. We selected OPC UA, GS1 EPCIS and ANSI/ISA-95 (IEC/ISO 62264) standards in order to ensure interoperability across different platforms/systems and across different solution architectures. Another goal of ours is to ensure that, for each system, equipment level, controller level, line-level systems, plant-level systems, and Enterprise systems, they are all part of a seamless serialization and track and trace implementation. With OPC UA, we have a proven technology which includes security

and data modelling and can be used within a protected automation environment and in Enterprise and cloud-based solutions. We used GS1 EPCIS to incorporate the international and widely accepted standards for serialization in the Supply Chain. Working with subject matter experts on GS1/EPCIS, we have specified how to use EPCIS correctly within an interoperable system, and how to further integrate it into the OPC UA environment. Likewise, we used the ANSI/ISA-95 standard because of its leading role in Manufacturing Operation Management Systems. Lastly, we have ensured that our OPC UA Companion Specification is aligned with the OPC UA Companion Specification for ISA-95.

The need for integration across serialization solutions is becoming more visible to manufacturing and distribution companies. Not only is it being used for track and trace and detection of counterfeits in the supply chain, but it is also being used in supply chain optimization, international trade monitoring, finances, and tax collection.

This effort has brought together technology and people to create something that brings great value to our families, our friends, and all healthcare patients around the world.

MARCEL DE GRUTTER
Executive Director OPEN-SCS





The Forty-First World Health Assembly, after reviewing the report of the Executive Board on the implementation of WHO's revised drug strategy, requested:

... governments and pharmaceutical manufacturers to cooperate in the detection and prevention of the increasing incidence of the export or smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations”.

OPEN-SCS – Open Serialization Communication Specification

INDUSTRY REQUIREMENTS

Healthcare supply chains need to be safe and ensure that counterfeit products are not introduced into the supply chain and to users. However, counterfeit pharmaceutical and healthcare products are widely produced and distributed globally. The estimated value has increased from \$10 Billion USD in 2012 to \$130 Billion USD according to the World Health Organization (WHO).

In some countries, counterfeit products are estimated to account for 70% of the medications sold. Counterfeit products hurt and even kill patients, reduce customer confidence in life-saving treatments, and damage company reputations.

Governments are addressing the global healthcare counterfeiting crisis by creating laws that require serialization of healthcare products, their aggregation onto shipping pallets at the manufacturer or repackager as well as authentication and verification at the dispenser. These laws require healthcare manufacturers to apply unique, serialized identifiers to individual instances of physical objects for track and trace purposes.

SERIALIZATION FOR PRODUCTS, CARTONS, CASES, AND PALLETS

Everyone in the healthcare supply chain will need to support serialization, starting at labelling and packaging lines, through distribution centers, and on to final sellers. This usually requires new equipment in the production or packaging lines, both at the individual salable item level, at the carton level, at the case level, and at the pallet level (figure 1). Integration and validation of new printer and associated scan-

ners can be expensive and time consuming. But, integration does not stop there, the laws and regulations mean that the packaging and warehouse equipment and associated plant operations management systems must exchange information with both the manufacturers' supply chain management systems and with dispensing support systems.

OPEN-SCS provides a standard interface for serialization equipment, allowing for seamless integration of systems from printers to corporate IT serialization systems. OPEN-SCS is designed to allow plug-and-play integration of the industrial printers and visualization systems that are required to implement an effective and validated serialization solution. OPEN-SCS defines the standard for exchanging product serialization information across an enterprise and their contract partners.

While the initial work of OPEN-SCS is focused on the healthcare industry and related laws and regulations, the OPEN-SCS Packaging Serialization Specification is designed to be effectively applied in other industries that are increasingly requiring serialization of products. Security is a vital element in a serialization solution. Criminal and terrorist organizations have increasingly attacked corporate networks to cause harm and, in

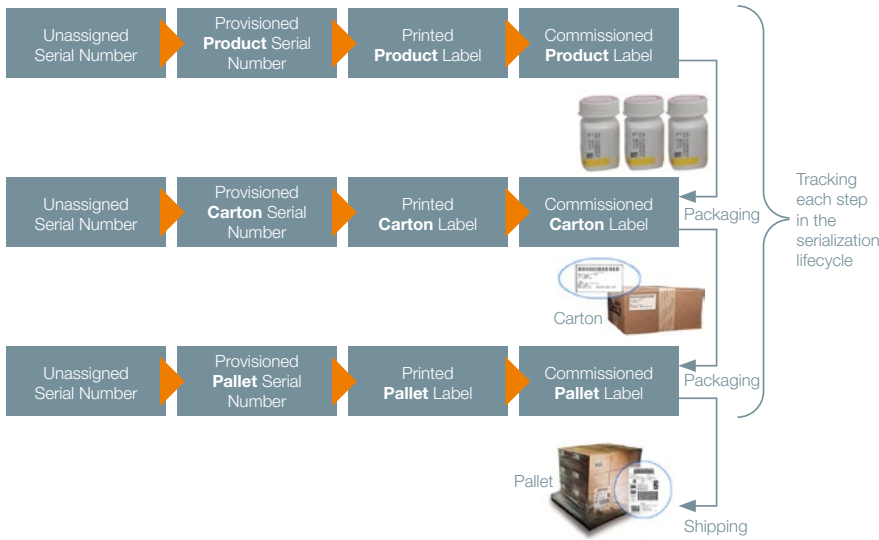


Figure 1: Serialization for products, cartons and pallets

some cases, extract ransom payments. Corporate network vulnerability to these attacks extends down to production systems and the interfaces between them – even entirely within the four walls of the corporation. OPEN-SCS defines a highly secure interface that is considered to be the best in industrial system security. Stolen serial numbers have a high value because they are used with counterfeit products. Using the OPEN-SCS specifications, manufacturers can implement industry best practices to keep their serialization systems secure and serial numbers protected. The OPEN-SCS specifications can be used to securely track product, carton, case, and pallet serial numbers from unassigned, semi-random numbers to commissioned products.

OPEN-SCS IN YOUR GLOBAL SUPPLY CHAIN

OPEN-SCS is defined to be complimentary to the GS1 and the EPCIS standards that deal with busi-

ness-level Track and Trace standards. The GS1 CBV/VOC terminology has been used throughout the OPEN-SCS specifications to ensure easy integration of serialization systems using OPEN-SCS communication models with the EPCIS message models. GS1/EPCIS subject matter experts directly participate within the OPEN-SCS Technical Committee’s engineering team. OPEN-SCS uses the GS1 (www.gs1.org) specified data identifiers and structure, where appropriate, and defines OPEN-SCS specific events and state changes in serialization within production, packaging, and distribution systems. This extra information allows tracking of serial numbers and serialized products within a facility and at a finer level of detail than GS1’s Electronic Product Code Information Specification (EPCIS).

OPEN-SCS must also be compatible with the industry’s manufacturing best practices, so that, through a close partnership with the International Society for Pharmaceutical Engineering (ISPE), OPEN-SCS is aligned with GAMP (Good Automated Manufacturing Practice) best practices. ISPE subject matter experts directly participate on the OPEN-SCS Technical Committee’s engineering team.

OPEN-SCS provides the serialization management system interfaces that support global regulation reporting requirements and the packaging serialization management processes from the enterprise serialization manager to the packaging lines for serialized products throughout the manufacturing lifecycle. OPEN-SCS also supports the activities of CPO (Contract Packaging Organizations), CMOs (Contract Manufacturing Organizations), 3PLs (Third Part Logistics organizations) and reporting to government regulatory authorities as shown in figure 2.

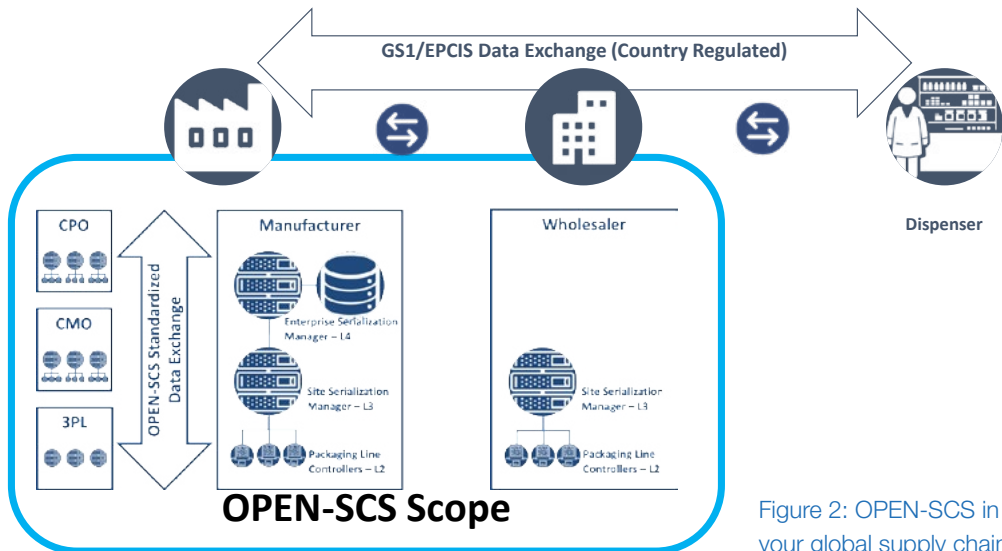


Figure 2: OPEN-SCS in your global supply chain

OPEN-SCS AT A GLANCE

CHALLENGE

Healthcare supply chains need to be safe and ensure that counterfeit products are not introduced into the supply chain and to users. Governments are addressing the global healthcare counterfeiting crisis by creating laws that require serialization of healthcare products, their aggregation into shipping pallets at the manufacturer or re-packager and authentication and verification at the dispenser.

AVOID VENDOR LOCK-IN

These laws require healthcare manufacturers to apply unique serialized identifiers to individual instances of physical objects for track and trace purposes. Everyone in the healthcare supply chain will need to support serialization, starting at labelling and packaging lines, through distribution centers, to final sellers. Proprietary solutions will create multiple interfaces, high efforts to support different solutions and finally will result in a vendor lock in.

STANDARD INTERFACE – SEAMLESS

HORIZONTAL AND VERTICAL INTEGRATION

OPEN-SCS provides a standard interface for serialization equipment, allowing for seamless integration

of systems from printers to corporate IT serialization systems. OPEN-SCS defines the standard for exchanging product serialization information across the enterprise.

BASED ON INTERNATIONAL STANDARDS

OPEN-SCS has not reinvented the wheel – instead OPEN-SCS is based on existing accepted international standards like OPC UA (IEC62541), GS1, EPCIS, and ANSI/ISA-95 (IEC/ISO 62264). OPEN-SCS is compatible and aligned with industry best practices e.g., with the International Society for Pharmaceutical Engineering (ISPE) and GAMP (Good Automated Manufacturing Practice).

SECURE, RELIABLE INTEROPERABILITY

OPEN-SCS is based on OPC UA technology – a world accepted IEC standard which delivers a secure, reliable transport of data and information from the shop floor to control systems, to production planning systems, and to the cloud and back.

OPC UA is the key technology for the digital transformation migrating from the protocol-based automation pyramid to the modern information network.

STRONG SECURITY THAT IS SCALABLE

OPEN-SCS defines a highly secure interface that is considered the best in industrial system security. Stolen serial numbers have a high value because they are used with counterfeit products. In addition, the underlying OPC UA technology is based on accepted security concepts and standards that are also used for secure internet communications including Secure Sockets Layer (SSL), Transport Layer Security (TLS) and Advanced Encryption Standard (AES). OPC UA offers protection against unauthorized access, sabotage, modification of process data and careless operations.

ROBUST INFORMATION MODELING

Robust information modeling is built into the heart of the OPC UA standard. OPC UA defines base building blocks and consistent rules to build object-oriented models with them. In OPC UA it is possible to expose and discover information models in a consistent and universal manner between all OPC UA entities. OPC UA defines a few industry-agnostic information models that other organizations use as a common starting point to define their own OPC UA based information models. OPC UA also defines the

mechanisms needed to facilitate dynamic discovery and access to OPC UA information models. OPEN-SCS is one of the many information models under the OPC Foundation umbrella.

GROWING AREAS OF ADOPTION

The functional breadth of OPC UA makes it universal and applicable for use in an ever-growing list of new markets and applications. From local plants to remote field stations behind firewalls – OPC UA is consistently the preferred choice. Other standards bodies increasingly use OPC UA as an interoperability platform for defining and implementing their own information models. Currently, the OPC Foundation cooperates with over 63 such groups from various industries including discrete and process automation, energy, engineering tool manufacturers, industrial kitchen equipment, and now pharmaceutical with OPEN-SCS.

verifarma



We believe in open and fruitful cooperation with our partners and customers, always thinking of our common goal – the wellness and safety of the patient. Here is where OPEN-SCS plays a crucial role by providing a common understanding about interoperability and flexibility between every link in the value chain.”

SANTIAGO A. SPECTOR MENTASTI,
CEO Verifarma



QUOTES



facilityboss



From facilityboss’ perspective, joining the OPEN-SCS Working Group was an obvious choice. It is our vision to equip a heterogeneous production with our homogeneous level-spanning solutions. By doing this, a lot of time and effort is concentrated on closing the gaps between our solution and different customer’s infrastructures. A standard developed by OPEN-SCS aims to close this gap and makes it easier for all of us to meet requirements across organizations and regulatory bodies. Simultaneously, this is making the customer more flexible in their decisions and enables fast and efficient scalability. Therefore, as a software manufacturer operating in the field of serialization, the ongoing effort to support OPEN-SCS’ latest features in our products and our customer’s installations saves money, time, and, as seen due to the events of 2020, actively helps people by preventing counterfeits by guaranteeing safe medical products. Given this context, joining OPEN-SCS is not only a sound business decision but a moral duty.”

MAX LARSSON,
CEO facilityboss GmbH





“The work we are doing with all the members of the OPEN-SCS Working Group, is a commitment to patients for quality and affordable medications. At Vimachem, we have developed interfaces to nine serialization Level 2s and the cost to monitor and maintain them is a yield to productivity and cost-efficiency. Through the OPEN-SCS Working Group, we have developed pilots using the OPEN-SCS standards, which are to be rolled out to Global Pharmas to standardize all serialization interfaces and optimize the operationalization of track and trace.”



ALEX VIDRAS, Optimizing Pharma manufacturing, Track and Trace – Pharma 4.0, Adjunct Faculty at Columbia University



“Maximum flexibility and communication across multi-vendor platforms are paramount for both our customer and us. To guarantee that the manufacturing processes and the production of their highly sensitive products are quick, error-free and reliable, the OPEN-SCS standardization, combined with our flexible solution, supports a multi-vendor approach.”

THOMAS KREUTLE, Head of Development & Operations, Digital Solutions bei Uhlmann Pac-Systeme



“Business requirements for serialized product identity and availability of accurate product status is the new normal across today’s diverse and evolving global pharmaceutical and healthcare supply chain. OPEN-SCS is leading the way in helping ensure a secure, interoperable foundation for this information through the standardized flow of critical serialization data and related events between packaging and serialization systems in the production and packaging ecosystem.”

BRIAN DALEIDEN,
VP Industry Marketing/Community and Co-Founder @ TraceLink





“ We have faced several projects where cross-vendor integration has been a crucial factor in our success. We believe that, by cooperating together within OPEN-SCS, we can define a common approach, procedure, and method to close the existing gaps within standards and create value for the pharmaceutical industry. SEA Vision has a flexible architecture, which facilitates easy integration of OPEN-SCS methods in order to be complaint with upcoming specifications.”

GIANLUCA SALA,

Technical Product Manager presso SEA Vision



“ I have been a supporter of OPEN-SCS from the beginning – for Abbott, it will give us the opportunity to much more easily integrate equipment from different suppliers and move more easily to the latest technology instead of reinvesting in a full line. This will help us to keep our innovations in packaging as well as our efficiency high – especially for the emerging markets, which deserve much more attention in the future.”

ULF SUERIG,

Director Supply Chain Optimization Abbott



“ Focusing on a real Level-3 Serialization Site Server translates for our solution to easily connect with all partner systems – line level, global repository, and MES. Providing an interface technology, which is quick to implement, easy to configure, and stable to use is key – and that is part of our companies’ DNA for more than 50 years. Being STC member and active contributor for OPEN-SCS is therefore important for us. OPEN-SCS makes the difference by enabling interoperability! ”



JÜRGEN LASKOWSKI,

Director Global Manufacturing Integration & Serialization Solutions
Körber Business Area Pharma

METTLER TOLEDO



Mettler Toledo PCE is actively following the developments of the OPEN-SCS standard with great interest. OPEN-SCS fits in with our development philosophy because the focus is on interoperability and standardized communication of serialization systems. The event-based exchange of messages is efficient communication between different manufacturers and ensures the best possible integration into their infrastructure for customers."

ALEXANDER EL BERINS,

Head Product Management & Engineering, Mettler-Toledo



WIPOTEC OCS
WEIGHING AND INSPECTION SOLUTIONS



As a Founding Member of the OPEN-SCS Working Group and its Steering Committee, WIPOTEC-OCS is supporting a very open and flexible connectivity approach. The benefits are outstanding and we are convinced that it's worth fighting against the global lack of standardization for serialization / T&T equipment in packaging lines and data exchange. But also, faster implementation through standardized interfaces, smooth validation processes through consistent functionalities, and avoiding vendor lock-in, results in better prices."

VOLKER DITSCHER,

Director Global Sales Track & Trace



...MORE QUOTES

OPEN-SCS TECHNICAL OVERVIEW

The OPEN SERIALIZATION COMMUNICATION STANDARD (OPEN-SCS) is a set of interface specifications for exchanging product serialization information across an enterprise and their contract partners from the packaging process to the distribution warehouse.

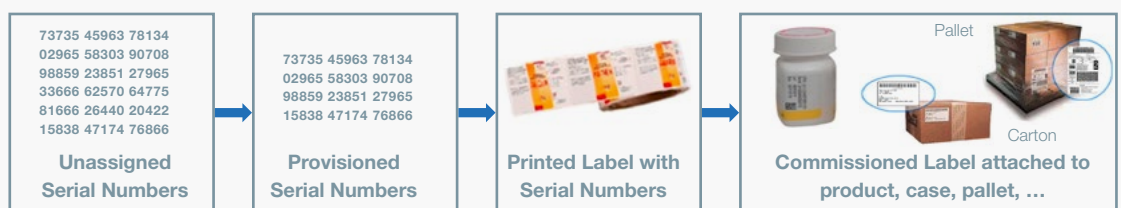


Figure 1:
The Lifecycle of a
Serial Number

The interface specifications are called the OPEN-SCS Packaging Serialization Specification and the OPC UA OPEN-SCS Companion Specifications. These specifications define formal information and transaction models for the exchange of product serialization information that is required to meet known healthcare supply chain serialization regulations and associated standards. It specifies the requirements for the implementation of system components and interfaces that manage the lifecycle of product serialization information from a packaging process to a distribution warehouse.

THE SPECIFICATION DOCUMENTS INCLUDE:

- OPEN-SCS Packaging Serialization Specification (PSS)
- **OPC 30260** – UA Companion Specification for OPEN-SCS V1.1
- **OPC 30261** – UA Companion Specification Profile for Job Control V1.0
- **OPC-10030-4** – UA Companion Specification for ISA-95 Job Control V1.0
- **OPEN-SCS OPC UA** Implementation Guidelines

In order to meet the requirements for both in-facility and supply chain tacking, the Serial Number lifecycle is described from creation of the serial number (usually a semi-random number), to merge with an electronic product code (EPC as defined by GS1 global

on a label, to applying the label to the serialized product, to final delivery of the product.

FIGURE 1: THE LIFECYCLE OF A SERIAL NUMBER

When the serial number is printed, it is combined with other information required on the label, for example: product code, lot number, expiration date, etc.

- **1.** An unassigned Serial Number, where the number has not been assigned to any specific product, assembly, production order, or packaging run.
- **2.** A provisioned Serial Number containing the serial number in a digital form that has been associated to a specific product, package type, production order, or packaging run.
- **3.** The Serial Number as it is printed on a label and combined with other label information, but not yet applied to the physical product (called a printed label).
- **4.** The printed label as it is applied to the physical product (called a commissioned label), which is now called an SID in the OPEN-SCS specification.

In some cases, the activity of serialization includes the packing of serialized child objects (packages) into serialized and parent objects (containers) in a process identified as aggregation. Serialization ag-

gregation events usually start with the Lowest Saleable Unit (LSU) (e.g., bottle or carton) and potentially includes multiple levels in the packaging hierarchy (such as a pallet made up of cases, cases made up of packages, and packages made up of cartons, with serialization information defined at each level of the hierarchy.)

THE OPC 30260 – UA COMPANION SPECIFICATION FOR OPEN-SCS DEFINES MULTIPLE OPC UA OBJECTS:

- A Serial Number Pool Manager: which provides methods and data to obtain serial numbers from a pool maintained by the server, to return unused serial numbers back to the pool
- An Event Manager: which provides methods to notify of changes in state of serial numbers (unassigned, provisioned, printed, commissioned, sampled, scrapped, and released from production/packaging). It also provides methods to receive GS1/EPCIS formatted files to provide interoperability with corporate supply chains.
- An Aggregation Manager: which provides methods to specify aggregating products (such as cases to pallet) and un-aggregating products (such as pulling cartons from a case for sampling or redistribution).
- An SID Class: which provides information about the serial number ID collection owner, the serial number syntax specification, and the allowed

character sets for serial numbers. This allows for complete flexibility in defining serial numbers so that systems can support the many different country regulations for syntax and character sets.

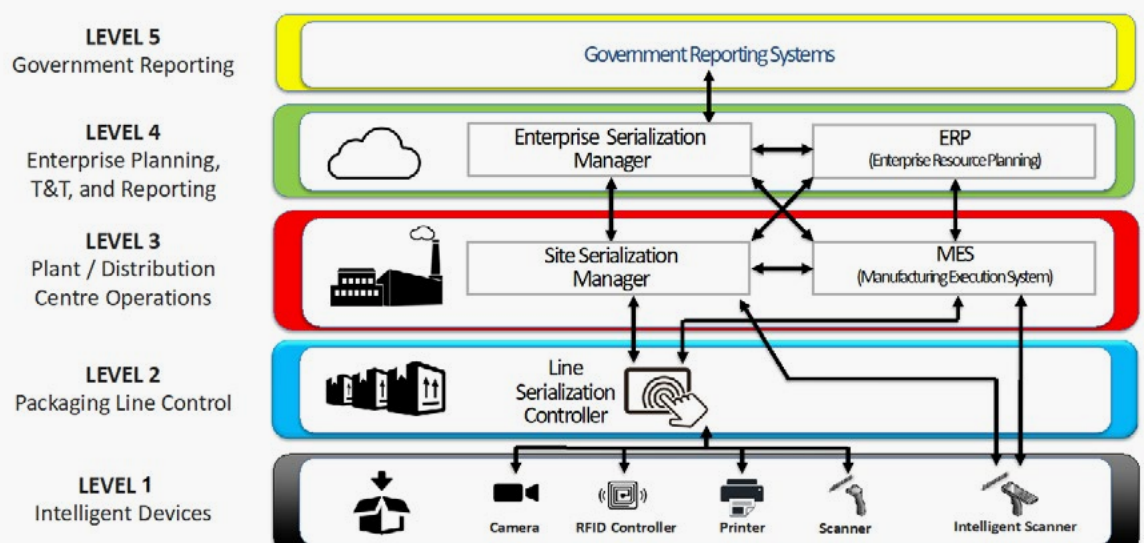
The specification also defines a set of server profiles to support interfaces to Level 2 systems (smart printers and controllers), Level 3 systems (MES and site serial number management systems), and Level 4 (business and supply chain systems).

FIGURE 2: TYPICAL SCOPE OF THE PACKAGING SERIALIZATION SOLUTION

The OPC-10030-4 – UA Companion Specification for ISA-95 Job Control Specification defines the methods and data to control production and packaging orders. It follows the ANSI/ISA-95 and IEC/ISO 62264 standard for Job Orders and Job Responses, providing a real-time secure interface to executing jobs. It defines a generic model for control of jobs, which can be used in any industry.

The OPC 30261 – UA Companion Specification Profile for Job Control extends the Job Control specification with profiles that define the specific security requirements for controlling serialization jobs and receiving job responses. OPC 30261 also defines the industry-specific product master data properties used in serialization solutions, such as regulated product name, warning copy description, brand name, and product packaging code.

Figure 2:
Typical Scope of
the Packaging
Serialization Solution





WHY USE OPC UA BASED SOLUTION

OPC Unified Architecture (OPC UA) is the information exchange standard for secure, reliable, manufacturer and platform-independent industrial communications. It enables information exchange between products from different manufacturers and across operating systems.

For nearly two decades, OPC has been, and continues to be, the go-to connectivity standard in industry. With the advent of the Internet of Things (IoT) era, OPC adoption has also shown growth in new, non-industrial markets.

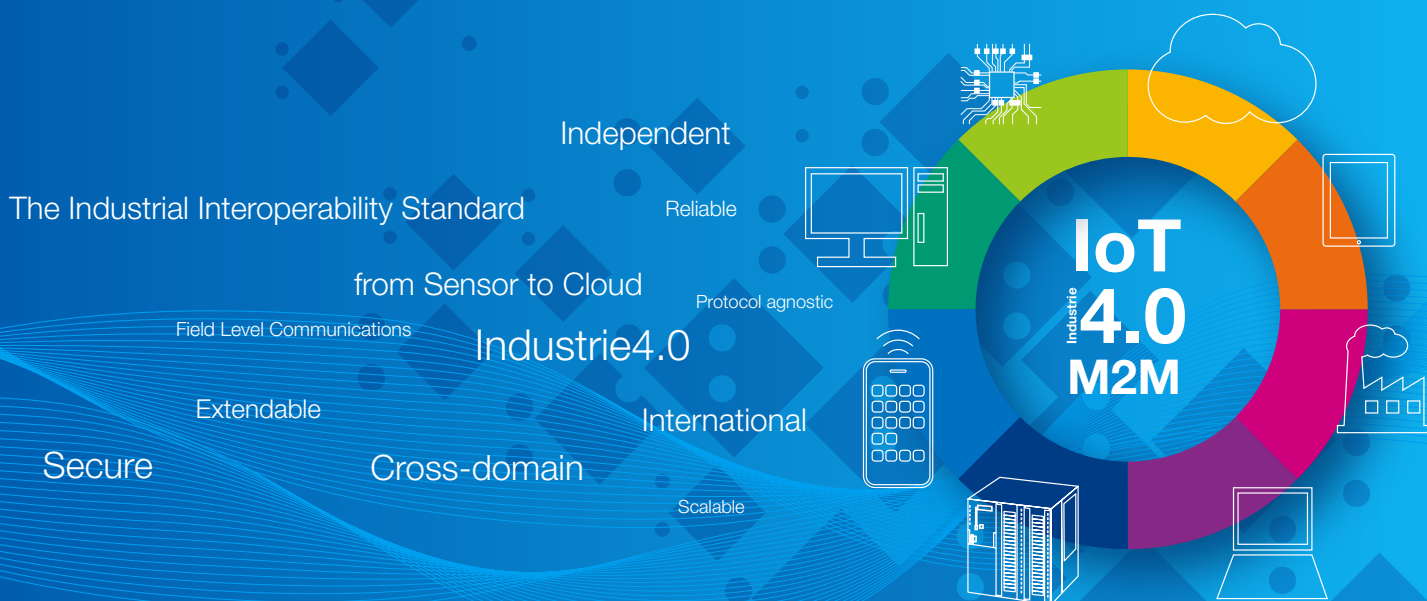
OPC UA is an IEC standard and is therefore ideally suited for collaboration with other organizations. As a global, independent, non-profit organization, the OPC Foundation coordinates the further development of the OPC standard in collaboration with users, manufacturers and researchers.

Activities include:

- Development and maintenance of specifications
- Certification and compliance testing of implementations
- Cooperation with other standards organizations – like OPEN-SCS.

WORLD'S LARGEST ECO-SYSTEM FOR INTEROPERABILITY

With over 800 members around the world, the OPC Foundation is the world's largest ecosystem for se-



cured, industrial interoperability. Whether it is large hyperscaler providers, such as Amazon Web Services, Google Cloud and Microsoft Azure; or chip-level companies such as Intel, Qualcomm, NXP, and Microchip; or end users such as Foxconn, Samsung, Equinor, Volkswagen, Continental, Miele, and Pfizer; the vast majority (80%) of the top-50 automation companies worldwide are members of the OPC Foundation.

SECURE, RELIABLE INTEROPERABILITY

OPC UA is the latest generation of OPC technology from the OPC Foundation. OPC UA rewrites the original OPC standard from the ground up and extends its relevance by addressing a broad range of modern communication requirements. As such, OPC UA delivers a secure, reliable transport of data and information from sensors and the shop floor to control systems, production planning systems, and cloud platforms (and back).

PLATFORM AND VENDOR-INDEPENDENT

OPC UA is an open standard that neither depends upon nor binds to proprietary technologies or indi-

vidual vendors. Hence, all OPC UA communications are 100% independent of the vendors who implement them, the programming languages used, and the platforms upon which such products run.

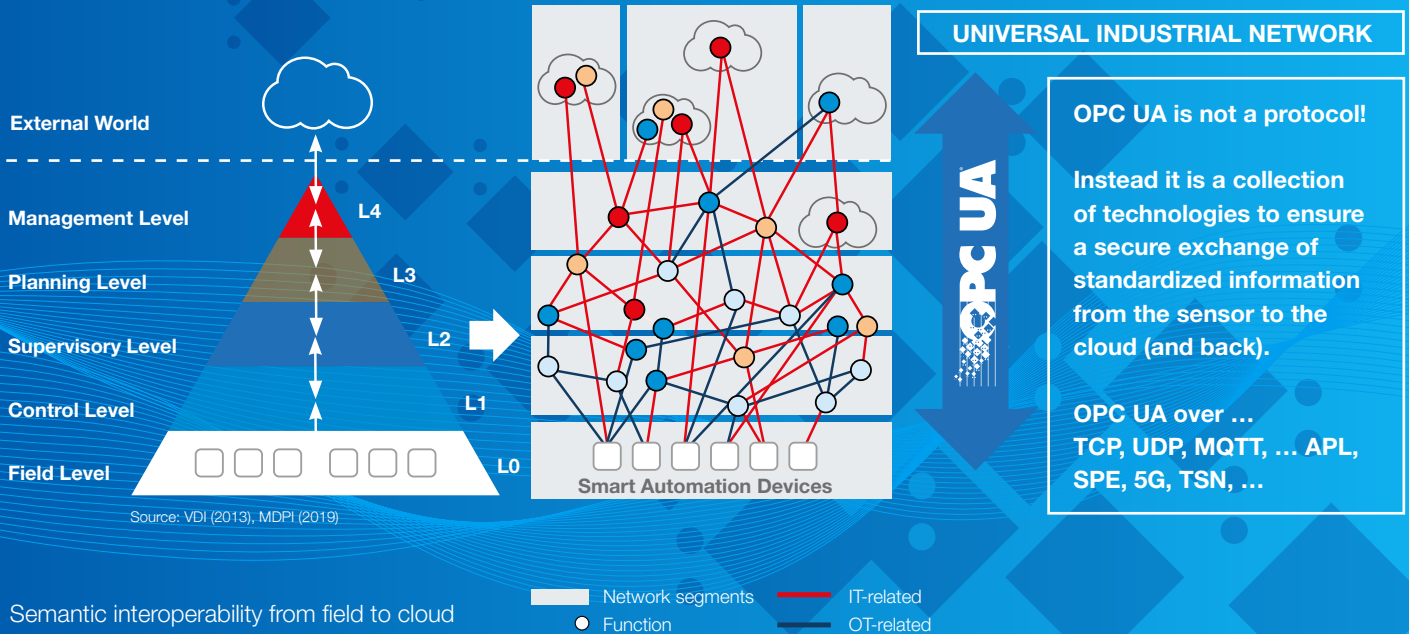
OPC UA IS IEC62541 STANDARD

This IEC standard, known as IEC62541, is ideally suited for collaboration with other organizations. Consequently, the OPC UA standard has been localized in different parts of the world, including China, South-Korea, and Singapore.

STRONG SECURITY THAT IS SCALABLE

OPC UA is based on the same industry-accepted security concepts and standards used in secure internet communications. Examples include SSL, TLS, and AES. OPC UA offers protection against unauthorized access, sabotage, modification of process data, and careless operations. OPC UA security mechanisms include: user and application authentication, signing of messages, and data encryption. While users are free to choose which OPC UA security functions they want to use, based on their infrastructure and context, vendors are obliged to imple-

From Automation Pyramid to Information Network



ment all of them depending on the OPC UA profile they want to support.

This ability to choose which security features are used, makes OPC UA usable (scalable) in all types of environments (e.g. limited computing resources vs. large computer systems).

ACCESSIBILITY AND RELIABILITY

OPC UA defines a robust architecture with reliable communication mechanisms, configurable timeouts, and automatic error detection that restores communications between OPC UA Clients and Servers without data loss. In addition, OPC UA redundancy functions for both client and server applications make OPC UA suitable for high-availability applications.

USES THE LATEST OPEN STANDARDS

OPC UA is based on various types of standards and protocols carefully chosen based on their ability to meet the needs of specific OPC UA use cases.

For example:

- For OPC UA Client-Server communications, OPC UA uses an optimized TCP based binary protocol for data exchange over the IANA registered port 4840.

- For Cloud-based communications, OPC UA uses popular protocols like MQTT and AMQP.

- For communication across field applications, OPC UA uses UDP and specialized protocols like TSN or 5G for deterministic communication.

- Web Sockets may also be used to support browser-based OPC UA Clients. New protocol bindings like QUIC (UDP-based Internet protocol) can be integrated easily without breaking existing functionality.

ROBUST INFORMATION MODELING

Robust information modeling (IM) is built into the heart of the OPC UA standard. OPC UA defines base building blocks and consistent rules to build object-oriented models with them. With OPC UA, it is possible to expose and discover information models in a consistent and universal manner between all OPC UA entities. OPC UA defines a few industry agnostic IMs that other organizations use as a common starting point to define their own OPC UA based IMs. OPC UA also defines the mechanisms needed to facilitate dynamic discovery and access to OPC UA IMs. This is crucial for third-party interoperability because different OPC UA implementations will natively

implement different IMs. Key OPC UA functions include:

- Browsing: A look-up mechanism used to locate object instances and their semantics
- Read and write operations: used for current and historical data
- Method execution
- Notification for data and events

SIMPLIFICATION BY UNIFICATION

OPC UA defines an integrated address space and a unified information model that supports process data, alarms, historical data, and function calls (methods). Beyond OPC classic functionality, OPC UA also supports the description and use of complex procedures and systems in uniform object oriented components. Hence, OPC UA Clients, which may

only support basic rules, can still process data from OPC UA Servers without any knowledge of the complex data structures residing in the OPC UA Server.

GROWING AREAS OF ADOPTION

The functional breadth of OPC UA makes it universal and applicable for use in an ever-growing list of new markets and applications. From local plants to remote field stations behind firewalls – OPC UA is the right choice upon which to standardize. Other standards bodies increasingly use OPC UA as an interoperability platform for defining and implementing their own information models. Currently, the OPC Foundation cooperates with over 65 such groups from various industries, including: discrete and process automation, energy, engineering tool manufacturers, industrial kitchen equipment, and many more.

Find more information here: www.opcfoundation.org

The screenshot shows the OPC Foundation website. At the top, there is a navigation bar with links for 'About', 'Membership', 'Products', 'Certification', 'Markets & Collaboration', 'Resources', and 'News & Events'. A search bar is located on the right. The main content area features a large video player titled 'Minute OPC UA YouTube Video' with a 'Watch the Video' button. Below the video, there is a 'Welcome to the World of OPC' section with introductory text. To the left, there are two 'OPC News' articles: 'The OPC Foundation welcomes Amazon Web Services (AWS) as a new member' and 'The OPC Foundation welcomes Invoiance (China) as its 800th member'. To the right, there is an 'Upcoming Events' section listing 'Hannover Messe (Digital)', 'OPC Day 2021 - International', and 'OPC Interoperability Workshop, Japan'. A right sidebar contains a 'SUBSCRIBE NEWSLETTER' form, a 'BECOME A MEMBER' button, and lists of 'Newest Members' and 'Certified Products'.



OPEN-SCS SECURITY

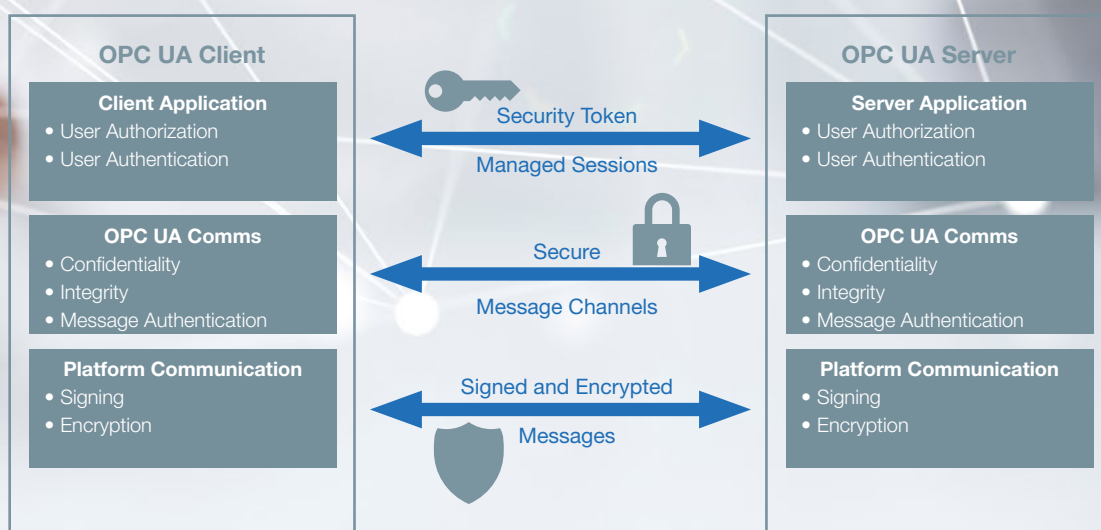
Product-specific, unique serial numbers have a high value in the life-sciences industries. Counterfeit products, with little to no actual medicine, can be sold for huge profits to unsuspecting patients. Counterfeit products can destroy patient confidence in medicines and can even kill people.

Countries are now requiring unique serial numbers on products so that dispensaries, pharmacies, and patients can be confident that they have true and safe products. Criminals want to get their hands on valid serial numbers to put their counterfeit products into your supply chain or even to directly sell them to your customers. Additionally, hackers and terrorists will try to disrupt supply chains for vital medicines by corrupting serial number databases, labeling equipment, or packaging lines.

For these reasons, the OPEN-SCS specifications place a high value on security to protect against misuse or corruption of serial numbers as they move across systems.

OPEN-SCS uses the three levels of security protection provided by OPC UA:

- 1. Client and server application user security**
- 2. Client and server session security**
- 3. Signed and encrypted transport security**



These levels of protection allow manufacturers to configure exactly the level of security that they require. OPEN-SCS also defines a minimum level of security to meet OPEN-SCS compliance. Security certificates are required, client and server authorization and authentication are required, and data encryption is required. The use of the OPC UA security policy SECURITY_POLICY_NONE is not allowed. These security policies protect data at all levels of utilization, including printers and scanners, control systems, site serialization systems, and up to corporate serialization systems. They ensure that only signed, approved applications and systems have access to manage your serial numbers.

DEFENSE IN DEPTH

The security concept of “defense in depth” is used to provide assurance that your valuable information is protected using the multiple layers defined above. As a result, an attacker must break through several barriers before compromising or accessing your secure data.

Of course, no system is safe unless it is implemented correctly within products, and then installed correctly during construction.

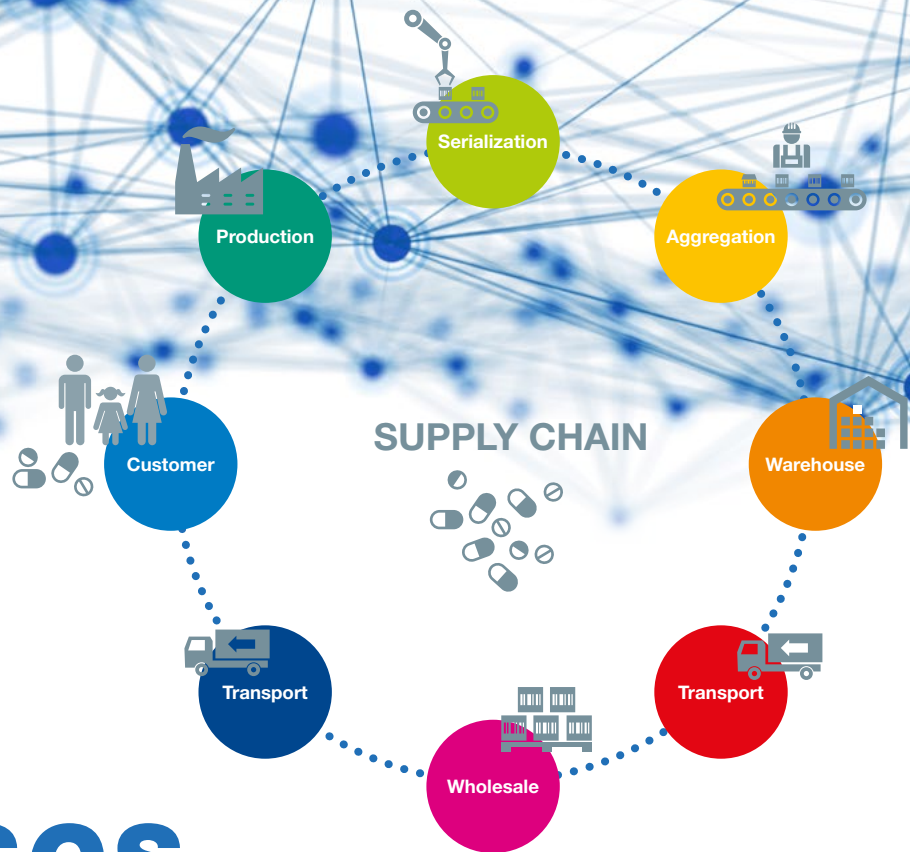
The OPC Foundation members and partners have published the whitepaper

→ [Practical Security Recommendations for Building OPC UA Applications](#)

to assist developers and users in the proper methods needed to create and maintain a secure system.

SUMMARY

The OPC UA specification and OPEN-SCS requirements use the trusted information triad of message confidentiality, integrity, and availability, and use access control following the AAA framework of user authentication, user authorization, and audit accounting. These measures provide an industry-proven security solution that protects information as it moves through your networks, thus preventing counterfeit products or stolen serial numbers from entering your supply chain.



OPEN-SCS WORKING GROUP

The OPEN-SCS Working Group is organized as a Joint Working Group in the OPC Foundation. It was created in 2015 by eleven (11) original companies who desired to use OPC UA as the basis of their serialization technology.

Those eleven companies formed the original Steering Committee, which was headed by Mr. Marcel de Grutter from Abbott. To advance the work necessary to fulfill their Charter, the Steering Committee formed two sub-Committees, a Technical Committee and a Marketing Committee.

TECHNICAL COMMITTEE

The Technical Committee, which is headed by Dennis Brandl from BR&L Consulting, includes Cos Pipro, an SME from Beeond and numerous volunteers who create, edit, and submit for vote, the Working Groups specifications. Those specifications include the OPEN-SCS Use Cases, the Packaging Serialization Specification, the OPEN-

SCS OPC UA Companion Specification, all of which are available on the web site <https://open-scs.org>.

MARKETING COMMITTEE

The Marketing Committee includes volunteers from Abbott, Advanco, BR&L Consulting, OPC Foundation, Rotzinger, Körber Pharma Software, and WIPO-TEC-OCS.

PRODUCTS

First products, based on the above specifications, have emerged from Advanco, Rotzinger, Körber Pharma Software, and WIPOTEC-OCS, with many others in the pipeline.



OPEN-SCS
Working Group

THE MEMBERSHIP TODAY INCLUDES COMPANIES

 **Abbott**

 **advanco**

 **HAPA**
a coesia company

 **KÖRBER**

 **Laetus**

METTLER TOLEDO

 **Roche**

 **ROTZINGER**
PharmaPack

 **SEAVISION**

 **Uhlmann**
UHLMANN GROUP

 **verifarma**

 **WIPOTEC OCS**
WEIGHING AND INSPECTION SOLUTIONS

For membership information, please contact Michael Bryant at
michael.bryant@opcfoundation.org.

OPEN-SCS RESOURCES

SPECIFICATIONS

The OPEN-SCS Engineering Team is a group internal to the OPEN-SCS Working Group where Members can participate on the creation, review, and delivery of all OPEN-SCS specification and supporting resources.

The team meets at least monthly to review the progress and coordinate their activities with the OPC Foundation for the review and release of specifications according to the formal policies.

The OPEN-SCS specifications are organized by functional scope:

- **Packaging Serialization Specification (PSS):** this specification defines formal information and transaction models for the exchange of product serialization information required to meet known healthcare supply chain serialization regulations and associated standards.
- **Use Cases:** this document illustrates a set of representative examples of the the application of the serialization process as defined by the PSS.

→ **OPC UA Companion Specification for Serialization:** this document defines the OPC UA Information Model for exchanging product serialization information across an enterprise and their contract partners from the packaging process to the distribution warehouse.

→ **OPC UA Companion Specification for Job Orders:** this document defines the OPC UA Information Model for ISA-95 Job Orders, ISA-95 Job Responses, and access to queued, executing, and completed job order status and responses.

The released specifications are posted on the public facing website (<https://www.open-scs.org/>) as they are approved. They are also posted on the OPC Foundation website among all the approved Information Models for the various industry domains ([https://opcfoundation.org/developer-tools/specifications-OPC UA-information-models](https://opcfoundation.org/developer-tools/specifications-OPC-UA-information-models)).

OPEN-SCS Members can also access a Members SharePoint Portal to follow the review-cycle of the new specifications, propose and approve changes, and access implementation resources.



TRAINING MATERIALS

OPEN-SCS Members can access training and development resources to help further the integration of OPEN-SCS interfaces:

- **Training Videos:** a series of videos on the fundamentals of OPC UA solutions, and the implementation of the OPEN-SCS OPC UA Companion Specifications.
- **OPC UA Nodest files:** OPEN-SCS maintains a private GitHub repository to access the OPC UA Nodest files, which represent the OPC UA Information Models in an XML form and can be used to implement the interfaces.
- **OPEN-SCS Reference Implementation code:** a .NET application has been developed to demonstrate and train developers on the implementation of OPEN-SCS specifications using the OPC Foundation Reference Implementation OPC UA SDK.

IMPLEMENTATION GUIDELINES

The OPEN-SCS Engineering Team maintains a series of practical use cases and scenarios to address the concerns related to the implementation, deploy-

ment, securing, and maintenance of OPEN-SCS solutions. This publication will be made available to Members to help with the rollout of their solutions. At times, usually as new revisions of the specifications are being drafted, Members will participate in interoperability workshops, where every vendor will be able to test their products with the other participants.

CERTIFICATION OVERVIEW

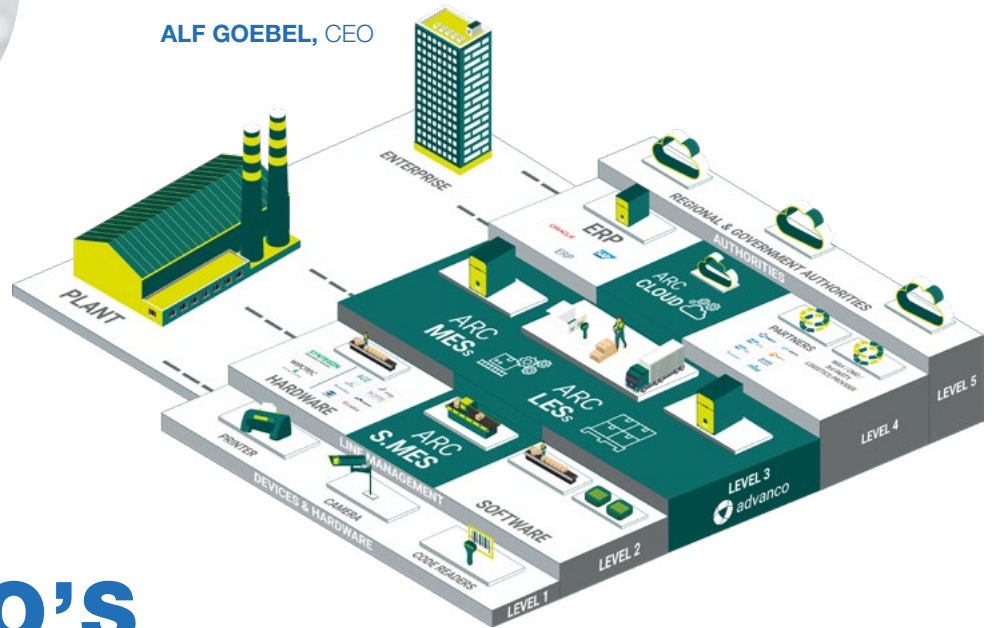
The OPC Foundation has a certification process for general OPC UA products, which provides vendors a means whereby they can certify their Clients and/or Servers and then obtain a logo which attests their compliance to the standard specification for selected profiles. Information on the OPC Certification process can be found on the OPC Foundation website at <https://opcfoundation.org/certification/how-to-certify/>. In addition to that, OPEN-SCS can be certified by an independent lab to comply with this standard by testing against existing products that have already been certified.

Offices Brussel, Cancun, Cologne, Istanbul, London, San Francisco



For more than 41 years, advanco has been delivering open solutions for the supply chain and continues now with the implementation of OPEN-SCS.”

ALF GOEBEL, CEO



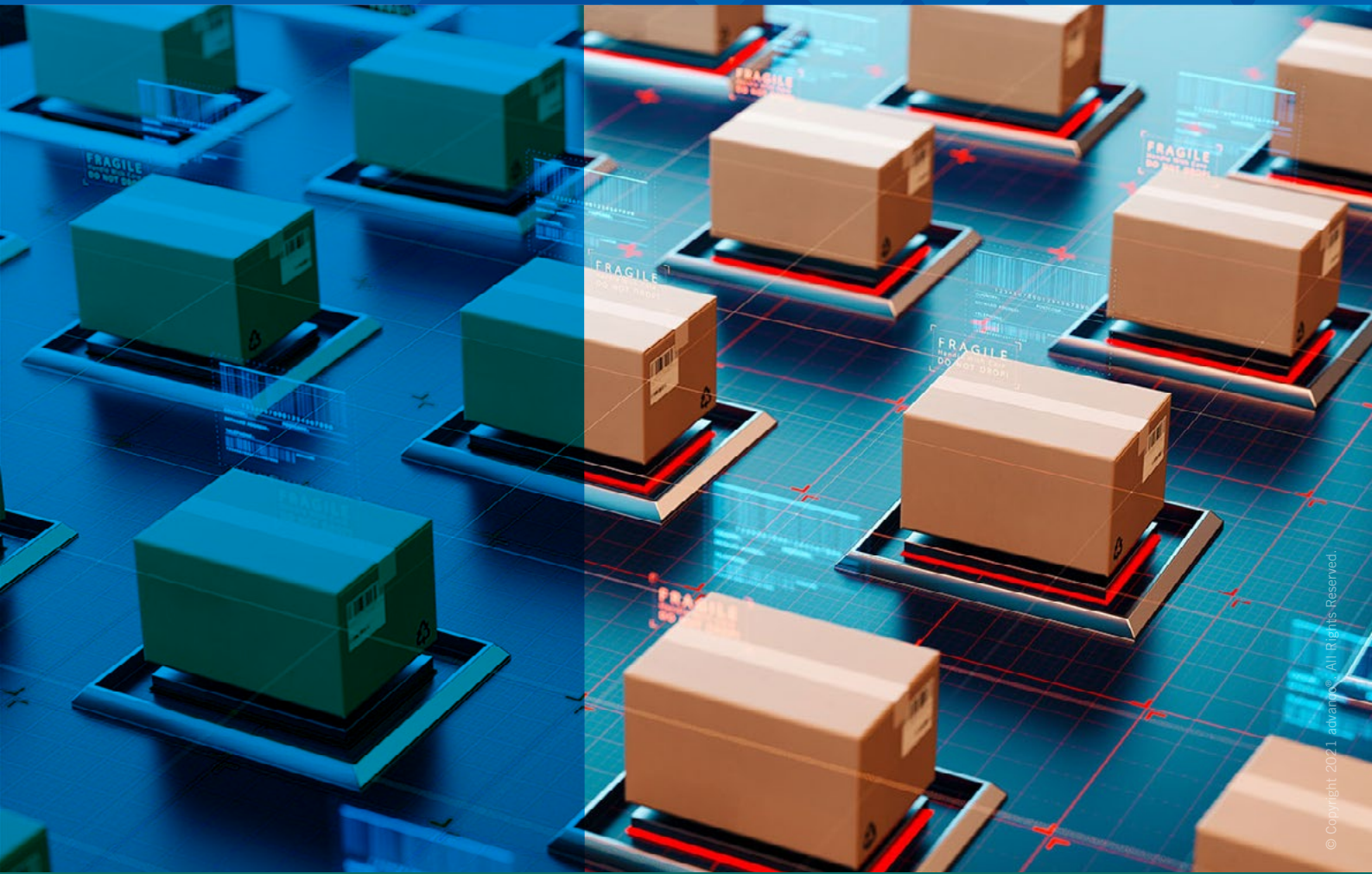
ADVANCO'S OPEN-SCS OFFERING

As the leading provider for Level 3 and Level 4 Item Level Serialization, advanco has been offering extensive, holistic and mission critical solutions in the fields of supply chains as well as track and trace for more than 41 years.

Our Development and Support team draws on over four decades of experience in the supply chain sectors, arming our customers with an industry-leading software platform, known as ARC. This end-to-end solution works seamlessly through manufacturing, packaging, and along the entire supply chain, featuring track and trace. Advanco is the first founding and

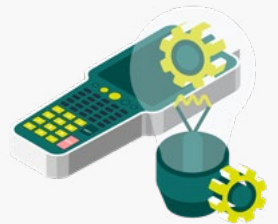
executive member of the OPEN-SCS group. ARC Open-Serialization Communication Standard Service acts like an orchestrator between Levels 2 and 4. ARC OPEN-SCS Packaging Serialization service manages serial numbers by requesting serial numbers from Level-4 entities with secure OPC UA communication protocol. ARC OPEN-SCS Job Order service manages packaging orders and sends the necessary information to the Level-2 systems. In 2020, advanco implemented Job Order service and tested the full cycle serialization process with Rotzinger.





ARC PLATFORM | ARC MES_s  ARC LES_s  ARC CLOUD 

PROCESSES SUPPORTED BY ARC PLATFORM



SERIALIZATION PROCESSES:

- **Global Serial Number Management** – ARC Cloud will act as Global Serial Number Management System
- **Local Serial Number Management** – ARC has the capability to manage serial numbers on-site level
- **Serial Number Provisioning** – ARC connects to Level-4 or internal Local Serial Number Management
- **Label Printing** – ARC provides serial numbers to Level-2 for label printing
- **Label Commissioning** – ARC sends the commissioned items to Level-4 after packaging
- **Product Delivery** – ARC LESs manages shipping activities

JOB ORDER PROCESSES:

- **Job Order** – ARC OPEN-SCS Job Order Service sends the job order to the Level-2 system
- **Label Commissioning** – Level-2 system sends the packaging hierarchy to ARC OPEN-SCS Job Order Service



Rotzinger's aim is to set and enlarge global standards. It was clear to join the OPEN-SCS working group and also to implement the interface as a standard for our track and trace portfolio to offer the highest flexibility on the customer side. The open approach realizes many benefits in terms of fast and easy integration, standardized validation procedures and allows customers to choose the best of breed of different systems. The future is openness combined with partnering on all levels."

ROTZINGER

PharmaPack

MATTHIAS HEINRICHS,
Director Sales and Marketing

UNLOCK YOURSELF AND FEEL THE FREEDOM TO COMBINE BEST-IN-CLASS SOLUTIONS

Rotzinger is a leading global provider of process and packaging technology, offering complete solutions for the pharmaceutical and food industries for over 50 years.



Based on decades of experience, Rotzinger can refer to numerous successful projects in the pharmaceutical, automotive and other industries around the globe. The portfolio includes hardware, software from Level 1 to Level 3 for track and trace as well as Industry 4.0 store floor digitization and line packaging solutions. Open communication and experienced

support, offer customers maximized flexibility in machine handover and the following benefits:

- Fast integration
- Interoperability of different systems
- Freedom to choose best of breed equipment
- No lock-in to one supplier.



Enhanced Serial Number Management

Import / Export,
Serial Number Generator



Line Manager and Automation

Smart and flexible shop floor
digitalization



Master Data Functionality

Automatic processing of all
production relevant data



Single Objects Data Acquisition

Create digital twins of
single products



Warehouse

Rework De-/Re-aggregation,
re-labelling, status change

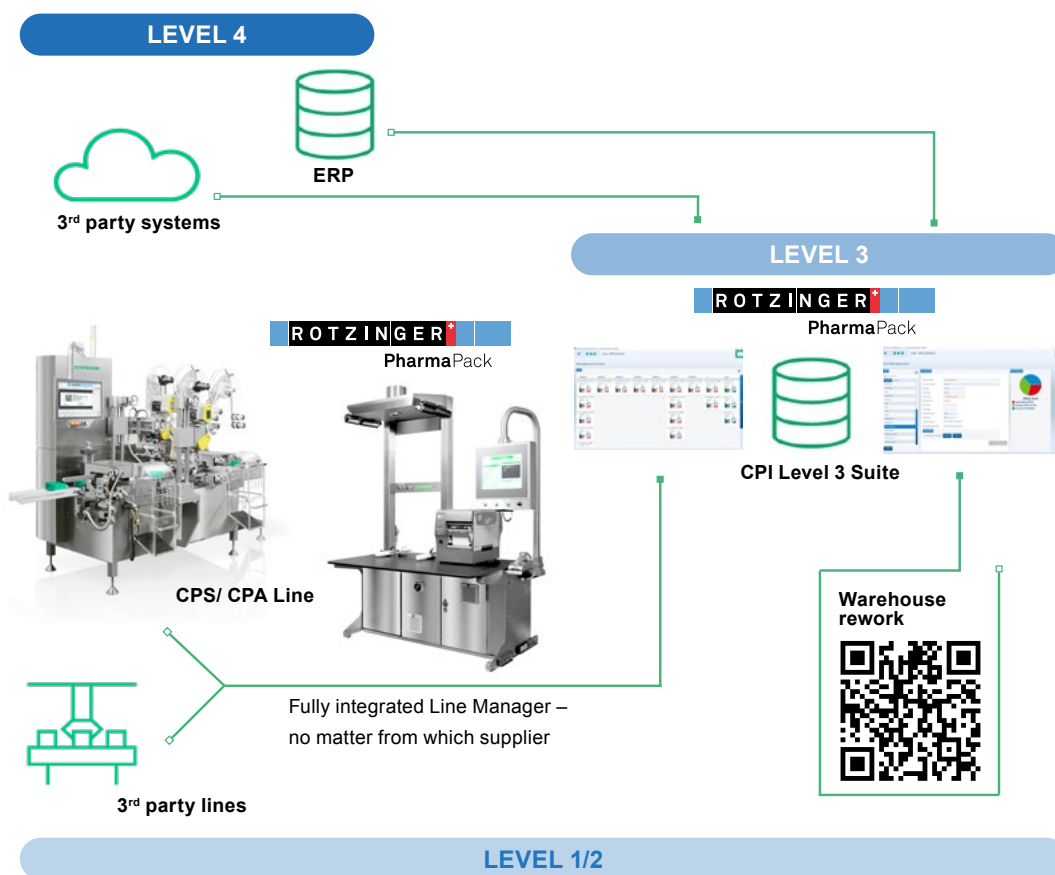


Monitoring and Business Intelligence

Reduce TCO and improve OEE



Open and Standardized Interfaces at all levels





As a leading supporter of OPEN-SCS, we're exactly the opposite of "all talk and no action"! Join the standardization journey for global interoperability and help us to continuously improving supply chain visibility with global standards!"

VOLKER DITSCHER,
Director Global Sales Track & Trace

WIPOTEC OCS
WEIGHING AND INSPECTION SOLUTIONS



BREAKING THE CHAINS OF VENDOR LOCK-IN

As companies around the world implement the necessary changes to become compliant, it will add an increased level of cost, risk, and especially complexity to today's operations.

Specifically, production floor and warehouse equipment should be able to exchange information with a customers' business system throughout the drug's packaging lifecycle. However, they do not indicate how this data should be exchanged. There are currently multiple vendors in the industry offering serialization solutions to accomplish this, but these systems are proprietary and are often unable to communicate with each other.

CHALLENGE: AVOIDING DEPENDENCY ON ALL-IN-ONE VENDORS

Most vendors do not only sell serialization equipment, but they also provide the software and its integration into a company's IT infrastructure. As soon as such software is installed, it can be connected only with that vendor's hardware. In this scenario, it leaves the pharmaceutical company with an inability to do business with any other vendor, since the software, and often the hardware, are

incompatible with each other. But in a business, like the pharmaceutical industry, where constant changes are commonplace, systems need to be flexible enough to accommodate those changes.

SOLUTION: OPEN SERIALIZATION COMMUNICATION STANDARD (OPEN-SCS)

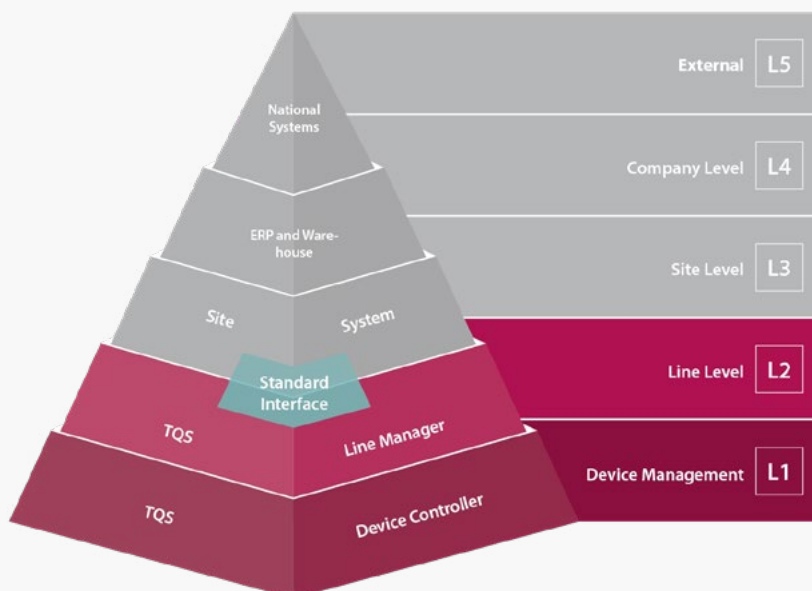
A consortium of pharmaceutical manufacturers and vendors are answering this call to action through a group collaboration called the Open Serialization Communication Standard (OPEN-SCS) Working Group. Its goal is to develop an industrial interoperability standard for healthcare packaging serialization regulations that improves deployment efficiency and reduces the high cost of compliance. OPEN-SCS enables a pharmaceutical manufacturer to follow a "best-of-breed" approach for different product presentations (carton, bottle, pouch, etc.) and pick the most suitable vendor for the particular application.



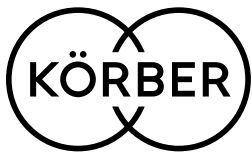
TQS: OPEN INTERFACES FOR MAXIMUM FLEXIBILITY AND COMPATIBILITY WITH ANY SITE LEVEL SOFTWARE

TQS relies on the use of one open standard interface, avoiding the creation of any proprietary island solutions. The TQS Line Manager software gives you the lowest possible IT overhead. The work order data can be input directly into the machine. The Line Manager software runs on any TQS module on the line and can easily and conveniently connect already to a huge number of Level 3 providers. The core of the Line Manager software is the production database which stores the data during the production operations. In the event of a temporary server and network infra-

structure failure, the production line is secured by means of a local buffer memory. The permanent data storage is performed only in the site management software system (L3). One open and standardized interface ensures unrestricted use with regard to all machines and components already in use at a manufacturer's site. WIPOTEC-OCS already deployed more than 3,000 TQS solutions globally and all of them utilize our open and flexible interface based on the OPEN-SCS approach. Our interface for secure and dependable data transport is already implemented by more than 85 individual L3 solution providers and thus proves flexibility and data integrity.



Easy integration through a highly flexible software solution distinguished by open interfaces



WERUM PAS-X TRACK AND TRACE SERIALIZATION AGGREGATION

Line controller independent solution for compliance with anti-counterfeiting requirements. Werum PAS-X Track & Trace provides serialization and aggregation functionality for packaging processes, integrating the ERP and the global repository with the shop floor packaging equipment and line controllers of any vendor.

PAS-X Track & Trace is a smart option to get started with our manufacturing IT solutions and can easily be extended to the PAS-X Packaging Solution or the full-scope PAS-X MES.



PAS | X

THE NEXT LEVEL OF SERIALIZATION BENEFITS

Benefit from Werum PAS-X Track & Trace Serialization Aggregation to comply with the anti-counterfeiting requirements of any country around the globe. Drug manufacturers can benefit from additional advantages of comprehensive production control and documentation, including equipment management, when integrating the serialization solution into our PAS-X packaging solution or PAS-X MES.

- Available as standalone T&T solution
- Or seamlessly integrated into the packaging solution with EBR or full-scope MES
- Easy extension with KPI functionality
- Proven GMP compliance for 30+ years
- Support around the world
- Line controller independency

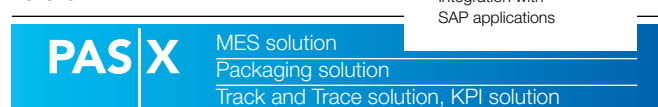
SYSTEM ARCHITECTURE

- 21 CFR Part 11 and Electronic Product Code Information Services (EPCIS) compliant
- Support of EPC Tag Data Standard for electronic product coding, e.g. SSCC, GTIN
- Smooth standard integration with multiple level 4 and level 2 systems:
 - Line controller: Seidenader, Systech International, Uhlmann etc.
 - ERP systems: SAP, ORACLE etc.
 - Central repositories: SAP (Auto-Id Infrastructure All, Object Event Repository OER)
 - IBM (Info Sphere Traceability Server ISTS, Websphere Sensor Events WSE)
 - Axway Track & Trace
 - Support of heterogeneous system landscapes
- Multiple language/unicode support

Level 4



Level 3



Level 0-2



WHY WERUM PAS-X TRACK AND TRACE

- Vendor-independent line controller integration
- Easy extension to the Werum PAS-X Packaging Solution including EBR and KPI/OEE
- Comprehensive product-based functionality out of the box
- Compliance with all international anti-counterfeiting requirements, such as Korea (KD code), China (preprinted serial numbers from CFDA), USA (DQSA H.R. 3204), Turkey (IST) etc.
- Based on global standards e.g. GS1
- Pre-configured standard solutions
- Turnkey projects and one-stop-shop solutions for every customer
- Experience from international deployments

KEY FUNCTIONALITIES

- Support of GS1 labeling information
- Management of modular packaging line layout including print layout recipe management
- Management of serialization numbers in operations
- Management of modular aggregation for e.g. item, bundle, pallets
- Integration with centralized Track & Trace repositories using standards like EPCIS
- Handling of packaging orders and batch information
- Handling of mass data for serialization and aggregation processes
- Dialogs to create, discard, aggregate and disaggregate units and hierarchies
- User management including rights management & audit trail
- Generation, randomization of serial numbers
- Support of multiple serial number formats e.g. SGTIN-96
- Providing serial number blocks to packaging lines
- Recording and reconciliation of used and unused serialization numbers
- Packaging line performance management out of the box using T&T connectivity



www.open-scs.org



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