



IMPORTANCE OF USING GLOBAL STANDARDS FOR TRACK AND TRACE

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Taylor's University, Malaysia

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CHARACTERISTIC OF PHARMA (IN RELATION TO TRACK AND TRACE)

- Highly regulated environment: Track and Trace as license to sell, short timelines to implement, sometimes with missing clear specifications and challenging technical requirements
- Drugs sold on prescription and highly controlled prices due to reimbursement (by insurance companies and governments)
- Systems to be implemented and integrated in a validated environment
- Large scale manufacturing (local and globally) full occupied capacity due to high investments
- Processes, Systems and organization are regularly inspected
- Authorities seeking to reduce costs and increasing visibility due to digitalization
- Conflicting requirements like reducing pack size to decrease environmental impact and lean manufacturing to reduce prices versus complex regulatory requirements
- Reluctance to change due to regulations but high pressure on costs and need for innovation

GLOBALIZATION – SLIDE 1

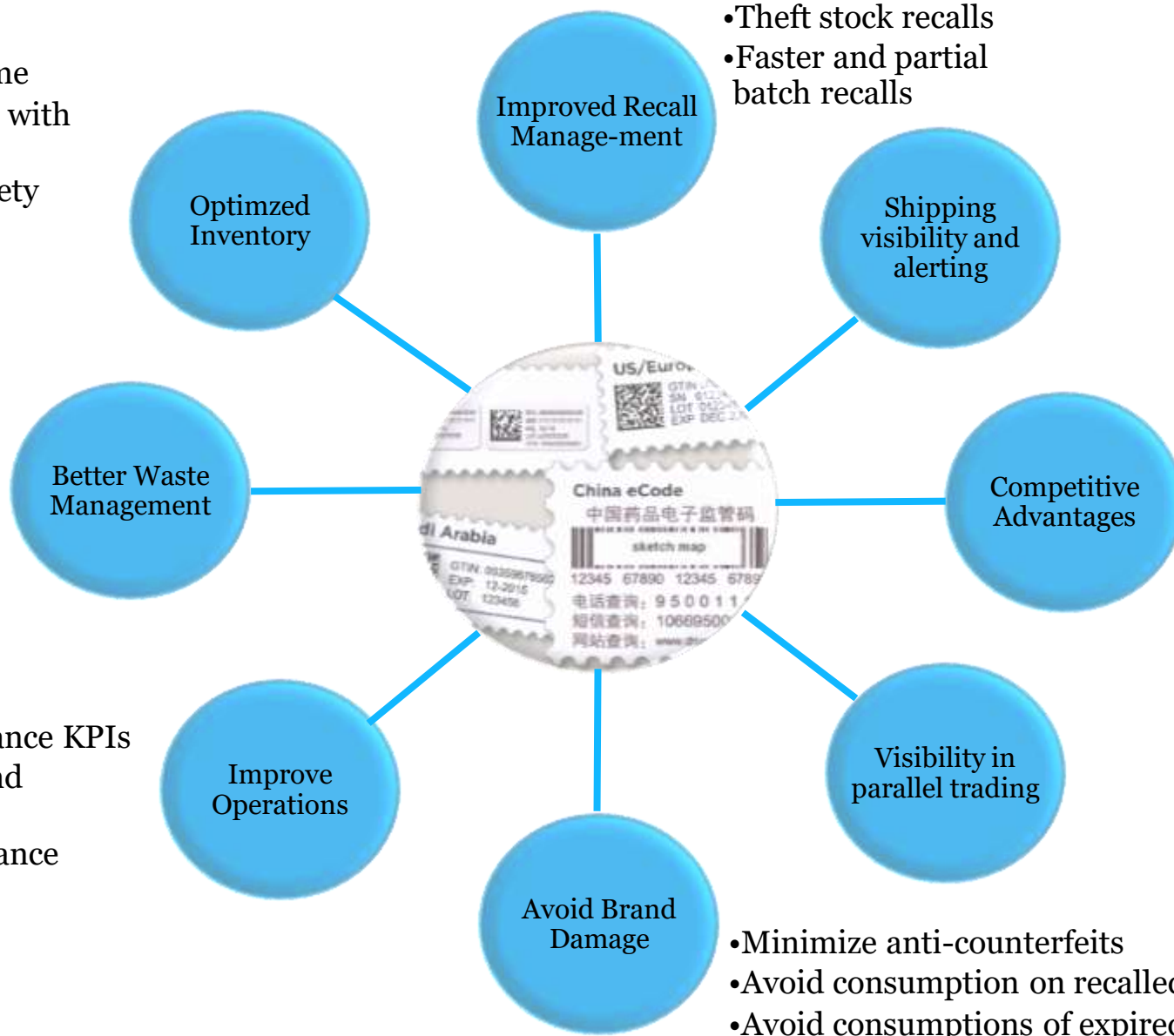
- **Globalization:** Boundaries between countries disappear, single global markets for labor, manufacturing, finance and service.
- **Globalization of Healthcare:** To get access to medication people from Emerging Countries **travel to other countries** but **expect local availability** (or buy via **Internet** or other channels)
- Marketing Authorization License Holders do use their **Third Party Manufactures Network around the Globe** to supply to lower cost and leverage capacity/investments
- **Shared packs** are used and mostly a **same packaging line operates for several countries** Shared packs do optimize Supply Chain Operations

SERIALIZATION BEYOND COMPLIANCE

- In-transit inventory
- Reduce & stabilize lead time
- Updated planning process with actual lead times
- Multi-stage inventory (safety stock)

- Waste Statistics (Intelligence)
- Avoid waste to revert to Supply Chain

- Gain warehouse performance KPIs
- Process harmonization and standardization
- Gain production performance



- Theft stock recalls
- Faster and partial batch recalls

- Error free pick & pack
- TPL performance management

- Value added services by T&T for customers
- Increase customer loyalty through loyalty programs (a:care)
- Inform patients better through e-leaflets and target info (a:care)
- Direct distribution to patients possible
- Customer consumption alerts/monitoring & compliance (a:care)

- Price adjustments
- Better negotiations with distributors / wholesalers

- Minimize anti-counterfeits
- Avoid consumption on recalled batches
- Avoid consumptions of expired batched

DIGITALIZATION

- Healthcare is in Digital Transition where data across several (global) platforms needs to be shared
- Digitalization effects all Business Processes (!) Accounting data will need to match with Supply Chain and Patient Data
- Increase demand for save and robust systems to ensure patient safety and traceability across the whole global supply chain, include storage conditions control and self steering supply chain
- Reliable and cost effective Data sharing requires a seamless Integration of Systems –even between MOH's- without data conversion and or manipulation and safety issues
- This requires Global Standards to be used so each Stakeholder can use the same data models and business processes will not have to be adapted to local country requirements or system requirements

BIG BANG DISRUPTION

- It used to take years or even decades for disruptive innovations to dethrone dominant products and services.
- But now any business can be devastated virtually overnight by something better and cheaper
- Examples GPS systems replaced by Google Maps on Smartphones, GoJek to get delivered your medication quickly and cheap to your home
- In Pharma some innovations will take time but they will come:

Examples: Dispensing medication, from yellow jacked to fool proof dispensing

Gojek, combined with prescriptions matching and full ordering and track and trace process

Usage of Mobile Apps, Emerging Countries go unwired but do rely on the data integrity and integration of the systems serving the mobile apps

DEVIATIONS FROM GLOBAL STANDARD WILL LEAD TO

HIGH COST: Localized / customized equipment and software that is not widely available and limits the choice of suppliers that will be attracted because of their capabilities, knowledge and costs (they do not coincide with those available worldwide)

OPERATIONAL ISSUES: To implement, maintain and operate is more complex and will lead to expensive systems and processes for all market participants, in addition to what is actually required to achieve the objectives of countering fraud, financial tracking and tax collection

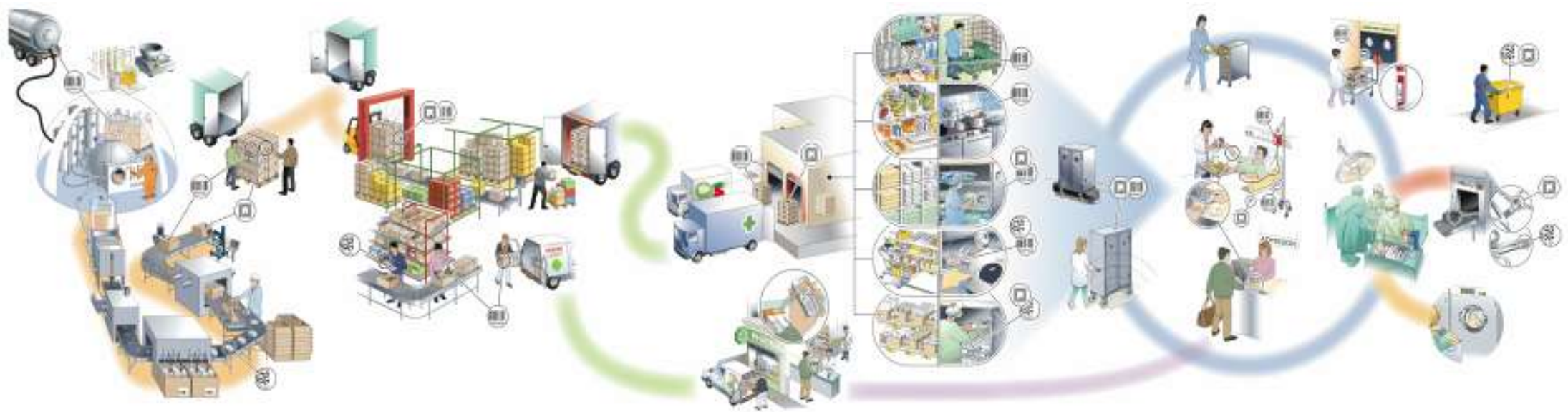
Impact on Quality (training, procedures, validation etc.), flexibility and knowledge sharing

NEGATIVELY EFFECT ON DEVELOPMENT OF HEALTHCARE: Disability to profit from Globalization and Worldwide developments (product and technology) in Healthcare

NEGATIVE EFFECTS TO EXPORT\IMPORT: When goods are sold abroad, it is necessary to use the same system and equipment, otherwise the codes cannot be recognized. It will effect Manufactures and even solution providers locally which like to extent globally

HEALTHCARE – A NEED FOR “UNIQUE” GLOBAL ID...

“Traceability is the ability to **track forward** the movement through specified stage(s) of the extended supply chain and **trace backward** the history, application or location of that which is under consideration”* ...generally using documented & recorded “**unique**” identification.



HEALTHCARE – DATA NEED BEYOND GTIN...

GS1 Keys prevail... but some users need more detailed information about that specific unit



Data Matrix



GS1 DataMatrix is the global preferred standard for Coding in Pharma and should not be mixed with QR Code!

QR Code



WHY GS1?

Global standards like GS1 are beneficial and achieve the intended effect only if they are implemented fully and without variation.

GS1 is a globally-recognized standards-setting body, and nearly every market implementing serialization mandates the use of GS1 global data standards, specifically for identification and serialization of pharmaceuticals products (GS1 DataMatrix, EPC-IS, DigitalLink)

Global standards facilitate international commerce through interoperability and promote competition and expansion. The use of country-specific standards—including country-specific variations to global standards—is a barrier to global trade.

By using Global standards customizations to adjust to the local requirements by vendors/manufactures operating globally can be avoided. That will decrease cost and will increase security and operability. This will reduce validation efforts and reduce issues during implementation and operation.

EPCIS, A GS1 AND ISO OPEN STANDARD

- defines interfaces for capturing & sharing data
- defines a framework data model for event data
- helps **share visibility data** across enterprises
- enables services & solutions for supply chain visibility
- GS1 Keys identify the “what, when, where, why” of visibility events...
 - ...encoded as data-carrier neutral EPCs
 - ...even when used with GS1 barcodes (instead of RFID)
- published as ISO/IEC 19987

EPCIS ENABLES SUPPLY CHAIN VISIBILITY

- **Tracking**

Where are the products we shipped?

- **Tracing**

Where did this batch of products come from?

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**

Which parties had custody or ownership of these products?

- **Inventory Management / Inventory Maintenance**

When does my available inventory expire?

- **Recall**

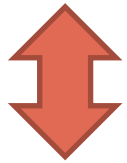
Find all Product Y shipped from facility X on 7 May 2018...

GS1 Verification Messaging Standard

What is GS1 Digital Link?

GS1 Digital Link provides a Web-friendly way to express any GS1 identifier (including compound keys) and associated data attributes as a Web URI that works on the Web and enables retrieval of associated information through a straightforward Web request (HTTP GET)

(01)00361414567894(10)400806(21)1908642E(17)170728



Translation into GS1 Digital Link format

<https://id.gs1.org/01/00361414567894/10/400806/21/1908642E?17=170728>

<https://id.gs1.org/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728>

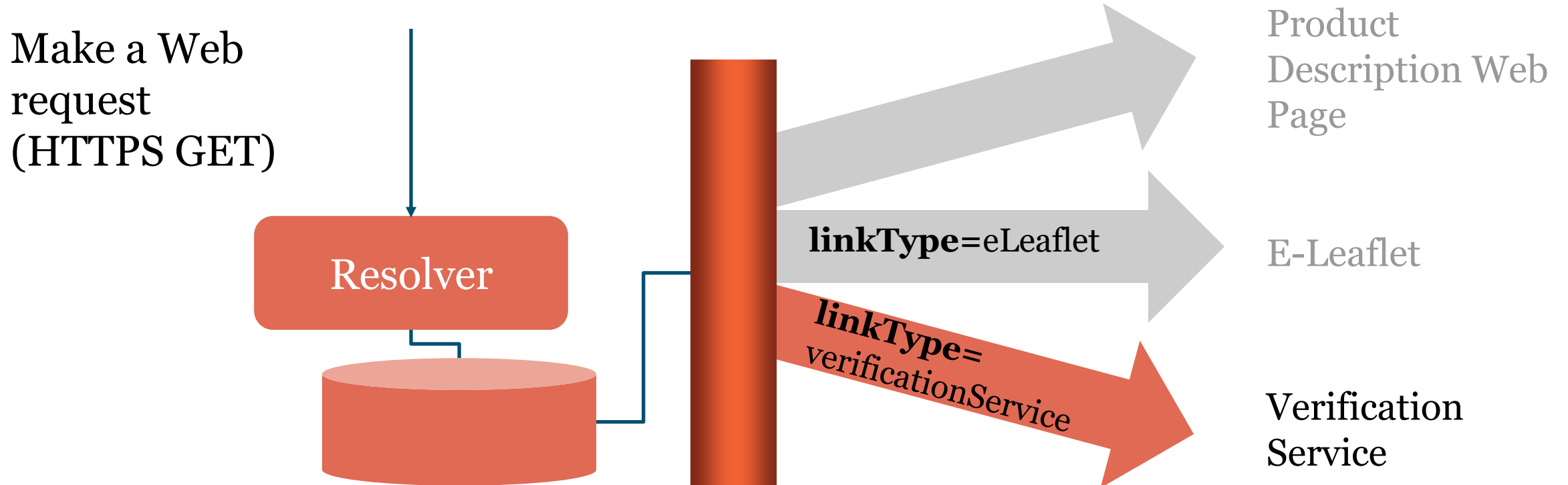
<https://example.com/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728>

NOTE: the *sequence* of URI path information – **gtin**, **lot**, **ser**, followed by **exp** in the URI query string – is important, and must be preserved.

GS1 Verification Messaging Standard

Redirection of GS1 Digital Links

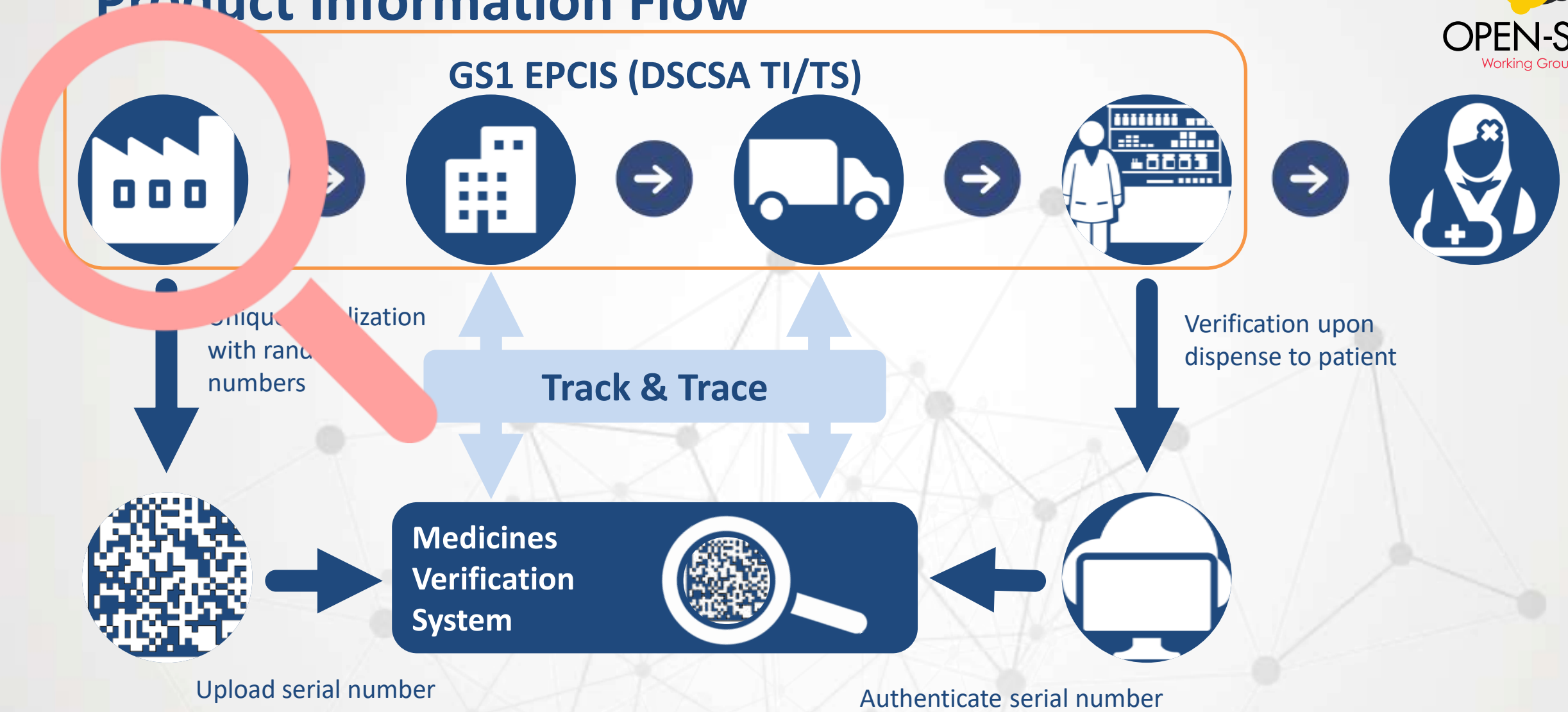
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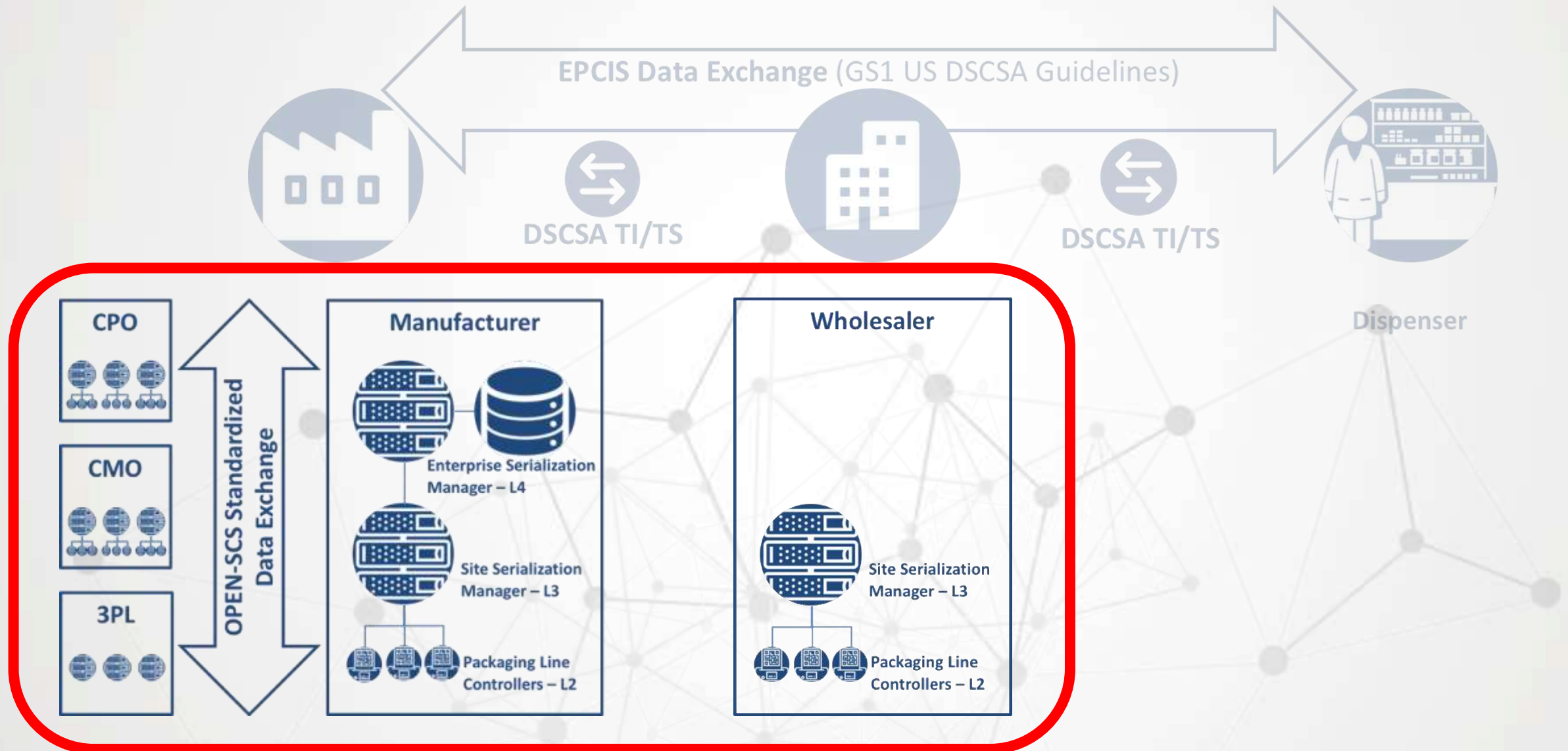
Product Information Flow



OPEN-SCS
Working Group



Serialization Data Exchange (OPEN-SCS Scope)



Manufacturing Serialization Information Flow

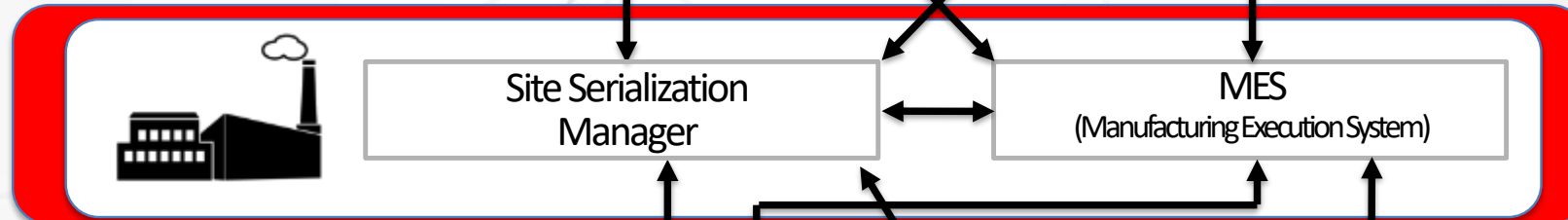
LEVEL 5
Government Reporting



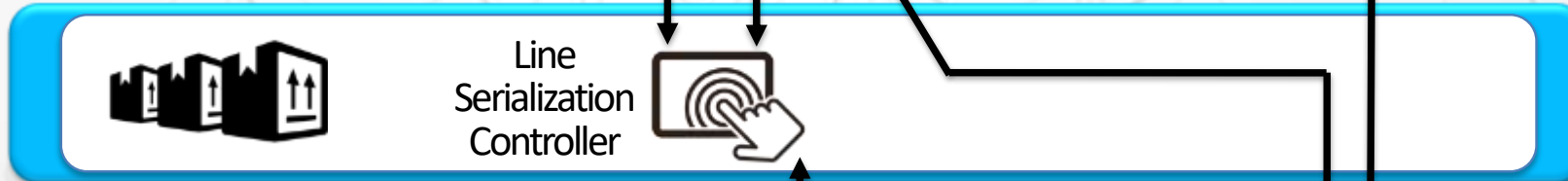
LEVEL 4
Enterprise Planning,
T&T, and Reporting



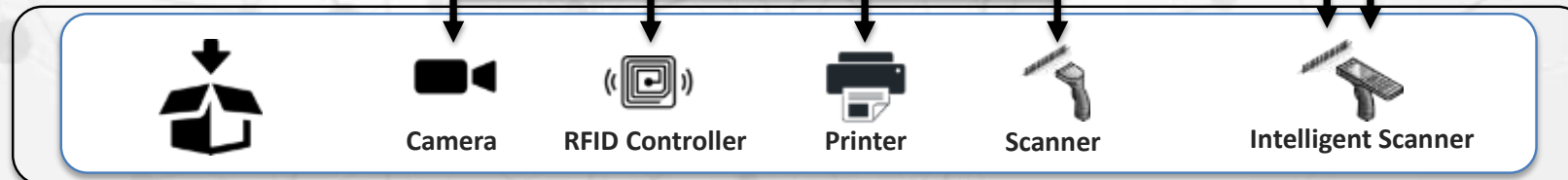
LEVEL 3
Plant / Distribution
Centre Operations



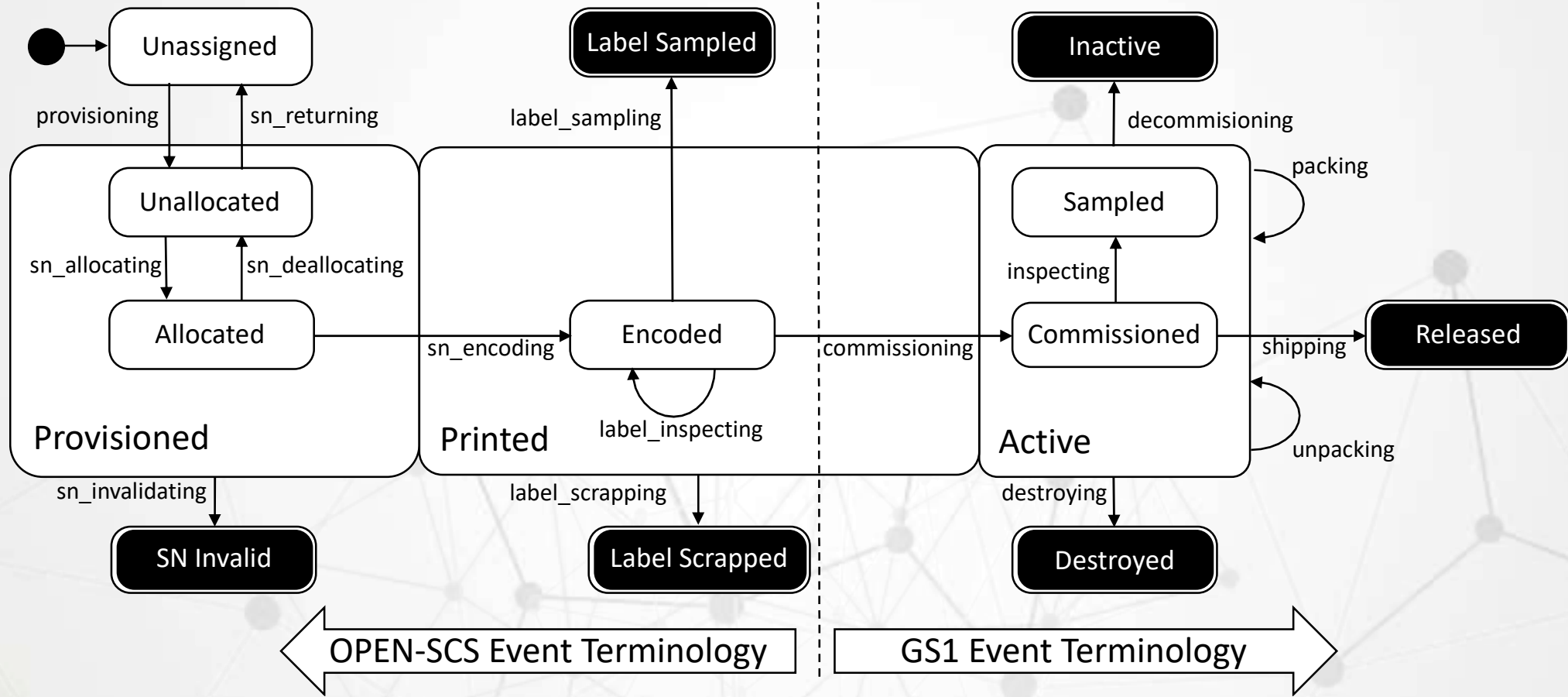
LEVEL 2
Packaging Line Control



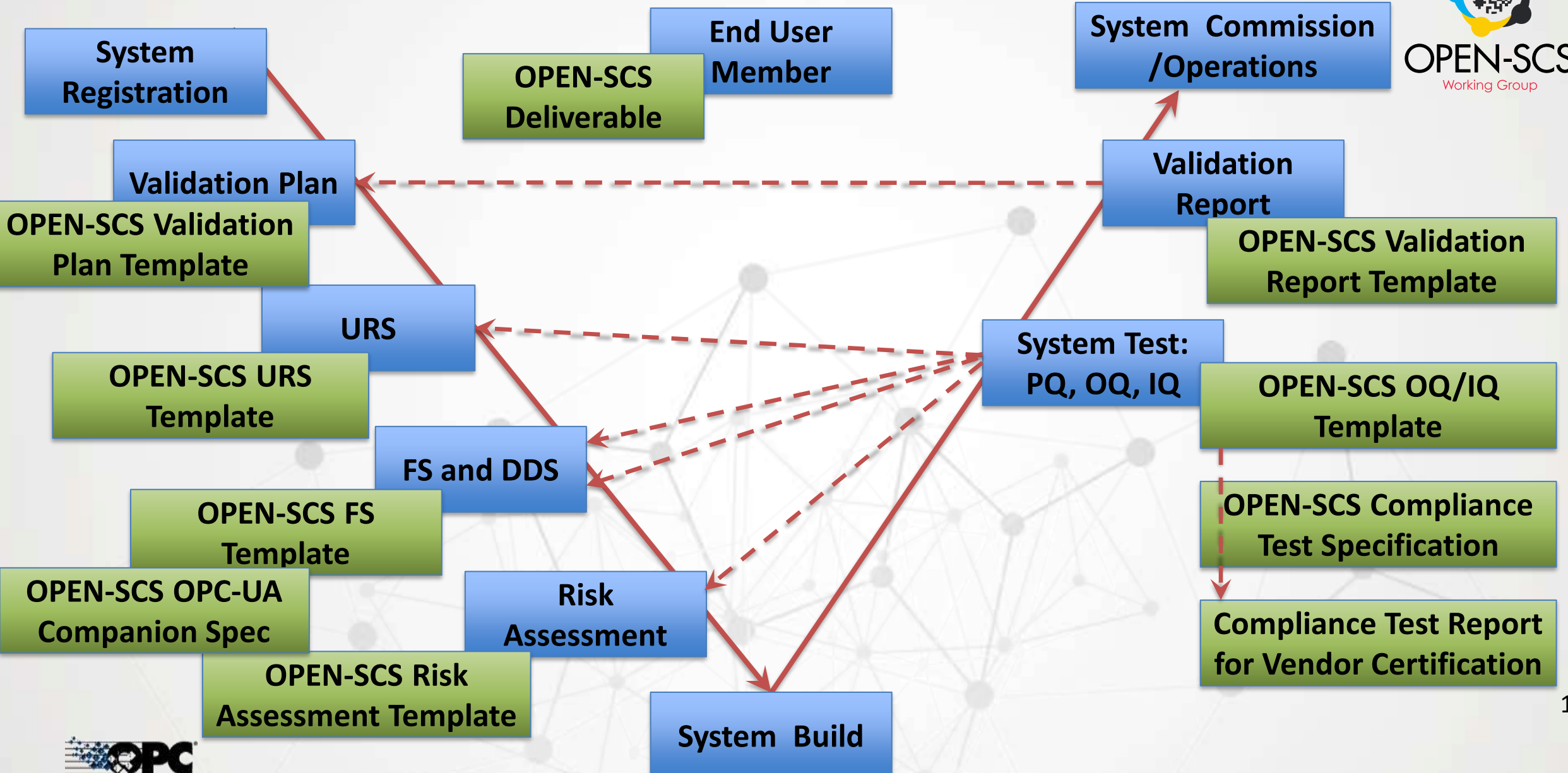
LEVEL 2A
Intelligent Devices



Serial Number State and Event Model



OPEN-SCS / ISPE GAMP Validation Approach



CONCLUSION

Our world is changing rapidly and we need to think more holistic:

- We live in a **Globalized World**
- We are just in beginning of the **Digital Transformation** and **Big Bang Disruption**

What they do have in common is that we need:

- **Interoperability between vendors, devices and systems**
- **Common language and standardized data models which can be validated and maintained in a controlled environment**
- **Increasing Reliability, Efficiency, Effectively and bringing cost down**

**>>> GLOBAL STANDARDIZATION <<<
IMPLEMENTED 100% CORRECTLY WITHOUT CUSTOMIZATIONS**

Q & A