THE EVOLUTIONAL JOURNEY – FROM BATCH CODING TO TRACEABILITY AND SUPPLY CHAIN VISIBILITY BY USING GLOBAL STANDARDS

APEC LSIF WEBINAR – WIPOTEC-OCS / 2021 / Volker Ditscher

WIPOTEC OCS
WEIGHING AND INSPECTION SOLUTIONS

AGENDA

Agenda

▲ **BATCH CODING VS. SERIALIZATION**

▲ **THE MOST UNDERESTIMATED PROJECT OF THE CENTURY**

▲ **TYPICAL CHALLENGES & BEST PRACTICES**

▲ **HOW TO PROFIT LONG TERM**

▲ **SUMMARY: IMPLEMENTING SERIALIZATION – A CHALLENGING AND MULTIDISCIPLINARY PROJECT**
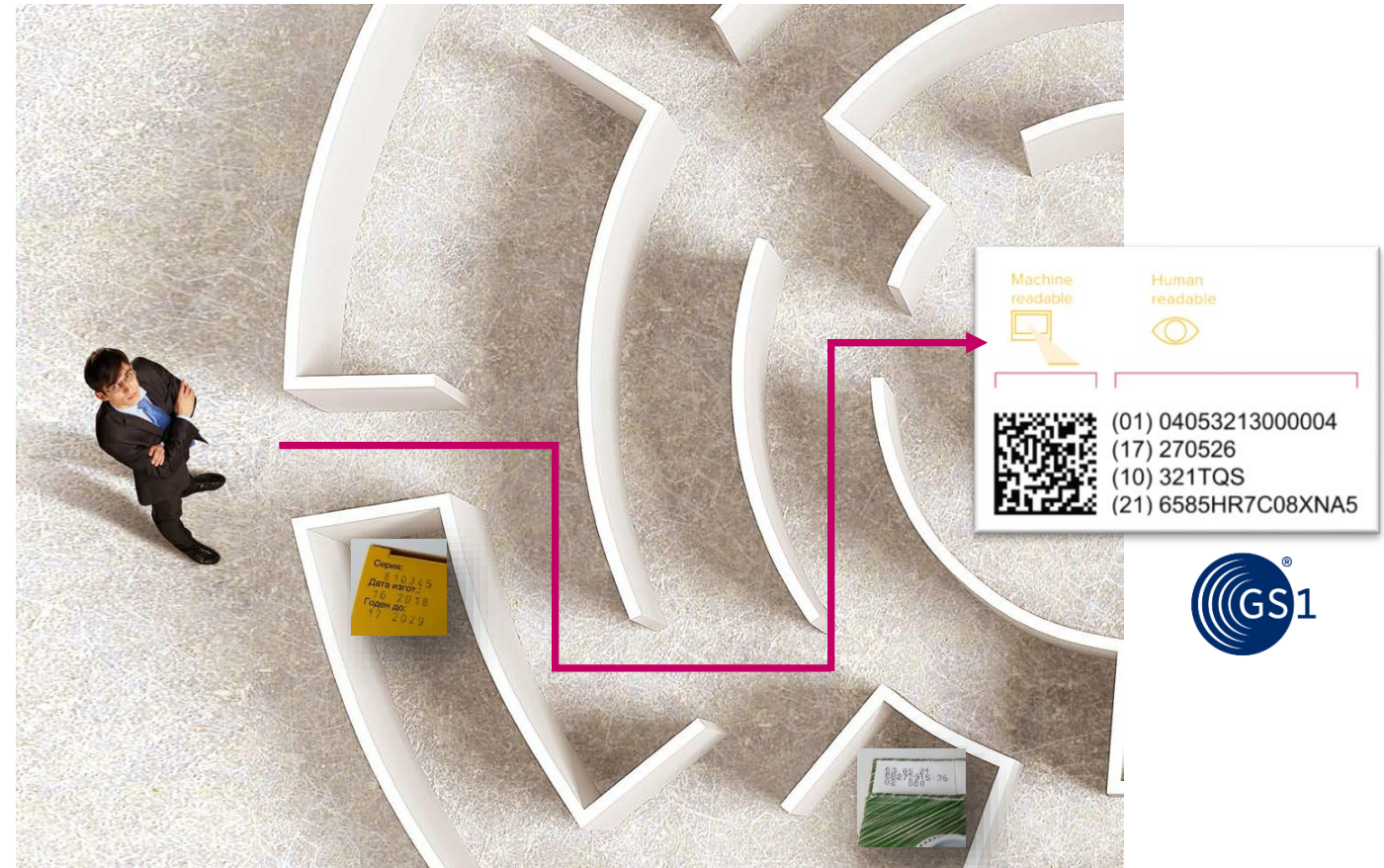
Batch Coding vs. Serialization

It's a Journey!

▲ To overcome the lack of standardized product identification

▲ Value beyond just batch coding

▲ Making use of the potentials of serialization

→ Implementing a **standardized solution** that *not only prints codes* but that can also effectively generate, manage and exchange data!

Machine readable   Human readable

(01) 04053213000004
(17) 270526
(10) 321TQS
(21) 6585HR7C08XNA5

GS1

Poll 1

Serialization – Why?

- Legal compliance
- Eliminate counterfeit pharmaceuticals
- Defend market position
- Brand & consumer protection

Track & Trace – Definitions

▲ **Track & Trace** is a holistic interoperable system that enables product traceability and in-depth visibility of the supply chain

    ▲ Tracking → Follow the product during movement trough the supply chain!

    ▲ Tracing → Identifying the origins of each movement in a retrospective view!

▲ **Serialization** protects products through the assignment of unique serial numbers

▲ **Aggregation** creates a parent-child relationship of many serialized goods
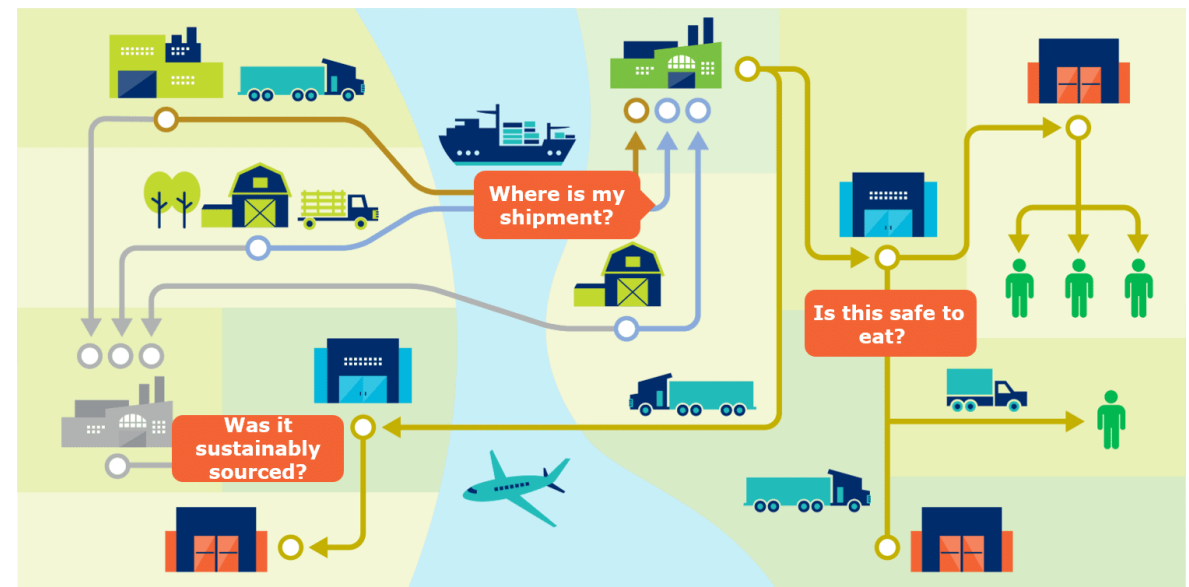
Source: GS1

The most underestimated project of the century?

Who is the "poor" person wearing the serialization hat?

▲ **Typical statements:**

    ▲ *"Serialization is just printing a code on a box"*

    ▲ *"The implementation of the legislation will surely be postponed"*

   ▲ *"We will not sell more when we implement Serialization"*

▲ The facts, however, are:

    ▲ Management underestimates complexity and impact on the organization

    ▲ No direct return on investment

    ▲ No acceptance within the company because of lack of visibility and lack of knowledge

    ▲ Most important compliance project in pharma of the last decade, and maybe longer

What if you do not comply?

▲ Big risk or opportunity? – Market shares will be restructured because of Serialization!

▲ Can you still deliver to the market if you do not comply?

▲ If your customers did not ask for Serialization yet, maybe they might be considering another business partner or CMO?
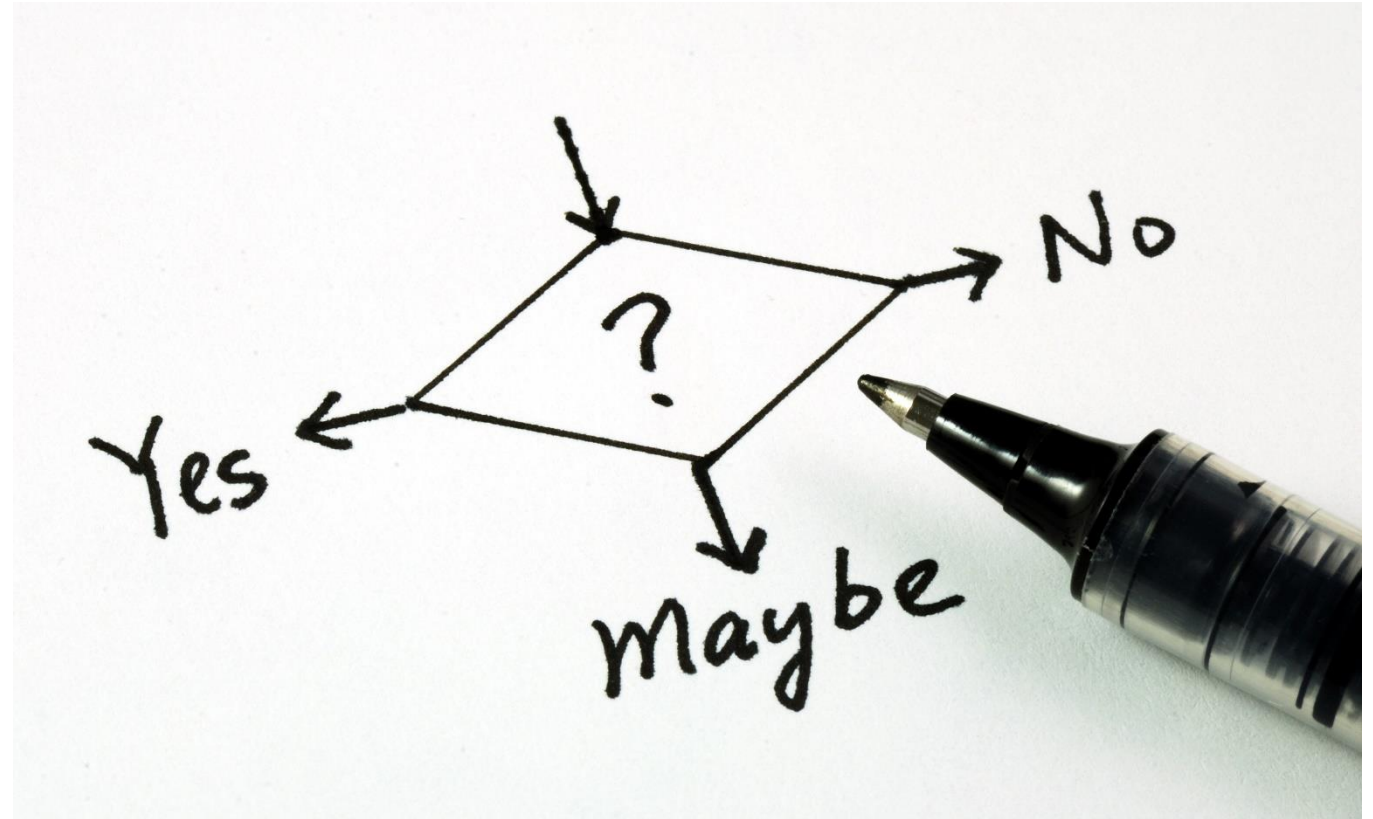
Typical Challenges - Best practices

Challenge: Who should solve the puzzle?

▲Board Level Management
▲Supply Chain
▲QA/QM
▲Legal affairs
▲Sales and marketing (artwork)
▲Engineering
▲Production
▲IT
▲…

→ **Serialization** is not solely an IT or solely an engineering project, it **is a strategic business project impacting the whole organization!**

Best practice: TEAMWORK

WIPOTEC OCS
WEIGHING AND INSPECTION SOLUTIONS

▲ **Project teams must cover all relevant functionalities for adapting internal / external processes!**

▲ Select external consultants or vendors wisely!

▲ It's a long term partnership!

▲ Check if vendors are monitoring global regulations on a permanent basis and implementing them "automatically" in their software releases!

▲ Look at long term costs and TCO!

▲ Consider tricky update- or software-maintenance strategies!

Challenge: Lack of Interoperability

▲ **Serialization projects are complex!**

▲ Are the experts of each profession talking to each other or will a "one-stop shop" approach end up in a vendor lock-in situation?

▲ Watch out for proprietary and non standardized offers!

▲ Downsides of proprietary / vendor lock-in proposals:

    ▲ Being fully dependent on one single vendor for all levels leads to financial autocracy! → **Financial risks!**

    ▲ If the selected scope cannot meet the requirements due to missing functionalities? → **No compliance!**

    ▲ Global country regulations are changing very frequently! → **Lack in** comprehensive release roll-out plans and **professional 24/7 SW hot-fixes!**

→ If no full interoperability is given or the vendor lock-in solution is down → No production!

Best practice: OPEN INTERFACES

WIPOTEC △ OCS
WEIGHING AND INSPECTION SOLUTIONS

OPEN-SCS Working Group

▲ WIPOTEC-OCS is founding member and part of the steering committee

▲ Developing a standardized communication protocol between L2 - L3 and L3 - L4 (along with the **GS1 EPCIS*** standard)

▲ Mission: PSS (Packaging Serialization Specification) allows functional **INTEROPERABILITY** across serialization-solution providers, organizations and regulatory bodies to seamlessly integrate their operations and business processes across their solutions using various system architecture!
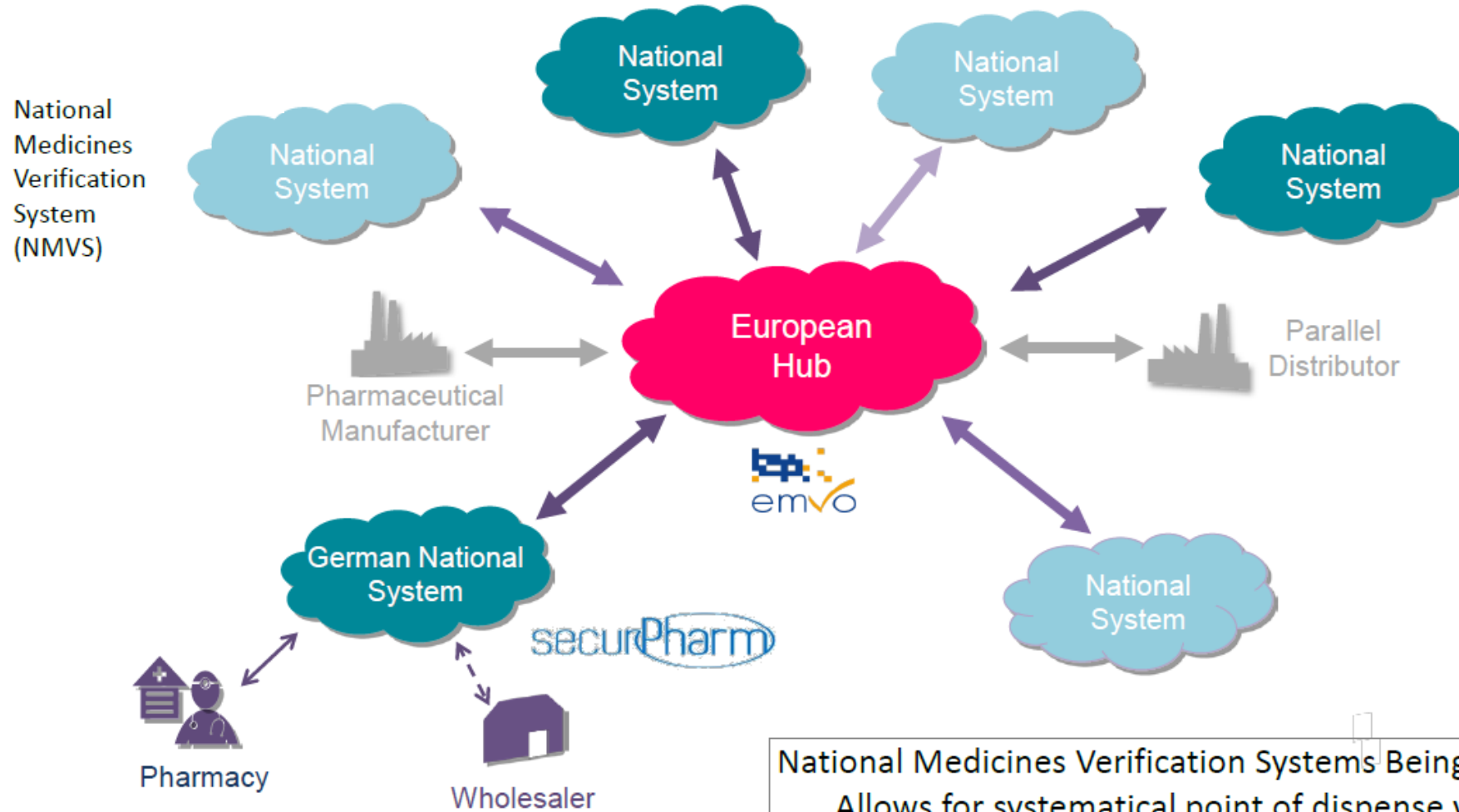
*Companies will use the GS1 Common Business Vocabulary (CBV) and the EPCIS schema (www.gs1.org/standards/epcis) and information exchange models. PSS defines the events and state changes in serialization **within a facility** and **many of the intra-plant interfaces are outside the data exchange scope of GS1's Electronic Product Code Information Specification (EPCIS).** In order to ensure easy integration of the intra-plant serialization using OPEN-SCS communication models with the EPCIS message models, the GS1 CBV terminology has been used throughout the PSS. The OPEN-SCS PSS uses the GS1 (www.gs1.org) specified data identifiers and structure where appropriate.

OPEN SCS
Working Group

https://www.open-scs.org/

Best practice: INTEROPERABILITY – ONE GLOBAL SERIALIZATION LANGUAGE FOR ALL FUNCTIONAL LEVELS!

WIPOTEC OCS
WEIGHING AND INSPECTION SOLUTIONS

ERP

Process orders
product master data

Order distrib.
Master data
Serial numbers

Serial no.
batch-
information

OPEN SCS
Working Group

CLOUD SERVICES / NATIONAL SYSTEMS | L5

EXTERNAL COMMUNICATION | L4

CORP.   SERVER

OPEN SCS

LOCAL MES / REPOSITORY | L3

SITE   SERVER

OPEN SCS

LINE VENDOR | L2

TQS   Line Manager

LINE VENDOR | L1

TQS   Device Controller
printer, camera and
machine controller

Reporting
Serialization- /
aggregation-
result

OPEN SCS
Working Group

Process orders
Serialization- /
aggregation result
Post lot rework

Status info
serialization- /
aggregation result

Best practice: HARMONIZATION – NATIONAL LEVEL

National Medicines Verification Systems Being Implemented
Allows for systematical point of dispense verification

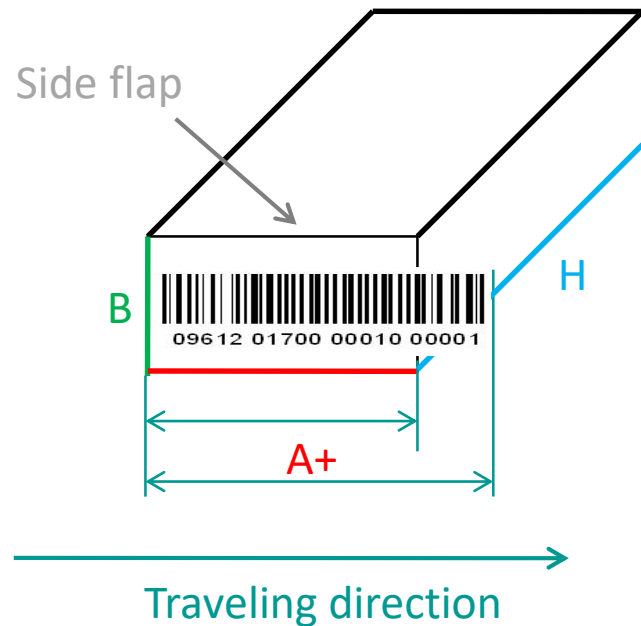Source: efpia
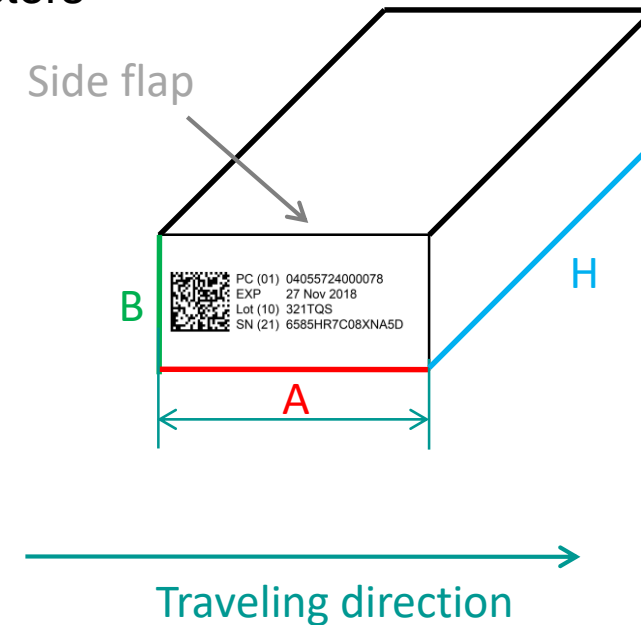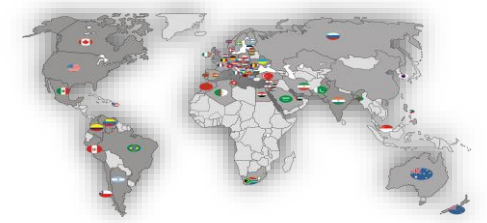
Best practice: STANDARDIZATION – 1D vs. GS1 2D Coding

▲ Space consuming

▲ Proprietary and country specific approach

▲ Scanners to be "programmed" individually

Side flap

B

H

09612 01700 00010 00001

A+

Traveling direction

▲ Very compact standardized solution

▲ ISO recognized

▲ Specified AI's

▲ Implemented across 25 industry sectors

Side flap

B

PC (01)   04055724000078
EXP   27 Nov 2018
Lot (10)   321TQS
SN (21)   6585HR7C08XNA5D

H

A

Traveling direction

Challenge: Lack of Space

- ▲ Production lines where designed at a time when serialization or even automation for bundle- or case packers was not given

- ▲ More and more machines came in over time

- ▲ Space for serialization or even aggregation is not foreseen

Best Practice: COMPACT ALL-IN-ONE SOLUTIONS

▲ Serialization, tamper-evident labelling and weighing combined

▲ One unit to meet all market requirements – Globally!

▲ Huge space saving – from typically 4.000mm to 1.8mm

1.800 mm

How to profit long term?

Poll 2

Optimizing OEE and Supply Chain Visibility
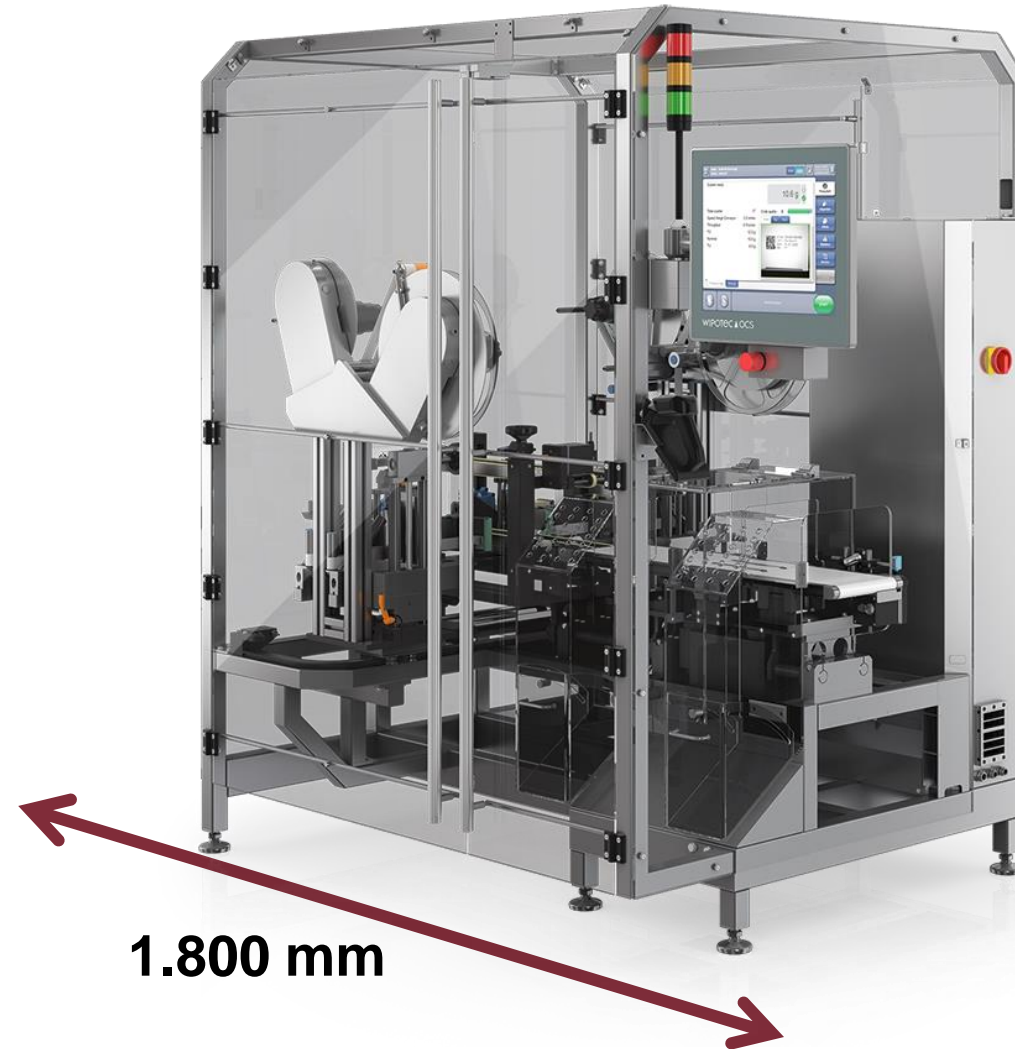
▲ In the beginning serialization will not lead to a better uptime of the lines due to the learning curve of all involved parties!

▲ Therefore it's important to invest in dedicated people, training and commitment towards the long term advantages, such as:

   ▲ **Increasing OEE** by consequently using innovative interfaces to create much more visibility and continuously sharing statistical information!

   ▲ **Improving product recall management.** Leveraging unit-based traceability allows companies to quickly locate and withdraw single units instead of full batches.

   ▲ **Ensuring full supply chain visibility** by Blockchain technologies!

Increasing consumer confidence and loyalty

▲ **Ensuring product safety and traceability, enhances your brand image** by showing customers that you care about the authenticity and safety of your products.

▲ **Prevent product diversion and illegal trade.** Manufacturers lose millions due to parallel imports and re-importation.

▲ **Sharpen your reporting, forecasting and planning**. Product traceability enables collection and analysis of production, warehousing and supply chain data.

▲ **Gain a competitive edge.** Since consumers prefer products from brands they trust, ensuring the authenticity and integrity of your products is a vital step to offering you a significant advantage over your competition and placing your brand in the forefront of consumers' mind.

# Summary: Implementing Serialization – A challenging and multidisciplinary project

A complex and multidisciplinary project

- ▲ The project cannot start without management commitment!

- ▲ Serialization is not a "ONE MAN SHOW"!

- ▲ Create a multidisciplinary project team!

- ▲ Make sure your team can invest time in the project!

- ▲ Don't see it as a burden, but make use of the OEE optimization and supply chain visibility advantages of T&T!
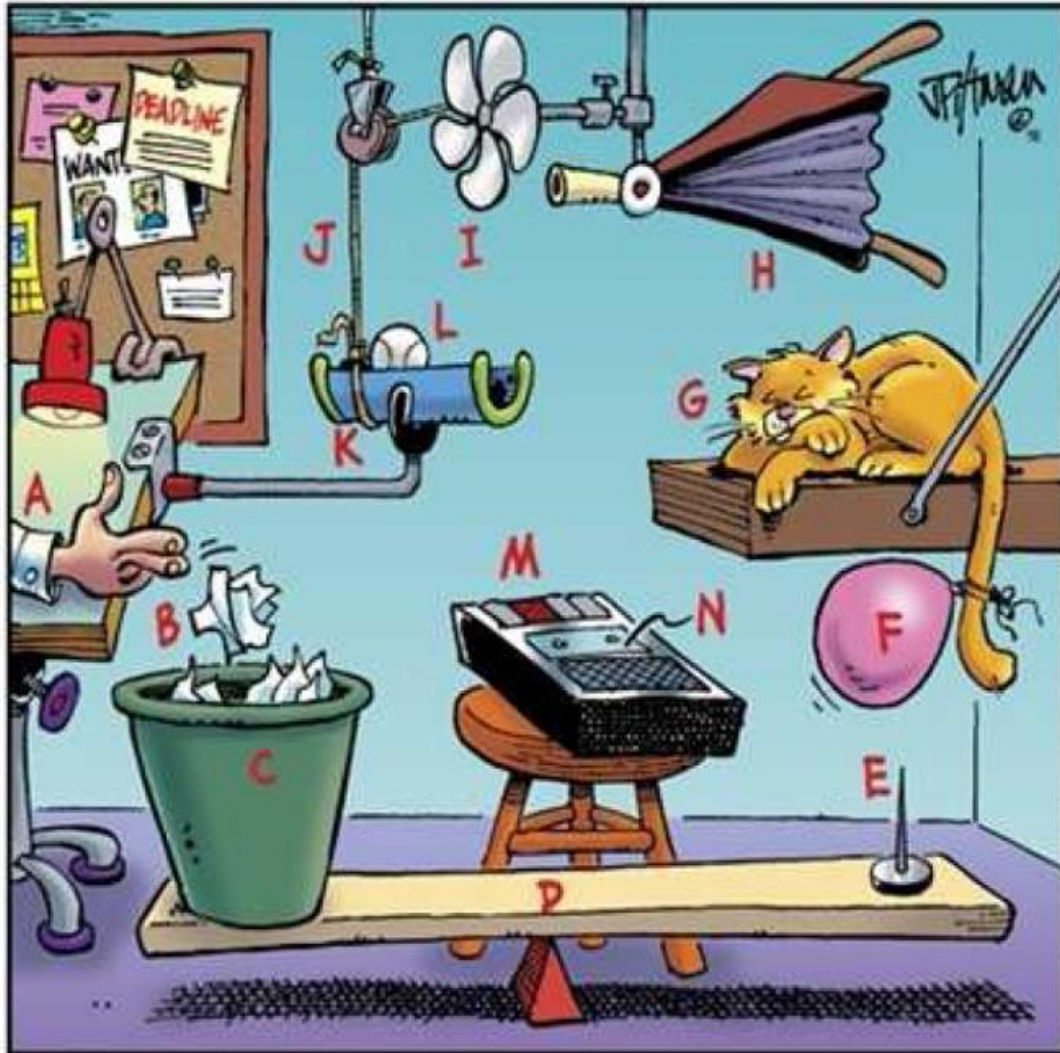
Start Now!

Responsible person **A** tosses upcoming T&T deadline memo **B** into trash bin **C** which causes board **D** to become unbalanced raising tack **E** to pop balloon **F** startling cat **G** who jumps up, pushing bellows **H**, thus blowing fan blades **I** which winds and shortens cord **J** lifting trough **K**, causing baseball **L** to roll down and onto PLAY button of recorder **M** which turns on subliminal message **N**:

CALL WIPOTEC for HELP! ;-)

About WIPOTEC-OCS

About WIPOTEC-OCS

▲ COMPANY: **WIPOTEC-OCS GMBH**

▲ HEADQUARTERS: **KAISERSLAUTERN, GERMANY**

▲ EMPLOYEES: **GLOBALLY > 1.100**

▲ VERTICAL RANGE OF

   MANUFACTURING: **> 85%**

▲ BUSINESS:

- DYNAMIC IN-MOTION **CHECKWEIGHING**

- EQUIPMENT FOR **MAIL & LOGISTICS**

- **X-RAY** SYSTEMS FOR PRODUCT INSPECTION

- **TRACK & TRACE** SYSTEMS

   → MORE THAN **3.000 TQS SYSTEMS**

   → OVER **1.900 PRODUCTION LINES**

   → MORE THAN 14 YEARS IN T&T BUSINESS

▲ CAPACITY: **> 3.000 SOLUTIONS / YEAR – ALL PRODUCT LINES**

GUARANTEED RESOURCES TO BUILD 800+ TRACK & TRACE SYSTEMS / YEAR

Thank you for your attention!

Volker Ditscher
Director Global Sales Track & Trace
volker.ditscher@wipotec.com

www.wipotec-ocs.com/en/solutions/track-trace

Disclaimer:

The illustrated and communicated information provided to the participants of the presentation is intended solely for internal company usage of the participants and not for the public or publications.

The WIPOTEC Group and the Speaker takes no responsibility for the correctness of this information. Copyright or other legal claims are excluded.

References to authors and documents are intended as an indication for the source. In all cases the indicated sources / authors have to ask for permission before using the material.