Serialization at Orion

FiMVO workshop 2.2.2018

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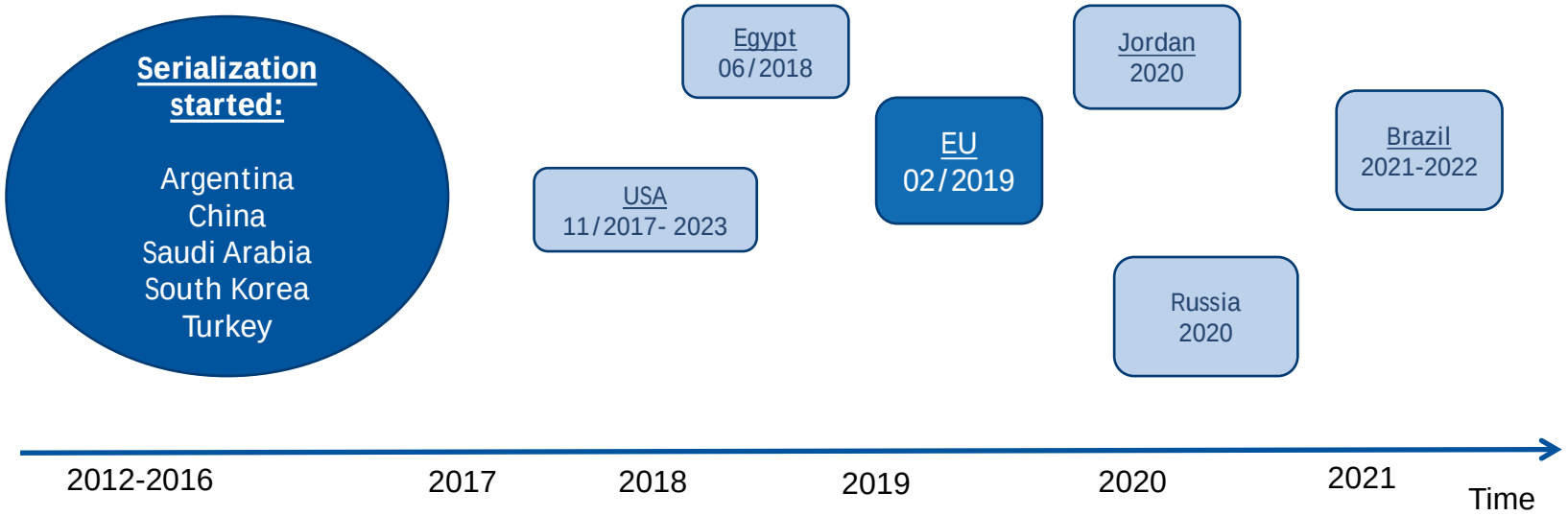
ORION
Building well-being

Falsifications are a global threat

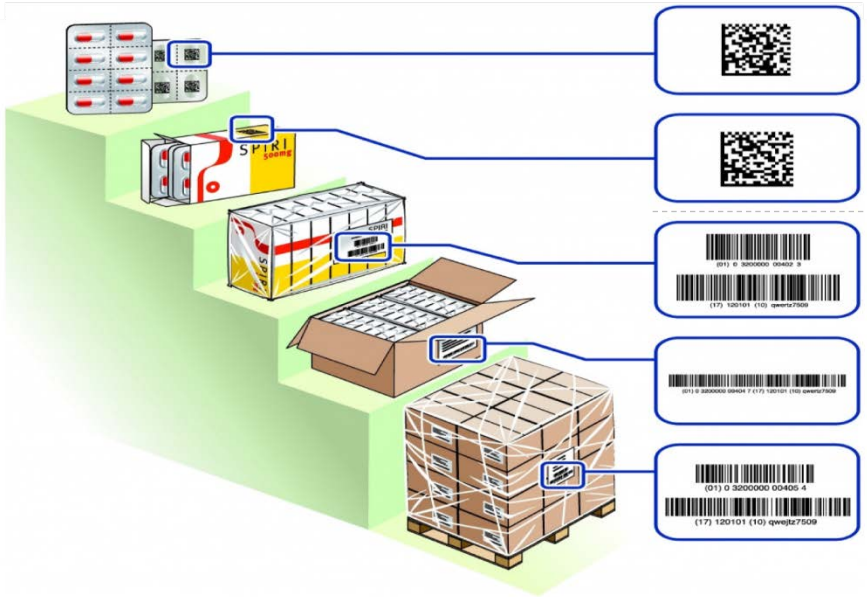
Serialization and Traceability in global view



Planning Phase: Canada, Colombia, Iran, Japan, Libya, Mexico, Oman, Pakistan, Taiwan, Ukraine,…

Orion solution

Serialization is adding unique identifier into finished pack while aggregation is creating “parent-child” relationship



Serialization

- Data matrix with product code, unique identifier, batch number & expiry date

Aggregation

- Relationship between unique identifiers assigned to packaging containers.

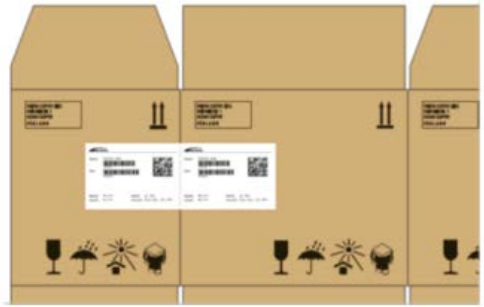
Source : GS1 2015, (slide modified)

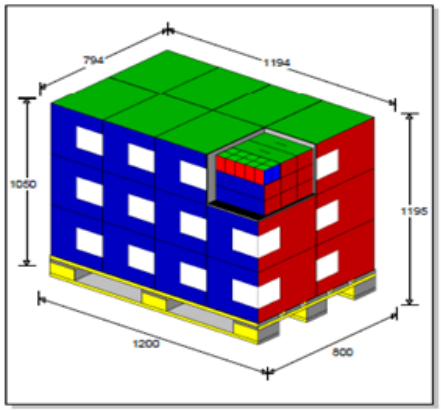
Note: Data carriers shown are for illustration purposes only!

Example coding: Carton, case, pallet – coding and human readable data

Print element	Data contents
GS1 Data Matrix code	• FNC1 prefix and group separator • (01) GTIN (PC) • (17) Expiry date **must** be of format YYMMDD • (10) Batch/Lot number • (21) Serial number
Human readable variable data	• Expiry date **should** be of format MM.YYYY (in cases if exact date is needed DD.MM.YYYY) • Lot/Batch number • Serial Number
Fixed text as part of artwork	GTIN PC Prefixes for: • Expiry date • Batch/Lot number

BUNDLE / CASE / PALLET - No specific requirements. Existing rules apply.

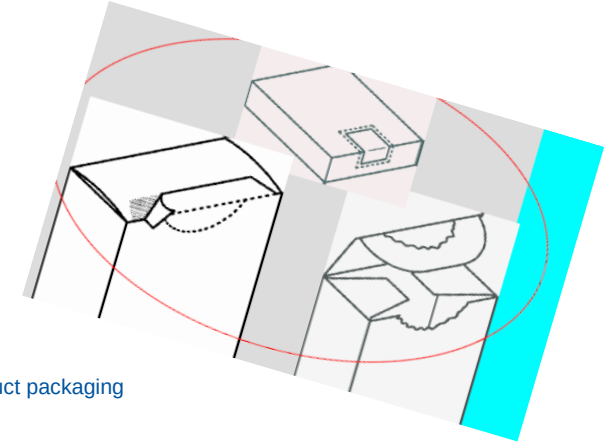


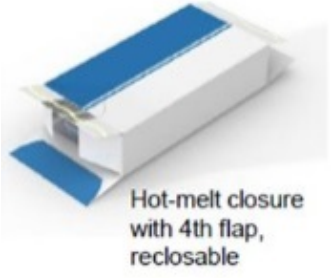


EU Safety features:Tamper evident of packaging, showing visible signs, if opened

Different alternatives TE:

- Glued cartons
- Tamper Evidence in carton structure (no glue)
- Sealed cartons /labelled
- Other e.g. wrapping





ISO/SFS 16679 – standard: Tamper verification features for medicinal product packaging

What is serialization?

Serialization is managed throughout the supply chain

Reporting of serialization data to the authorities or partners/customers

Reporting inventory changes (scrap/samples)

Serialization system architecture own production

TraceLink

Systech

Regulatory bodies

Level 5 – Network control

Repository

-> SN reguest
<- SN list / range
-> Commissioned SNs
-> WM out etc.
-> reporting

BO

Level 4 – Enterprise control

- Batch status, SN status change

-> SN request
<- SN list / range
-> Commissioned SNs

- Batch number
- Exp.date

SAP ERP

Level 3 – Site control

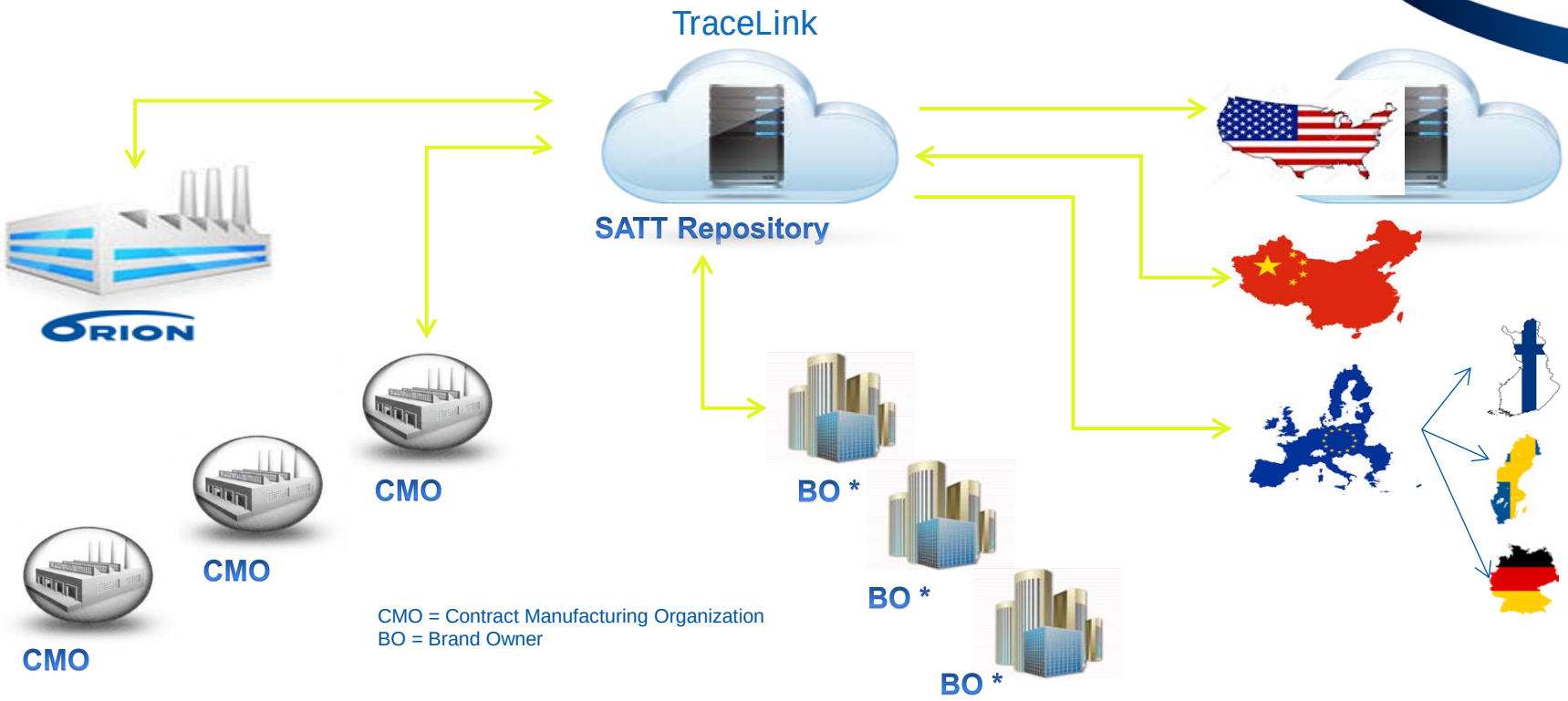
Level 2 – Line control

Level 1 – Line Device control

Print /serialization | Camera Check | Tamper evidence | Label print Case/Pallet | Camera check | Aggregate

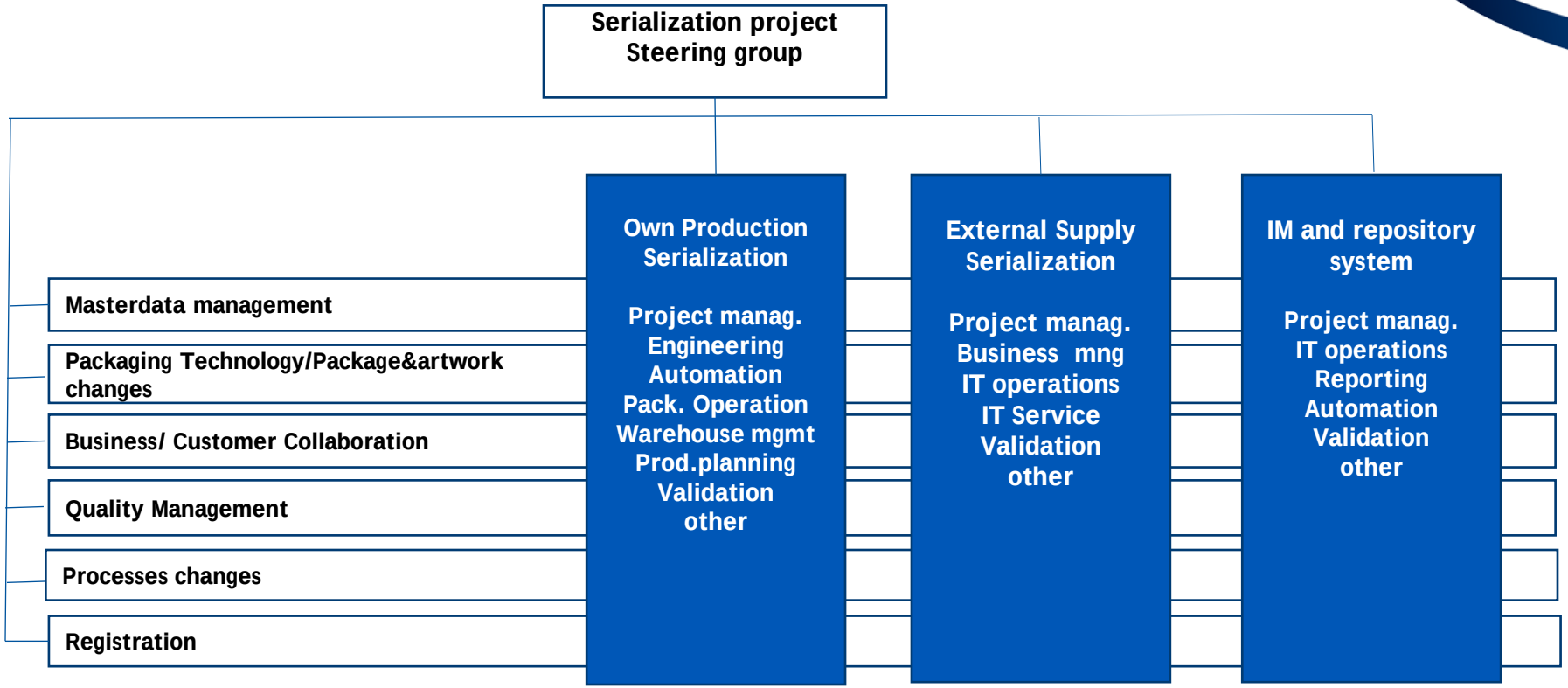
CMO = Contract Manufacturing Operator
SN= Serial Number
BO = Brand Owner

SATT Repository – centralized control of serial numbers

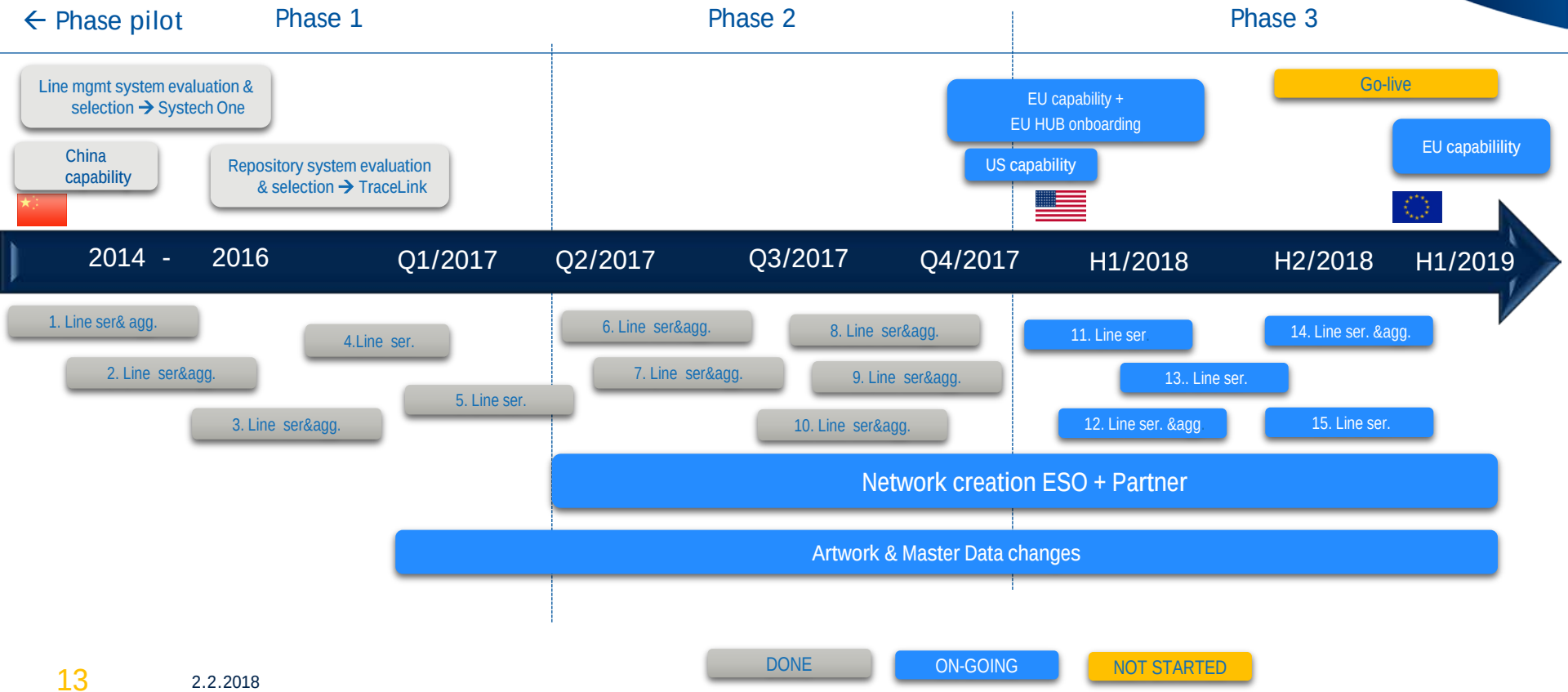


Our project

Serialization project organization Orion



Serialization implementation project



We have exciting times ahead of us…

- Orion has several years of experience in serialization
- However, we well recognize that there is a lot to be done before EU serialization can start
  - Production lines to be upgraded
  - Artworks changed
  - Master data updated
  - Reporting processes to be established

- First go-lives are expected H2/2018
- Artwork changes may be implemented in advance
- Orion is following up the local progress in different EU countries and planning the testing and go-live activities accordingly

2.2.2018

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