Implementing the Falsified Medicines Directive Compliance in a Pharma Company
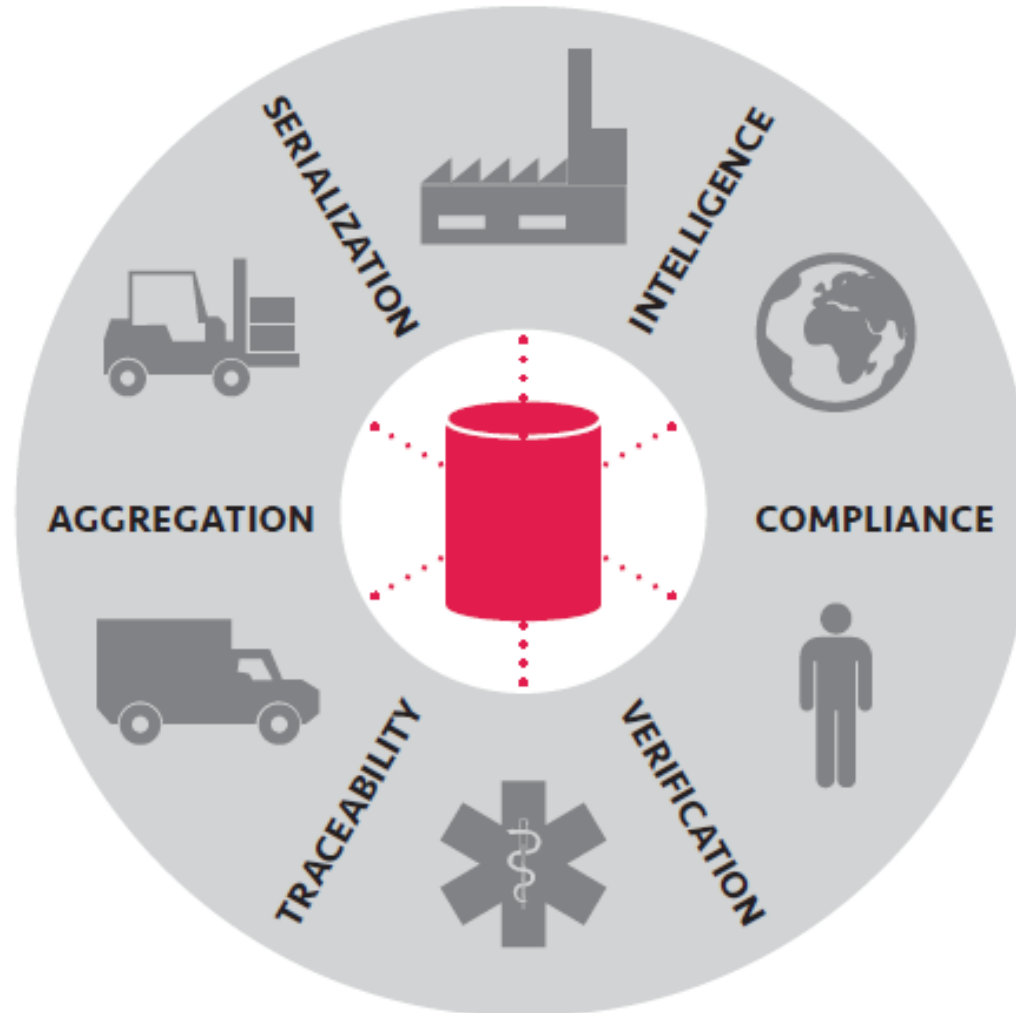
A Clear Vision For Life™ **Santen**
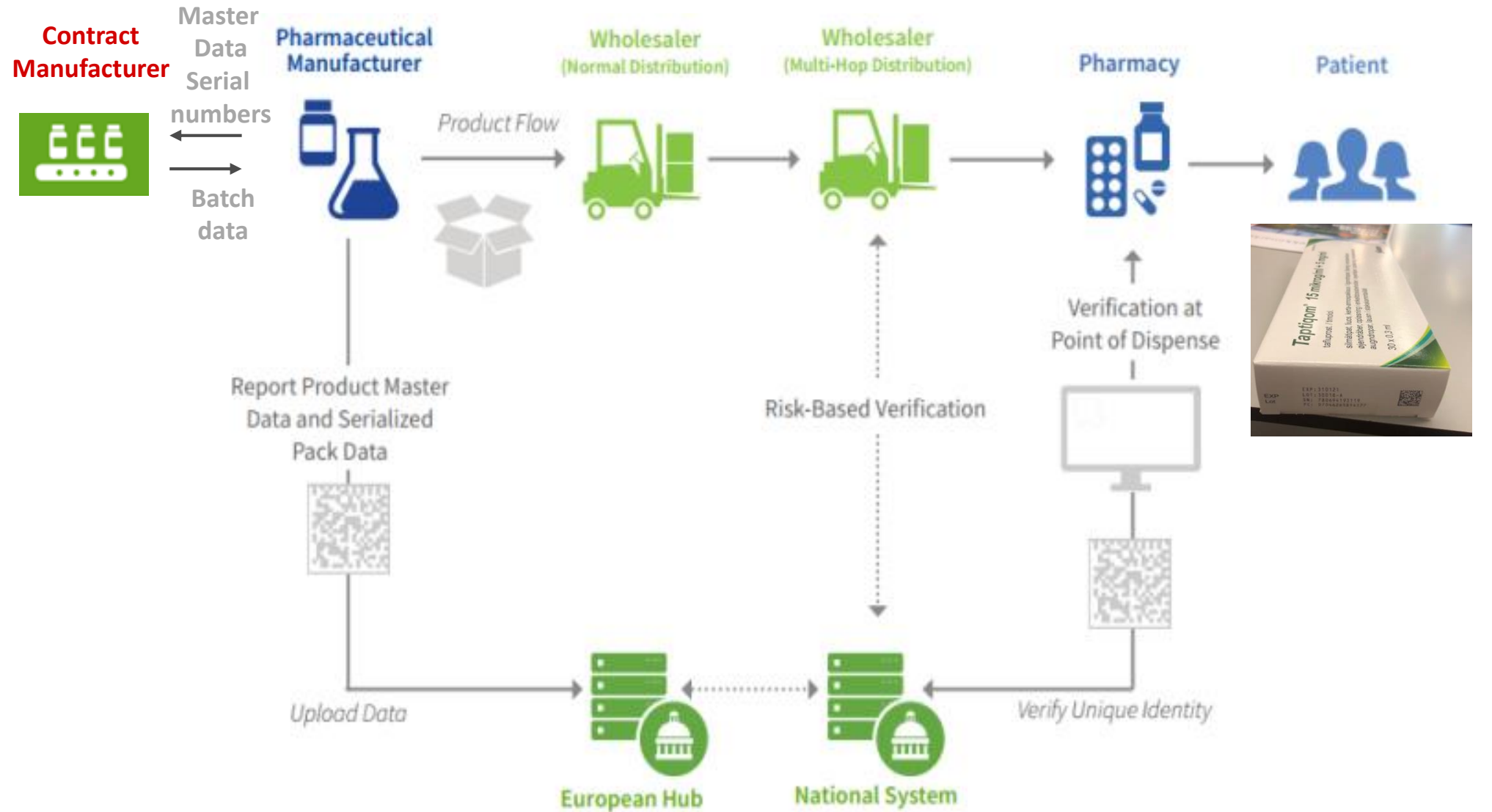
September 18th 2018

Pasi Kemppainen

The Big Picture: Serialization, Traceability, Tamper Verification and Compliance

Implementing the FMD Compliance

EU FMD Artwork Changes: Unique Identifier and Tamper Evidence With National Variations

Guidance

Art work changes for fitting the new variable data and datamatrix code

GTIN:	(01) 07046261398572
Batch:	(10) TEST5632
Expiry:	(17) 130331
S/N:	(21) 19067811811

Standardized online coding

Tamper evidence

Reality

PC	09504000059118
SN	10987654d3
Exp	11.2014
Lot	7654321D
PVP	€10,50
NN	10389358

Portugal

Verwendbar bis:

11.2014
Ch.-B. 7654321D
PC 09504000059118
SN 10987654d3
NN 10389358

Germany

PC/Sn/Exp/Lot

09504000059118
10987654d3
11.2014
7654321D

NN 10389358

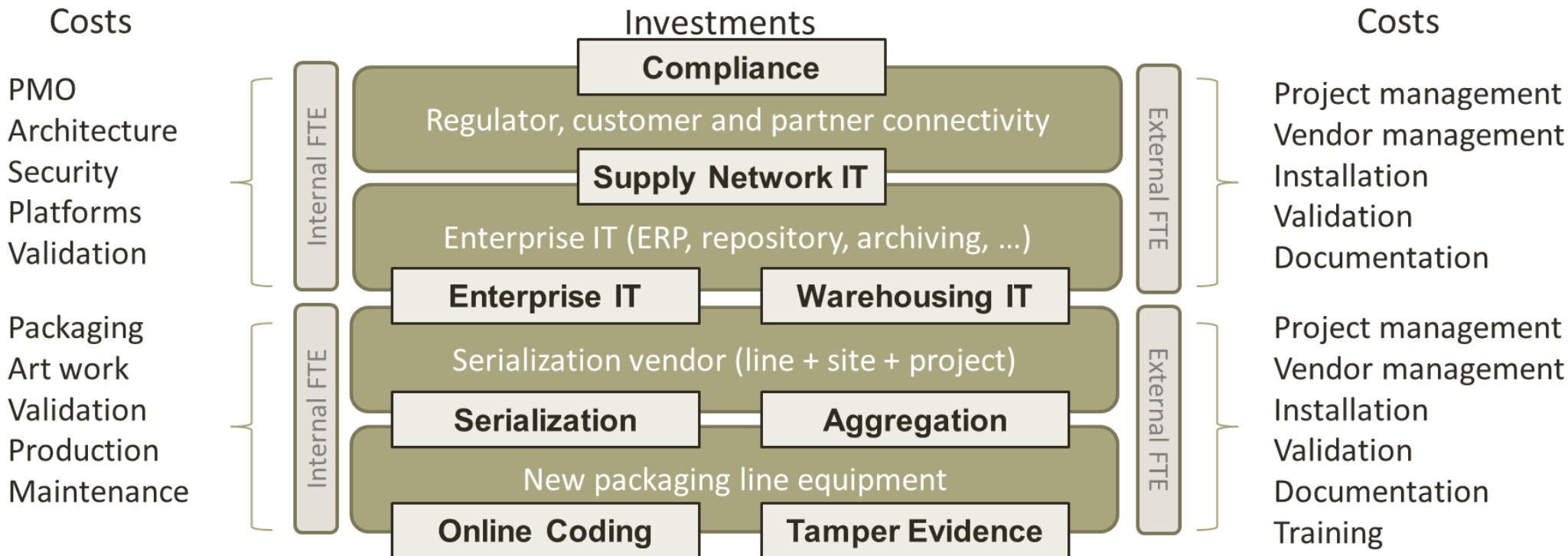Slovenia

Serialization and Traceability - Why so Difficult and Expensive?

- ■ **Serialization and traceability investments and costs can be roughly divided based on the organizational and technology responsibilities**
- ■ **In addition: CMO, RA, artwork, EMVO on-boarding and annual NMVO costs**

Costs

PMO
Architecture
Security
Platforms
Validation

Packaging
Art work
Validation
Production
Maintenance

Investments

Compliance

Regulator, customer and partner connectivity

Supply Network IT

Enterprise IT (ERP, repository, archiving, …)

Enterprise IT   Warehousing IT

Serialization vendor (line + site + project)

Serialization   Aggregation

New packaging line equipment

Online Coding   Tamper Evidence

Internal FTE

External FTE

Costs

Project management
Vendor management
Installation
Validation
Documentation

Project management
Vendor management
Installation
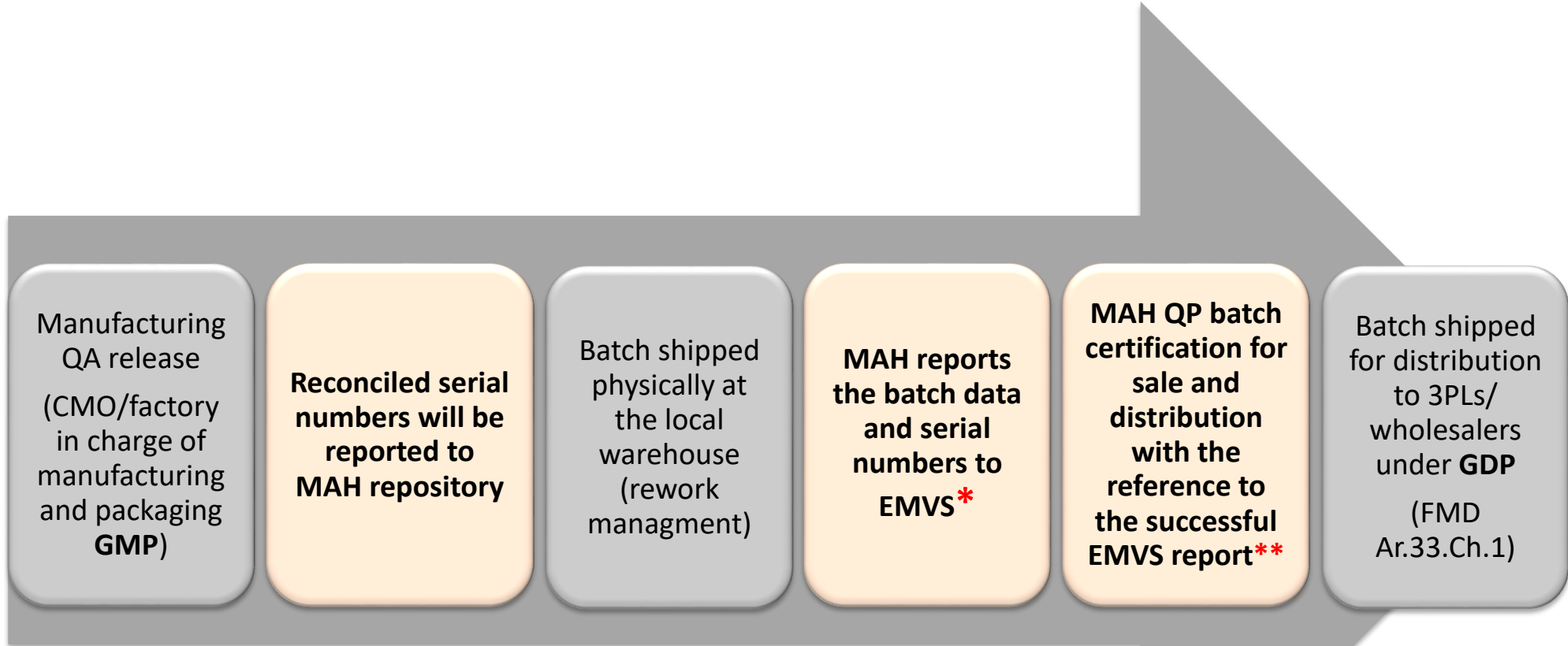Validation
Documentation
Training

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Average FMD Implementation Costs for MAHs

- **Total investments and costs per packaging line[1] c. <u>0,5 - 1,5 MEUR</u>**
  - In addition, share of CMO investment capital contributions

- **Additional site and enterprise IT investments (incl. serialization repository) per MAH[2] c. <u>0,3-0,7 MEUR</u>**

- **Additional annual on-going operational and maintenance costs in production**
  - Serialization costs **c. <u>0,05…0,20 EUR</u>** per sales unit[3]

- **Annual NMVS operational costs c. <u>10 kEUR</u> per MAH per country**
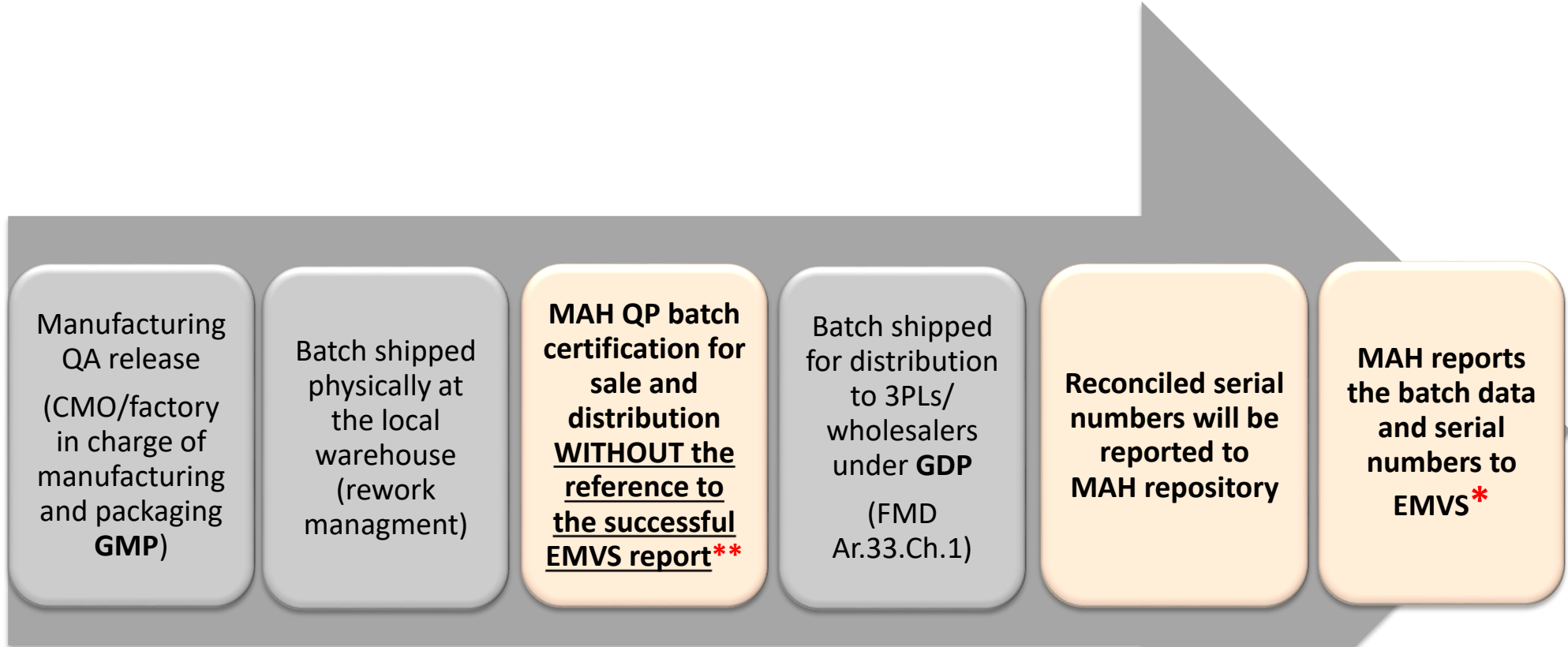
1) c. 12000 packaging lines in EU affected **2)** c. 2500 MAHs in EU **3)** c. 10B Rx packs p.a. in EU

One more thing...

QP Release with Reconciliation for FMD Reporting – THE CORRECT PROCESS

| Manufacturing QA release (CMO/factory in charge of manufacturing and packaging **GMP**) | **Reconciled serial numbers will be reported to MAH repository** | Batch shipped physically at the local warehouse (rework managment) | **MAH reports the batch data and serial numbers to EMVS*** | **MAH QP batch certification for sale and distribution with the reference to the successful EMVS report**** | Batch shipped for distribution to 3PLs/ wholesalers under **GDP** (FMD Ar.33.Ch.1) |

*) The amount of reported serial numbers == the size of the batch
(EU Commission Q&A Ch. 8.6.)

**) The data needs to be present in the EMVS at the time
the batch is released for sale and distribution
(EU Commission Q&A Ch. 7.13 & 7.16.)

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QP Release with Reconciliation for FMD Reporting – THE INCORRECT PROCESS

| Manufacturing QA release (CMO/factory in charge of manufacturing and packaging **GMP**) | Batch shipped physically at the local warehouse (rework managment) | **MAH QP batch certification for sale and distribution <u>WITHOUT the reference to the successful EMVS report</u>**** | Batch shipped for distribution to 3PLs/ wholesalers under **GDP** (FMD Ar.33.Ch.1) | **Reconciled serial numbers will be reported to MAH repository** | **MAH reports the batch data and serial numbers to EMVS*** |

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Serialization and Traceability is Not a Project But A Transformation Program

- **Achieving FMD readiness and compliance is much more than the sales pack level serialization**
  - Traceability (reporting)
  - Tamper evidence/verification
  - Art works
  - Master data and GTINs
  - Partner and supply network readiness
  - Global regulatory reporting
  - Changes in the QA and QP processes and reporting
  - Budgeting and contracts (vendors, EMVO and NMVOs)
  - Implementation orchestration: collaboration internally and with supply chain partners (CMO and 3PL/WS)

- **Global requirements are very diverse and fast changing: market and regulatory intelligence is essential**

- **The learnings so far… it's all about expectations management, execution and collaboration**
  - Internal decision making and commitment will take time
  - Scope is larger than you might even imagine (e.g. multi-country packs, master data, SOPs, mfg/enterprise IT changes, …)
  - Budgets are big in comparison to the usual compliance and packaging projects – expect surprises along the way
  - New technologies and competences required
  - Vendors are already fully booked for 8-12 months
  - CMO and 3PL readiness on timetable will be critical for the business continuity

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