Serialisation Solutions to Meet Global Requirements

Sean Mulholland,
Technical Quality Manager

ALMAC
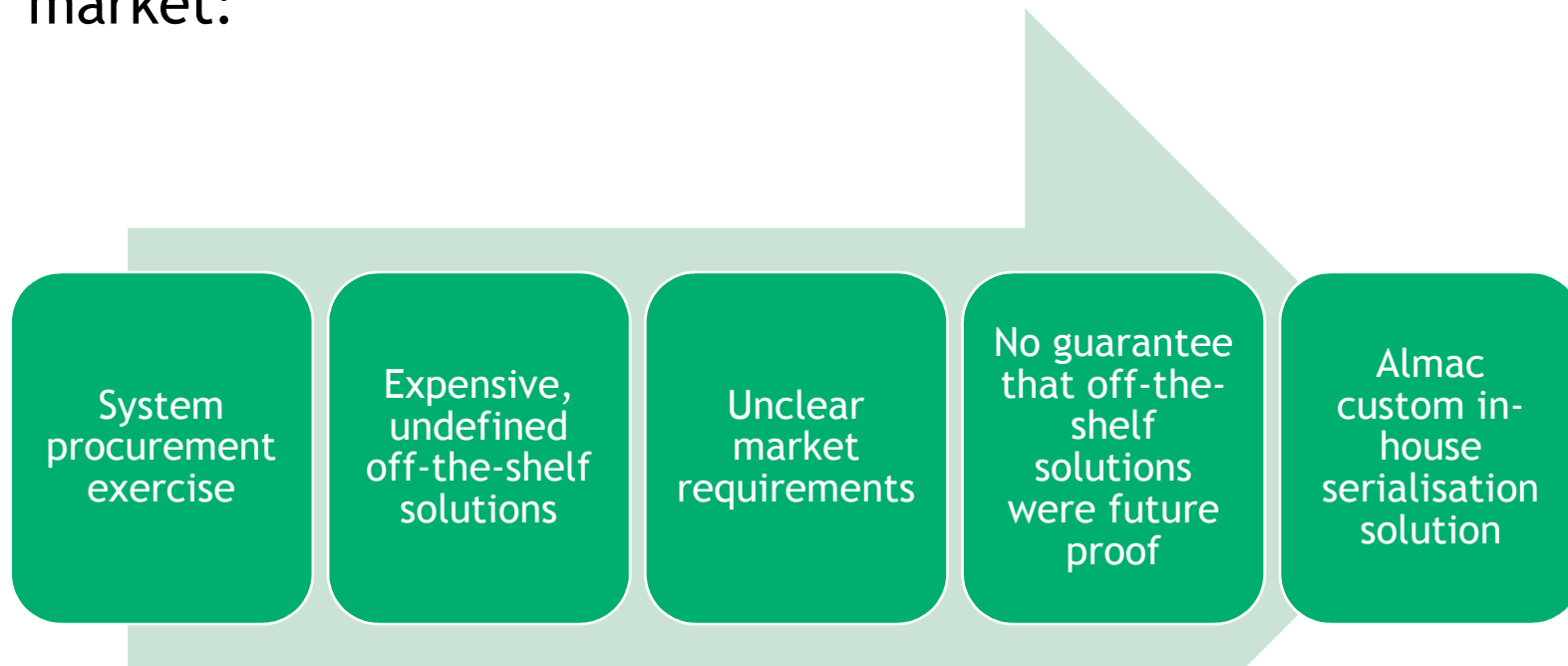
Agenda

- Almac's Serialisation History
- Current Plans and Future Development
- Key Serialisation Strategy Considerations
- Partnering with a CMO

Serialisation at Almac - How it all began...

ALMAC

How it all began

- 2009 – Requirement for serialised product launch in the Turkish market:

System procurement exercise → Expensive, undefined off-the-shelf solutions → Unclear market requirements → No guarantee that off-the-shelf solutions were future proof → Almac custom in-house serialisation solution

How it all began

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│                   User Requirements Specification                     │
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Off-the-shelf Options	Custom-built Options

System with required flexibility not available

Custom/configurable system offered the best way of reacting to change/introduction of new regulations

Not reliant on external sources to provide updates/back-up and the suppliers interpretation of the associated regulations

Allow for phased approached and focused validation effort inline with business and client requirements

Considered current internal processes, thus reduced the impact of integrating the new equipment/processes

Almac's Initial Serialisation Solution

Custom Built Solution by:

Almac Information Services

- Development of serialisation software solution

- Full system testing

- Integration testing

- Infrastructure

Almac Engineering Services

- Design of printing and inspection system

- Procurement of key components

- Commissioning

- Integration testing

Integration into multiple systems

Standalone line (portable)
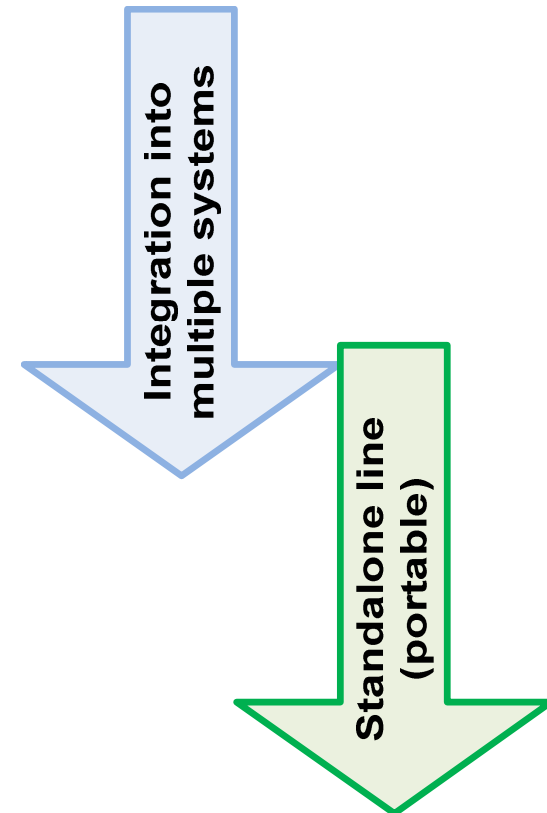
Almac's Initial Serialisation Solution

Custom Built Serialisation Solution

APPS (Almac Pharma Product Serialisation)

Site Software:
- Serial Number Generation
- Integration with external serial number solution providers
- Aggregation
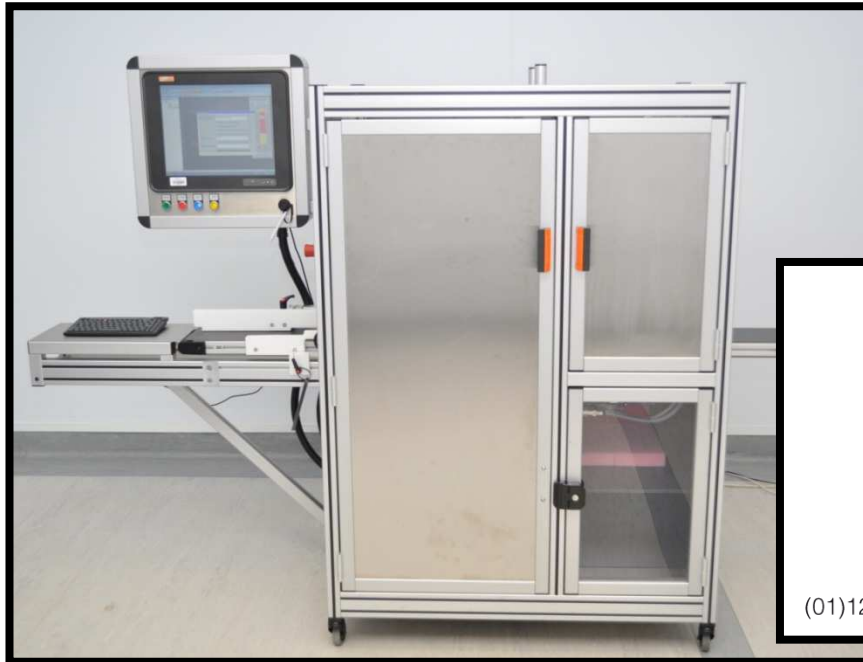- Reporting

OPSIS (Overprint Serialisation Inspection System)

Hardware / Serialisation Line:
- Hapa Red Cube Printer *(online application of 2D matrix)*
- Cognex Vision System *(online verification of 2D matrix & human readable information)*
- LVS Verifier *(off-line verification of 2D matrix)*

Serialisation to GS1 Standards

Almac's Initial Serialisation Solution
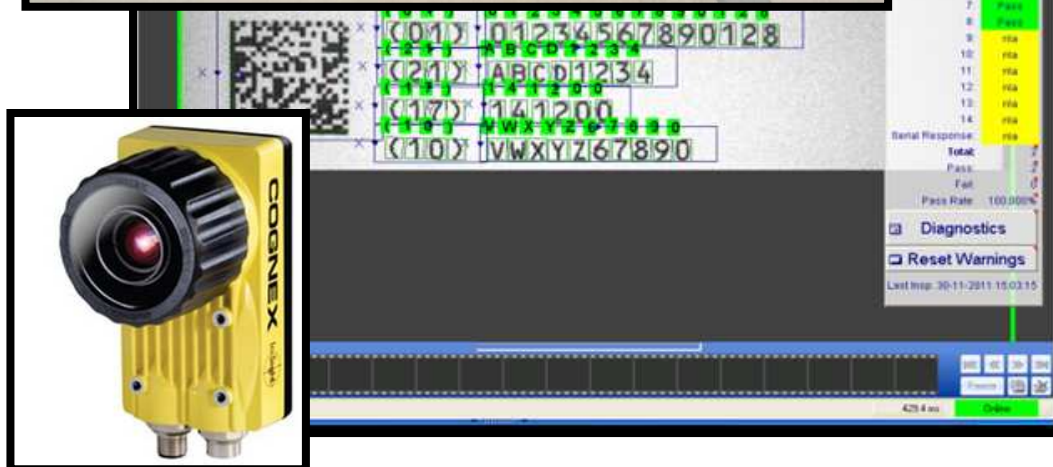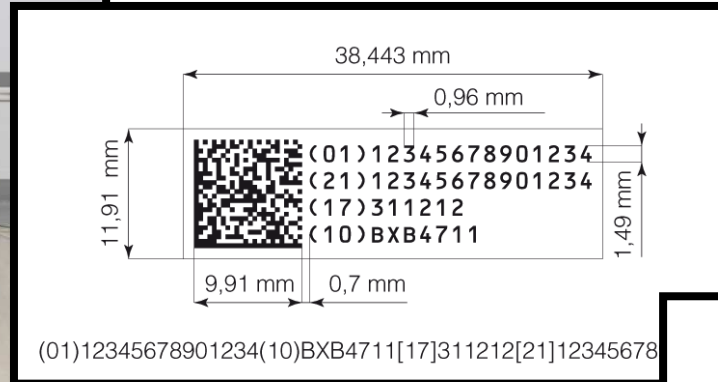
Almac's Experience

Markets

Turkey, South Korea & Brazil

- Saleable pack
- Unique SN required
- Aggregation (pack-shipper-pallet)

```
(01)08691234567890
(21)111323424679
(17)100331
(10)X25120613322
BN    XXXXXXX
EXP   MM YYYY
```

Austria

Demo
PZN:
LOT:
EXP: MM YYYY

- Unit & saleable pack (encoded pack)
- Pilot study
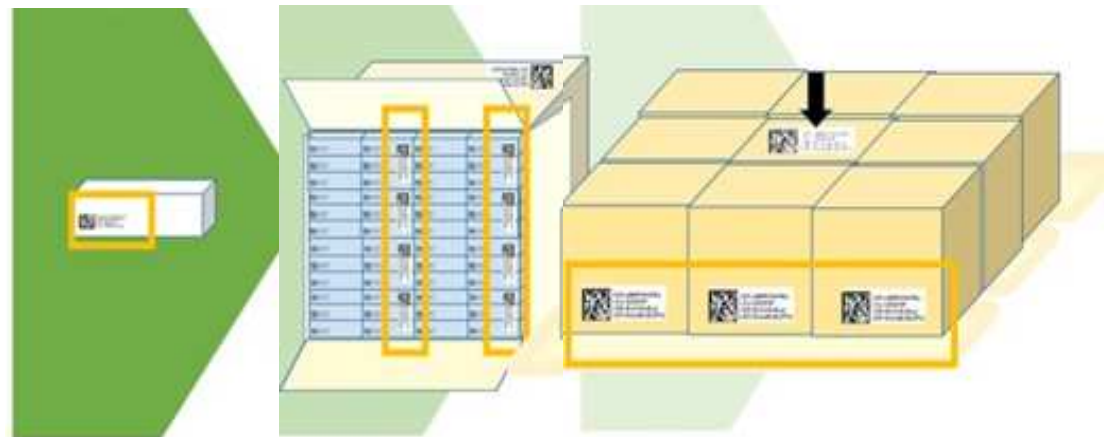- Cytotoxic / cytostatic drugs only

France

Demo
CIP:
LOT:
EXP: MM YYYY

- Saleable pack (encoded pack)

Interface with Tracelink & Axway for client data management processes

Almac's Experience

Aggregation (a must…)

Unit ➡ Shipper ➡ Pallet

Almac's Experience

Serialisation without Aggregation?

McKesson expects serialised item level product will be aggregated to…

As your company prepares to implement your serialisation solution, be

sure to consider the need for aggregation.

Current Plans & Future Development

EU FMD Review

4 Main Requirements of the EU FMD:

- Serialisation

- Safety Features

- Compliance Reporting

- Verification

EU FMD Review

- Requirement:

    – Serialisation of saleable unit (Unique Identifier)

    – 4 data elements* required (Product Identifier / Serial Number / Lot Number / Expiry Date) * Potential 5th element for some EU markets

    – Data management

    – Application of Tamper Evidence solutions

- Almac Solution:

    – Introduction of new technology to allow serialization of a wide range of pack formats that consider current and potential products.

    – Ongoing procurement exercise to introduce a number of tamper evident seal applicators.

Current Plans & Future Development

Early 2015…

Big question for Almac – Scalability…

Solution –   OPTEL ▲▼▲ VISION   Partner for *line supply* in *conjunction with APPS*

Current Plans & Future Development

The partnership…then

Optel were selected as the preferred vendor. The scope of the partnership included:

- Supply new stand alone lines

- Retro fit current lines

- Provision of line level software

Why?

- Optel identified as the perfect fit for Almac - they could provide Level 1 & 2 functionality but had limited Level 3 capability which was fulfilled via APPS

Current Plans & Future Development

The partnership...now

Almac have decided to extend their partnership with Optel through the implementation of their Level 3 software Open Site Master (OSM)

Why?

- Consistency across sites

- Training for Almac IS Development team to allow for maximum flexibility (e.g. integration performed by Optel trained Almac personnel)

- Support transition to multiple serialisation lines

- Improved integration with L4

- Almac and OPTEL expertise combined
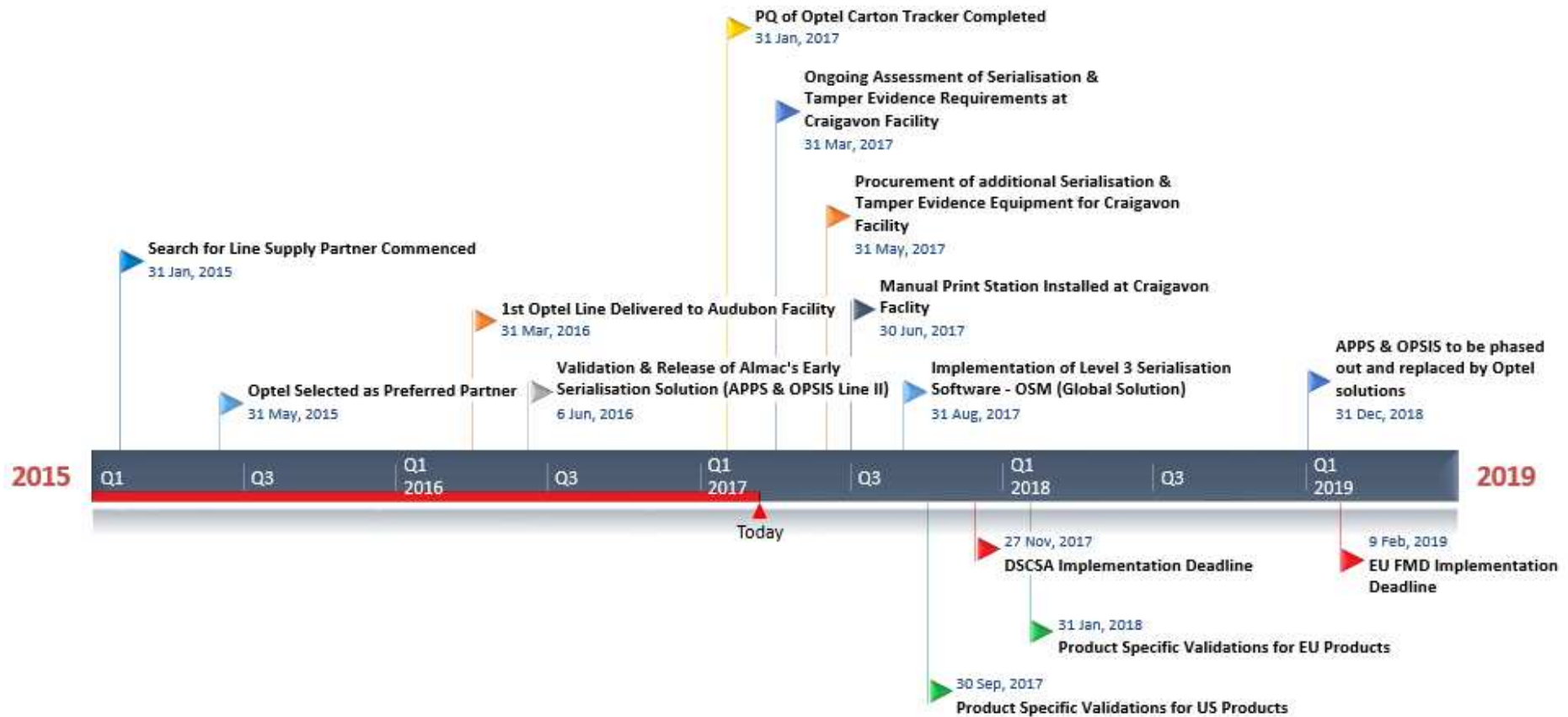
Current Plans & Future Development

Current Status

- Assigned Project Manager (Optel Vision)

- Assigned Solution Engineers (Optel Vision)

- Manual Print Station purchased for Craigavon site, installation scheduled for June 2017

- Audubon site Bottle labelling solution: installation scheduled for Q2 2017

- Implementation of Optel Vision's Level 3 Solution, OSM, Jun 2017
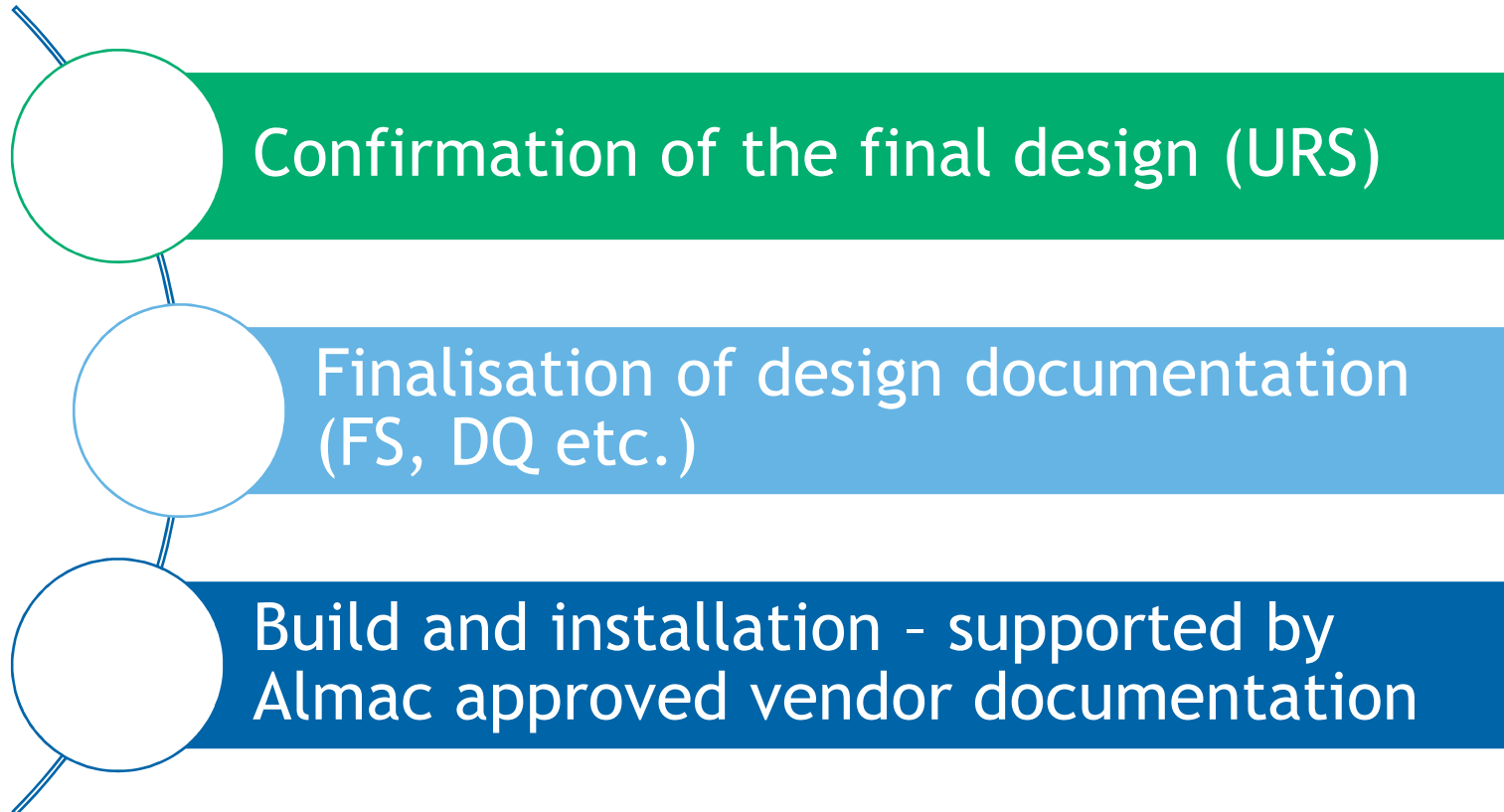
Current Plans & Future Development

Timeline Review

Current Plans & Future Development

Next steps for Almac...

Confirmation of the final design (URS)

Finalisation of design documentation (FS, DQ etc.)

Build and installation – supported by Almac approved vendor documentation

Key Serialisation Strategy Considerations

Key Serialisation Strategy Considerations

Key considerations for Almac Customers...

- BIG question – number management!

    – Will a partner be involved?

    – Who will generate numbers?

    – Number communication pathways?

    – Reporting requirements?

Per Section 3.2.1 General Principles of the European Medicines Verification Organisation: Requirements for the European Medicines Verification System – URS Lite, Version 1.7, dated May 27, 2016: **Section 3.2.1 General Principles, Item B.8:**

"It will be each manufacturer's responsibility to upload product pack data to the European Hub. This task cannot be transferred to another party, e.g. a contract manufacturer (CMO)."

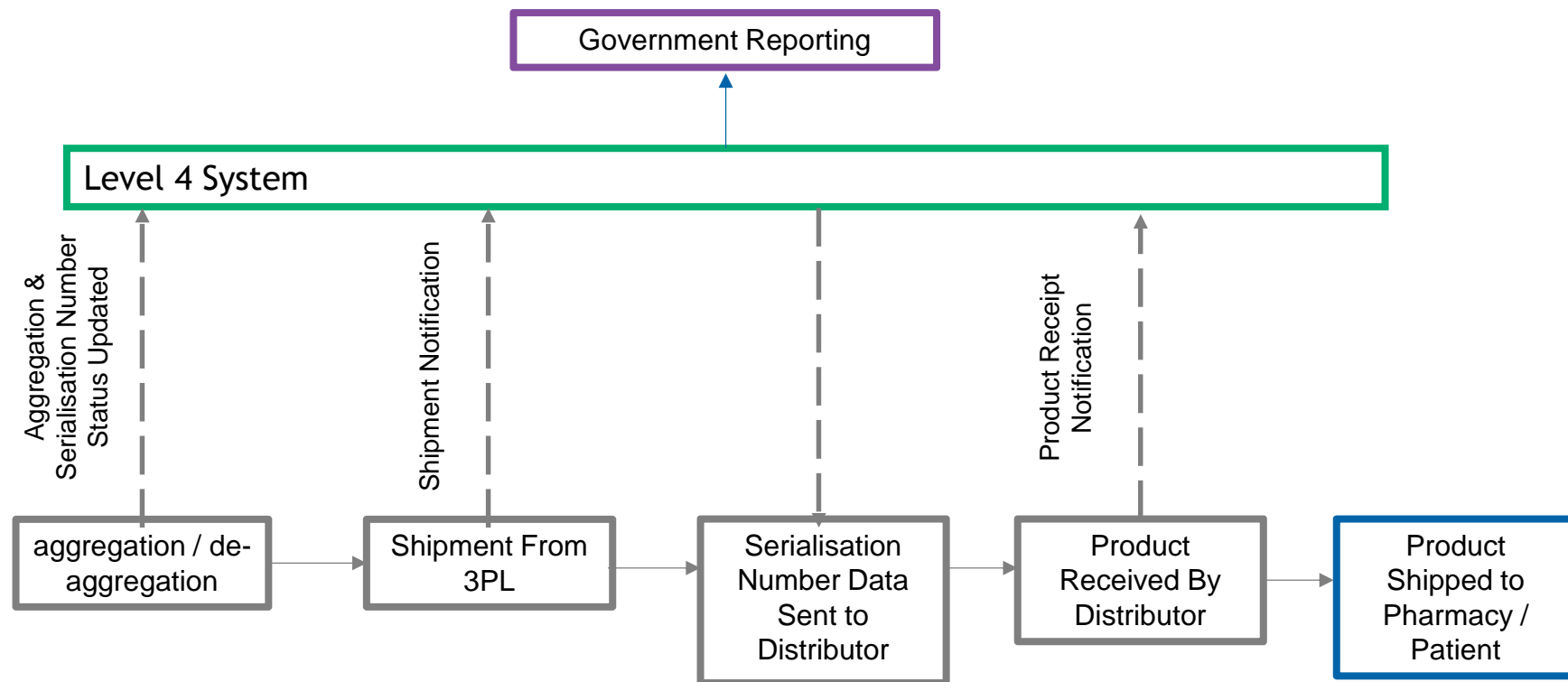# Key Serialisation Strategy Considerations

Level 4 Solutions

- Many Almac customers are partnering with a Level 4 solution provider;

- This approach seems to work well with a CMO solution as all parties within a MA holder's supply chain will use the same data communication channels.

- **Alternative** – each CMO will use their own solution to communicate data but the MA holder will then need to decide how they will manage and use this information.

Key Serialisation Strategy Considerations

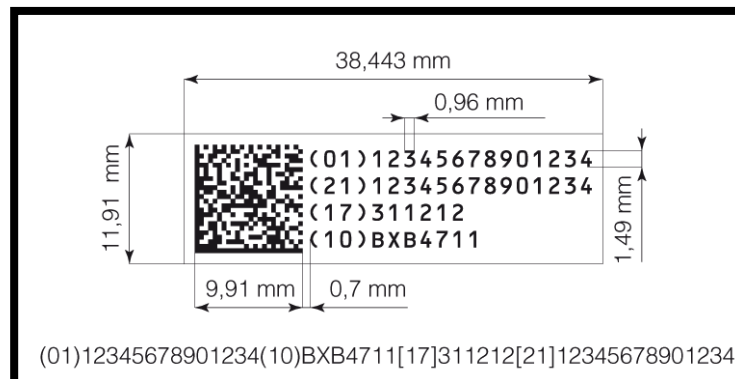## Serialisation – Distribution to Pharmacy...

Key Serialisation Strategy Considerations

Key considerations for Almac Customers…

Artwork management

- Assessment of current packaging….any changes required to accommodate printing?

    - Position on the product / carton

    - Size

    - Pack orientation in packing configuration

Key Serialisation Strategy Considerations

Key considerations for Almac Customers…

Outstanding questions

- Impact on Multi lingual packs (EU)

    - How will these be handled in conjunction with the central hub and national authority requirements?

- Cost of hub registration / maintenance for the MAH (EU)
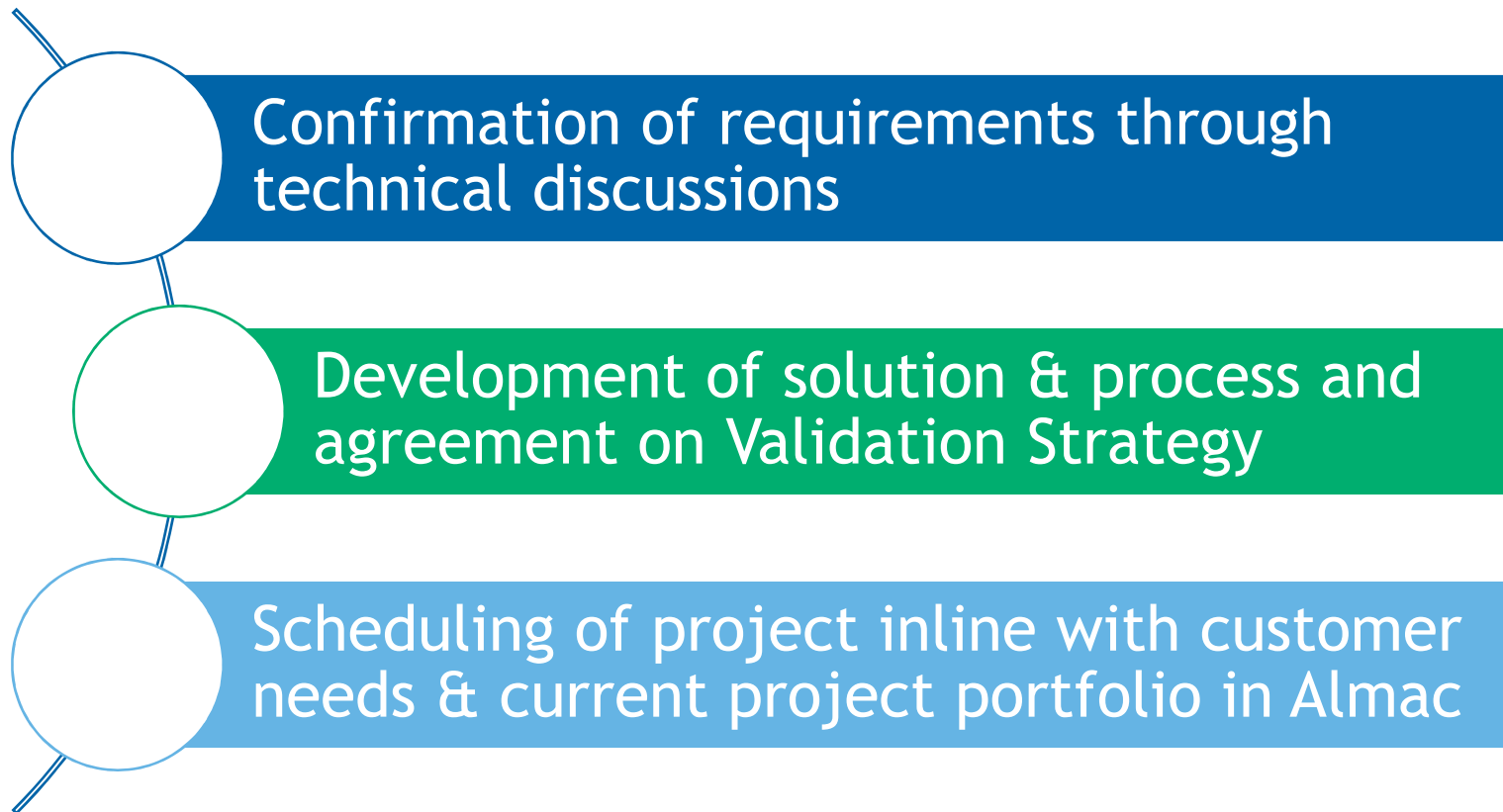
- Assessment of all parts of the supply chain… (Global)

Partnering with a CMO

Partnering with a CMO

Next steps for an Almac Customer…

- **Confirmation of requirements through technical discussions**

- **Development of solution & process and agreement on Validation Strategy**

- **Scheduling of project inline with customer needs & current project portfolio in Almac**

Partnering with a CMO

Specialist Serialisation Core Team

Dedicated Product Supply Manager

- Phil Lightowler, Head of Production (Sponsor)
- Darryl McConnell, Global Serialisation Technical Manager
- Robert Madden, Global Serialisation Operational Manager
- Peter Gaffney, Technical Quality Officer
  - Dedicated Quality and Validation resource
- Kwan Suh, US Serialisation Process Lead
  - Dedicated Operations resources
- Ciera Freeburn, UK Serialisation Process Lead

Key Supporting Departments

- Client Services
- Quality Assurance
- Quality Control
- Production
- Stores & Distribution
- Information Services
- Engineering Services

Thank you