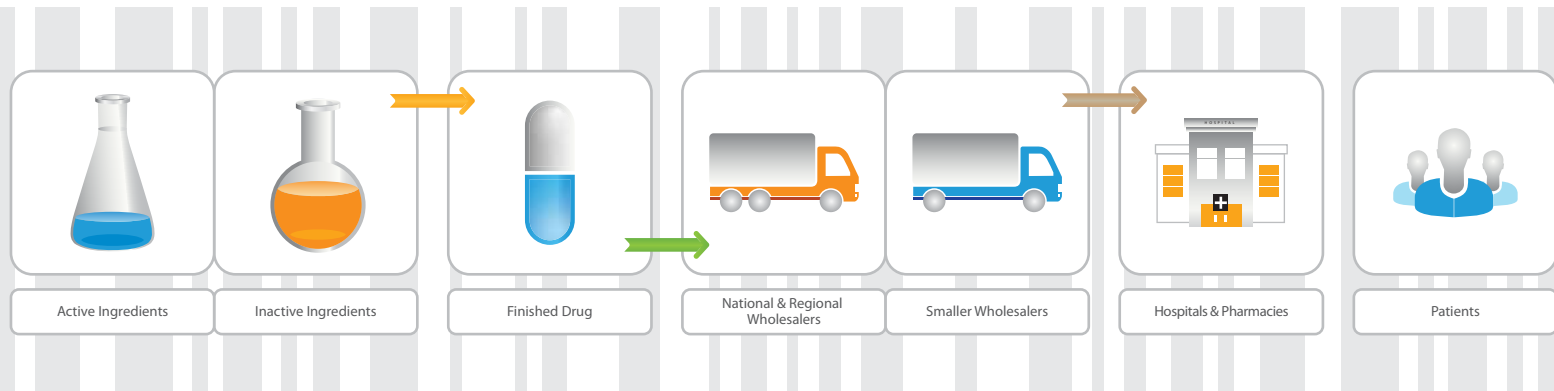# Infosys ®

Pharmaceutical Serialization Track & Trace

As more and more governments enact legislation requiring serialization of all pharmaceutical products to eliminate counterfeiting of drugs, several regional deadlines loom over pharmaceutical companies, especially around

2014/2015 when both the US and the EU will implement their final legislation. Pharmaceutical companies would do well to treat serialization projects as business-benefit driven programs rather than merely compliance-mandated investments, as

they will derive substantial payback from lower recall costs and better visibility across a secure supply chain. Consulting partners make a critical difference to the successful implementation of a Serialization Track & Trace program.

| Active Ingredients | Inactive Ingredients | Finished Drug | National & Regional Wholesalers | Smaller Wholesalers | Hospitals & Pharmacies | Patients |

Questions pharmaceutical companies must ask themselves

1. Do we understand EPCIS* and global regulatory requirements?

2. Do we have a strategy to handle the explosion in data volumes?

3. Do we have a global view that ensures all local compliance in the stipulated time periods?

4. Have we factored in the risk of obsolescence in technologies and acquisitions between vendors?

5. Are our partners experienced in dealing with all the links involved in a product's chain of custody?

*EPCIS: Electronic Product Code Information Services

Challenges posed in implementing a Serialization solution

- Each nation has, or is formulating, its own guidelines/legislation; there is currently no global regulatory body. As standards evolve, programs need to be flexible enough to adjust to directions taken by multiple regulators.

- Since serialization covers the entire supply chain it involves integration of a host of technologies, including legacy systems, core ERP, and cloud. This is complex.

- Given the number of packaging lines and distribution channels, a complete serialization program can take 4 to 8 years to implement. It is imperative to have rigorous control mechanisms in place, so that the company leadership keeps seeing results.

- Serialization data, estimated to double every 18 months, integrated with existing ERP data, is creating petabytes of Big Data – information, structured and unstructured.

Infosys Serialization Track & Trace preconfigured solution

Infosys Serialization Track & Trace preconfigured solution, which has been developed on SAP, uses SAP components like SAP ECC, SAP Auto ID-Infrastructure (AII), SAP Event Management (EM) and SAP ITS Mobile.

Highlights

- **Accelerator Packaging line Solution:** SAP AII/OER Integration Document refines the interface as per integration requirements between the Packaging Line Solution and SAP AII, based on EPCIS standards
- **Accelerator to speed up the configuration of SAP AII and SAP OER:** speeds up implementation of supply chain processes using pre-configured solutions

- **Accelerator for Testing:** Hierarchy upload Test Tool creates serialized test data and reduces the time and cost of testing and training
- **Infosys Life Sciences Center of Excellence:** ensures a talent pool of consultants with experience in global implementation of serialization, and sound knowledge of regulatory systems and compliance mandates including FDA, TGA, GxP, 21 CFR Part 11

On Track. Ahead of Time.

Infosys Serialization Track & Trace preconfigured solution keeps global biopharmaceutical giant on track to complete Phase I of serialization ahead of schedule.

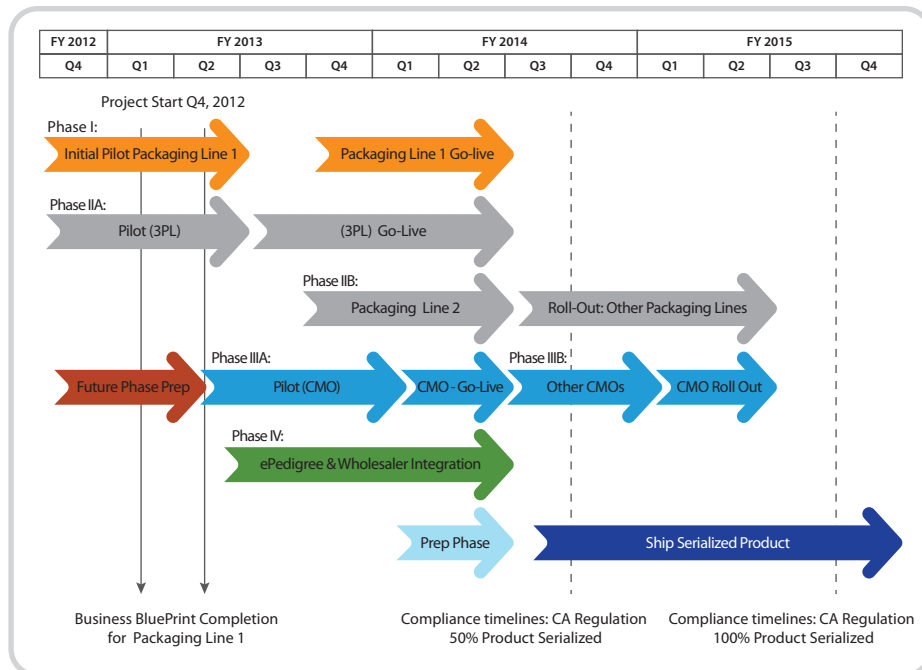## Benefits of Infosys Serialization Track & Trace preconfigured solution

Estimated to reduce implementation timelines by almost **30%** as compared to Standard SAP methodology

Preconfiguration can be leveraged to reduce the implementation effort, independently of client infrastructure

Easy integration with enterprise partner eco systems, including packaging and distribution lines, SAP (AAI & OER) and cloud

Single point access to the myriad skills required – in databases, package line integration, distribution line integration and mobile tracking – making implementation easy, fast and risk free

Experience of more than **5 years** in implementing serialization for major pharmaceutical companies resulting in a deep understanding of operational challenges, technologies involved and compliance requirements

FY 2012	FY 2013				FY 2014				FY 2015			
Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

Project Start Q4, 2012

Phase I:
Initial Pilot Packaging Line 1 — Packaging Line 1 Go-live

Phase IIA:
Pilot (3PL) — (3PL) Go-Live

Phase IIB:
Packaging Line 2 — Roll-Out: Other Packaging Lines

Phase IIIA:
Future Phase Prep — Pilot (CMO) — CMO - Go-Live — Phase IIIB: Other CMOs — CMO Roll Out

Phase IV:
ePedigree & Wholesaler Integration

Prep Phase — Ship Serialized Product

Business BluePrint Completion for Packaging Line 1

Compliance timelines: CA Regulation 50% Product Serialized

Compliance timelines: CA Regulation 100% Product Serialized

CMO - Contract Manufacturing Organization
3PL - 3rd Party Logistics

For more information, contact askus@infosys.com

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