ISPE Indonesia Event Serialisation

Thursday, 8 February 2018

Ian Haynes
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Ian Haynes

Ian Haynes is an engineer with a proven record of innovation. Ian has a strong record of working collaboratively within complex organisations, offering strategic insight and analysis lea innovative solutions.

Ian has an extensive background in the pharmaceutical and fine chemical sectors, including technology road-mapping, new product design & introduction, product security, **coding & serialisation and engineering projects**.

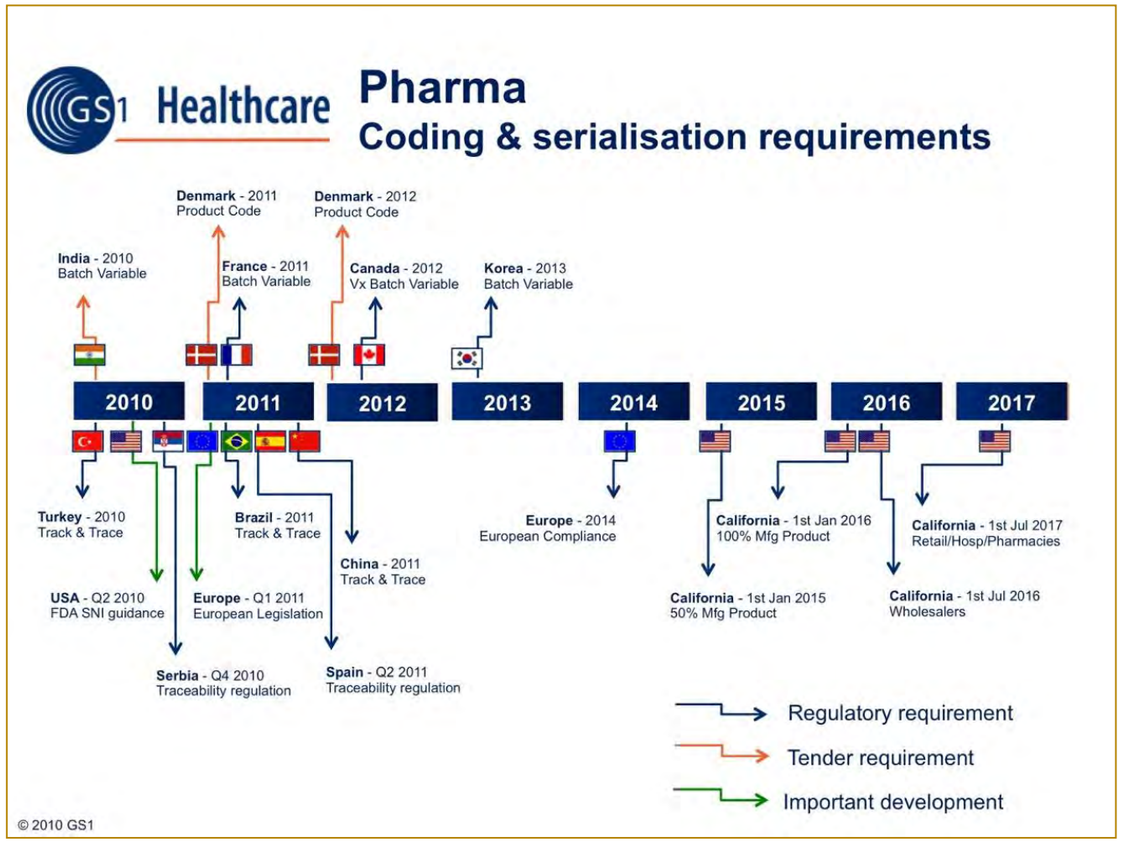
Ian was previously Associate Engineering Director in the Global Engineering Technology group at AstraZeneca Pharmaceuticals where, alongside other activities, from 2006 he played a key role in AZ's Pack Coding and Security Features programme. As a result of this work, AstraZeneca achieved a leading position with respect to serialisation and continues to play a key role in this field today.

Since 2012 Ian has been working alongside Christoph Krahenbuhl in 3C Integrity and continues to play a key role in 3C Excellis Europe. 3C's core business is to support participants in the phama supply chain in shaping up, planning and delivering their serialisation programmes.

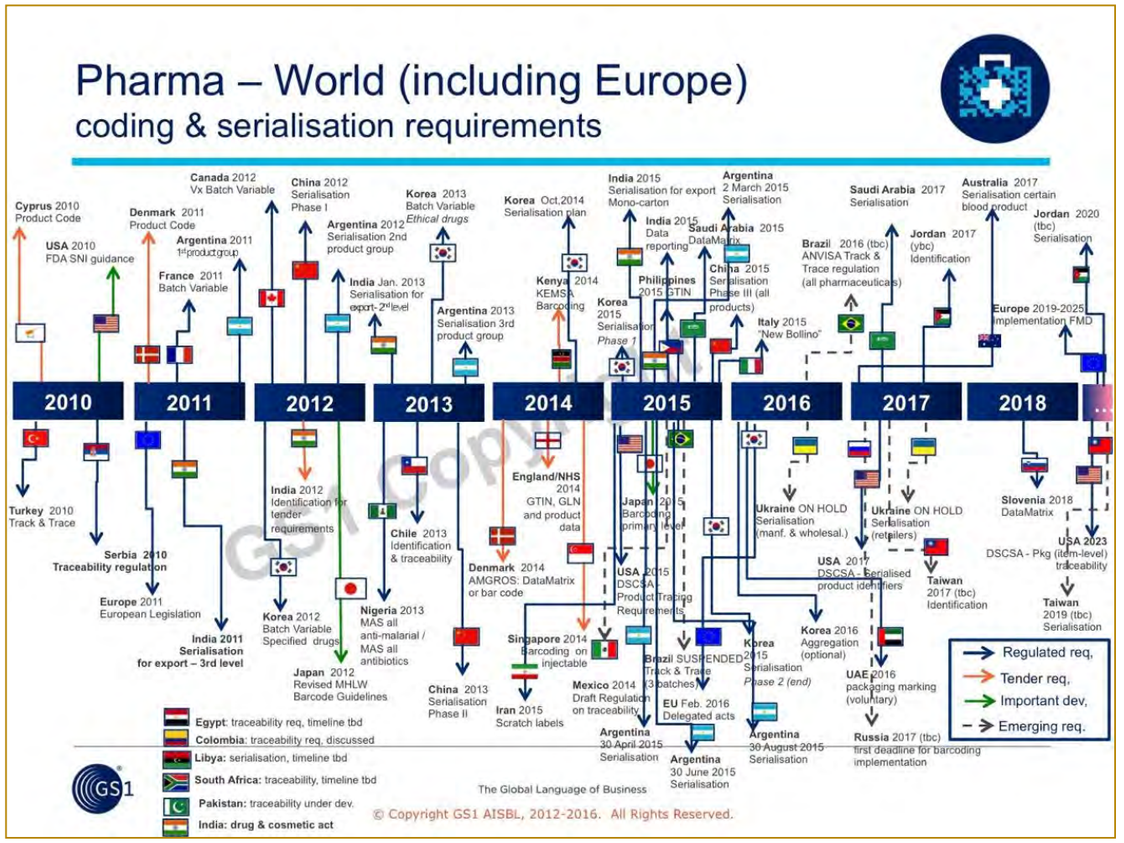
Ian's area of specialist expertise is a **solid, practical understanding** of these programmes, particularly from the perspective of manufacturing systems design, development and operation.

Serialisation: From Success to Challenge

2010



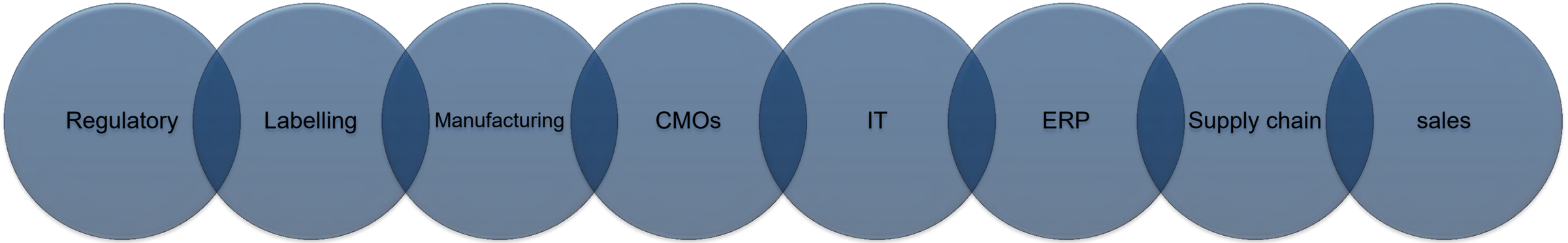
2017



Illustrations © GS1

A Holistic approach to serialization

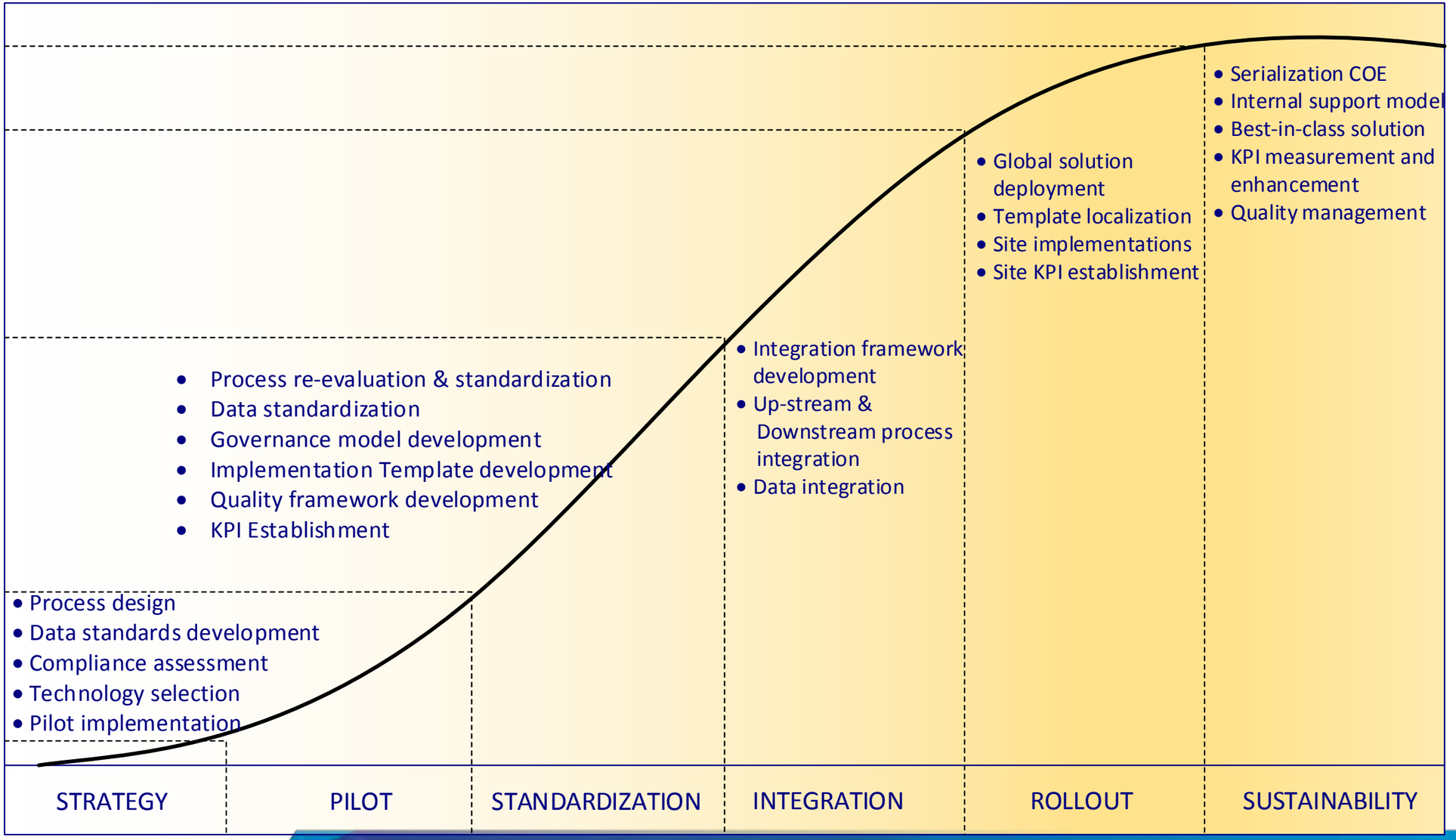
- Serialization is a **regulatory imperative**
- Serialization is still **evolving .** (Today : Turkey, Korea, US-DSCSA-EUFMD , many new regulations to come Russia, Middle-East, some regulations changes : Brazil, China, India,….)
- Your company is **evolving**
- Serialisation is an **enterprise program**



Serialisation Project Challenges

- Limited internal **bandwidth**…: implementing a major project like serialisation that touches many parts of the organisation
- Limited internal **knowledge**….: limited internal knowledge and experience of the particular challenges of serialisation
- How to understand the details and **impact of the requirements** in the many markets where the company operates
- Understanding what needs to be done to be **Serialisation-ready: Best Practices**

Methodology : Strategy to Sustainability



Agenda

- Background and Introduction
- Serialisation in Context
- Global Requirements
- Impact on Manufacturers
- Getting Started – a roadmap to success
- Want you want from your regulator – panel discussion

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Counterfeit or illegal trade?

Illegal trade = counterfeiting + illegal diversion + theft of medicines

Counterfeit

Medicine deliberately and fraudulently mislabeled with respect to identity or source:

Counterfeit products may contain:

- Wrong ingredients,
- No active ingredients,
- Insufficient or too much active ingredient,
- Fake packaging.

Illegal Diversion

The removal of products from one market into another market where it may not be approved or allowed to be legally imported.

Theft

Stolen products

Focus on Counterfeit Medicines?

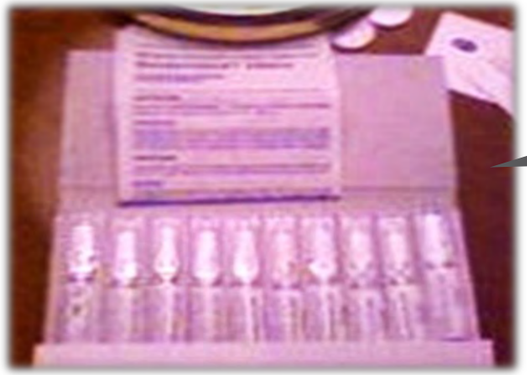
Counterfeit medicines are deliberately and fraudulently mislabelled with respect to identity or source:

- One of the biggest risks of counterfeit medicines is that patients may not get the therapeutic benefit expected from the product.
- The market in counterfeit and substandard drugs thrives in areas with weak regulation and enforcement of drug laws
- Their victims are the weakest in society: People who are suffering from sickness and illness
- They target areas such as lifestyle applications, nutritional supplements
- Counterfeit medicines are manufactured in clandestine laboratories with no standards, no regard for quality, no control.
- Their quality is unpredictable as they may contain the wrong amount of active ingredients, wrong ingredients or no active ingredients.

Harmful Ingredients Found In Counterfeit Medicines Have Included:

- Boric acid
- Leaded highway paint
- Floor polish
- Heavy metals
- Nickel
- Arsenic
- Brick dust

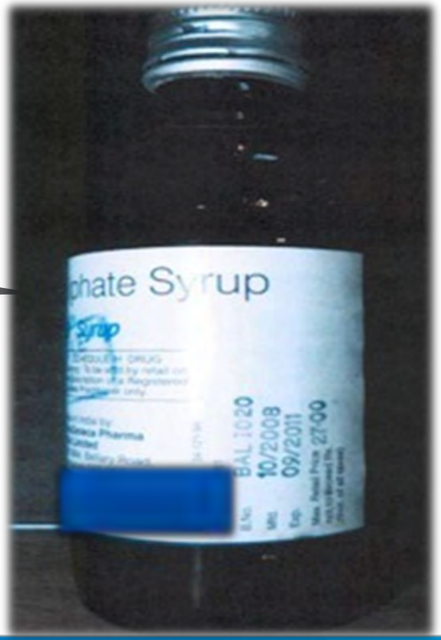
Fake medicines hurt real patients



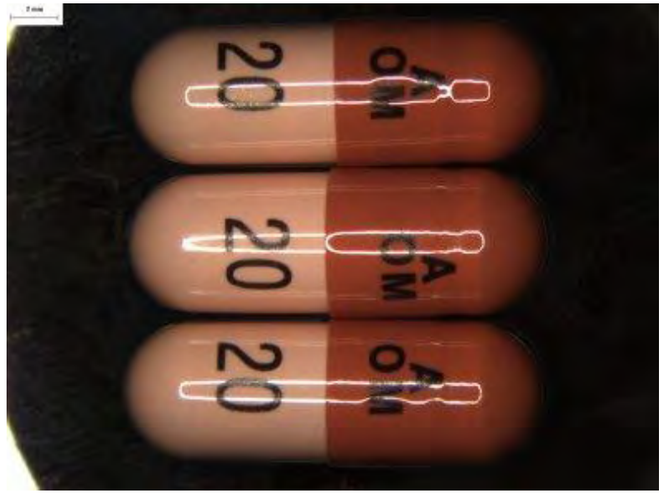
Injectable (China) found to contain tap water

Cough syrup (India) contained sugar and E. coli

IV Formulation (Philippines) had been used & contained Penicillin G.



Counterfeit Medication – a closer look



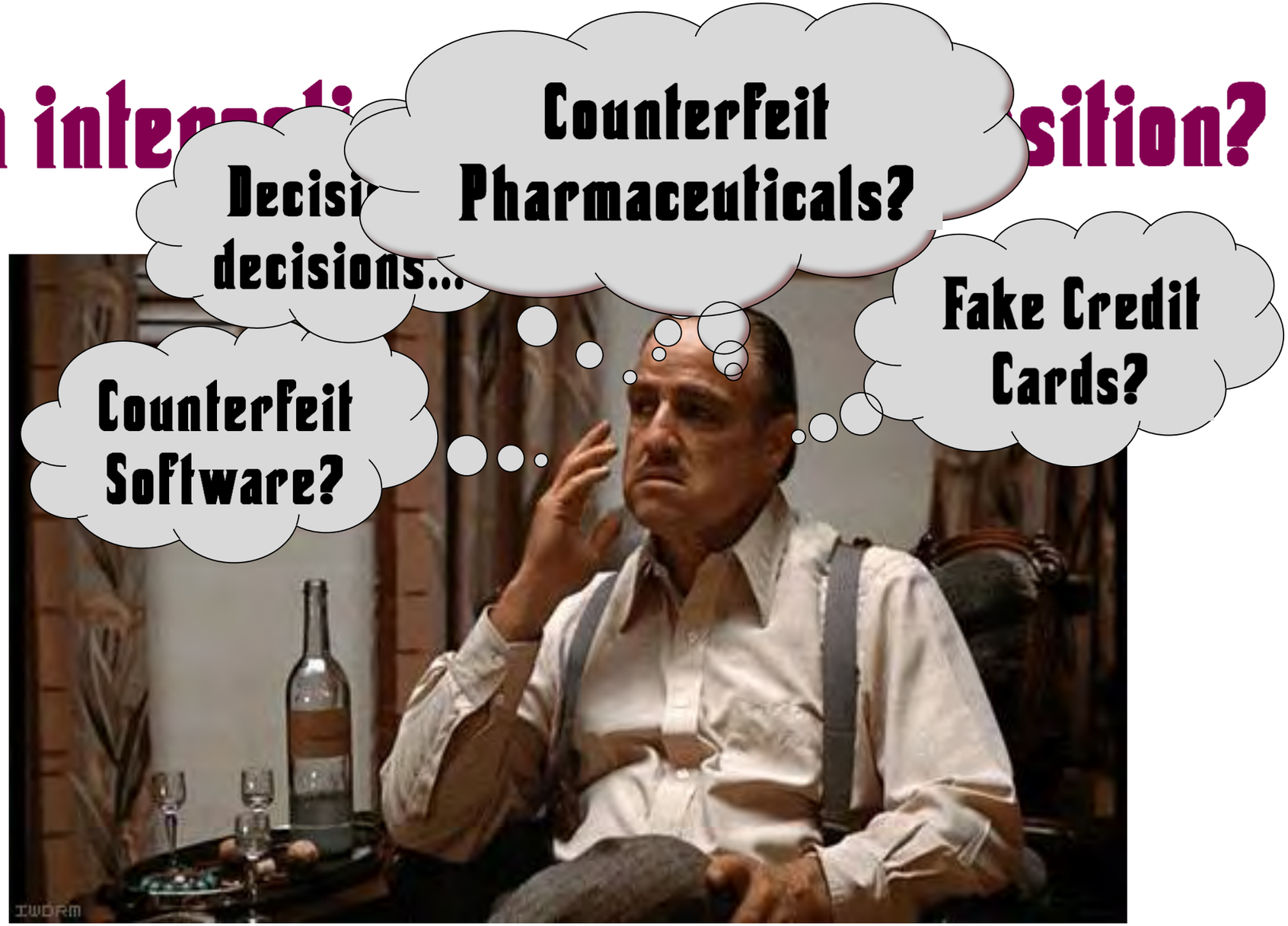
Authentic

Counterfeit

Verification of Sales Pack is critical

Counterfeit

An interesting decision?



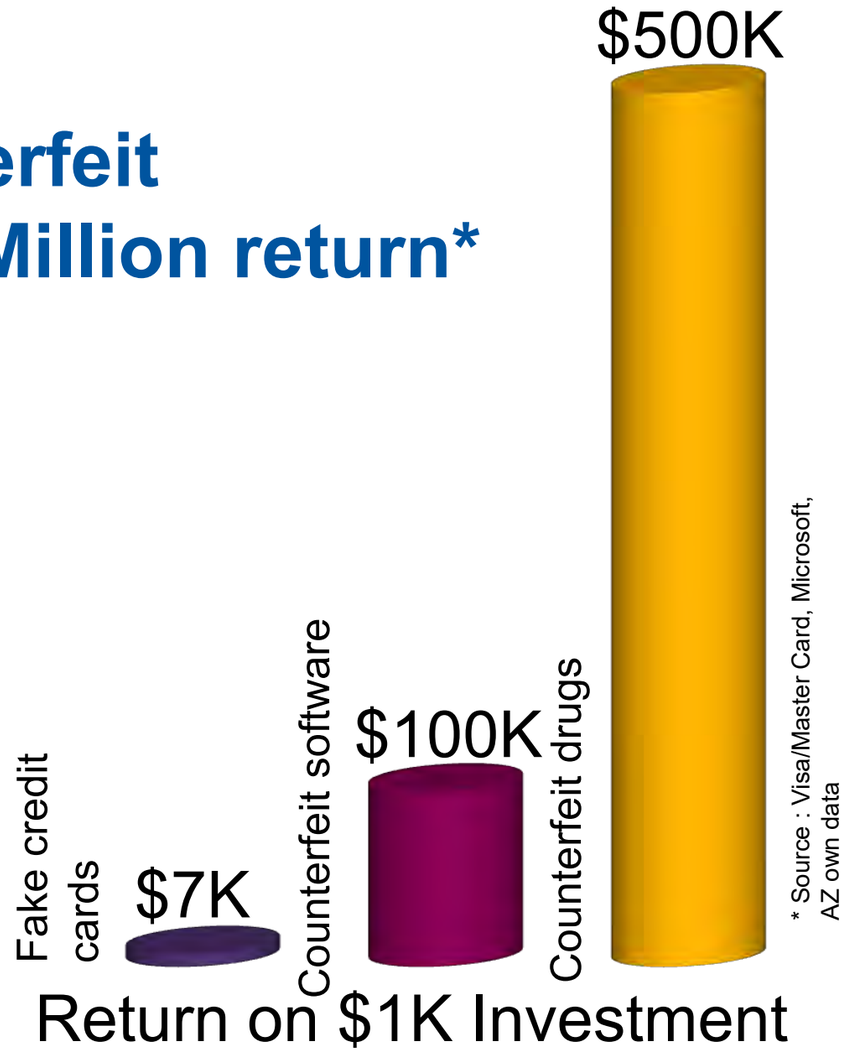
Counterfeiting is a lucrative business

For every $1000 invested, counterfeit pharmaceuticals generates $ ½ Million return*

Pharmaceutical Counterfeiting is seen as High Profit with Low Risk

So who may be involved ?

- Organised crime gangs
- Unlicensed businesses
- Licensed businesses: Brokers, Distributors, Wholesalers



A Global Problem

- Impacting lifestyle drugs
- Branded medicines
- Generics
- High value
- Low value
- High volume
- Low volume
- Internet pharmacy a particular problem

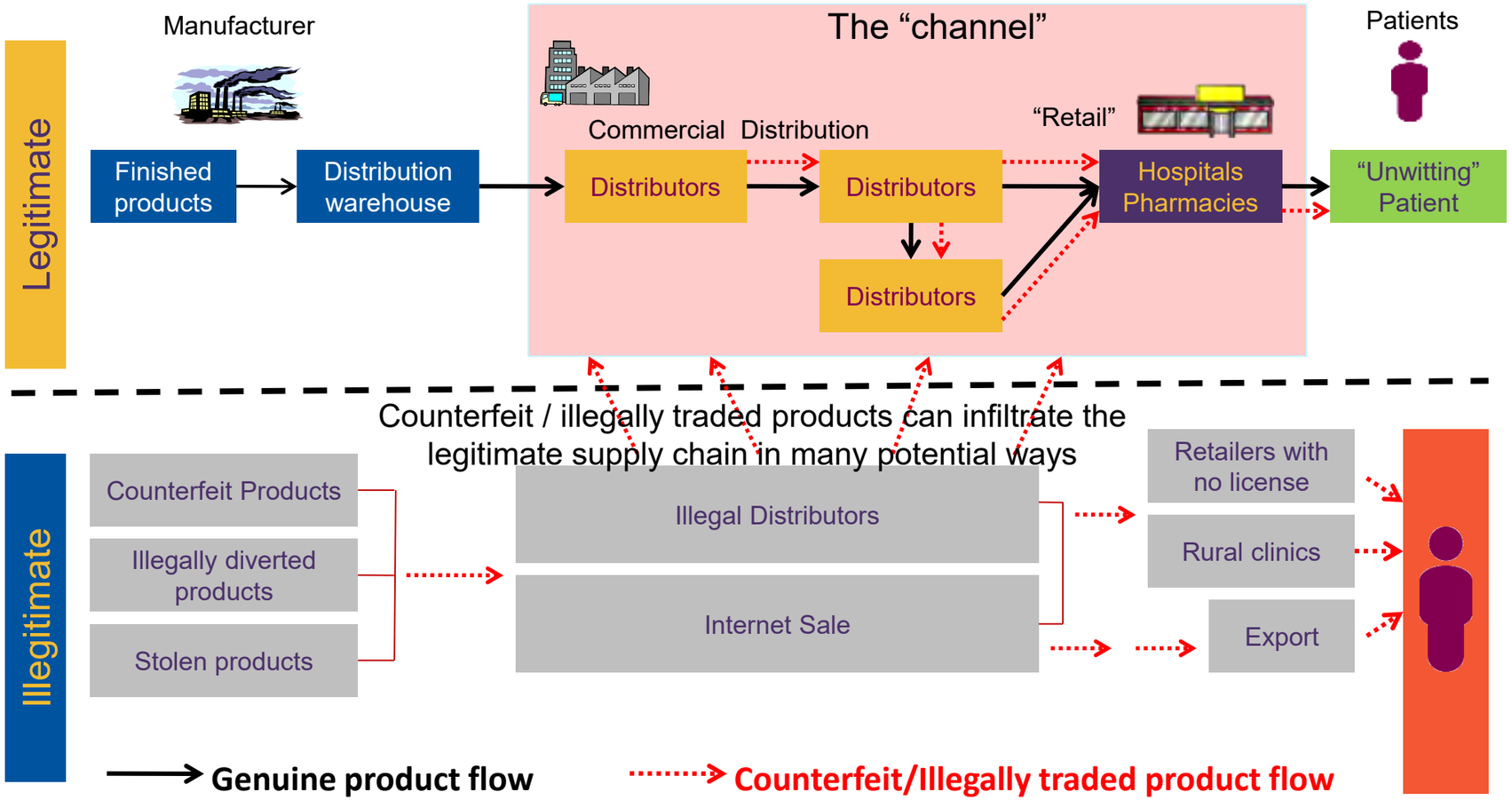
Impact of Counterfeit drugs

- **Direct Impact on Patient**
  - No therapeutic benefit
  - Over or under dosage
  - Harmful effects including death
- **Impact on Brand Owners**
  - Adverse events
  - Loss of revenue
  - Loss of brand
  - Loss of reputation
- **Wider Impact**
  - Loss of efficacy (Malaria drugs, Antibiotics)

Patient Safety

Brand Protection

How counterfeit / illegally traded product gets in the supply chain and reaches patients



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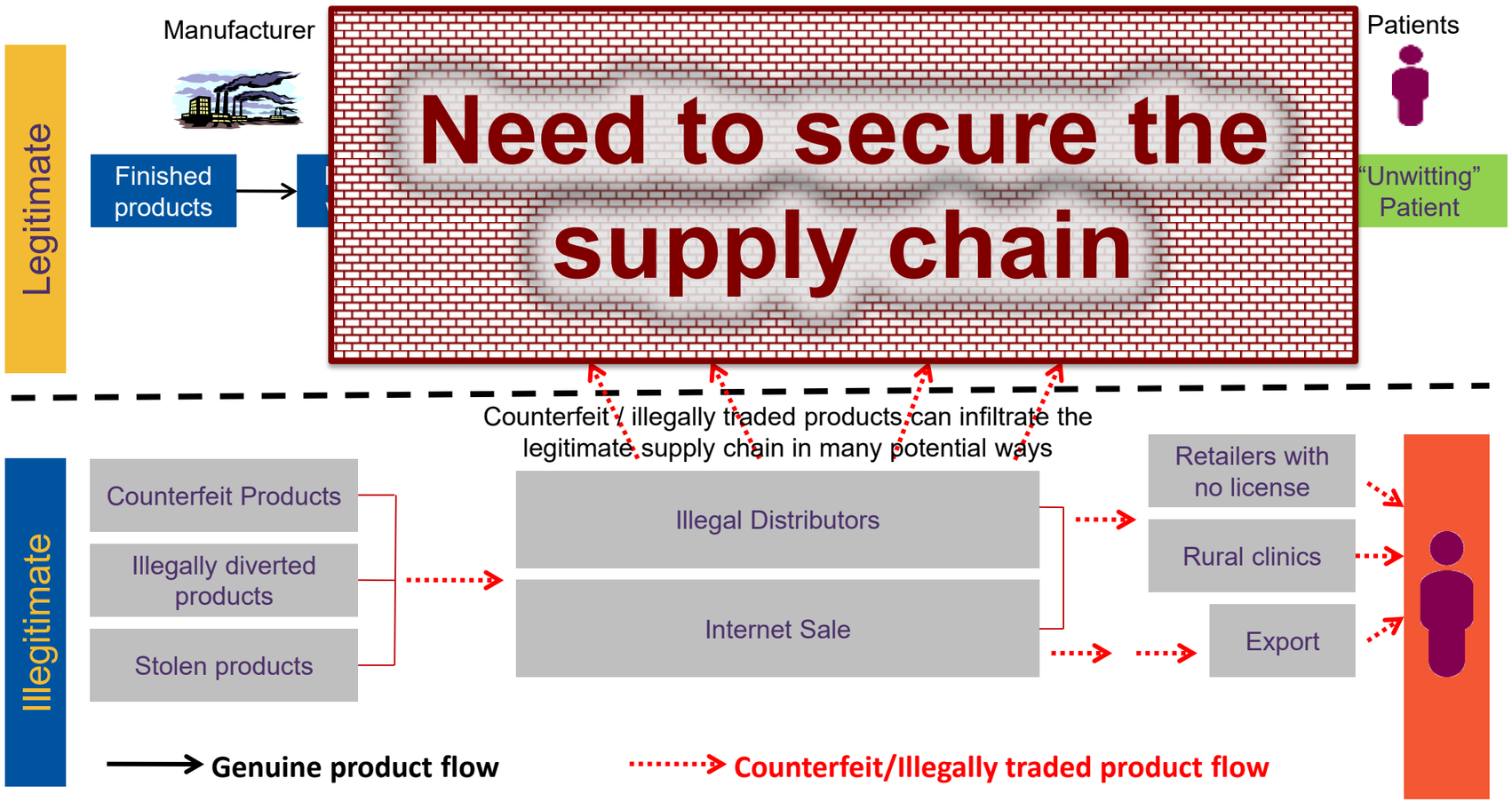
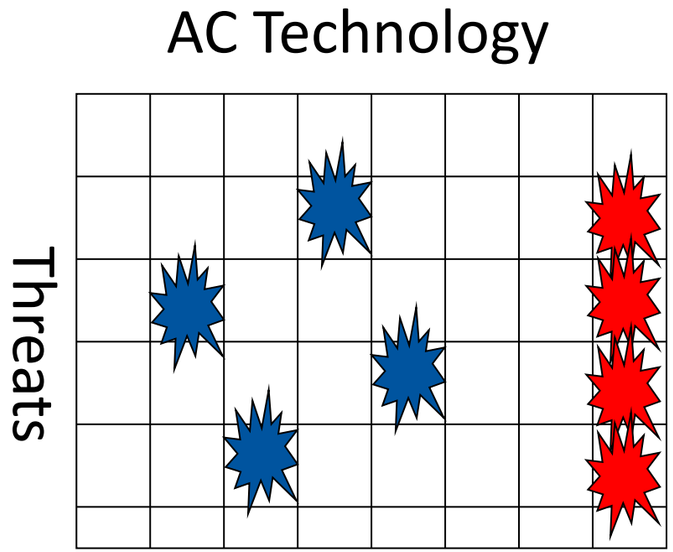


Strategies to fight counterfeiting and other threats



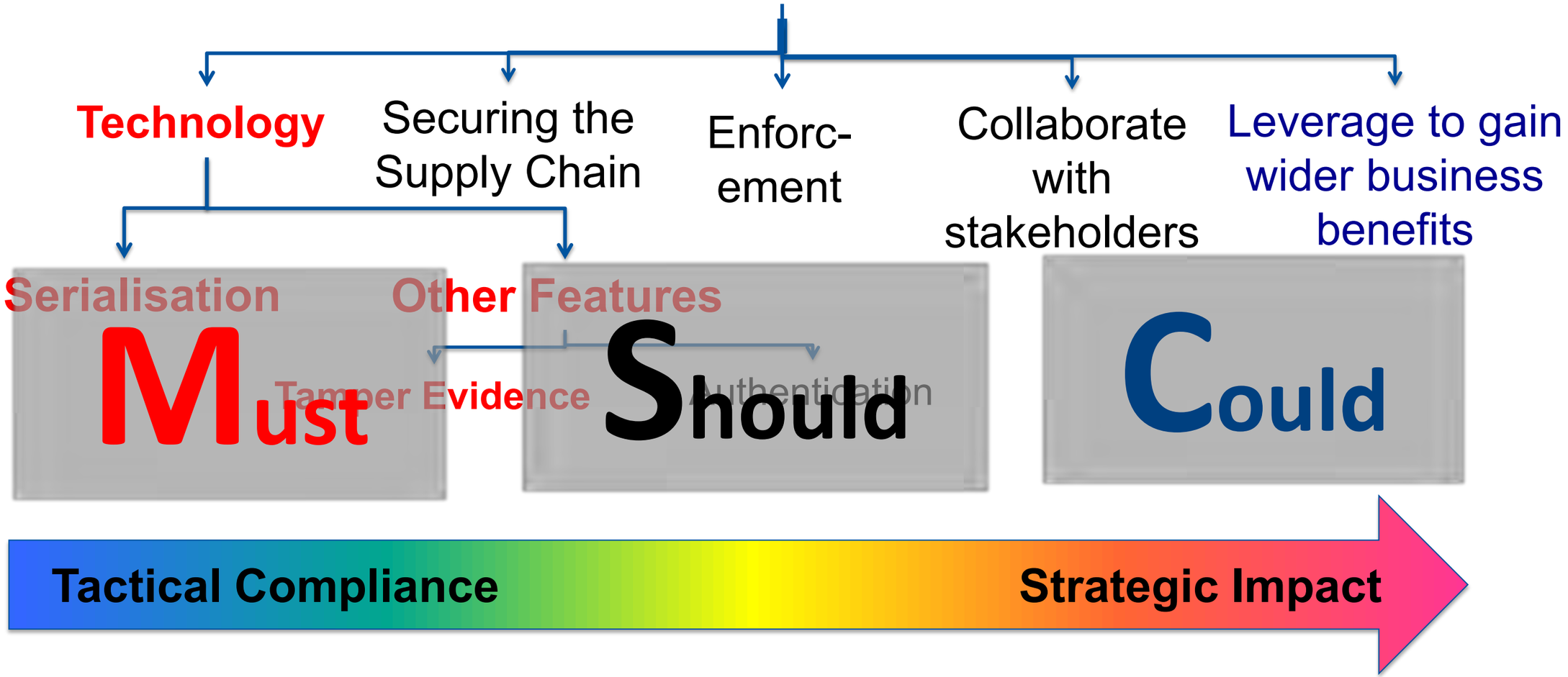
Authentication Features

- Overt
- Covert
- Forensic

Tamper Evidence

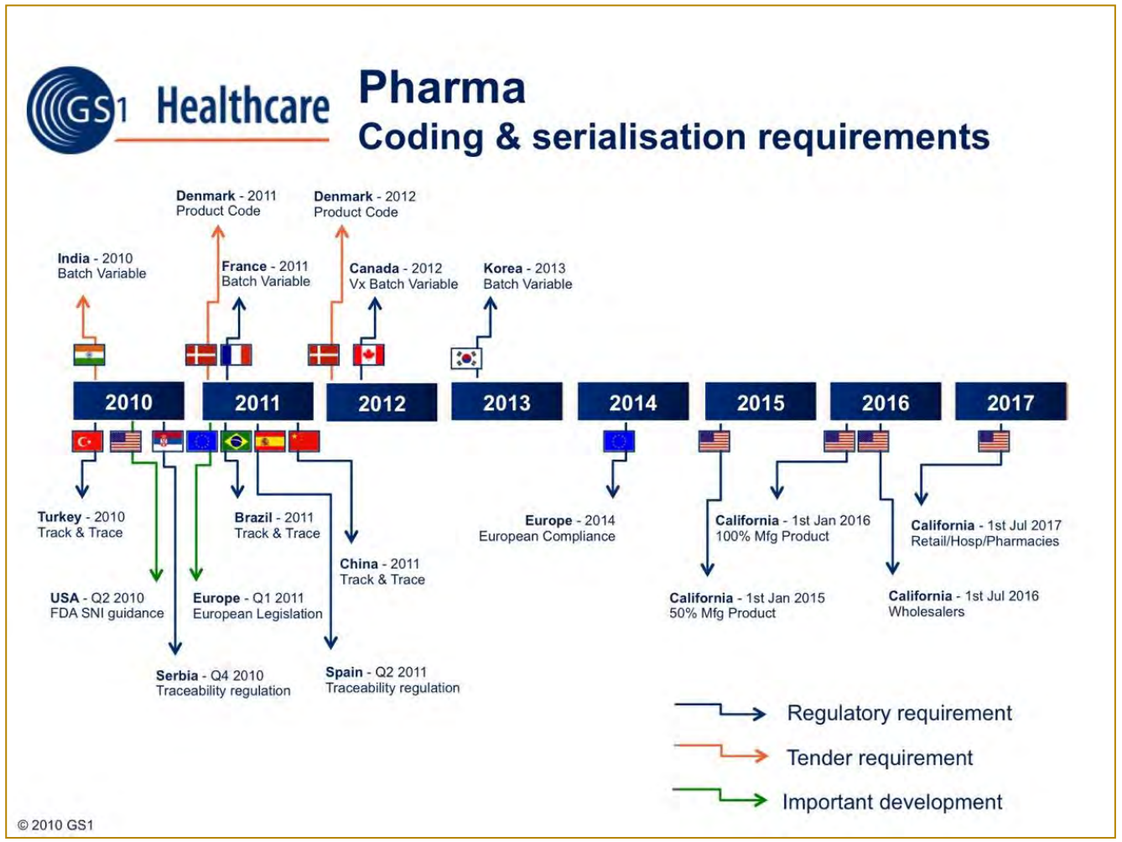
Serialised Code & Repository

BPSSC Strategy

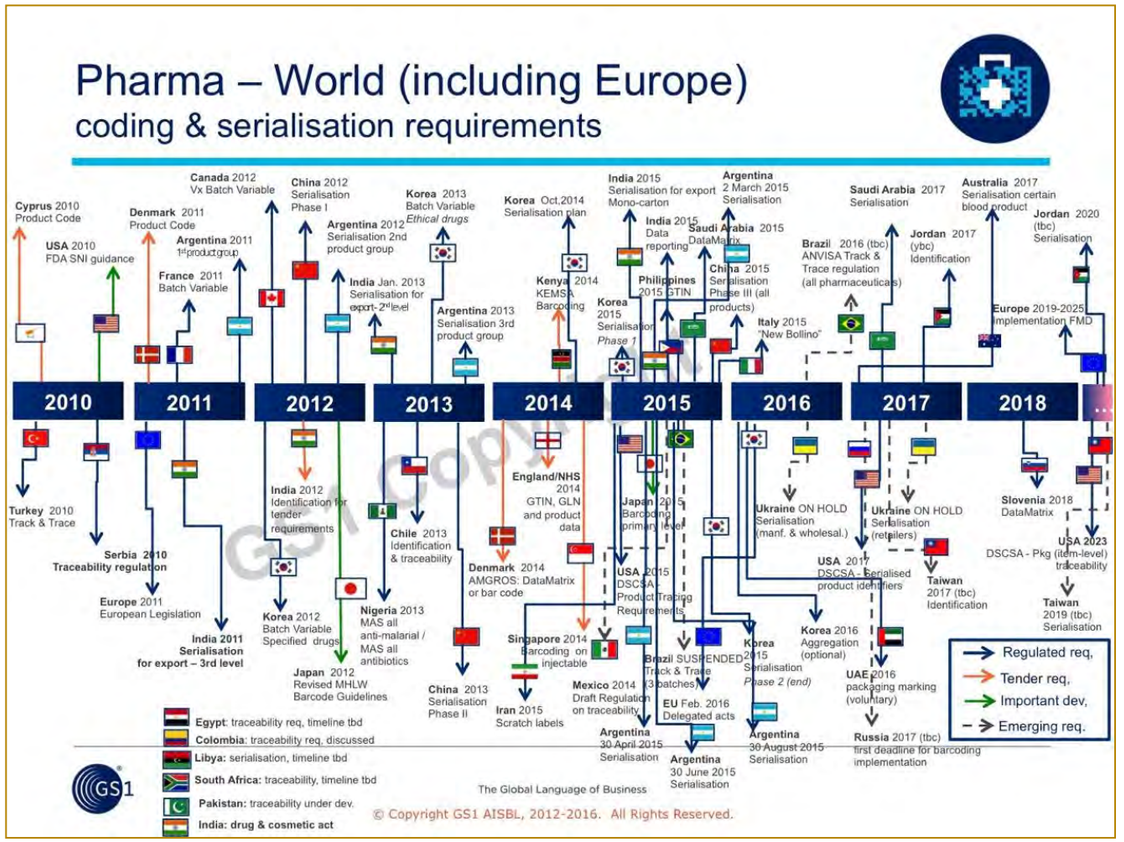


Serialisation: The Global Go-To Solution

2010



2017



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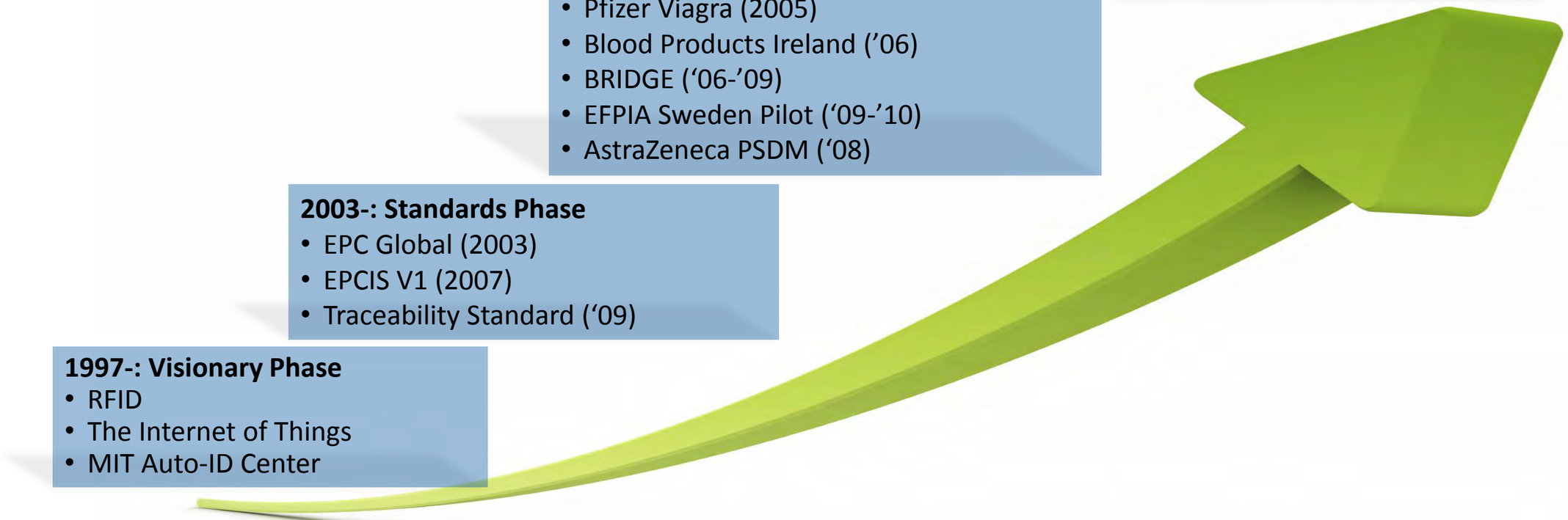
T&T – A brief history

1997-: Visionary Phase
- RFID
- The Internet of Things
- MIT Auto-ID Center

2003-: Standards Phase
- EPC Global (2003)
- EPCIS V1 (2007)
- Traceability Standard (‘09)

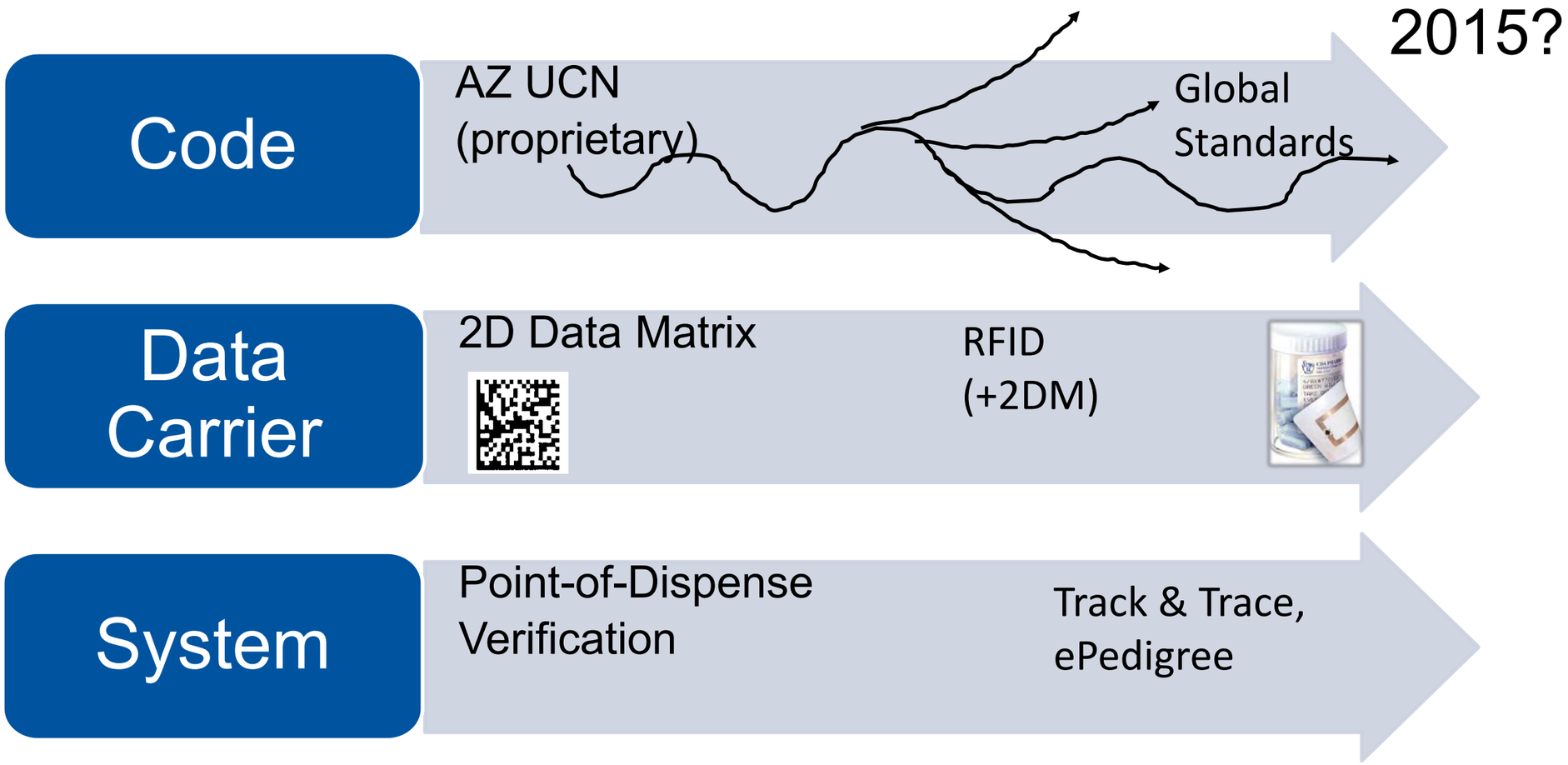
2006-: Pilots / Early Adopters
- Merck Serono Serostim (2003)
- Pfizer Viagra (2005)
- Blood Products Ireland (’06)
- BRIDGE (‘06-’09)
- EFPIA Sweden Pilot (‘09-’10)
- AstraZeneca PSDM (‘08)

2009-: Implementation
- Turkey
- France CIP-13
- California Pedigree
- China
- Argentina
- South Korea
- Etc.



A narrowing focus on compliance

An ~~un~~expected journey…



Serialised Pack

Unique Identifier, data carrier of choice:
2D Data-Matrix code: Compact, Robust, Cost-effective

Code contains defined key data elements e.g:

- 14 digit Manufacturer Product Code (usually GTIN)
- Randomised Unique **Serial Number**
- Expiry Date
- Batch Number (up to 20 alpha-numeric characters)

Example:

Product #:	(01) 0112345678901234
Batch:	(10) A1B2C3D4
Expiry:	(17) 101112
S/N:	(21) 12345AZRQF1234567890

Each pack has its own Unique Identity

Unique Identifi… … of choice: 2D Data-Matrix code:
Compact, Rol…
Code contai… …key data elements e.g.:

Globally unique, no need to co-ordinate across companies

- 14 digit Manufacturer Product Code (usually GTIN)
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Example:

Product #:	(01) 0112345678901234
Batch:	(10) A1B2C3D4
Expiry:	(17) 101112
S/N:	(21) 12345AZRQF1234567890

Drivers for coding - Aggregation

	Pallet	Logistics efficiency	Facilitate T&T / ePedigree
	Case / Shipper	Logistics efficiency	Facilitate T&T / ePedigree
	Sales Pack	Security, Patient Safety, Anti-fraud	Authentication / Verification; Product Identification / Dispensing errors; e-Health;
	Primary Package	Patient Safety, Efficiency	Product Identification / Dispensing errors; e-Health
	Single Unit	Currently none	Possibly Clinical Trials use

Scanning & Application Identifiers (AIs) in action...

(01)10857674002017
(17)141120
(10)NYFUL01
(21)192837

0110857674002017171411201021NYFUL012119283?

0110857674002017 **17**141120 **10**NYFUL01 **21**192837

10857674002017 20 Nov 2014 NYFUL01 192837

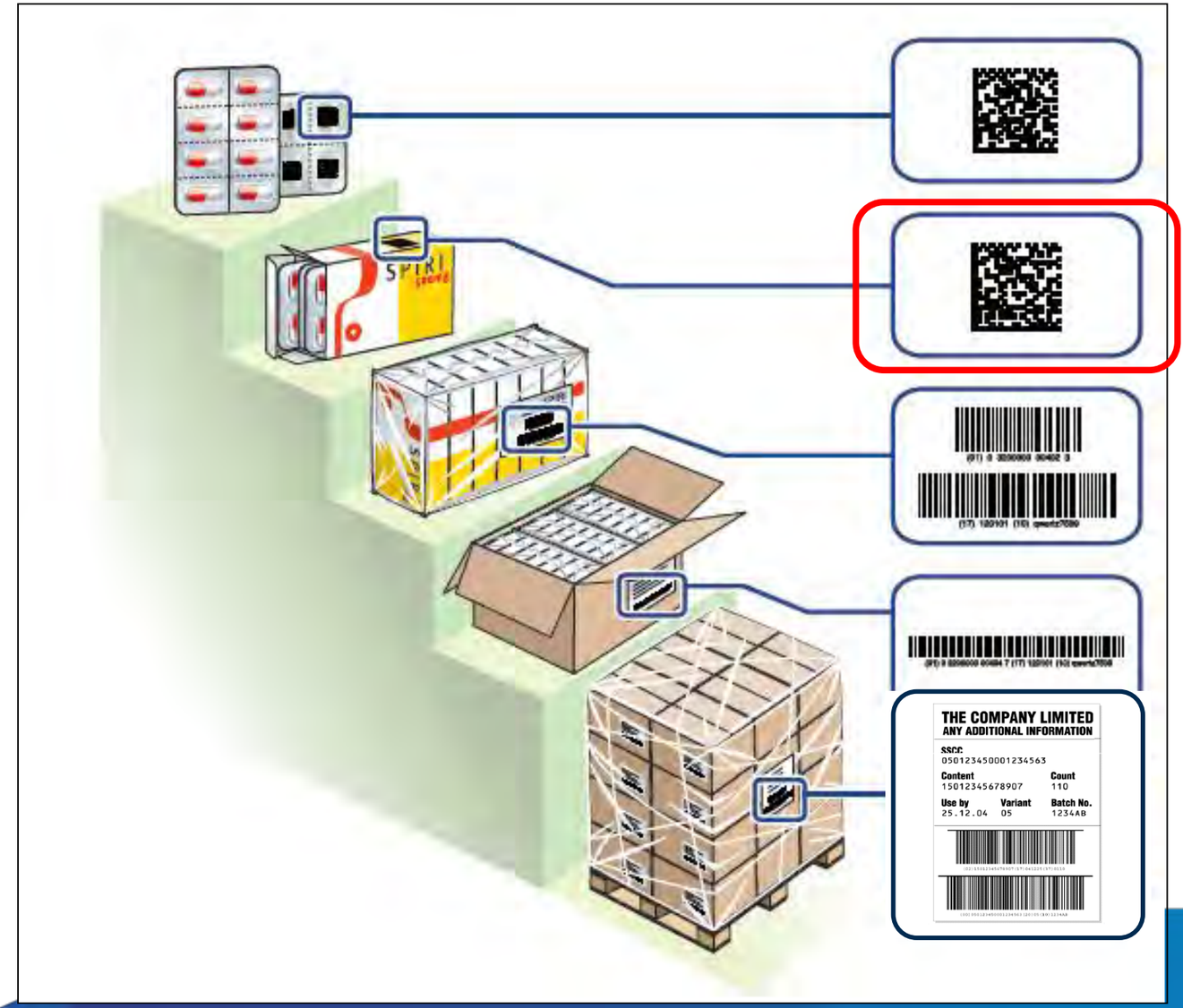
System Input

GTIN: SERIAL:

EXPIRATION:

BATCH/LOT:

Pack Hierarchy – Data & Carrier



Item

Process - What is track and Track?

1) What is T&T?

Track

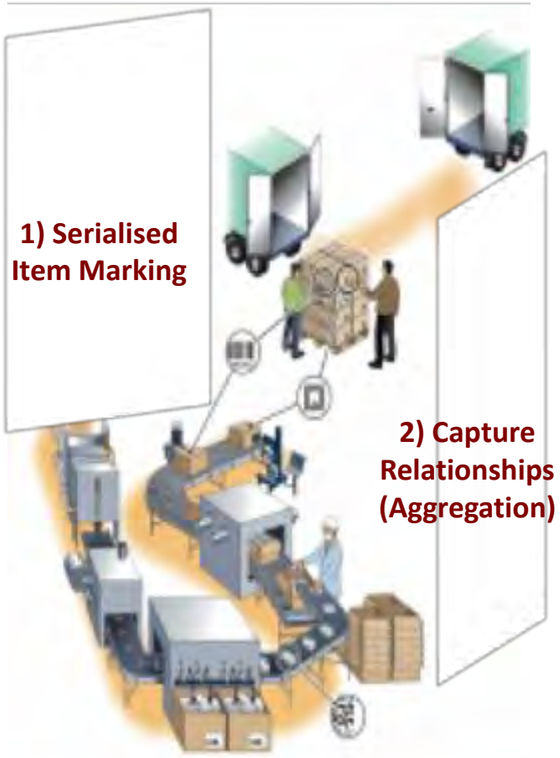
Trace

2) Key Enablers

3) Link to Business Events (e.g. shipment)

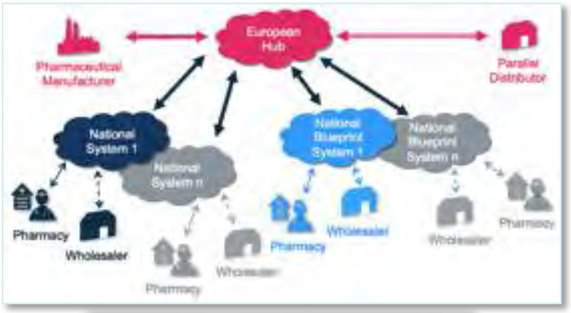
1) Serialised Item Marking

2) Capture Relationships (Aggregation)



3) Leading to

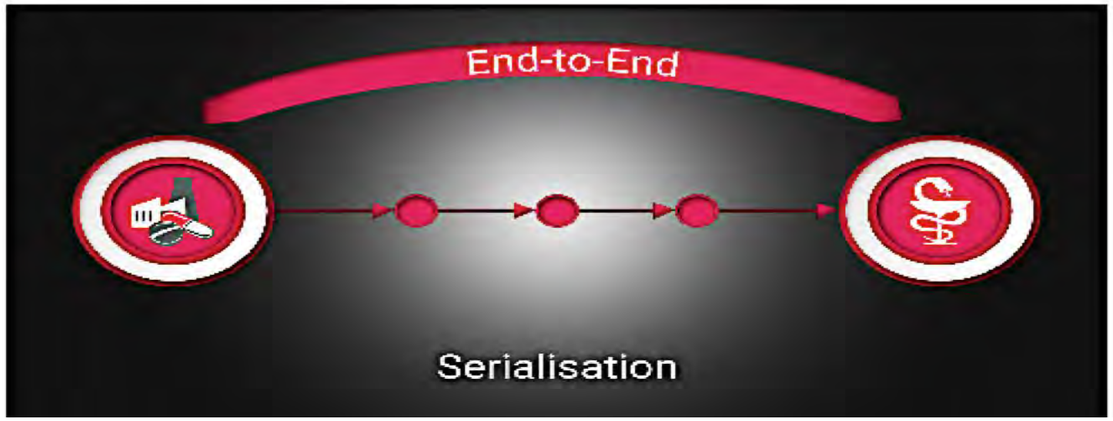
Information Sharing / Compliance Reporting



End to End vs Track and Trace

Pharmaceutical serialization – End-to-end control system

Serialisation encompasses the end-to-end application and the data technology to generate and record serial numbers during the manufacturing process. When the pharmacist, as the last link in the value chain, sells a prescription medicine to a patient, the package code is read in the pharmacy and sent to a central data base to be checked and verified.

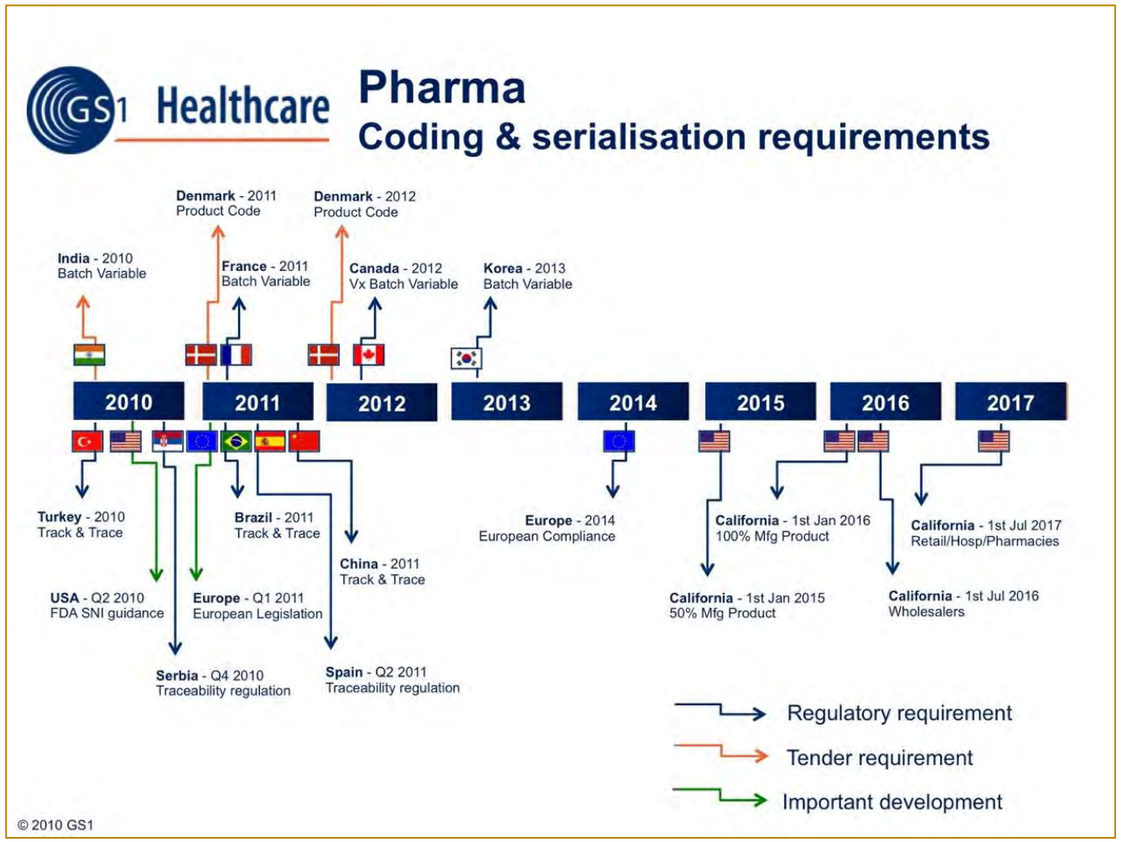


Track & Trace systems for drug companies

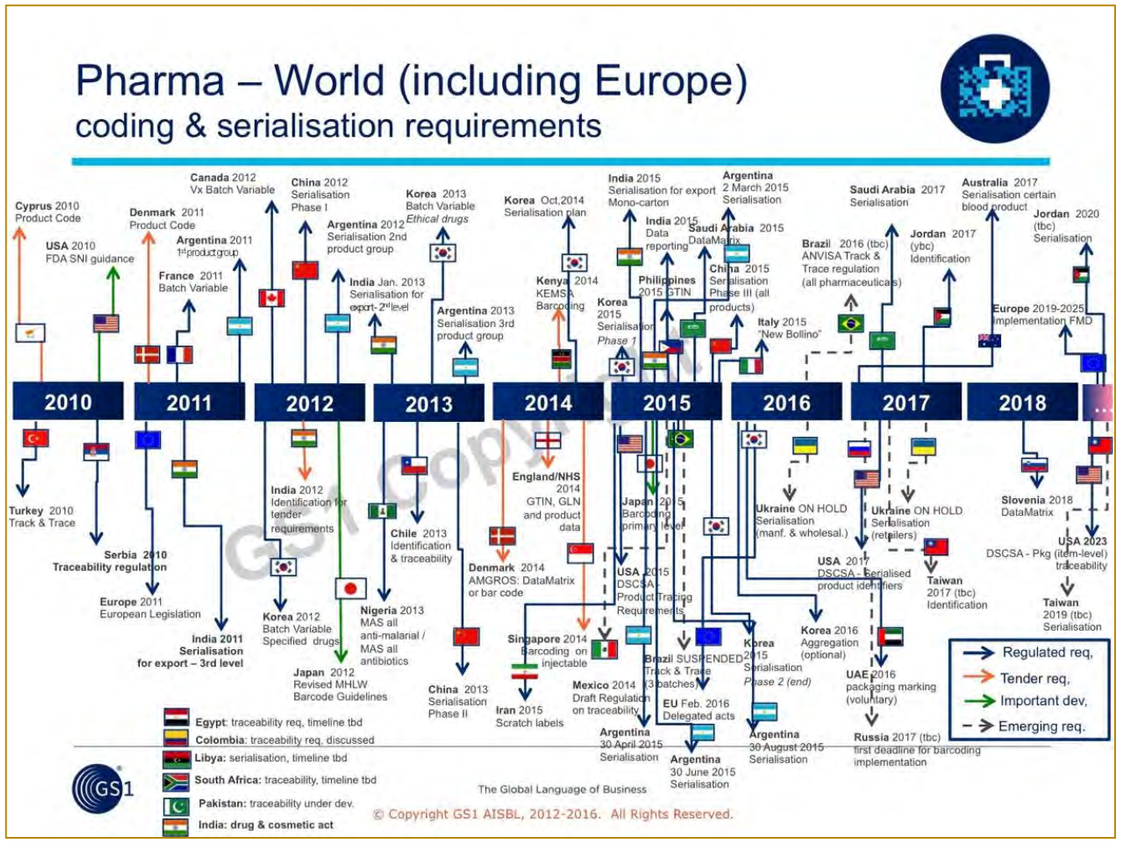
The Track and Trace solution includes any additional information generated at each packaging step during the various aggregation levels in the distribution chain and records it in the corresponding code sent to the central database. The complete supply chain is traceable, transparent, and secure.

Serialisation: The Global Go-To Solution

2010

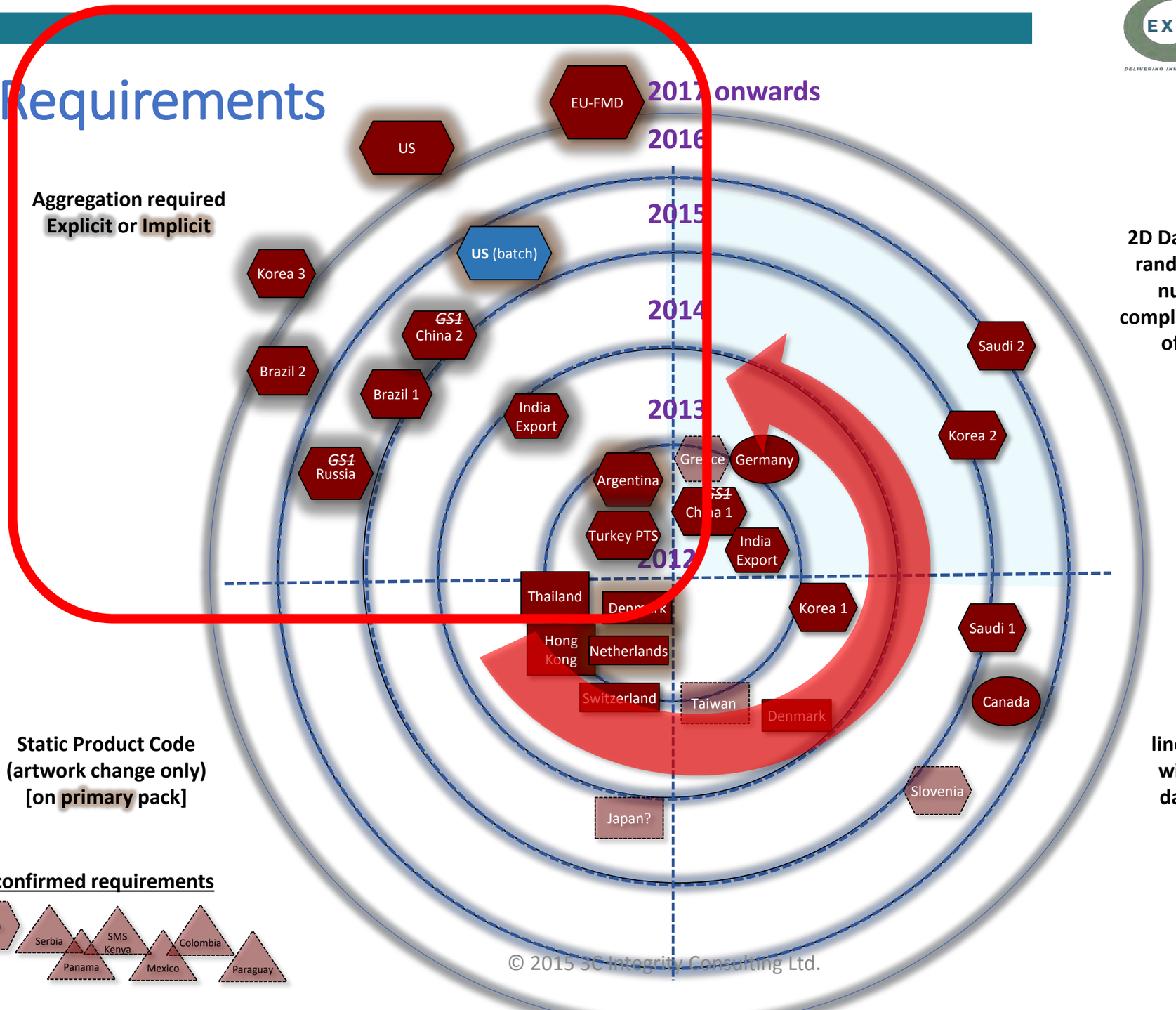


2017



Illustrations © GS1

Coding Requirements

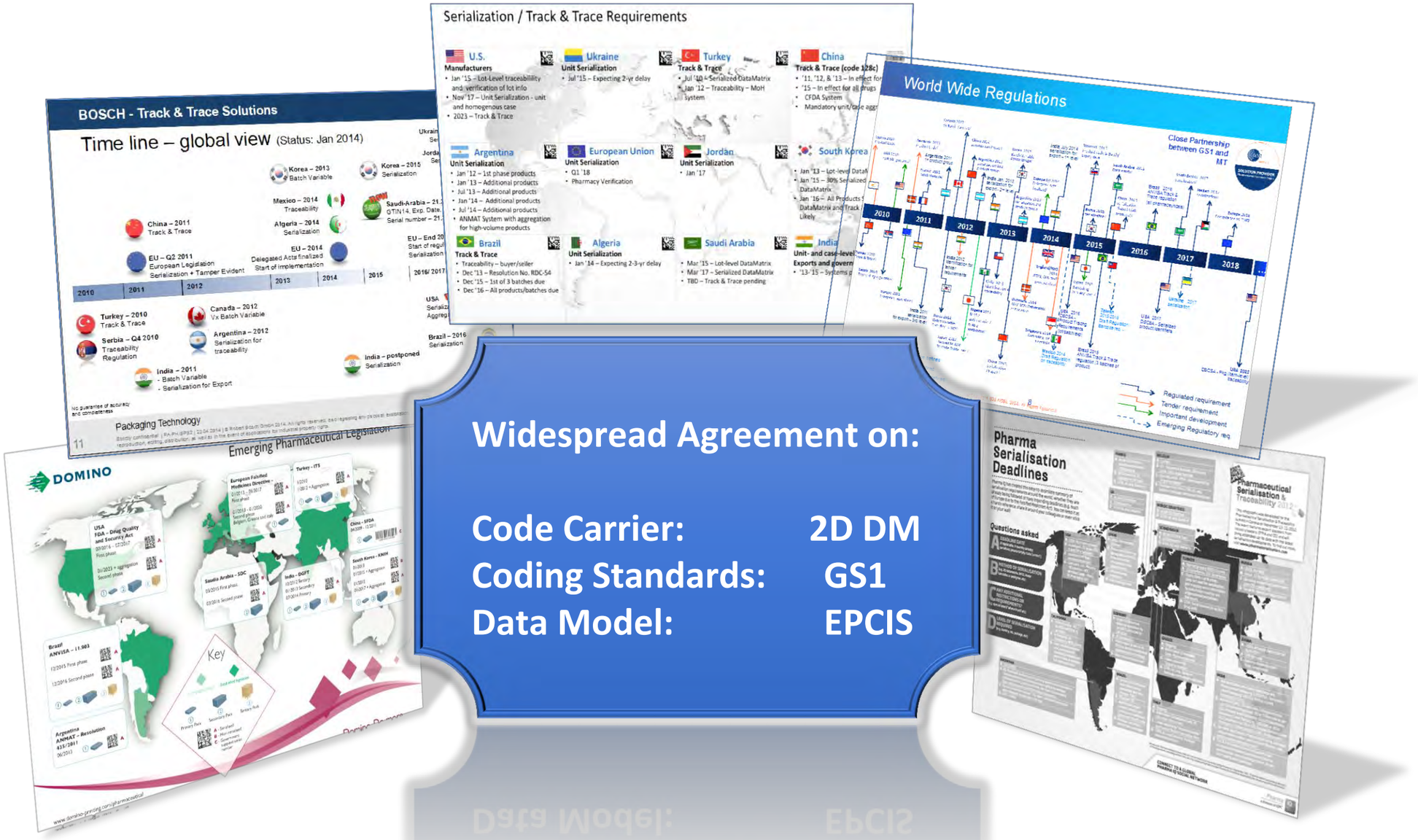


Regulatory / legal requirement
Commercial / Supply Chain
Roadmap / Standard
Other

2D Datamatrix with randomised serial number (and compliance reporting of numbers)

Unclear/unconfirmed requirements

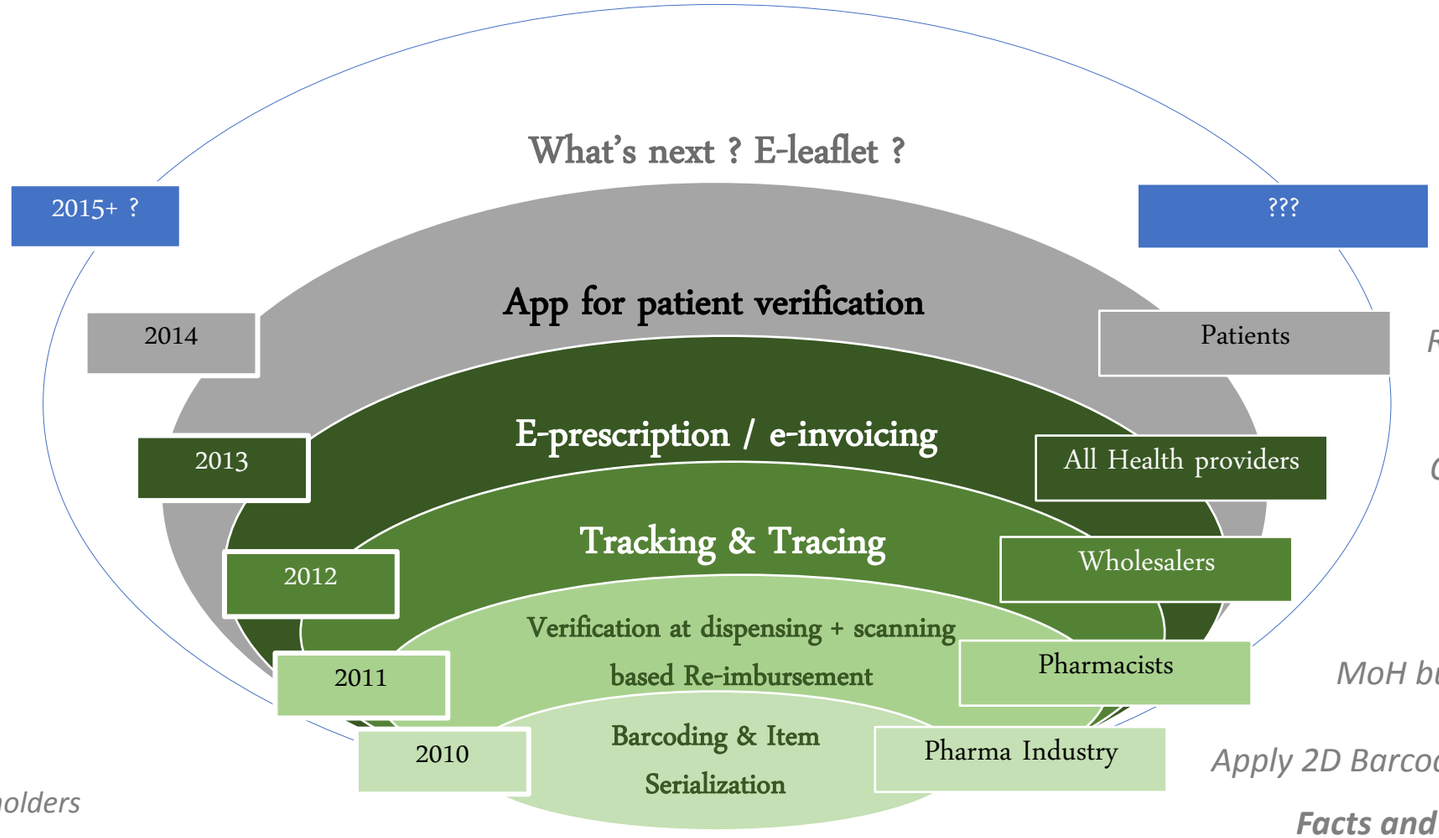
India domestic, Algeria, Serbia, SMS Kenya, Colombia, Panama, Mexico, Paraguay


Serialization / Track & Trace Requirements
U.S.
Manufacturers
Ukraine
Unit Serialization
Turkey
Track & Trace
China
Track & Trace (code 128c)
Argentina
Unit Serialization
European Union
Unit Serialization
Jordan
Unit Serialization
South Korea
Brazil
Track & Trace
Algeria
Unit Serialization
Saudi Arabia
India
BOSCH - Track & Trace Solutions
Time line – global view (Status: Jan 2014)
China – 2011
Track & Trace
EU – Q2 2011
European Legislation
Serialization + Tamper Evident
Korea – 2013
Batch Variable
Korea – 2015
Serialization
Mexico – 2014
Traceability
Algeria – 2014
Serialization
EU – 2014
Delegated Acts finalized
Start of implementation
Saudi-Arabia – 21.
GTIN14, Exp. Date,
Serial number – 21.
EU – End 20
Start of regul
Serialization
2016/ 2017
USA
Serializ
Aggreg
Brazil – 2016
Serialization
2010
2011
2012
2013
2014
2015
Turkey – 2010
Track & Trace
Serbia – Q4 2010
Traceability
Regulation
Canada – 2012
Vx Batch Variable
Argentina – 2012
Serialization for
traceability
India – 2011
- Batch Variable
- Serialization for Export
India – postponed
Serialization
Packaging Technology
World Wide Regulations
Close Partnership
between GS1 and
MT
2010
2011
2012
2013
2014
2015
2016
2017
2018
Regulated requirement
Tender requirement
Important development
Emerging Regulatory req.
Emerging Pharmaceutical Legislation
DOMINO
Key
Pharma
Serialisation
Deadlines
Questions asked
Pharmaceutical
Serialisation &
Traceability 2012
Widespread Agreement on:
Code Carrier: 2D DM
Coding Standards: GS1
Data Model: EPCIS

Institutional Ambition Drives Scope Extension

The example of Turkey's implementation roadmap

The same can currently be observed in Argentina & in Korea (live since 2010/2013)



Reach out to public

Onboard & Connect

Onboard & Connect

MoH builds IT infrastructure & Database

Apply 2D Barcode / Technical features

In scope

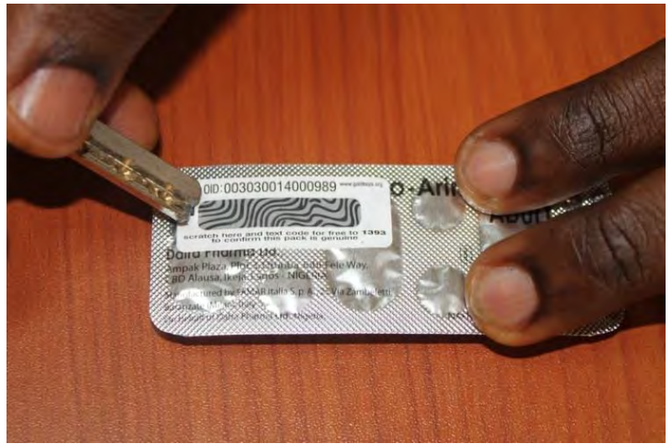
40'000 Stakeholders

- *Hospitals*
- *Health Centers*
- *Family Physician Centers*
- *Pharmacies and Pharmacy Warehouses*
- *Manufacturers*
- *Importers*
- *Reimbursement Institutions*

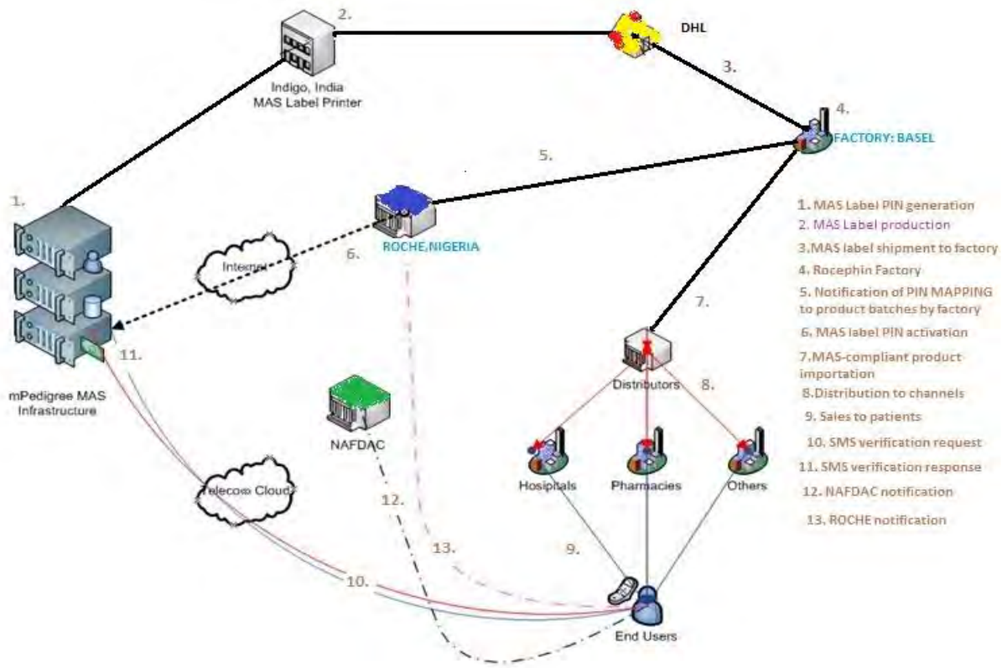
Facts and Figures

Number of drug types in İTS: 18 900
Number of drug units in İTS: 7 000 000 000
Number of daily operations in İTS: 45 000 000
Number of operations per second in İTS: 520
Response time of system: < 1 sec
ROI in ONE YEAR!

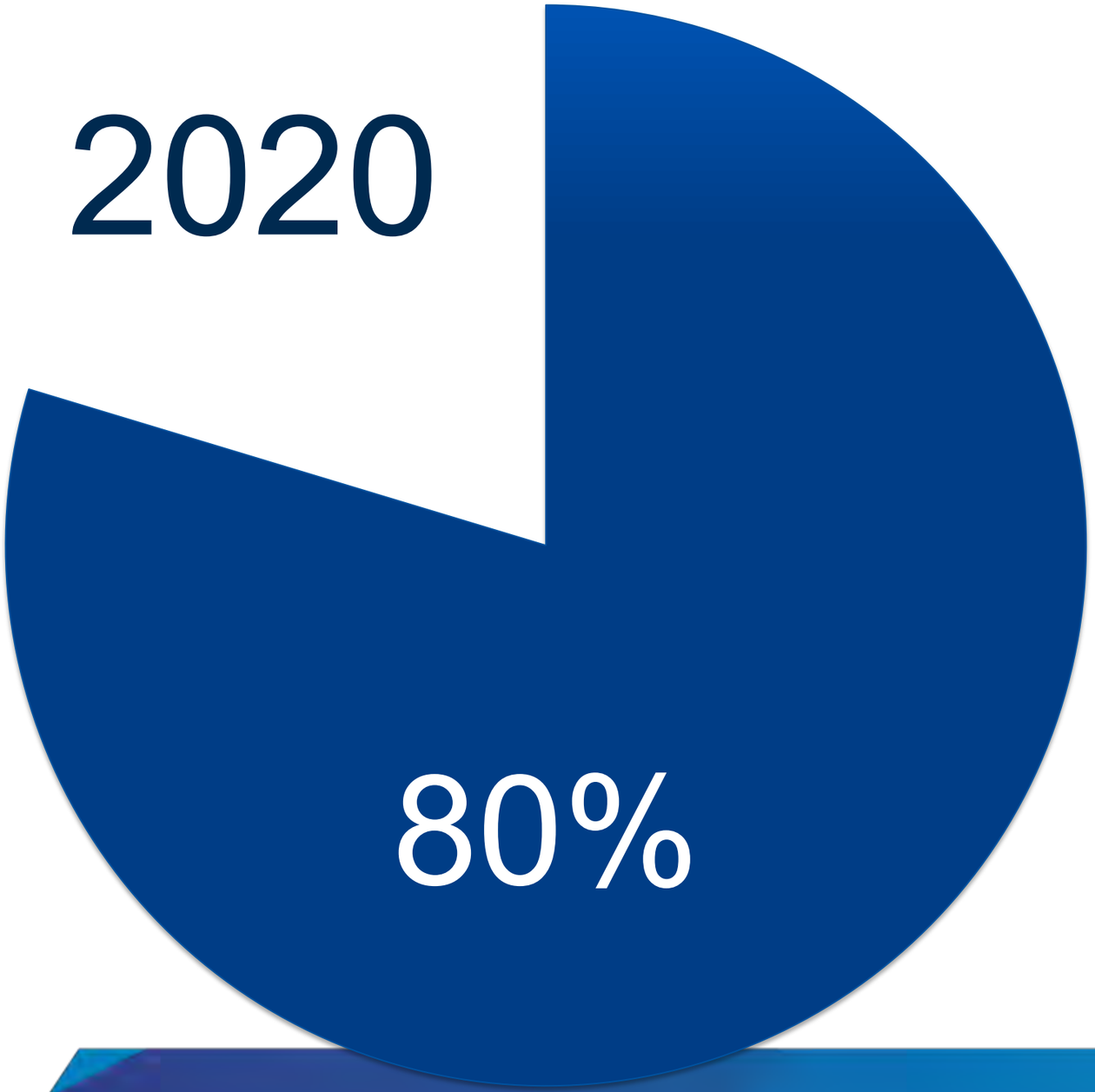
An example of a non collaborative approach
Food & Drug Regulatory Authority in Nigeria, NAFDAC



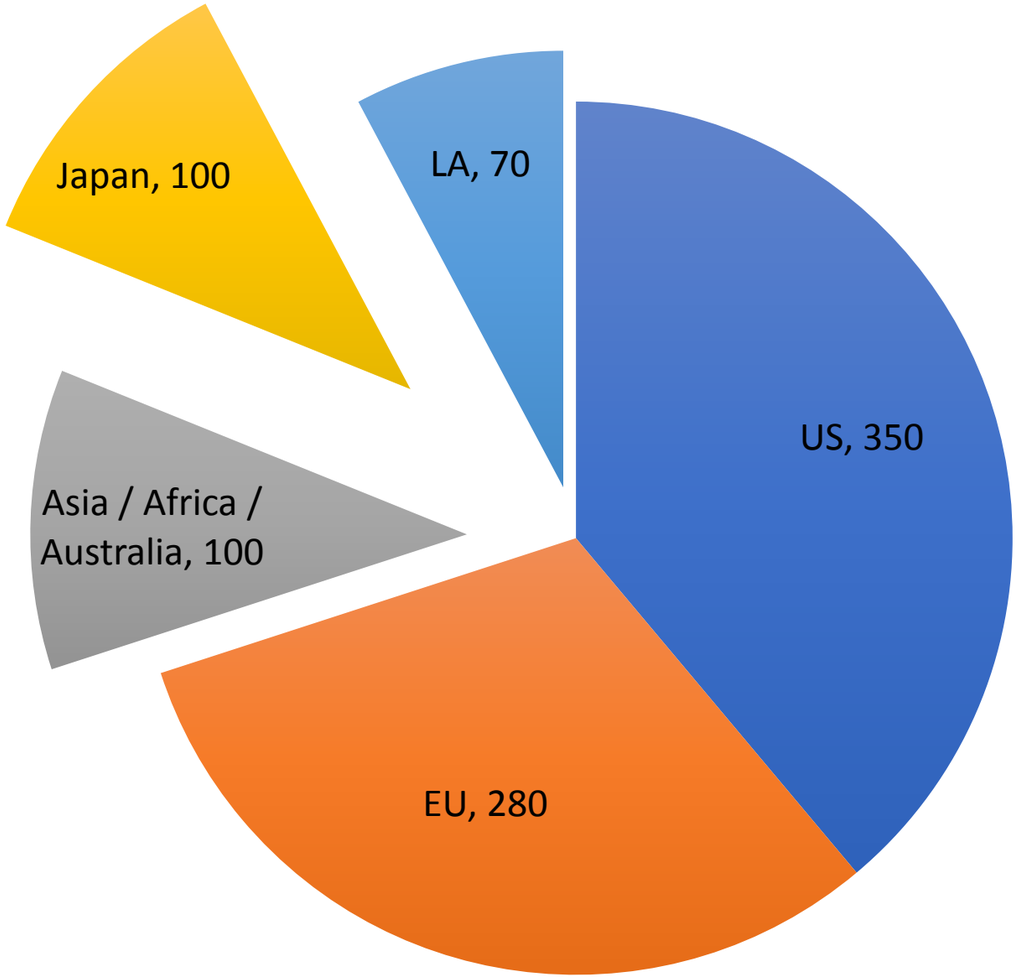
Mobile Authentication Service
Flow Diagram



Industry was not willing to take action, HA's imposed a solution


2020
80%

Global Pharma sales bn $ 900

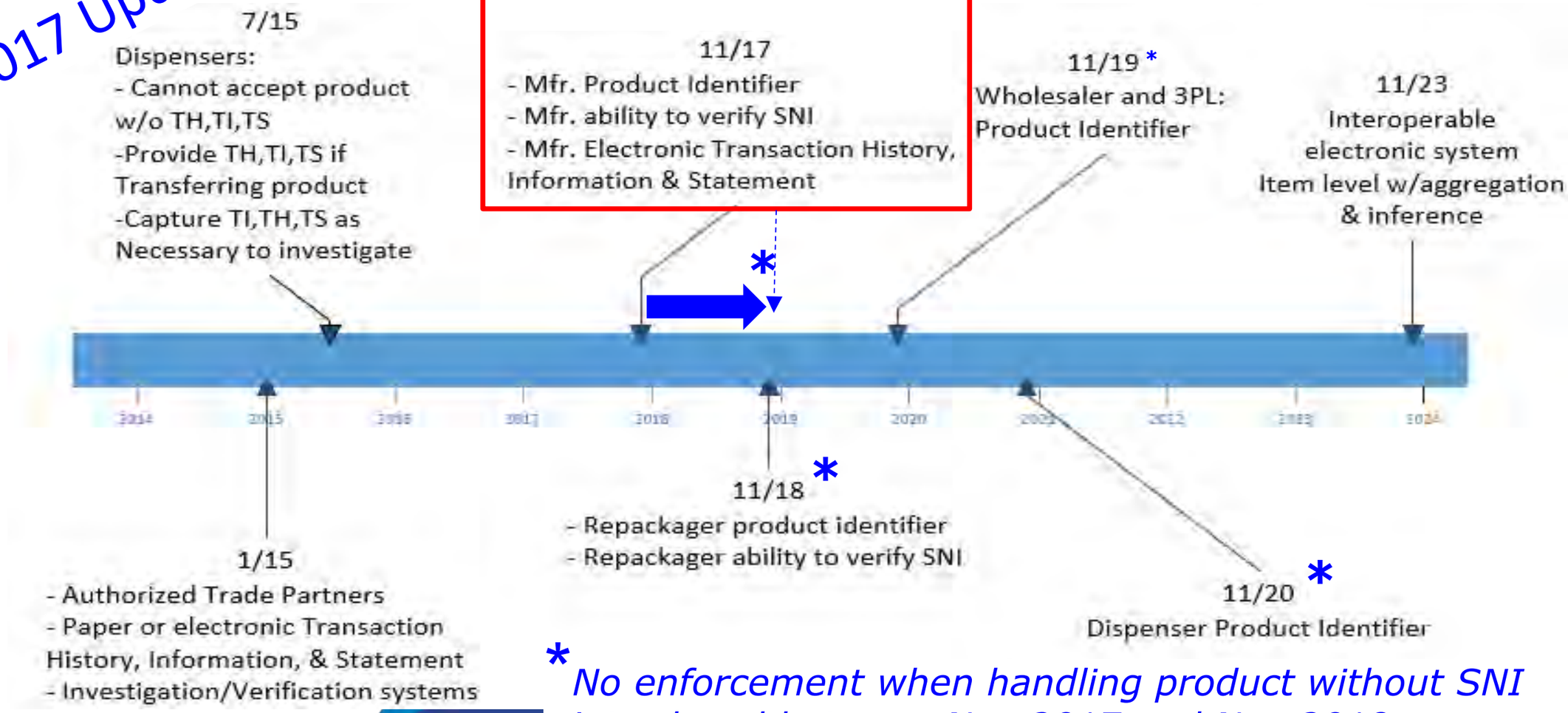


DSCSA Timeline

July 2017 Update

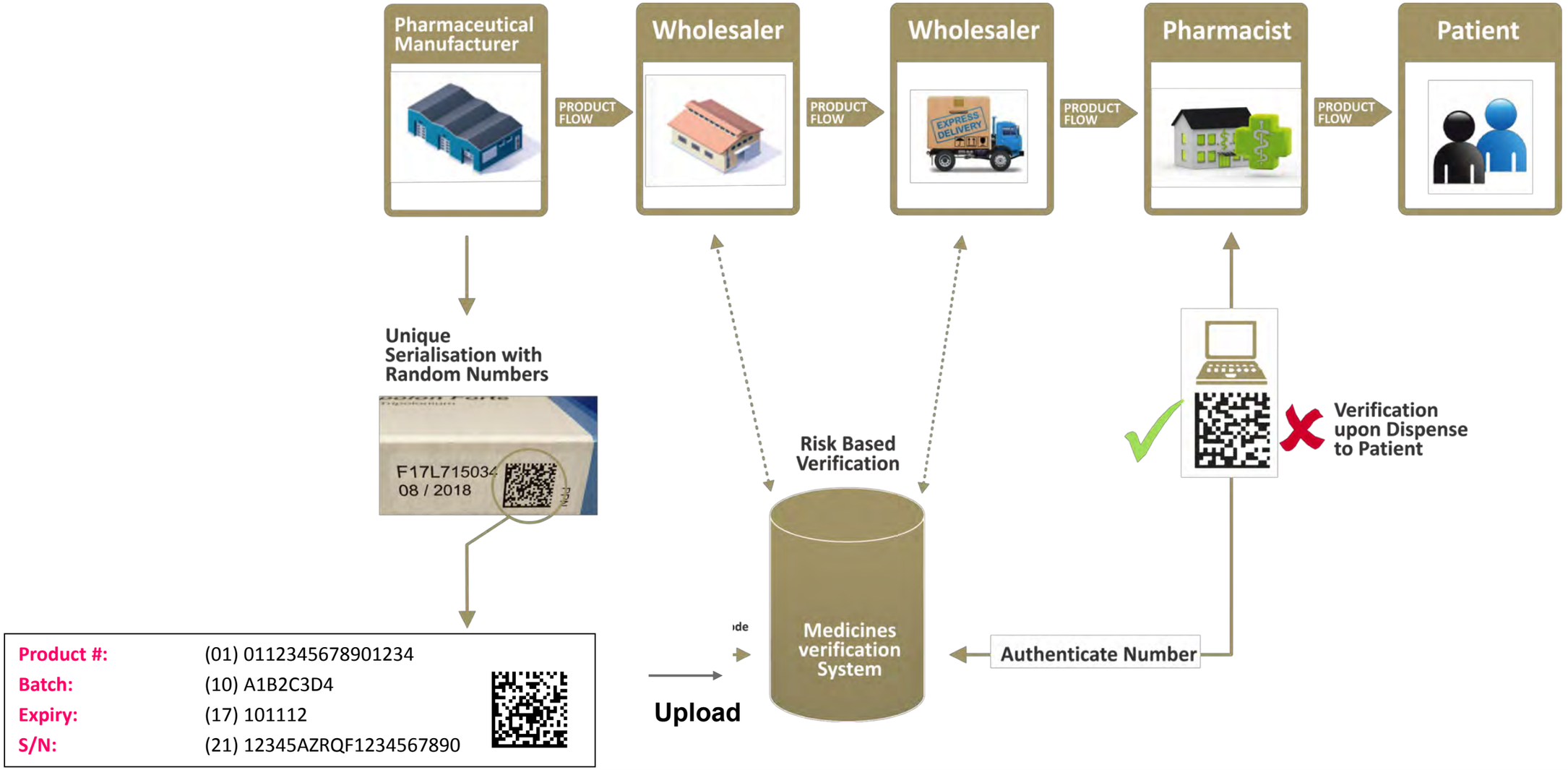
MFG Requirement

GTIN (01) 20354482053011
SN (21) xxxxxxxxxxx
Exp (17) YYMMDD
Lot (10) xxxxxxxx



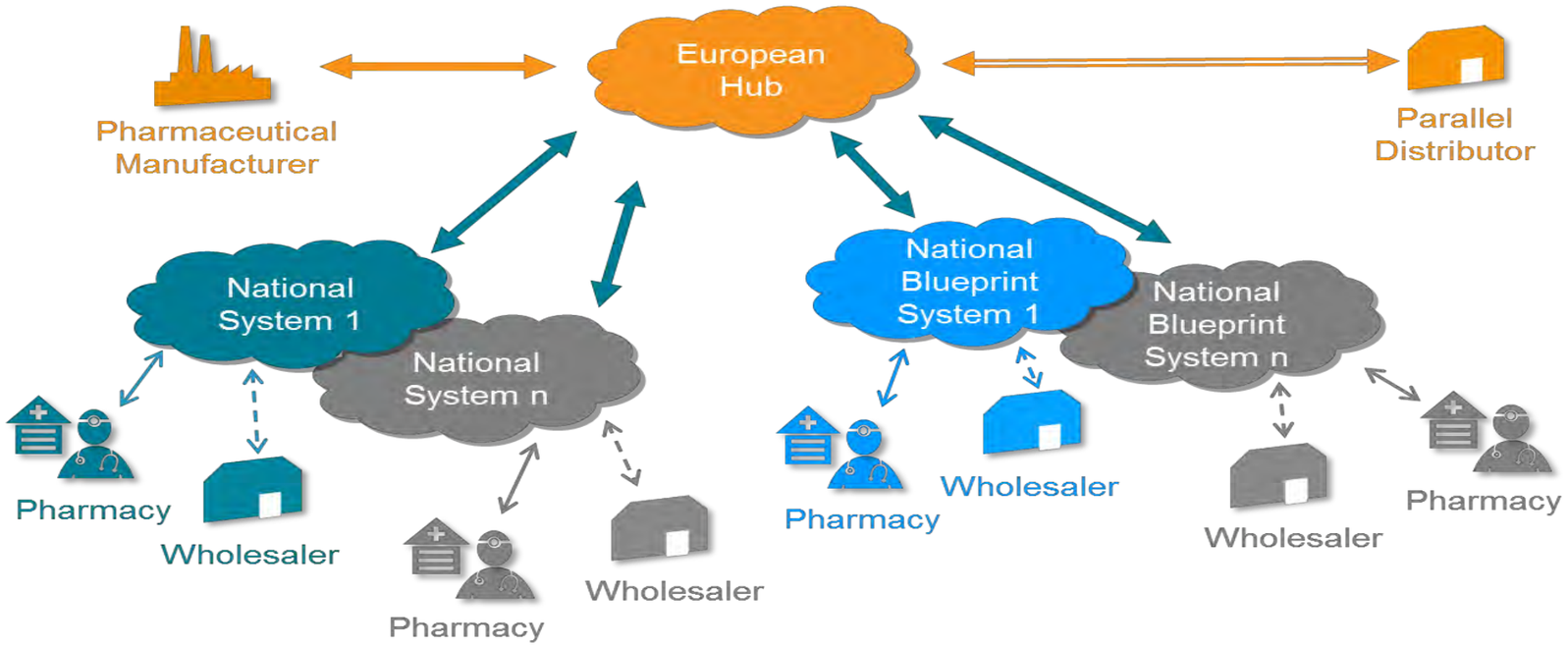
* *No enforcement when handling product without SNI introduced between Nov 2017 and Nov 2018*

EUFMD “Point of dispense verification”

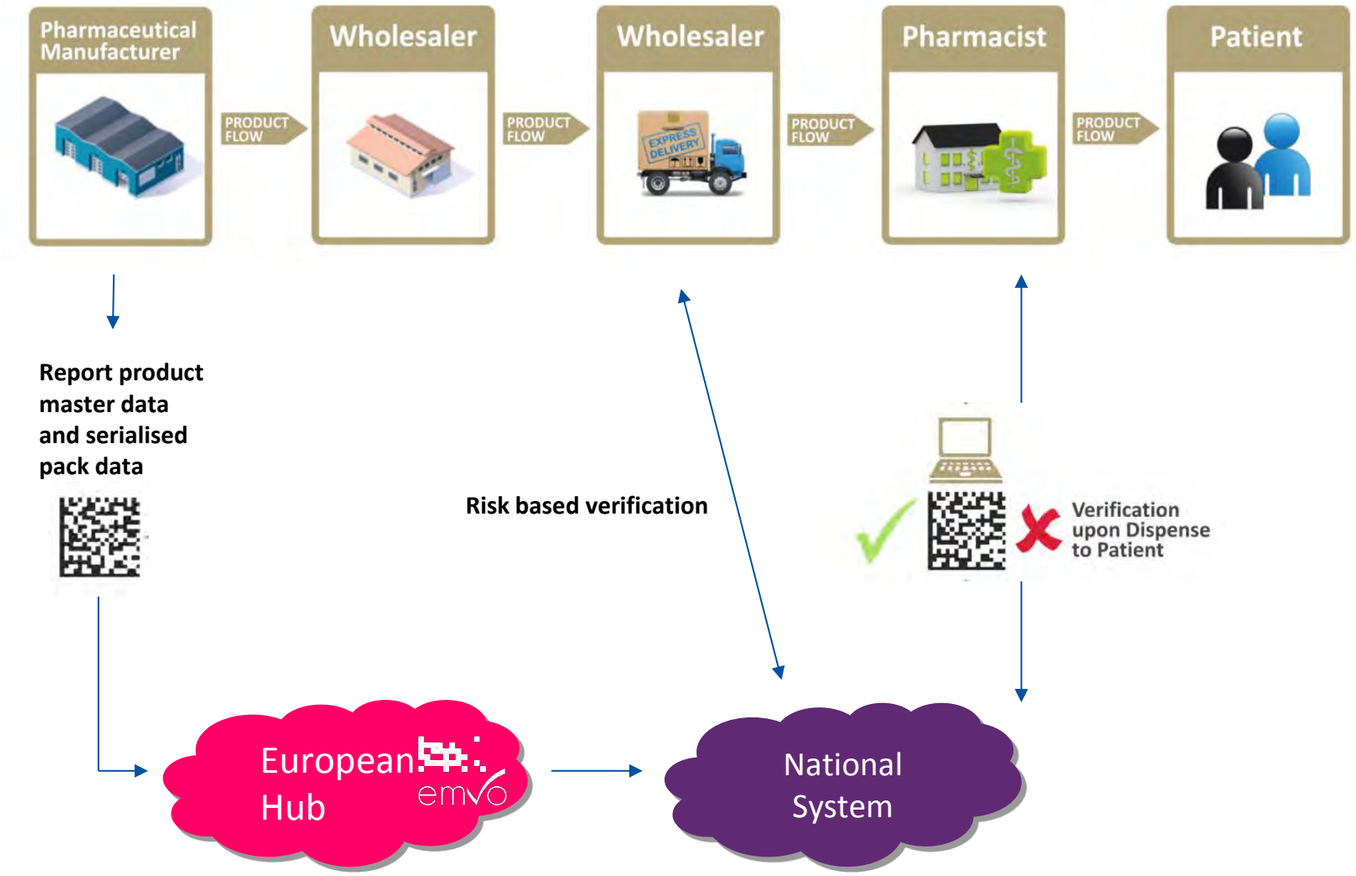


The Road to EU-FMD Compliance: 9th Feb 2019

System Landscape



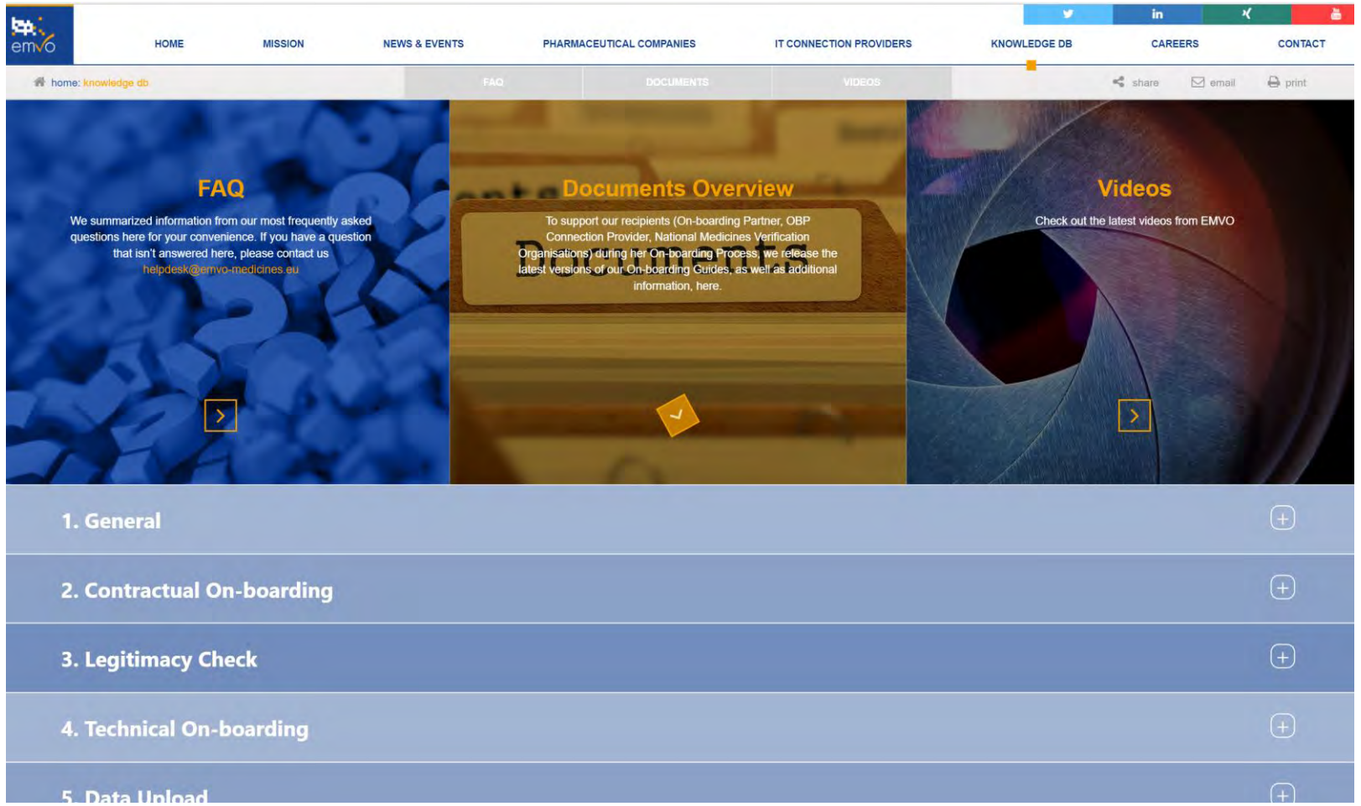
Systematic “Point of dispense verification”



EMVO Knowledge Base

Substantial amount of information available to support stakeholders who have obligations under these requirements

https://emvo-medicines.eu/knowledge-database/

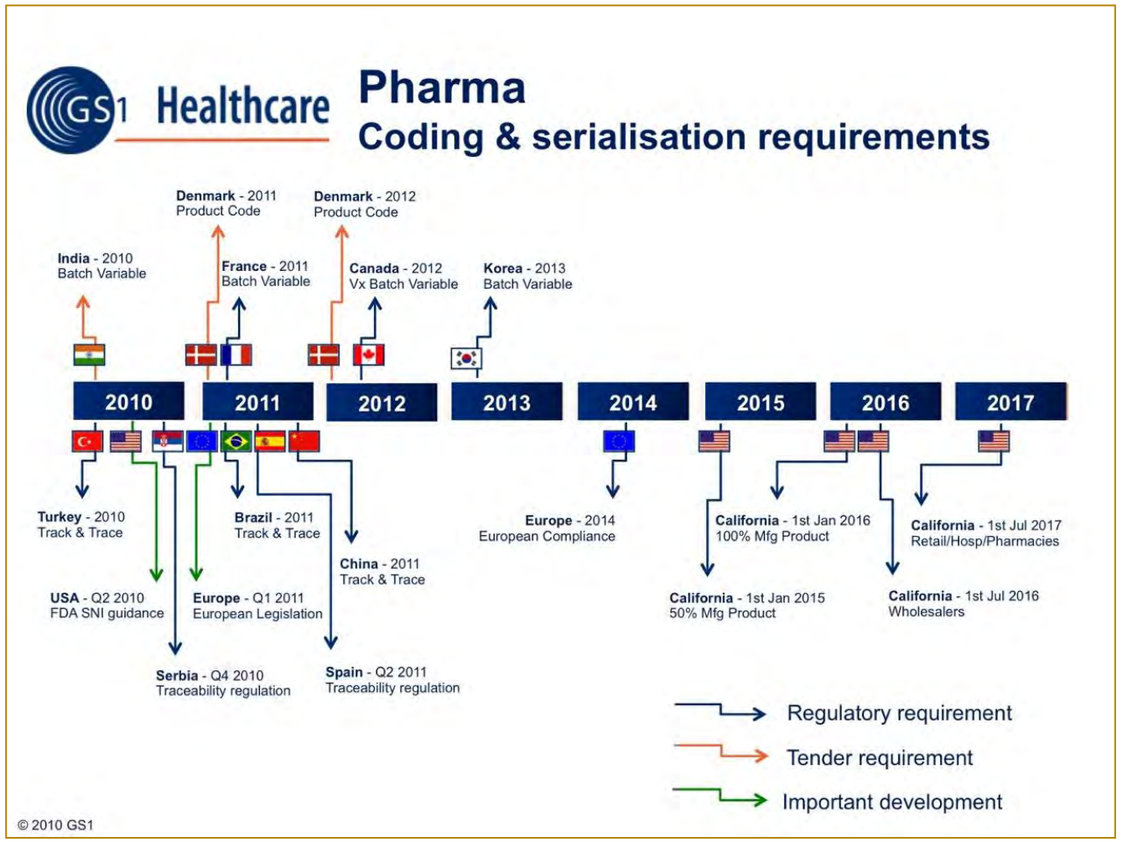


Agenda

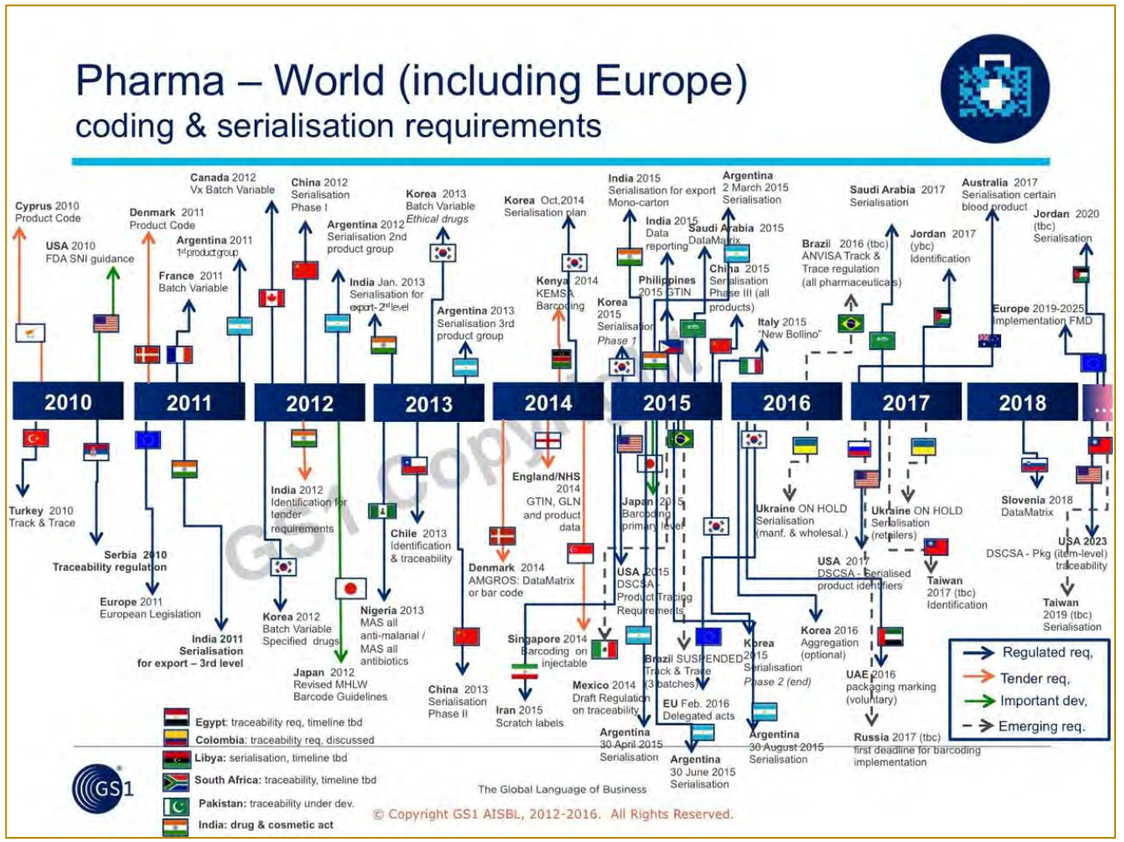
- Background and Introduction
- Serialisation in Context
- **Global Requirements**
- Impact on Manufacturers
- Getting Started – a roadmap to success
- Want you want from your regulator – panel discussion

Global Requirements – The Challenge

2010

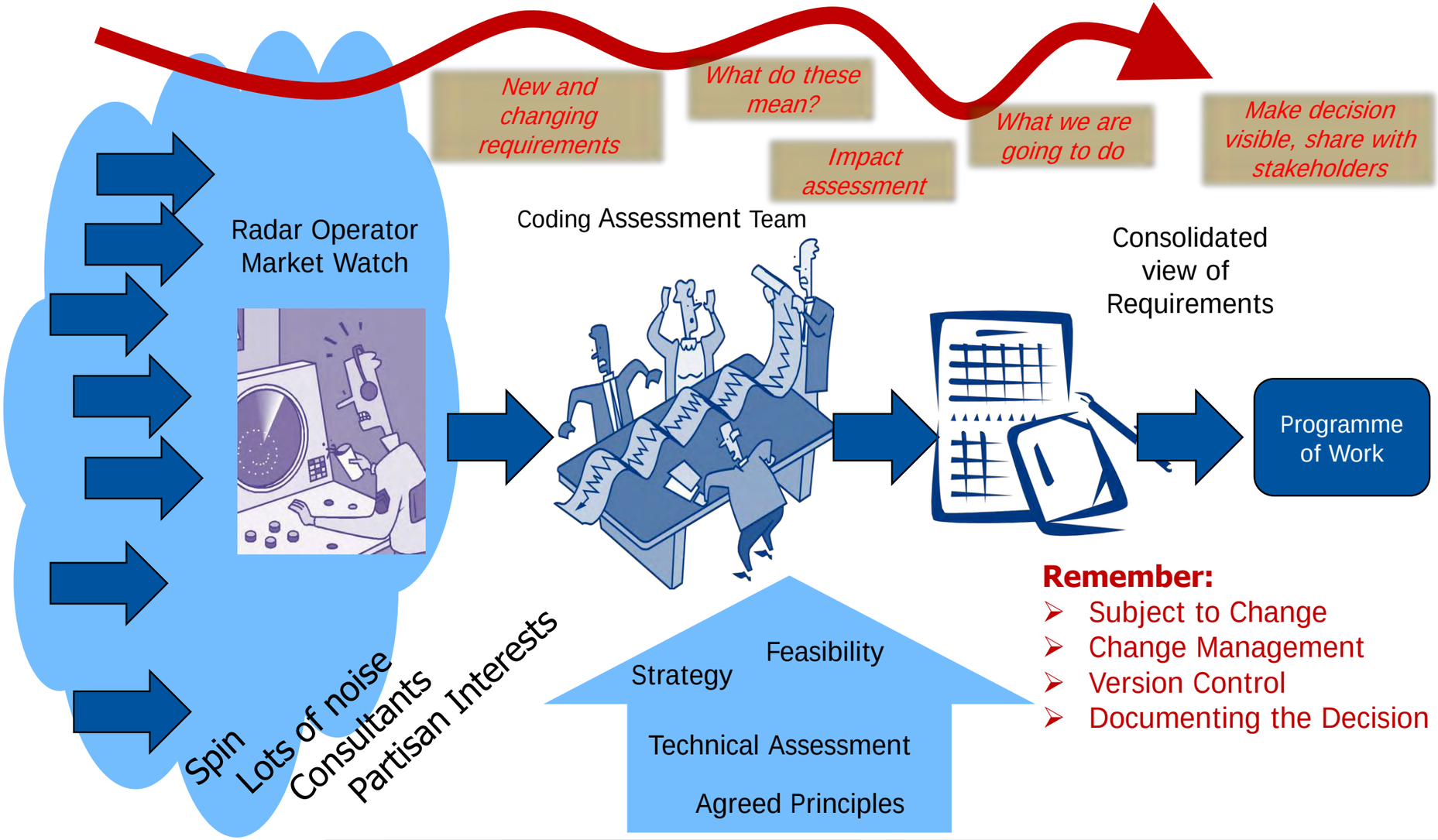


2017



Illustrations © GS1

Coding Assessment Process



Running your own radar – Keeping on top of requirements

- Sources of information
  - Internal global regulatory folk
  - Internal in-market regulatory folk (critical to get local understanding and where appropriate advocacy)
  - Standards bodies GS1
  - Linked in – Gurus group
  - Talking to your peers (inc. industry associations)
  - Solution providers
    - » Web sites
    - » Compliance reporting tools (may come for free)
  - Clients….

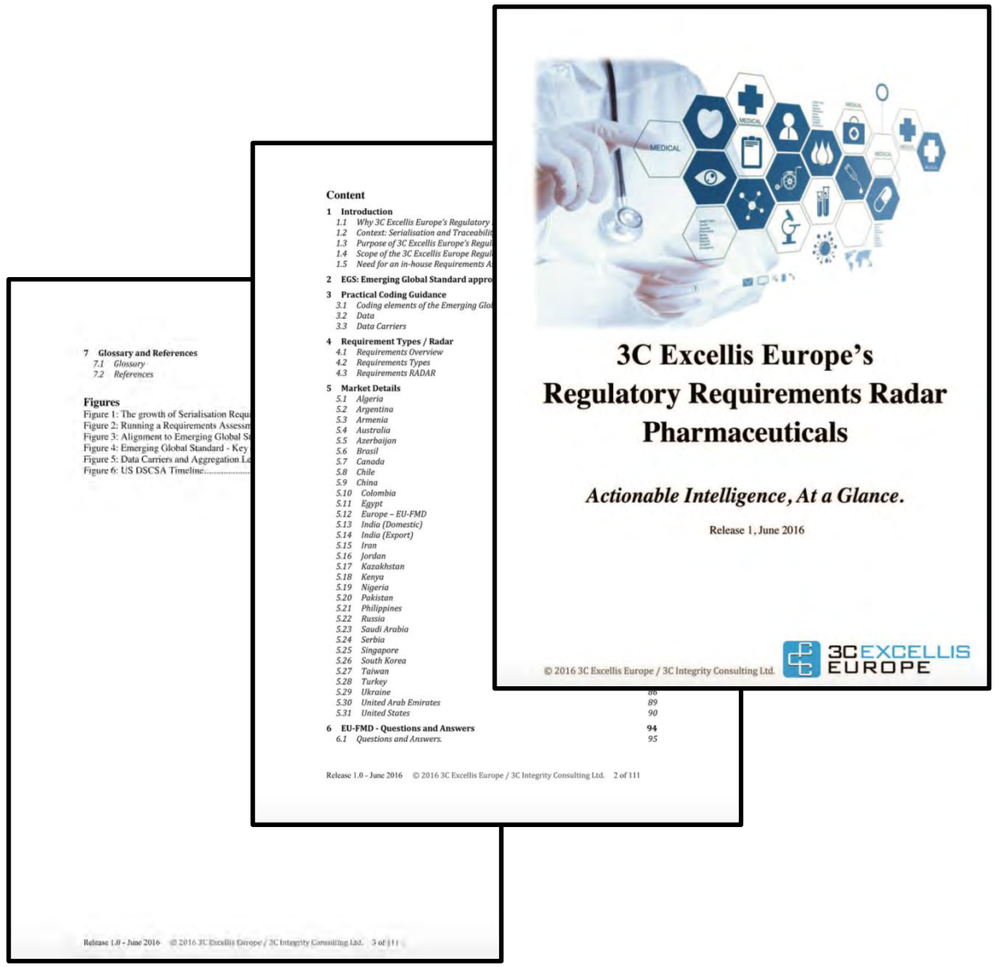
Coding Impact Assessment

- **Critical internal tool to manage response to emerging and changing requirements**
- **Key elements**
  - Reference info
  - Schedule
  - Tech requirements interpretation
    - » By pack level
    - » Code content and format
    - » Human readable implications
  - Process flow map
  - Sites and products impacted (inc. dist. and logistics)
- **Create them and maintain them!**

Regulatory watch : 3C Excellis Europe Regulatory Requirement Radar

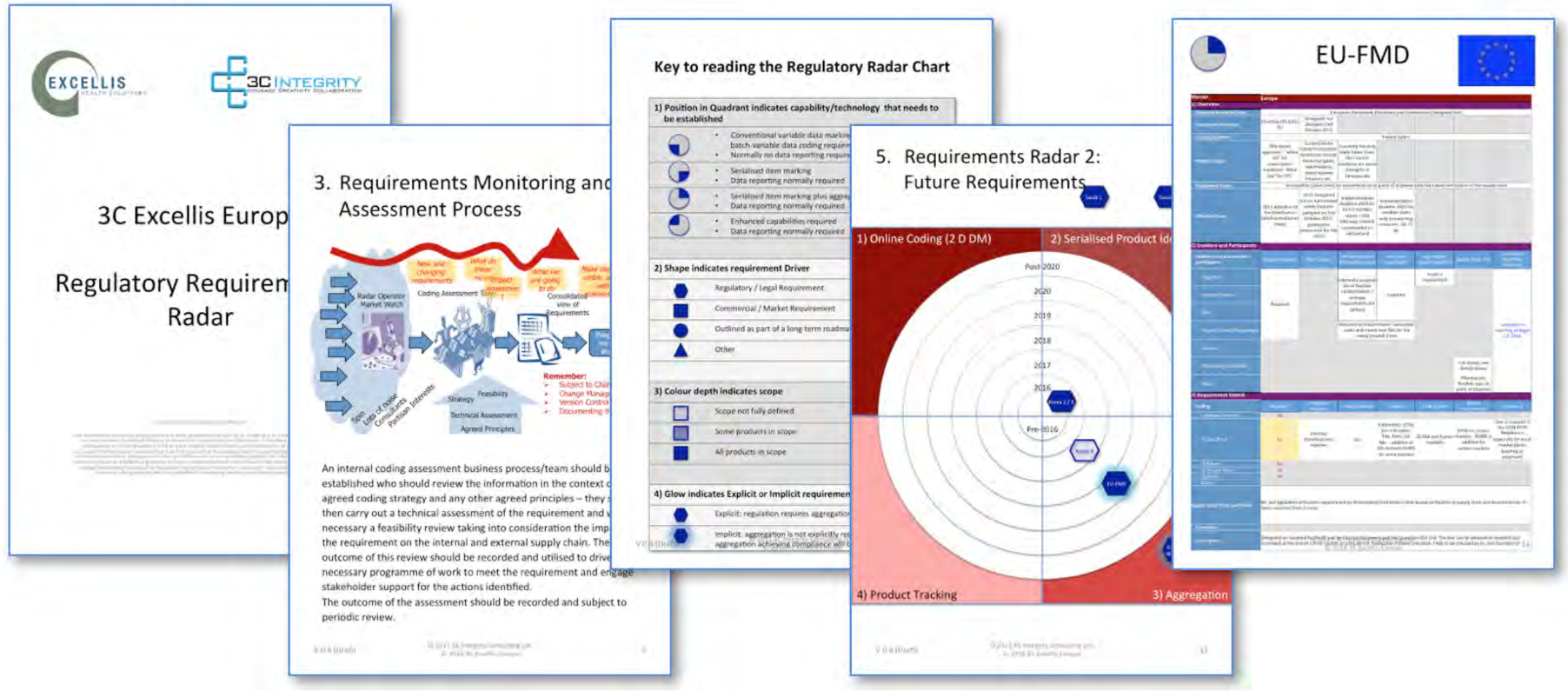
Comprehensive, systematic overview of the existing and anticipated regulatory requirements for coding of pharmaceutical products

The Radar details the enablers/capabilities necessary to fulfil the requirements along with a view of the role of supply chain participants in the requirement and their obligations and thus provides early warning of new and emerging coding requirements in order to feed the regulatory monitoring and assessment processes of pharma supply chain participants.

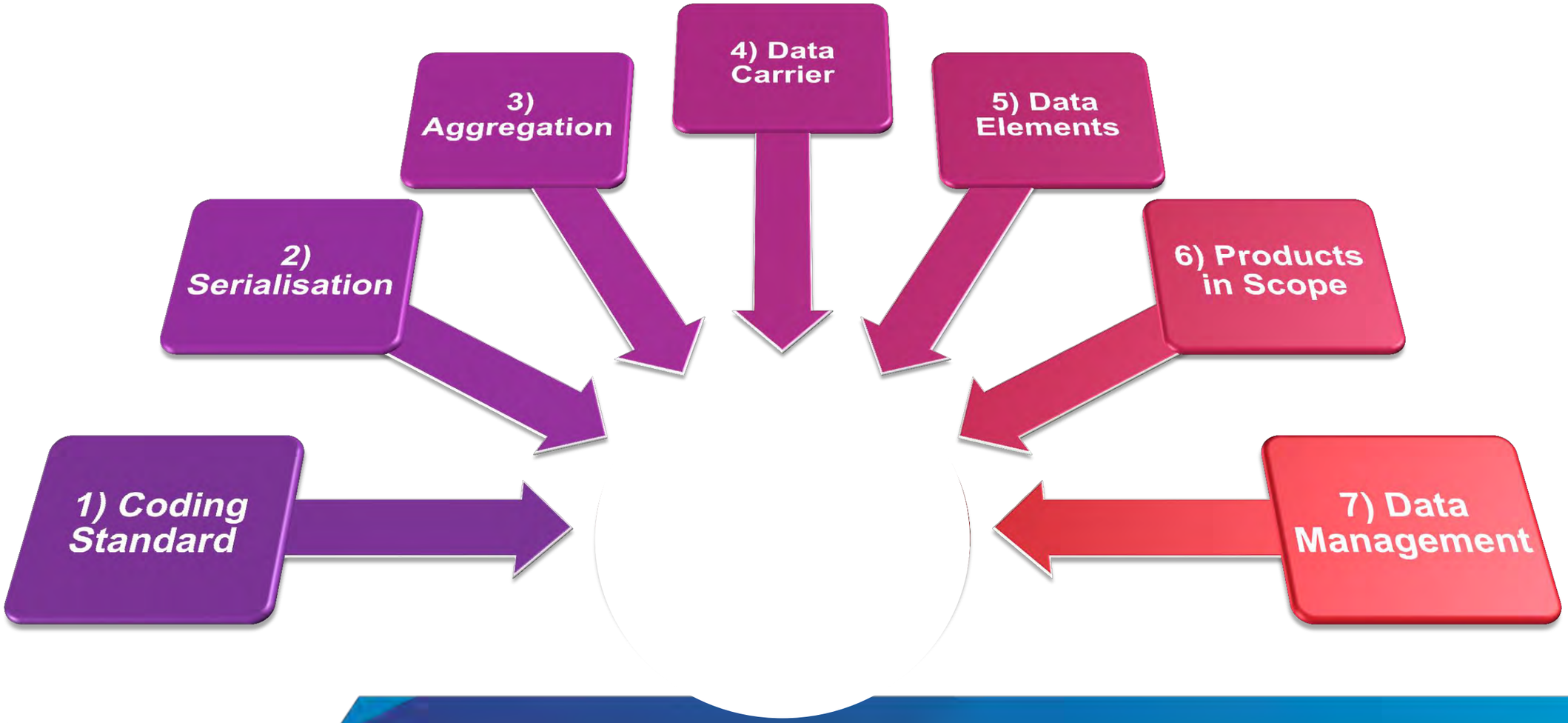


RRR Content

Sample Pages



A silver cloud on the horizon – Emerging Global Standard



Is the Emerging Standard Right for You?

Factors to consider

- What is the risk in the supply chain?
  - Re-use of packaging – counterfeit manufacture – theft?
- What are the end points of the “secured” supply chain
  - Pharmacy – patient?
- What is the true nature of the supply chain
  - Who are the participants – what are their use cases?
- How do products travel through the supply chain
  - Original packaging between end points – re-packaging – partial dispensing?

European Medicines Verification System

Beyond the Emerging Global Standard...

- **Three additional factors that should be considered**
  - The selection of the item
  - Tamper Evidence
  - Source of serial numbers - codes

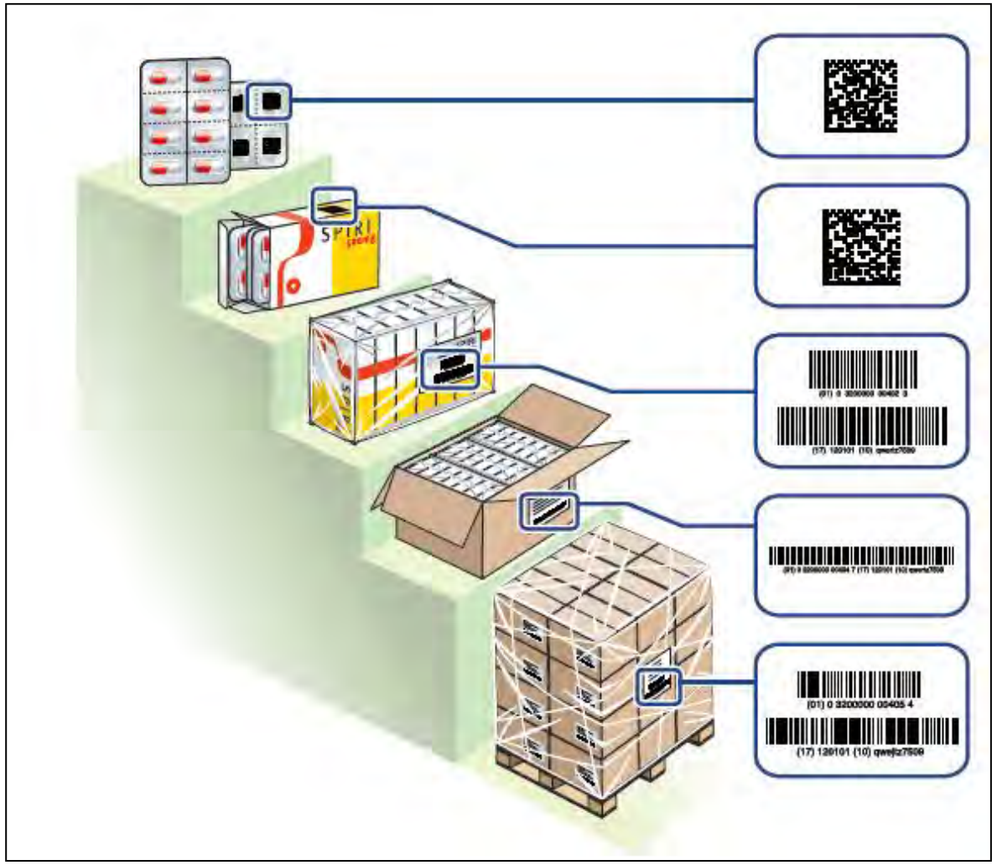
Product #:	(01) 0112345678901234
Batch:	(10) A1B2C3D4
Expiry:	(17) 101112
S/N:	(21) 12345AZRQF1234567890

What is the Item and Tamper Evidence?

This can be discussed, however a working hypothesis might include the following;

- Item must be tangible i.e. real
- Item must be an integral unit in the supply chain, ideally right up to the point of dispensing (does not rule out part units being dispensed)
- Item definition must reflect the actual dispensing behaviour of the market under consideration
- The item must (?) be tamper evident
- The item may have overt, covert or forensic authentication features
- Primary/secondary pack may not be a good guide

The lowest level traded item – the “each”



The Source of Serial numbers

The “code” on the pack is collection of “attributes” bound together in a data carrier e.g.

Product #:	(01) 0112345678901234
Batch:	(10) A1B2C3D4
Expiry:	(17) 101112
S/N:	(21) 12345AZRQF1234567890

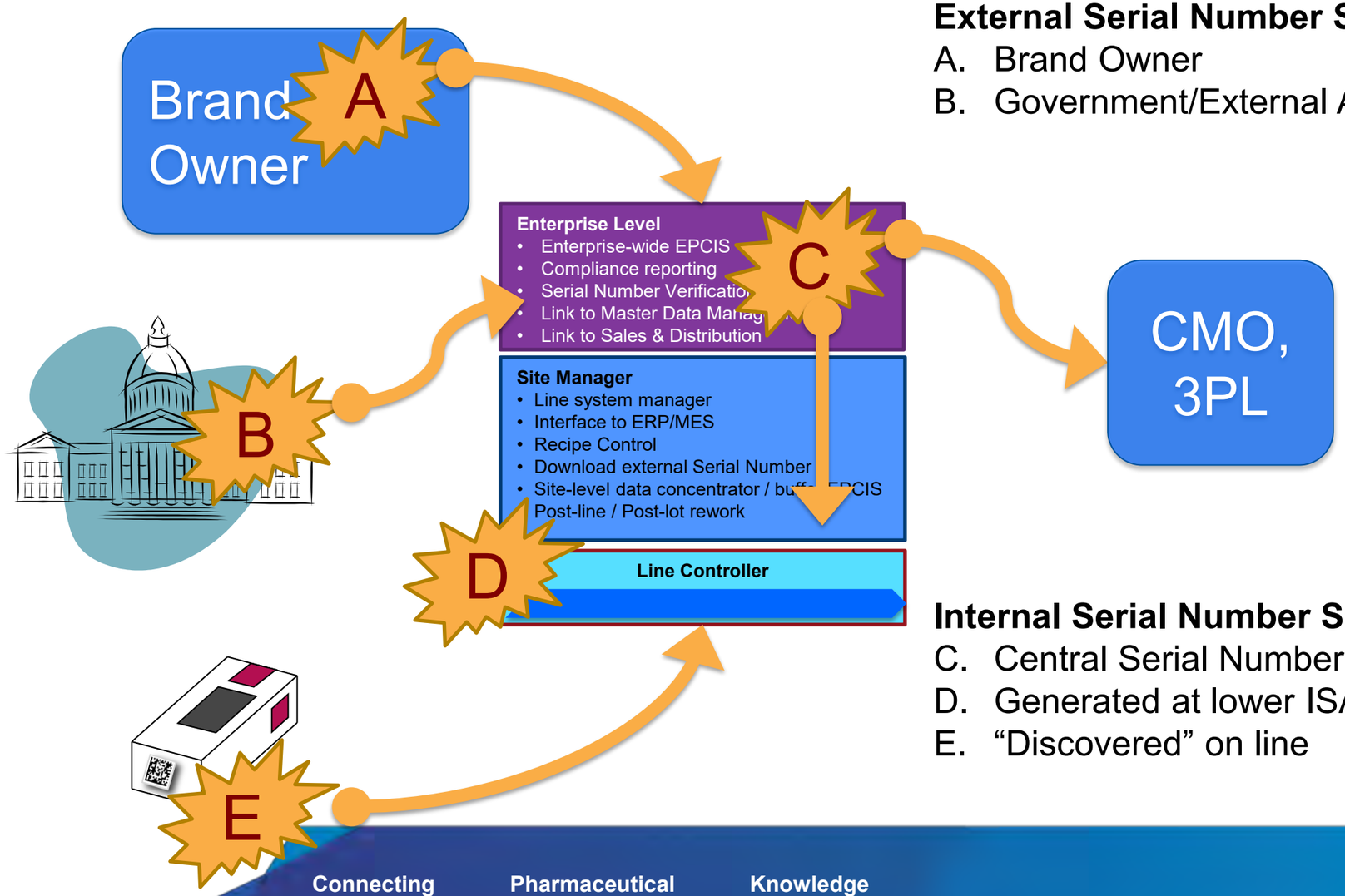
Some attributes are static for the sku e.g. product code

Some attributes are batch variable e.g. batch number and expiry date

The serial number is dynamic – unique (more or less)

The source of serial numbers is a key consideration.

Serial Numbers – Provisioning



External Serial Number Sources:

A. Brand Owner
B. Government/External Authority

Internal Serial Number Sources:

C. Central Serial Number Generator
D. Generated at lower ISA-95 levels
E. “Discovered” on line

The Benefits of Adhering to the Emerging Global Standard

- Staying close to the emerging global standard allows you to take advantage of the technology solutions and experience gained already in the early adopter markets
- Stepping outside of the standard has the potential to increase risk which may impact the costs, time to deploy and manufacturing impact
- Early adopting manufacturers are playing an advocacy role influencing emerging requirements

Agenda

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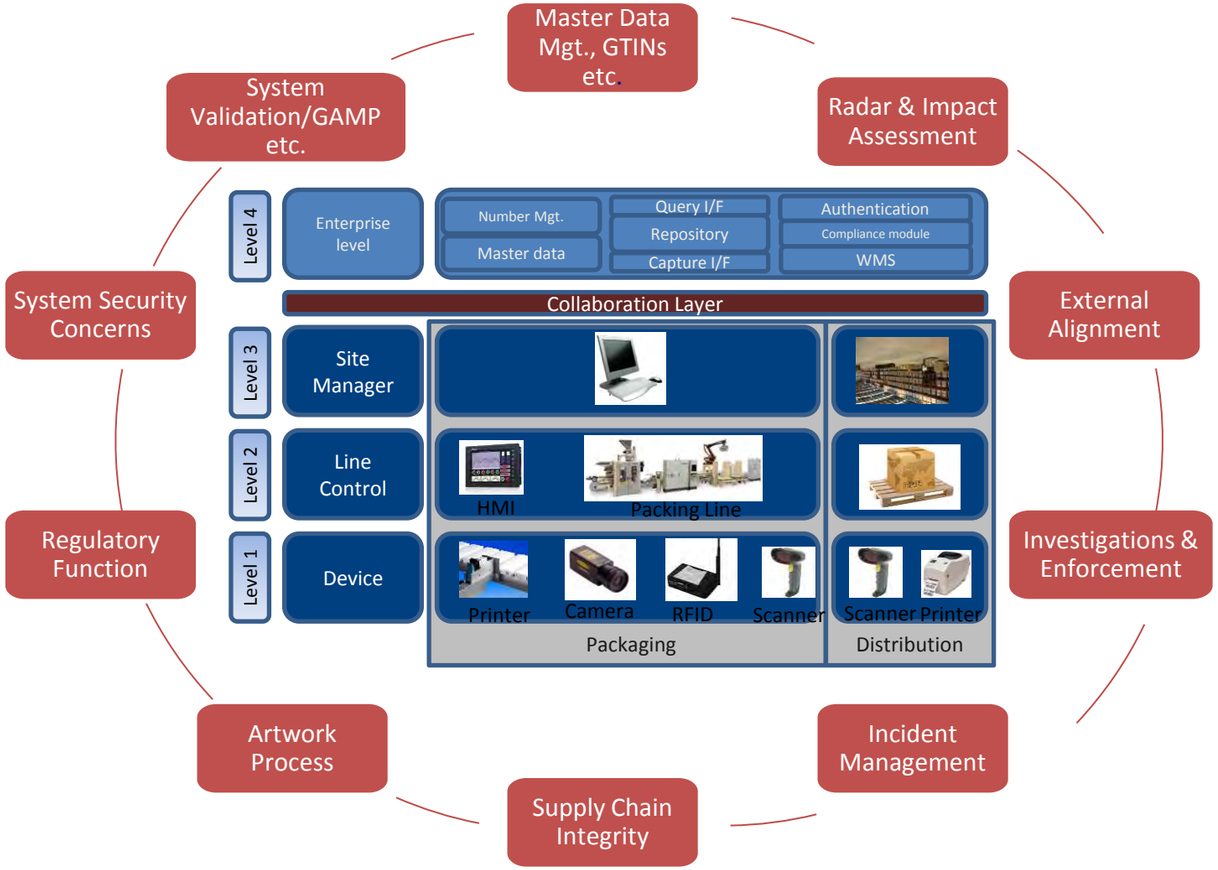
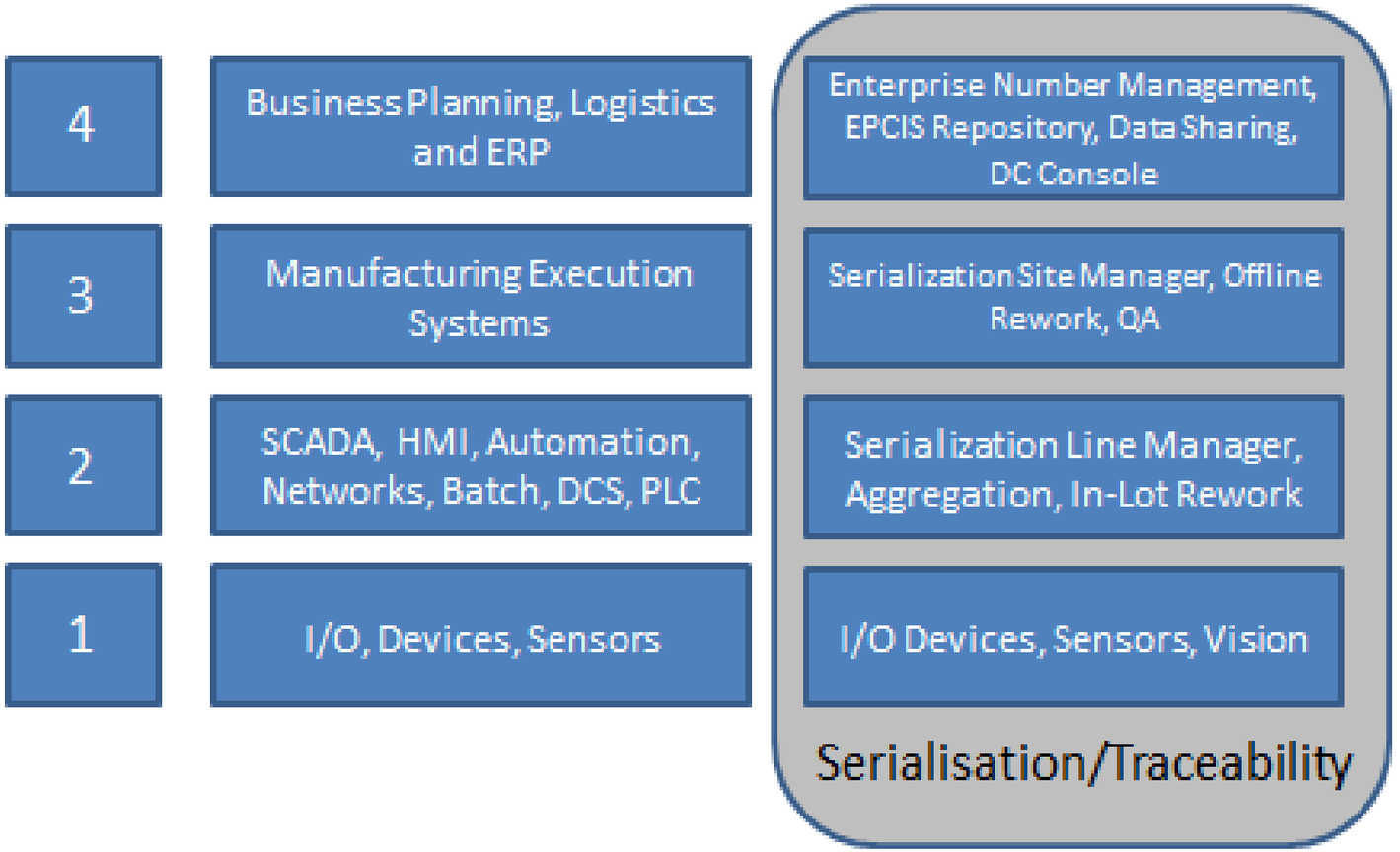
Serialisation – an Enterprise Programme

- Experience across multiple companies setting out to achieve compliance with various serialisation requirements indicates that this is likely to be the biggest and most complex programme you will deal with.
- And it may not always be plain sailing...

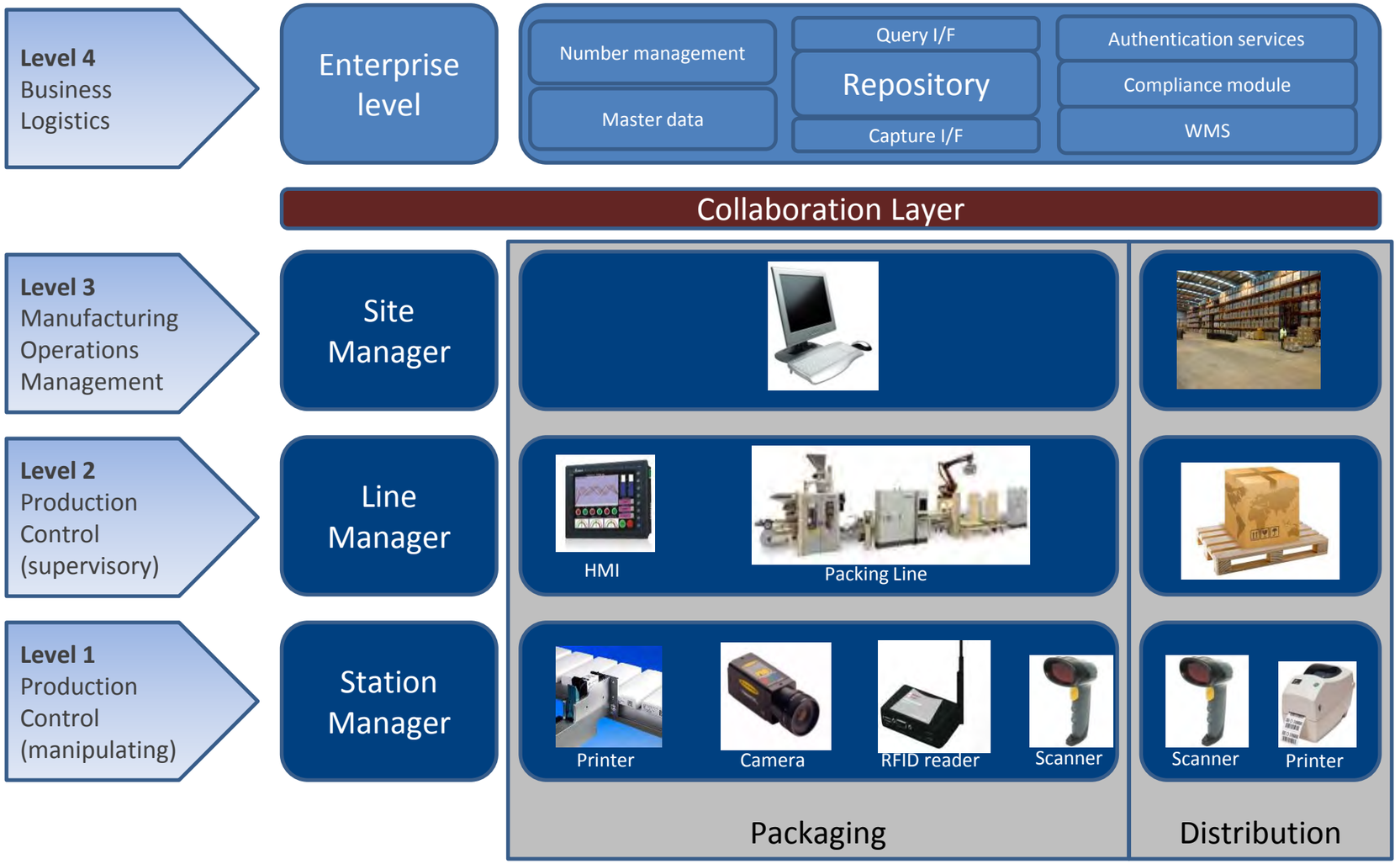
This is not just a technology project



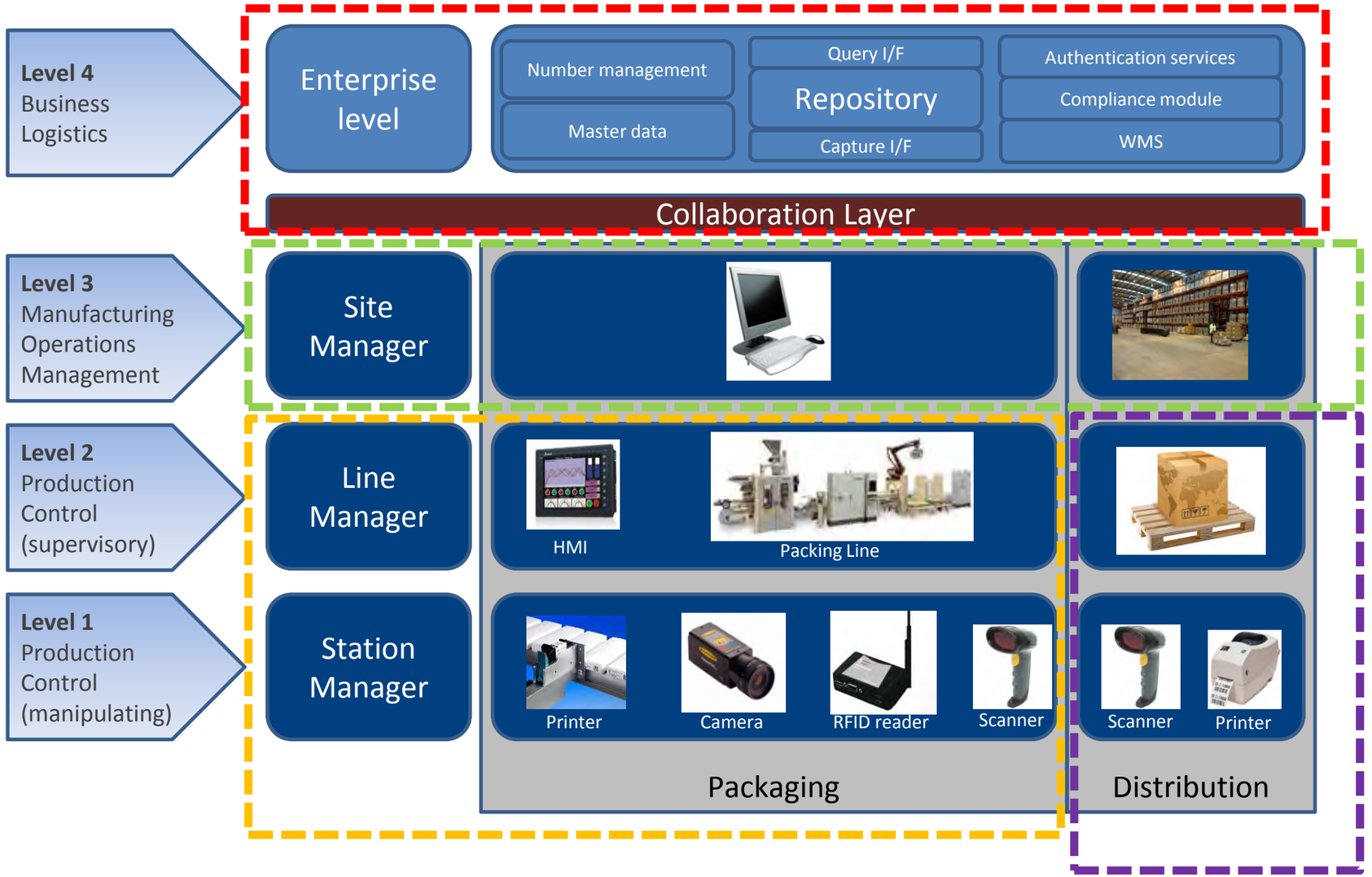
ANSI/ISA-95 Model



The Serialisation Solution Stack

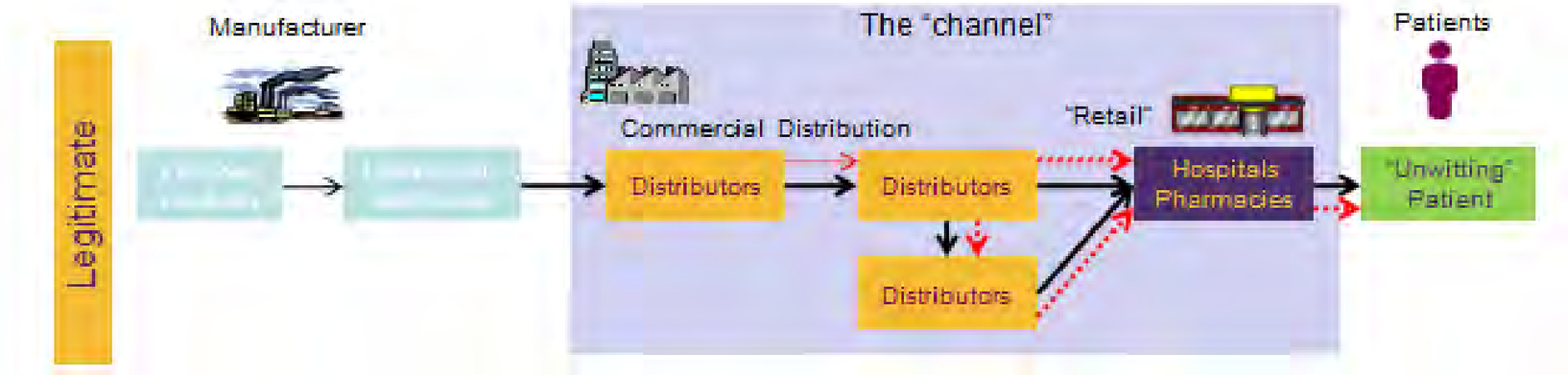


The Serialisation Solution Stack Components



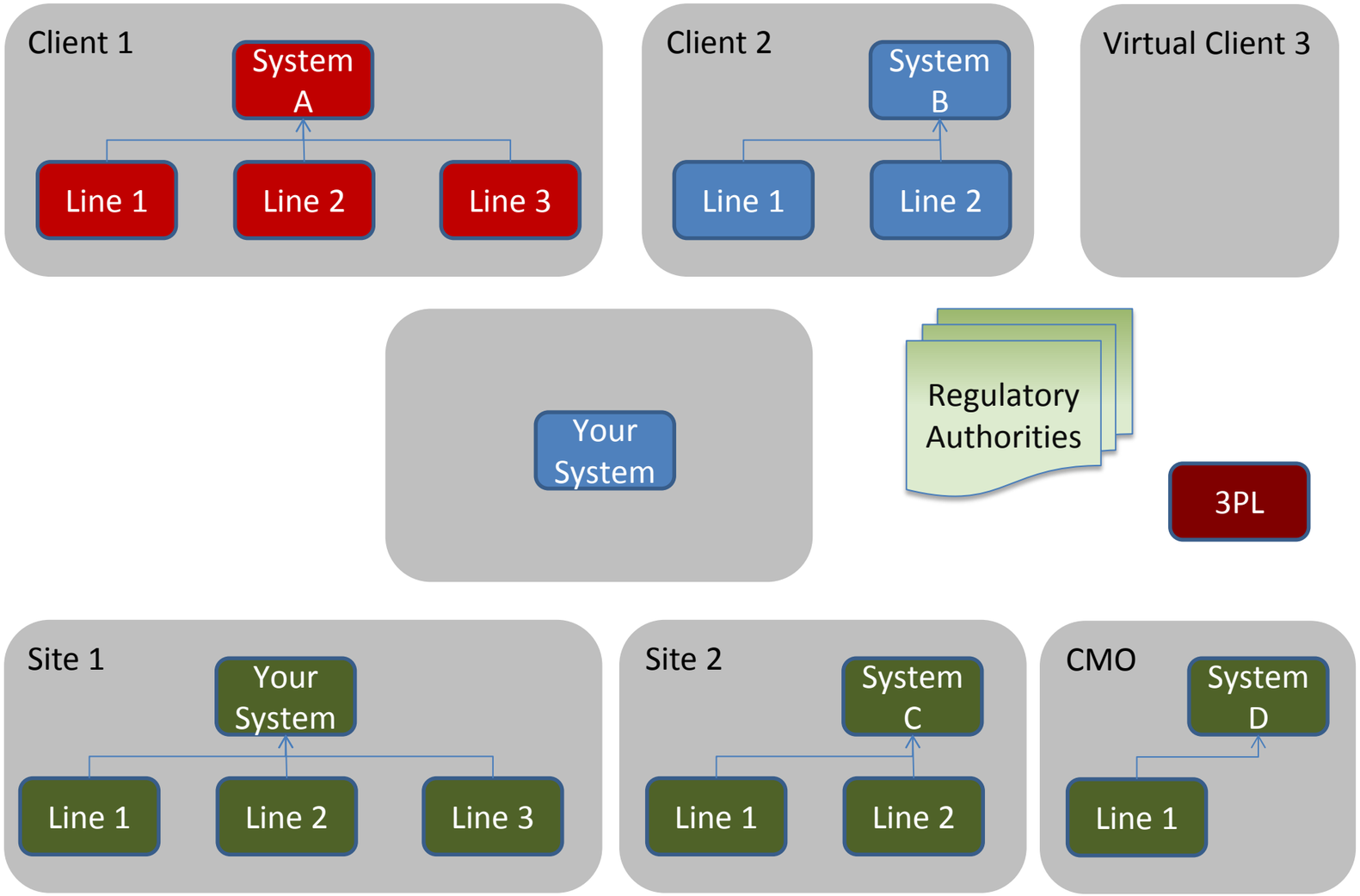
What type of Manufacturer are you? Internal vs external Supply Chain

- What are the characteristics of your supply chain up to the point of “change in title”?

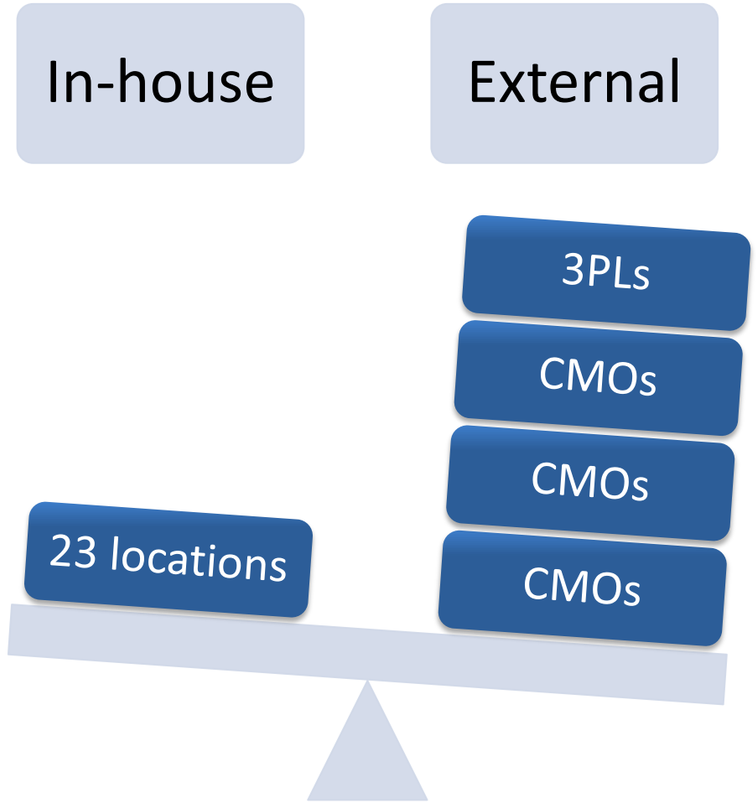


- Your supply chain reaches beyond your packing line, factory and organisation!

Wider System Landscape



Where is the centre of gravity of your project?



Impact on Manufacturing

How do you turn all these requirements and uncertainties into something practical that we can deliver?

Types of Requirements – Driving new Capabilities

Factor	France CIP13	EU-FMD	Turkey /US	Italy*	China
T/E	(✓)	✓	(✓)	✓	n/a
Static data	✓	✓	✓	✓	✓
Item level serialisation	n/a	✓	✓	✓	✓
Aggregation	n/a	(✓)	✓	n/a	✓
Vignette	n/a	n/a	n/a	✓	n/a
2D DM	✓	✓	✓	!	✗
GS1-Coding	✓	✓	✓	n/a	✗

The ‘worst-case-proof’ hardware?

Starting from the base line of a conventional blister line with no TE and embossed variable data …….what would the ultimate **item level** coding station look like?

- Tamper evident labeller (probably…)
- Addressable printer with associated vision system
- Integrated reject station

Pre-configured expansion options of:

- Additional addressable printer and vision system(s)
- Vignette labeller plus vision system
- Addressable printer for the vignette
- Future proofed for other data carriers

Future proofed through implementing a scalable solution….implement with the minimum capability for current (and near future) demand but with ***pre-engineered*** expansion options available to grow rapidly and painlessly with requirements.

Manufacturing Impact

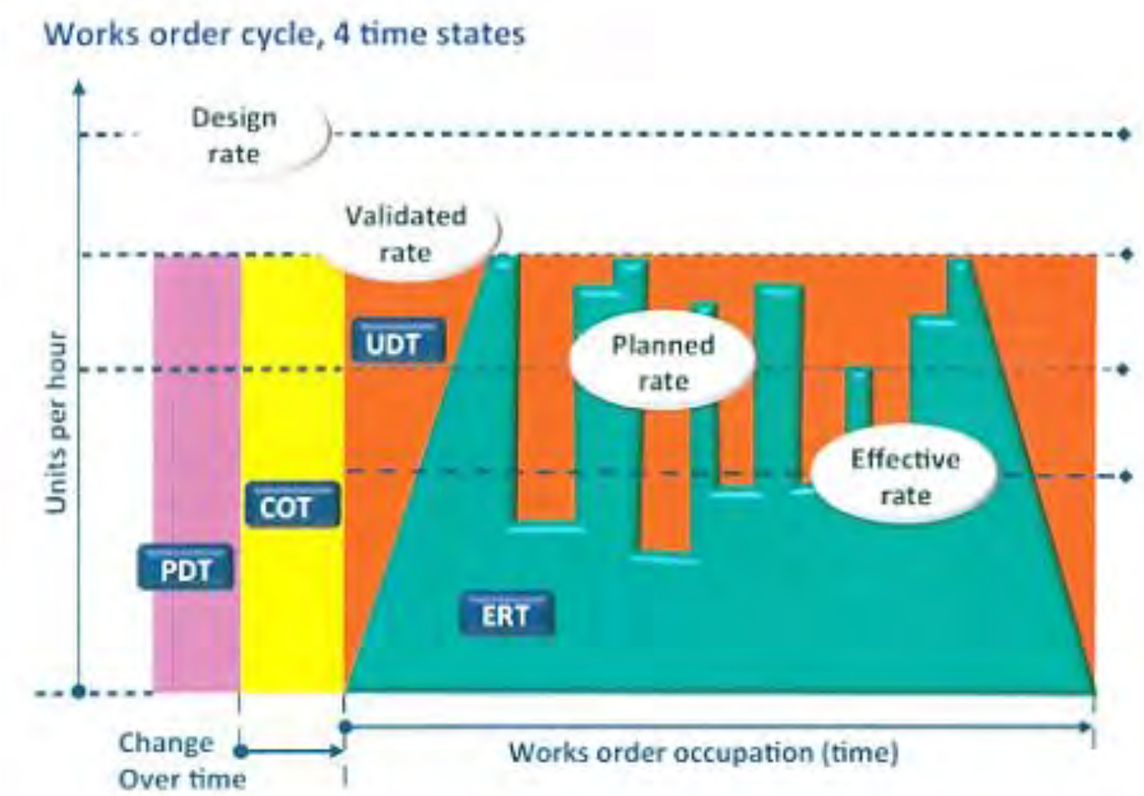
Early adopters reporting significant impact

with 2 to 4 years required to recover OEE

  - Many reporting permanent OEE hits

- Why is this and what steps can you take in your system specification to avoid it?
- Is there anything that can be done now to mitigate the impact?
- Recognise the need to create capacity to implement
- Light at the end of the tunnel?

Pharma Alliance Tempograph



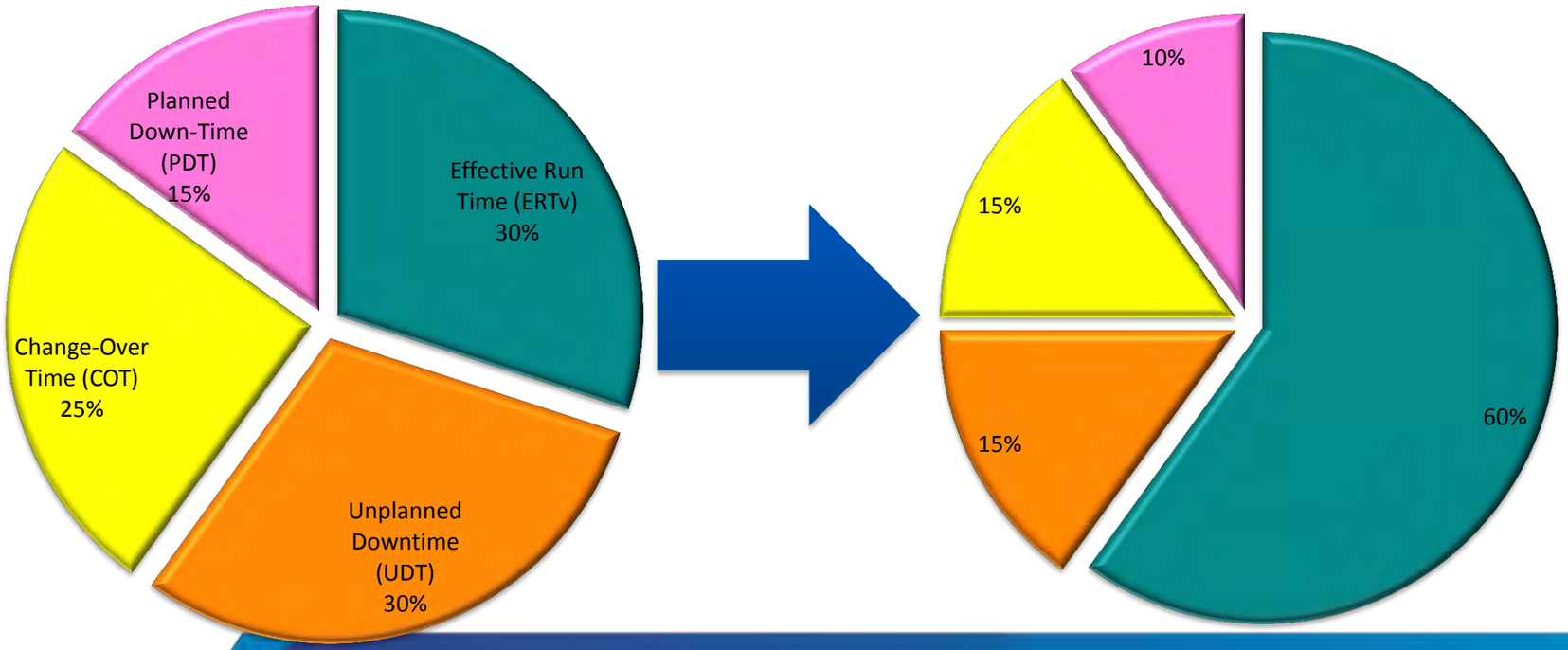
2m 30s good time in every 5 minute cycle!!

Source: Pictures & Notes Publications
Packaging line productivity Infoflip
©2014

System Specification

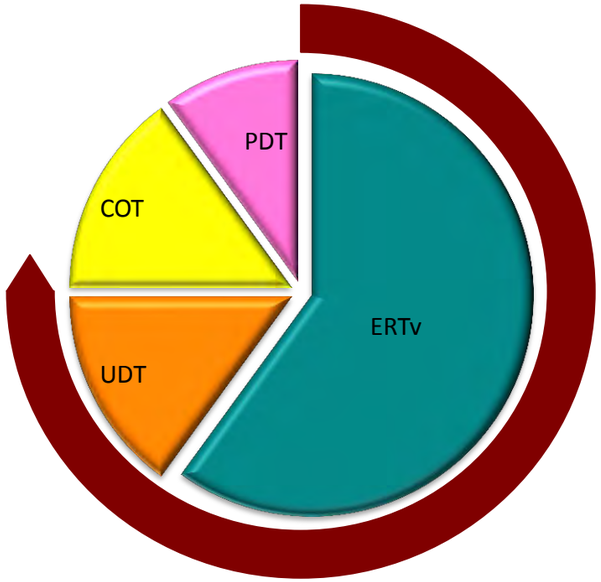
Can we specify the system to

- increase works order occupation time and then
- increase effective run time?



Focus on Works Order Occupation

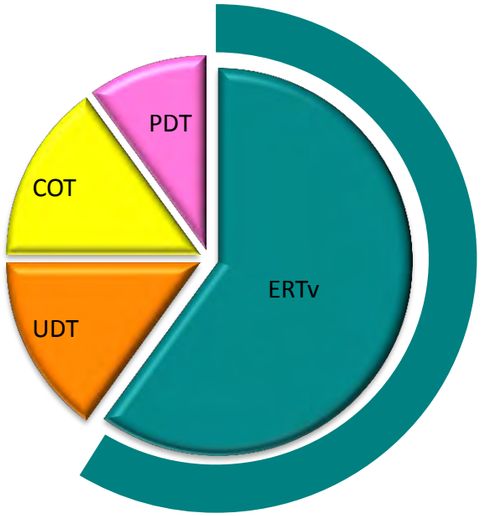
PDT (planned down time) may be fixed by policy, increasing COT (change over time) decreases WOO (works order occupation)



- Serialisation system must have rapid error free changeover time
- Recipe driven
- Ease of use
- Aim to minimise the impact on line changeover …you could aim higher?

Focus on Effective Run Time

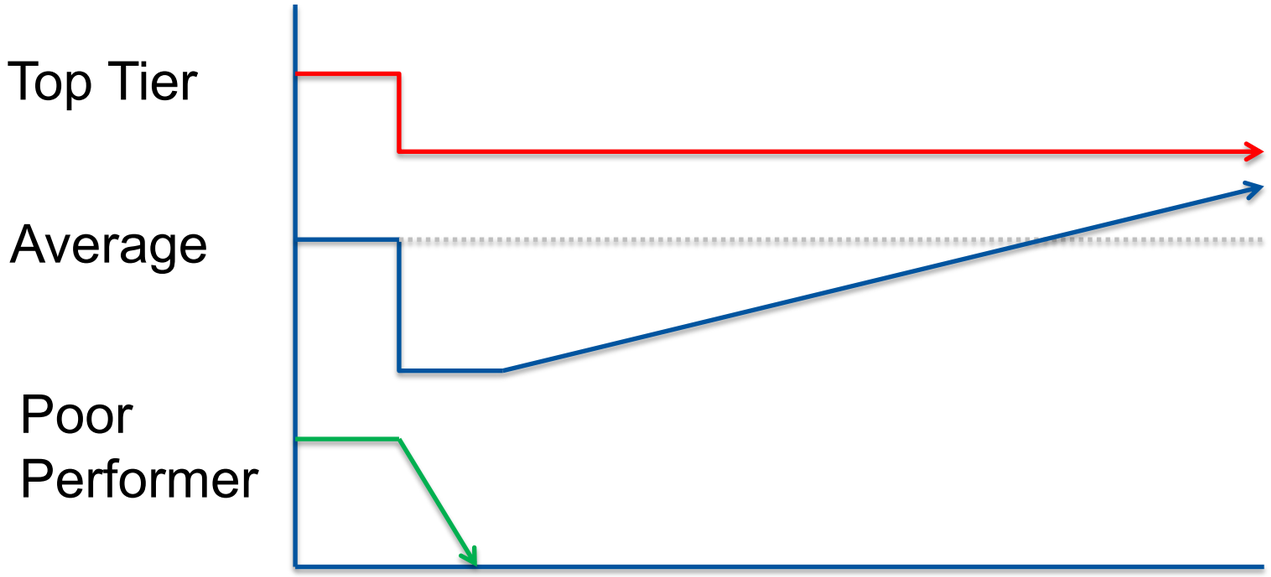
- ERT is reduced by stoppages on line – serialisation system is additional kit that brings with it potential failure and stoppages



  - You can specify MTBF (mean time between failures)
  - You can specify MTTR (mean time to repair)
  - These can be measured and allow you to predict operational impact

- Don’t forget the rate – serialisation should not be a rate limiting step

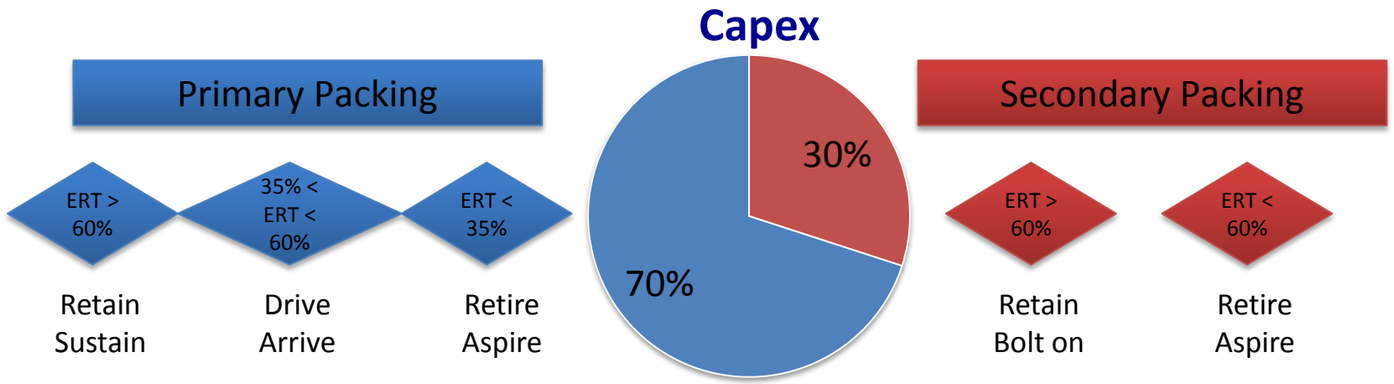
What can you Expect?



Top tier line – a small but permanent drop in OEE – 5%
Average line – significant early drop in OEE followed by recovery and the prospect of improved performance in the long term
Poor performer – rapid decline in performance – little chance of recovery

What Can We Do Now?

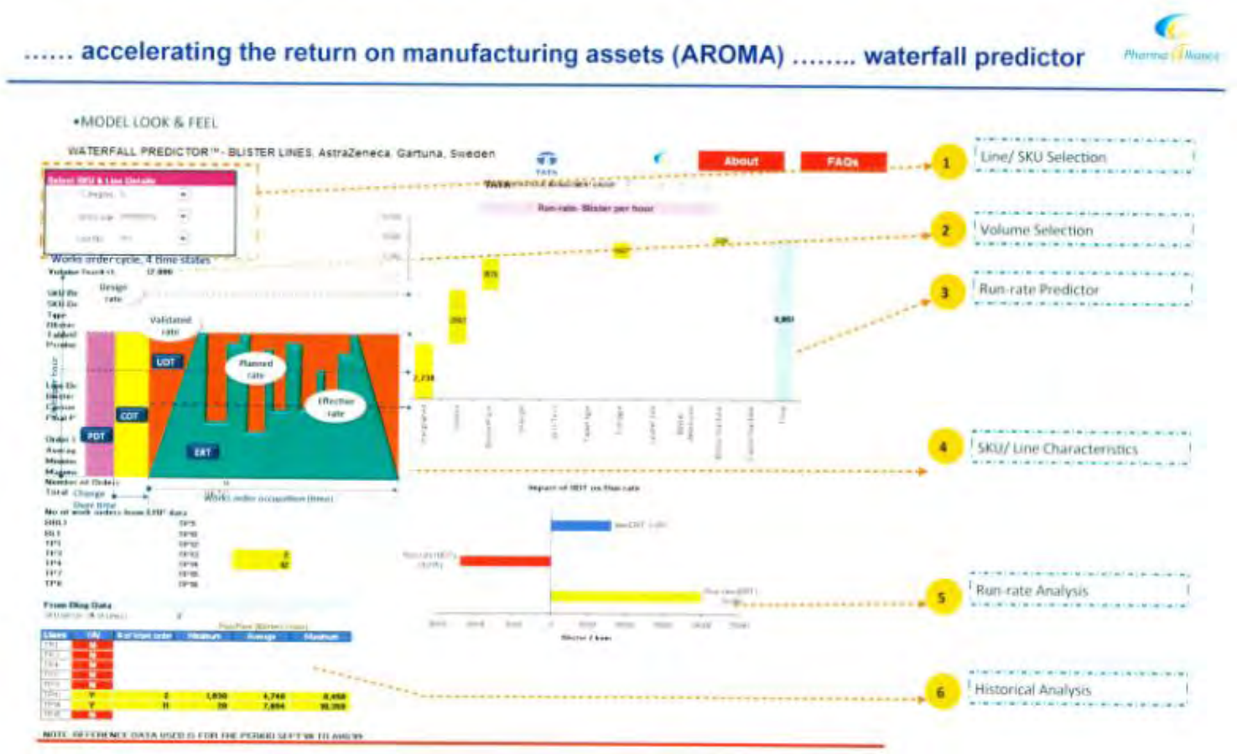
- Enemy of serialisation is disturbance from the steady state
- Take time under normal circumstances but serialisation increases the complexity of recovery – reconciliation of the physical and data assets
- Work on the performance of your assets now;
- Drive ERT (Effective Run Time) up
- Consider reinvestment where assets are poor performers



Creating Capacity

- Implementation requires line time
- Line time is required to install, commission and validate serialisation and train staff.
- Assets are increasingly hard pressed with many companies claiming utilisation figures in excess of 100%
- **Another reason to work on performance now**
- How much capacity can you release?

Light at the end of the Tunnel?



Pharma Alliance engaged to analyse the performance of a main AZ manufacturing site – utilised a tool which then utilises regression analysis to determine the key factors in play driving performance and predict performance impact of changes

Light at the end of the Tunnel?

... accelerating the return on manufacturing assets ... Tamper Evident Seal System (TESS)

TP3	SKU TESS Yes	No
# of works order	68	70
Total Volume (Blisters)	9,426,780	2,577,004
Total Time (hrs)	1,600	790
Run rate (Blister/hr)	5,892	3,262

TP8	Yes	No
# of works order	176	12
Total Volume (Blisters)	12,054,138	395,020
Total Time (hrs)	2,766	119
Run rate (Blister/hr)	4,358	3,319

Example:

Line- TP3	SKU*	Volume (Blister)	Time (Hrs)	Run rate (Blister/Hr)
SKU without TESS	181002089	67,650	31	2,209
	181250288	565,870	90	6,323
	182010589	20,250	4	5,672
	Total	**653,770**	**124**	**5,286**
SKU with TESS	000218002	96,750	19	5,135
	000242301	29,700	4	8,390
	180205098	61,200	27	2,298
	182005651	241,440	80	3,020
	186590298	4,262,400	604	7,057
	Total	**4,691,490**	**733**	**6,401**

Run rate – blisters per hour

5,286 without TESS

6,401 with TESS

Notes: We can not ascertain the exact root cause without additional data

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Some good news and some bad news

The Bad News:

- Serialisation projects are big projects
- The impact of failure is potentially huge
- Often complex, involving many areas and requiring collaboration across boundaries
- They can suffer from high degrees of uncertainty and change

Some good news and some bad news

The Bad News:

- Serialisation projects are big projects
- The impact of failure is potentially huge
- Often complex, involving many areas and requiring collaboration across boundaries
- They can suffer from high degrees of uncertainty and change

But there is Good News:

- The core capabilities that need to be established are not too complex and increasingly well understood
- These can actually be pretty straightforward projects in terms of planning
- But need to seize the opportunities to simplify: Decouple, use generic approaches that are flexible and adaptable
- Sound programme/project management practice is essential

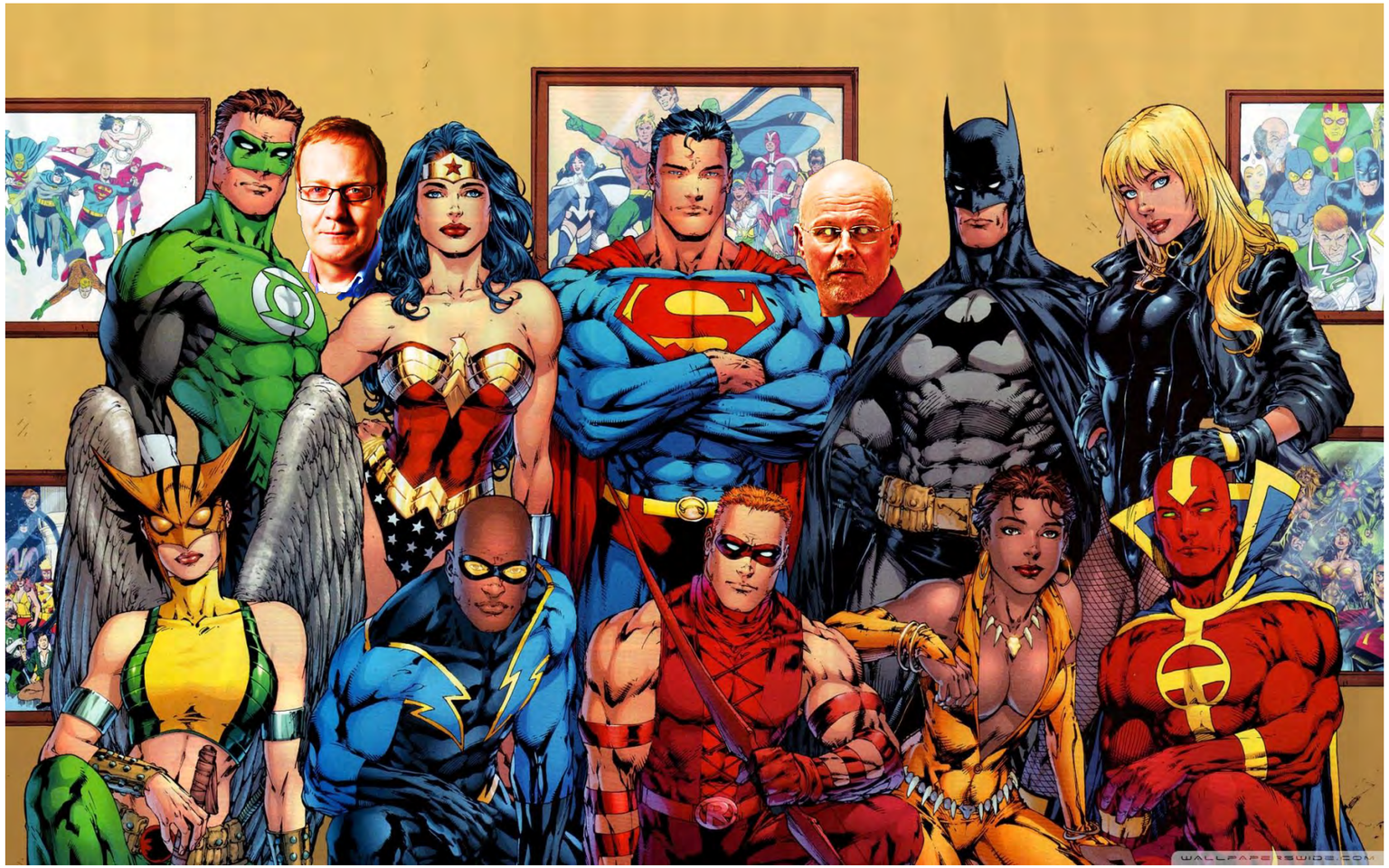
Inherent Conflicts

Serialisation Projects are prone to more conflicts than other projects because of:

- Size and Scale of the undertaking
- Diverse parts of the organisation with diverse standards, guidelines, processes and “traditions” collide
- Operating to different (conflicting?) targets and objectives

In terms of project management: You are dealing with an IT project but also an engineering project, an artwork project, a supply chain project, business change project etc….

You need the right team



So who should lead the team?

Research lists the following suspects:

- ❑Supply chain management
- ❑Product Security Function
- ❑Production/Manufacturing Ops.
- ❑IT
- ❑Packaging
- ❑Regulatory

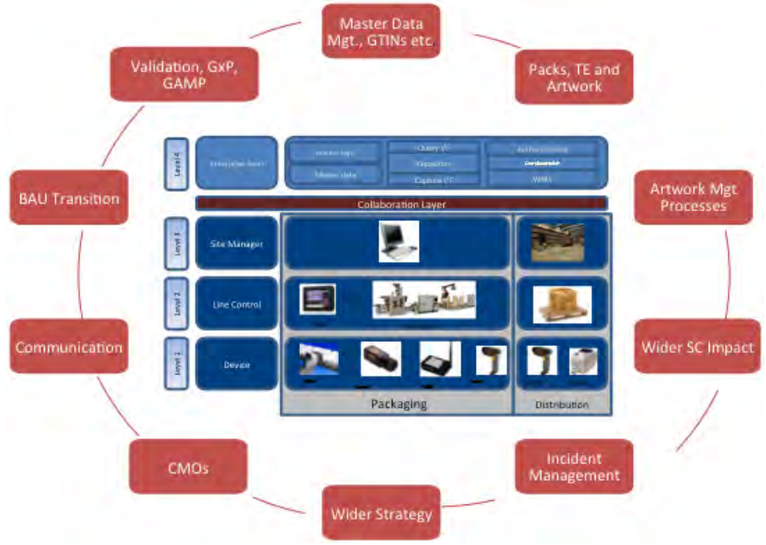
Questions:

- Where does the program emerge from?
- Where is the program best placed for now?
- Who will own this long-term in BAU?
- Who will suffer most if it goes wrong?
- Where should the Program Manager come from?

Who should be in the team?

- Regulatory
- IT
- Package Design/Labelling
- Package engineering
- Warehouse
- Distribution
- QA
- Validation and CSV
- Operations
- Planning and scheduling

- Supply chain and logistics
- Customer services/commercial
- Sourcing/Procurement
- Legal
- Any others?



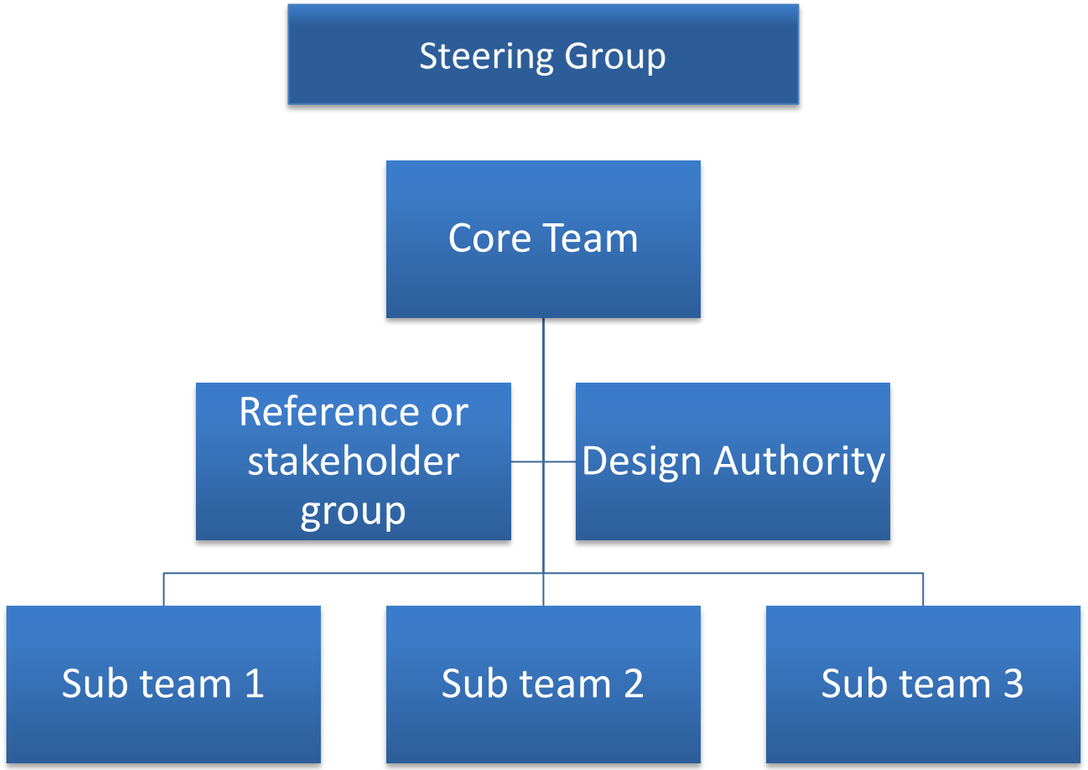
Program Organisation

Functions: / Teams:	Operations	Engineering	IT	Supply Chain / Logistics	Regulatory	Planning	Artwork	Quality	Validation	Product Security	Marketing / Commercial	External Sourcing	Procurement	Example FTE
Steering / Oversight Team	■			■	■					■	■			part time
Global Core Team	■	■	■	■	■			■		■		■	■	6 FTE
Site-based Implementation Team	■	■	■	■		■	■	■	■				■	30 FTE
Subteams (artwork, regulatory, master data & coding etc.)	■	■	■	■	■	■	■	■	■	■	■	■	■	part time
Example Pack Changes					■	■	■				■	■	■	3 FTE
Master data and Coding	■		■	■		■								
Ad-hoc support (security, marketing)														
External														
CMO														
Vendor														
Distributor														

Responsible
Accountable
Consulted
Informed

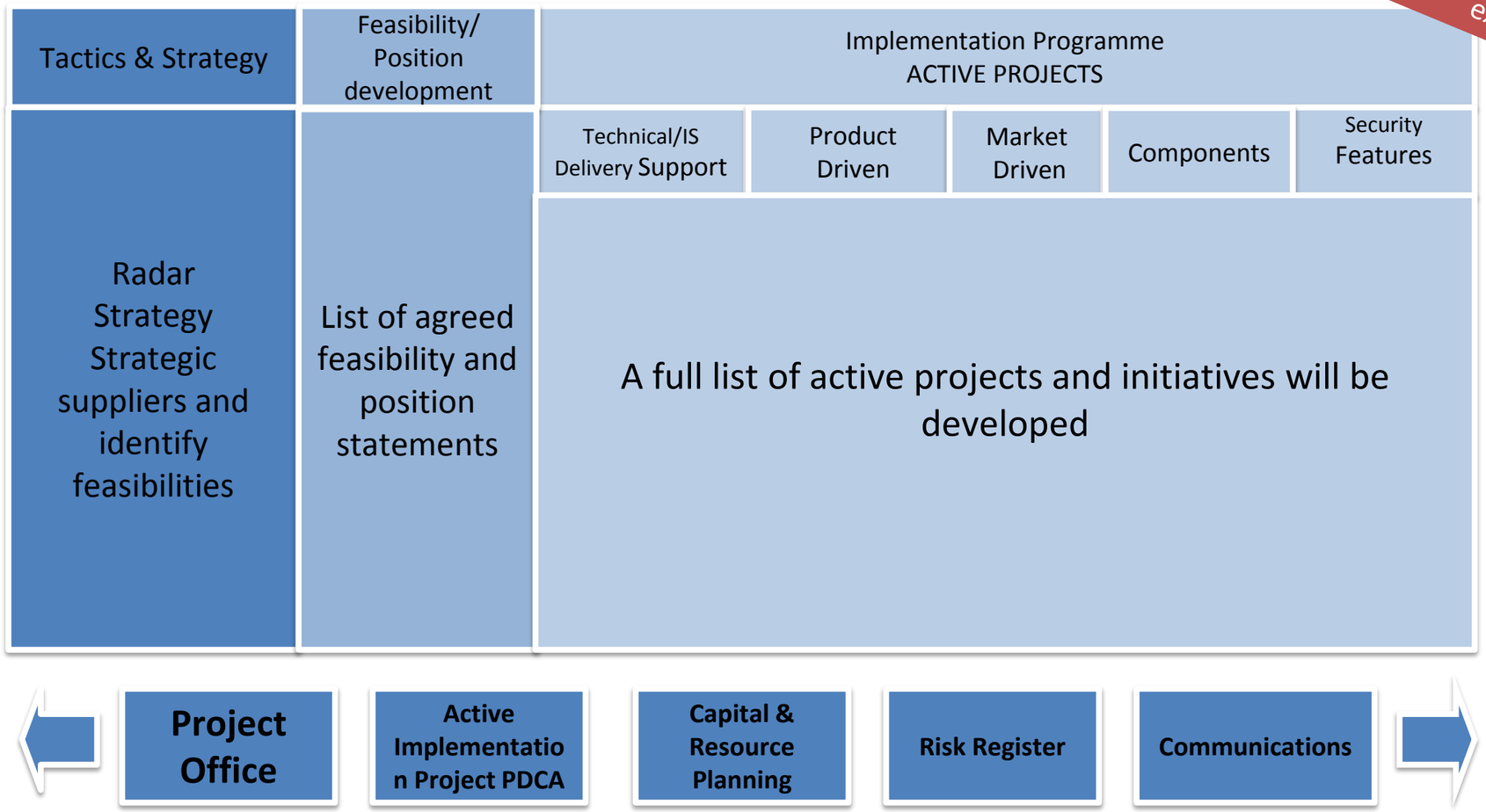
The real skill is to build the right sub-teams and to manage them when they are in and also when they are out

Program Organisation

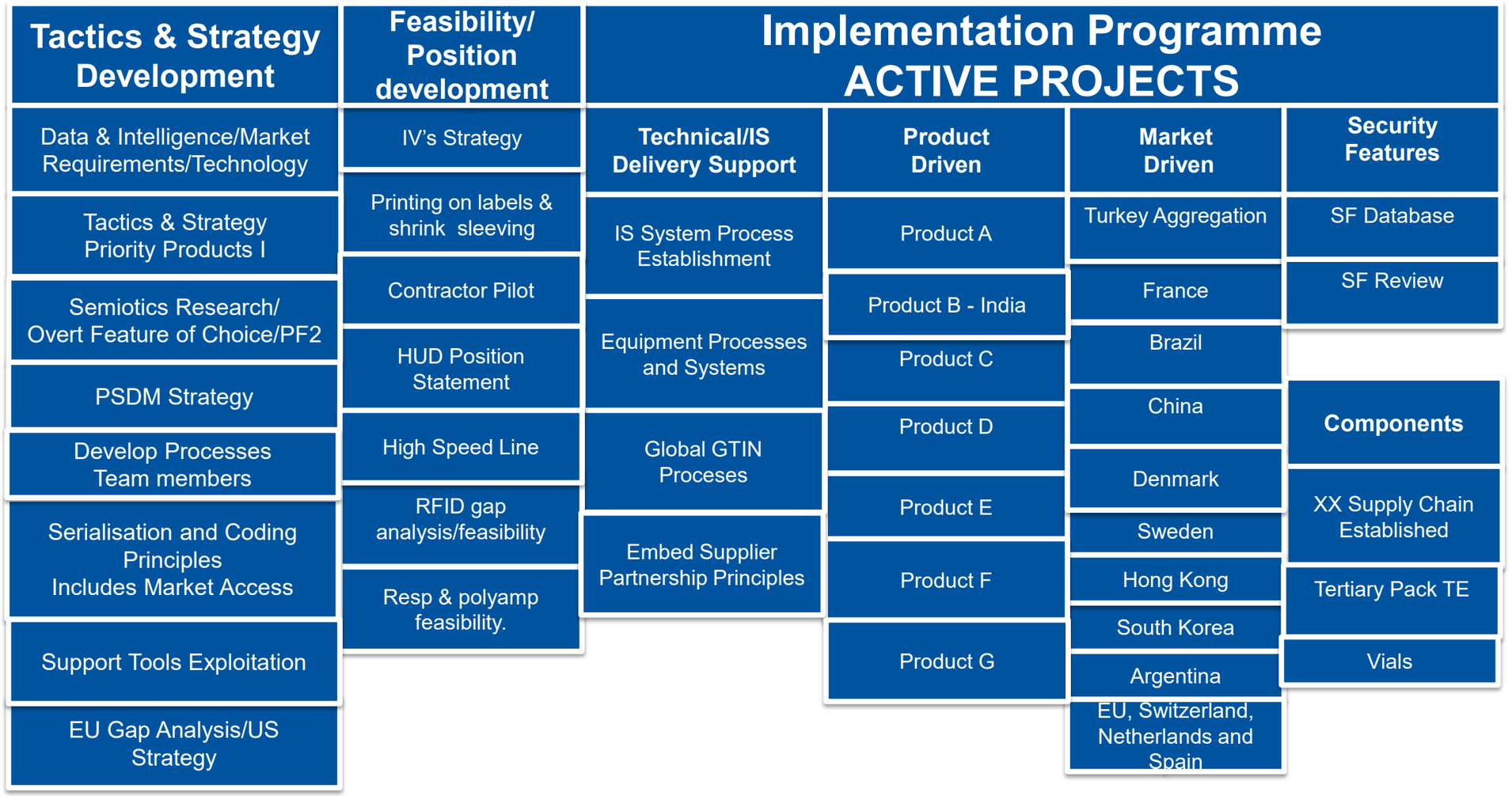


Pack Coding and Security Features Programme

A programme example!



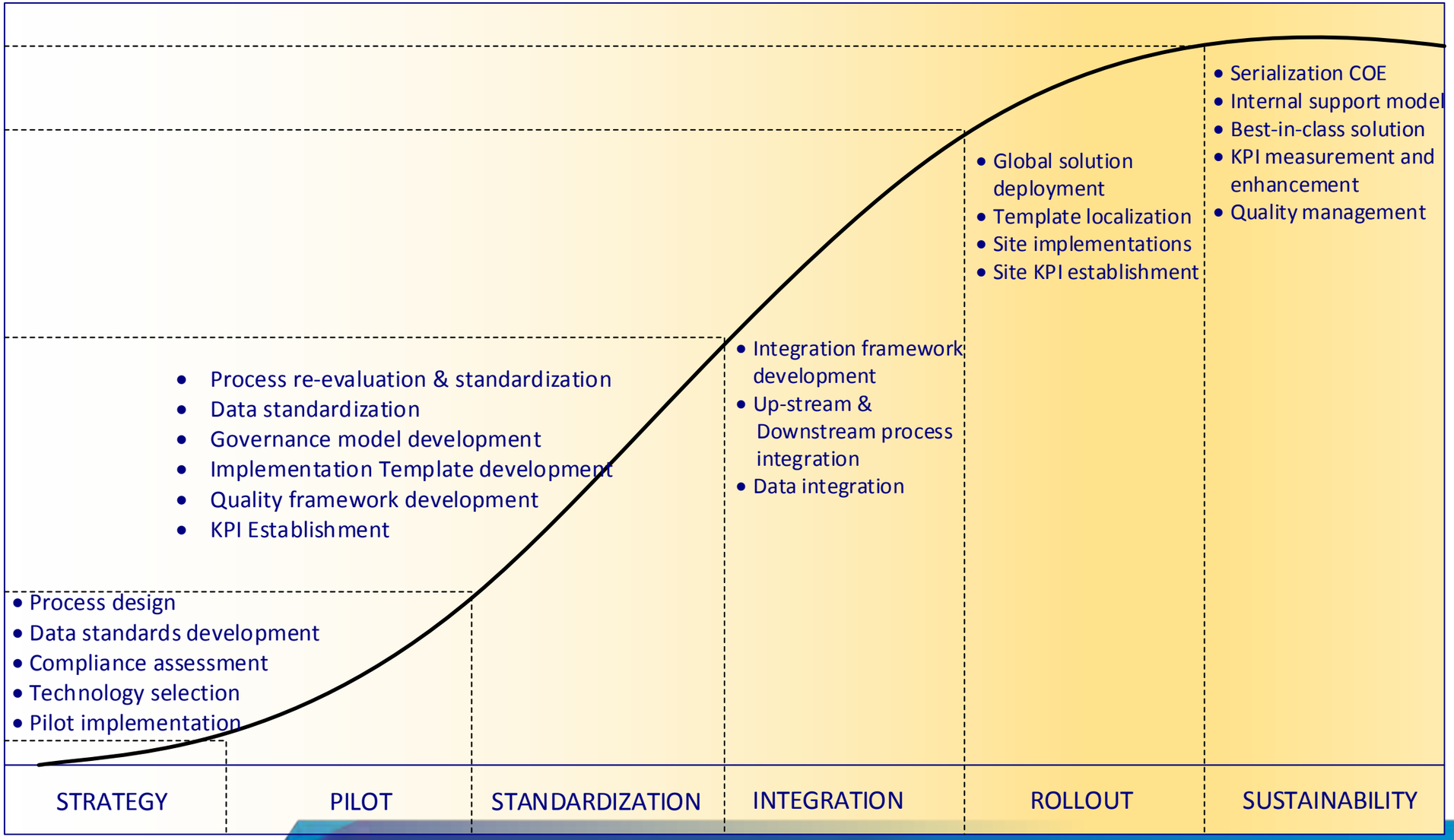
Pack Coding and Security Features Programme



Governance and Reporting

Who	Leader	What	Frequency
Security Council	VP Supply Chain	Strategy sign-off	Quarterly meeting
Product Security Strategy Team	Head of Product Security	Strategy development/enhancements	Monthly Meeting
Tactics Team Global Implementation Team	Programme Lead	Tactics/Global Implementation & Support	Monthly Meeting Monthly Meeting
Security Regional Contact Meeting	Regional Product Security Lead and Regional Champions	Global Site /Regional Tactics & Communications	6 weekly meeting
Regional/Site Leadership	Global Site/Regional Champions	Communications /Implementation	tba by Global site/Regional lead
Site Implementation Team(s)	Nominated by Global Site/Regional Champions	Implementation	tba by Site Team Leaders

Example Methodology : Strategy to Sustainability



Example Project Delivery Methodology

- Understand the clients' business model, technologies and capabilities to develop a ***Strategy*** for compliance with serialization regulations in a timely fashion
- Deliver a ***Pilot*** phase to minimize project risk and ensure the solutions and processes being implemented are based on best practices
- ***Standardization*** of the solutions and processes based on Pilot success to be rolled out to the other sites, lines and business units.
- ***Integration*** with both internal and external supply chain partners based on a standardized integration framework to minimize risk
- The solution is then ***rolled-out*** to additional lines and sites requiring the capability to meet serialization requirements
- Development of a Serialization Center of Excellence to ensure long term ***Sustainability***

Serialisation As-Is Review

1. Strategy

- strategic initiatives
- critical elements and company topology
- current shape of the programme

2. Solution Implementation

- existing systems architecture
- process design
- capability
- organization governance

3. Internal Logistics

- internal logistics
- distribution systems
- warehouse

4. Partner Integration

- CMOs
- External Logistics / 3PLs

5. Coding and Master Data

- pack range
- coding
- artwork
- labelling
- master data
- other security features

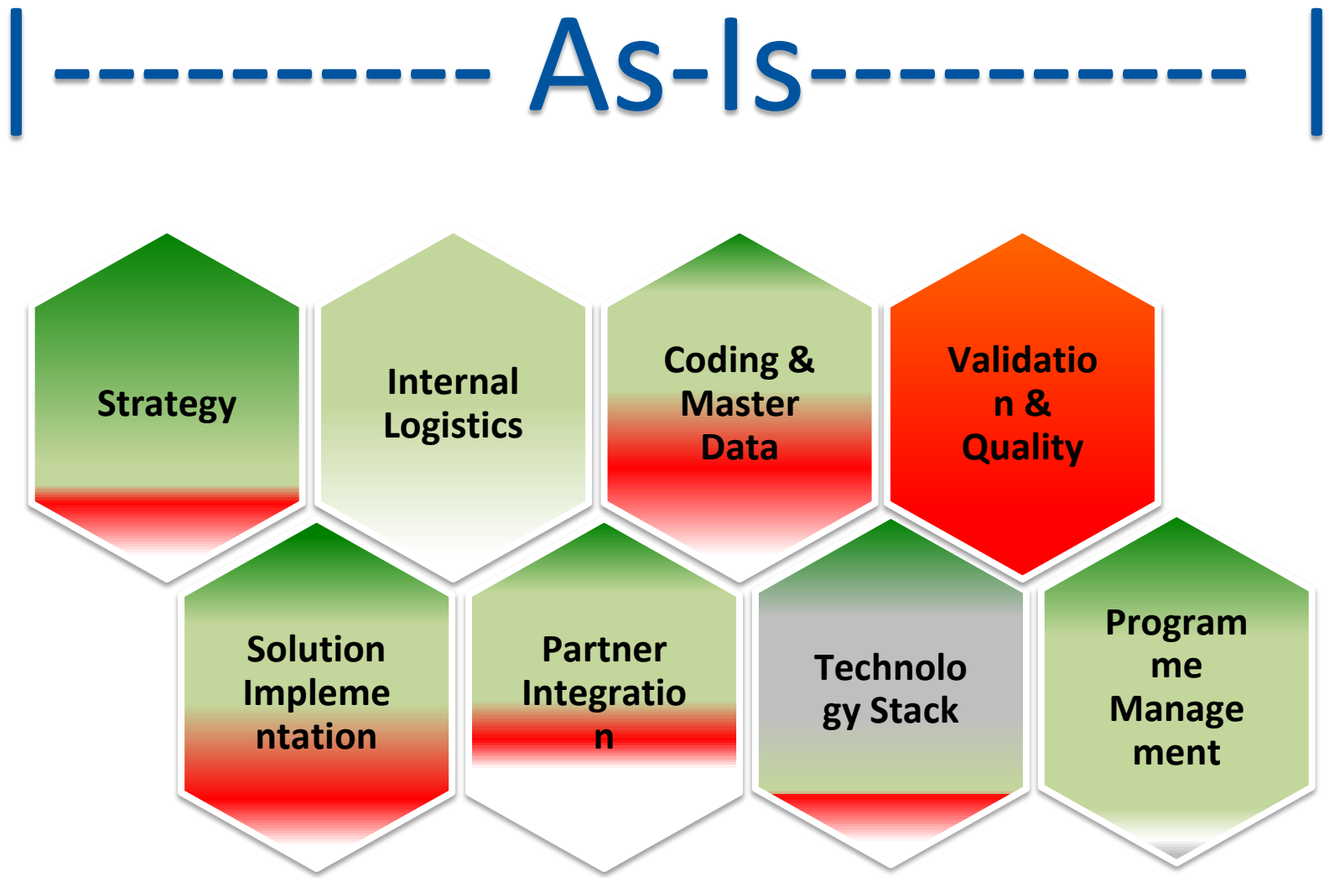
6. Technology Stack

- serial number management
- line engineering
- site level
- edge systems
- repository / EPCIS
- systems integration

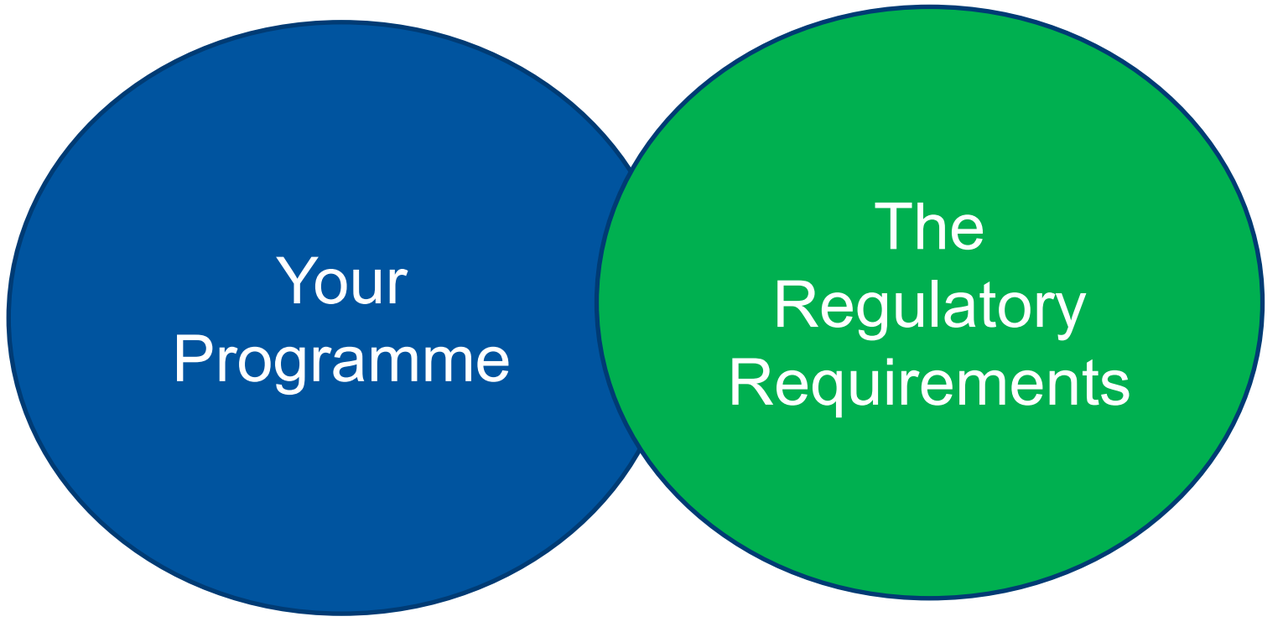
7. Validation / Quality

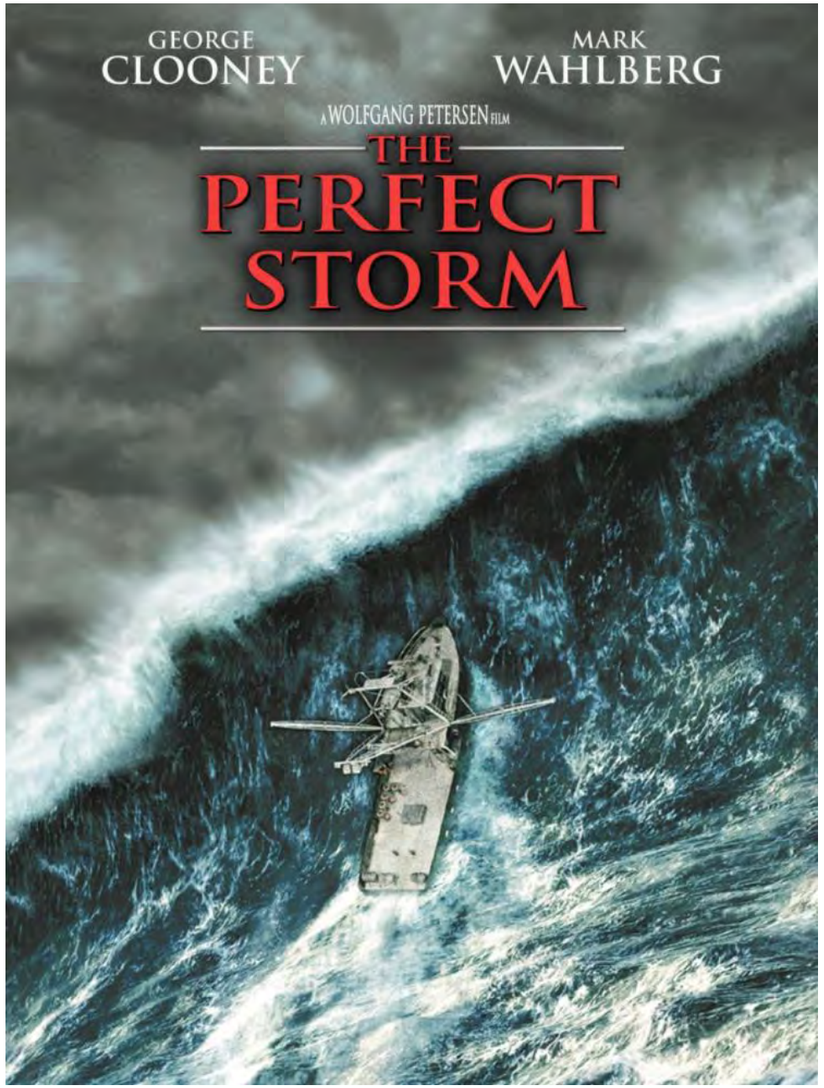
8. Programme Management

- project management
- risk management
- change management



What Goes Wrong?





What Goes Wrong - Engaging your Senior Stakeholders

What Goes Wro

Patient Journey = Program Journey

What Else Goes Wrong…

- Conflicting priorities
- Misunderstanding the scale and scope of the programme
  - Underestimating resource requirement – people, capital, capacity, time
- Master data management problems
- Lack of strategic clarity
- Failing to address the external supply chain in time
- Poor/limited regulatory understanding
- Unknown unknowns...

What Else Goes Wrong…Regulatory Issues

- **Poor understanding of the real supply chain**
- **Timescales for implementation**
  - Big bang
  - Phased roll out - roadmap
  - Long vs short lead times
- **Too many stakeholders under one umbrella**
- **Changing direction**
  - China, India export, Brazil,
- **Over ambition**
- **Failure to pilot to shake issues out**

Agenda

- Background and Introduction
- Serialisation in Context
- Global Requirements
- Impact on Manufacturers
- Getting Started – a roadmap to success
- Want you want from your regulator – panel discussion

- **Dialogue – a partnership approach to delivering patient safety through securing the supply chain leading to...**
- **Regulations**
  - Effective - designed to tackle the identified risks
  - Comprehensive – address the activities of all supply chain participants
  - Achievable – clearly defined with realistic time phasing
  - To as great an extent as possible aligning with the emerging global standard
    - Allows available and proven technology solutions to be exploited
    - Reduces risk – rapid deployment and predictable cost
    - Builds on the experience of others
    - Facilitates the creation of capability that is useful in the wider context supporting industry ambition

Thank You !

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