Setting the Standard for Automation™

Serialisation

GS1 Standards in Healthcare

Standards

Certification

Education & Training

Publishing

Conferences & Exhibits

Siobhain Duggan

- Director of Innovation and Healthcare at GS1 Ireland
- Siobhain is currently working on a number of projects to promote the adoption of GS1 Standards for healthcare in Ireland
- The industry is leveraging GS1 Standards and the support of GS1 experts to prepare for the Medical Device regulation (Unique Device Identification (UDI)) and the Serialisation requirements for the EU falsified medicines directive

Agenda

- Introductions & Background
- European Falsified Medicines Directive (FMD)
- Overview of GS1 Standards
- Key Takeaways

In the news...

"Fake pharmaceuticals: Bad medicine"
--Economist, October 13, 2012

"U.S. has drug recall problem"
--ABC News, June 4, 2012

"17,000 die from medical errors"
--Deutsches Arzteblatt International, March 5, 2010

"Medical error is expensive for life"
--In2EastAfrica, January 22, 2012

Pharma Serialisation
A new challenge for the industry

Serialisation in the pharmaceutical industry is becoming a very important challenge, not only for the manufacturers but also for their packaging suppliers. According to the Directive 2011/62/EU, pharma companies have three years to implement a successful strategy in all their products to be distributed in the European Union. Similar regulations are in place today in India, China, Turkey and some other countries.

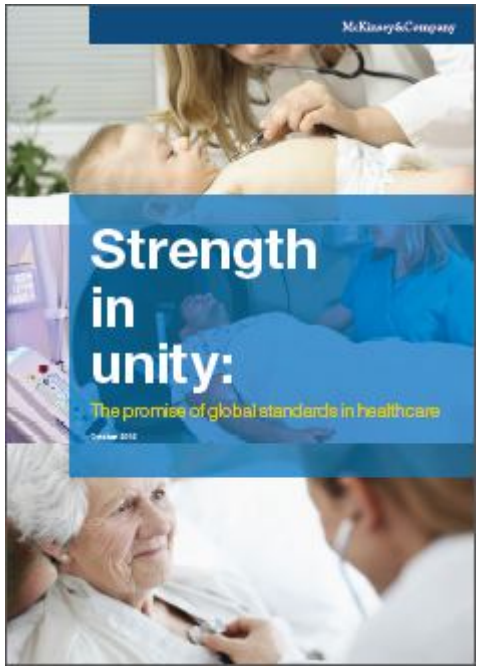
Counterfeiting a $200bn problem

EU FMD Compliance Deadline:

9th Feb 2019

International Pharmaceutical Industry, Summer 2013, Saul Serrano

McKinsey & Company report on benefits of a single global standard



"If there is a gap in supply chain security, someone will exploit it," concedes a VP for one of the major pharmaceutical manufacturers. "That's why every segment needs to be engaged. We need global interoperability if we're going to protect the entire value chain."

Source:
http://www.mckinsey.com

Available at:
http://www.gs1ie.org/healthcare

What are the regulators saying?

Medical Devices:
Unique Device Identification (UDI)

- (01) Product Code/GTIN
- (10) Batch
- (17) Expiry
- Serial number (where applicable)

Deadline for EU: 2018

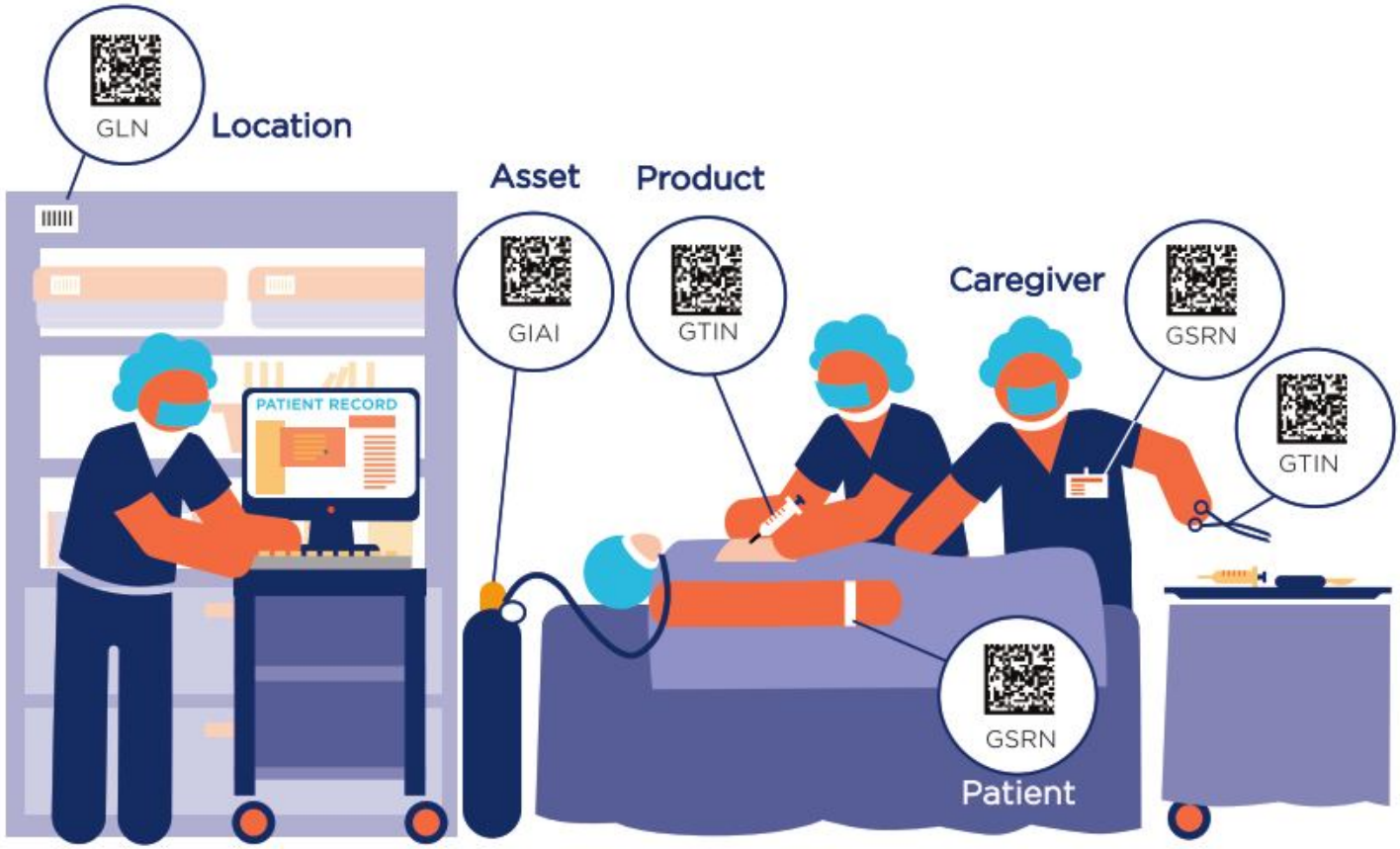
Note: FDA regulation exists for Class III and Class II/I, next deadline Sep 2016 Class II

Pharmaceuticals:
Falsified Medicines Directive (FMD)

- (01) Product Code/GTIN
- (10) Batch
- (17) Expiry
- (21) Serial Number

Deadline for EU: 9th Feb 2019

The Vision for healthcare
Traceability to the patient record



Interoperability based on standardisation

The Countdown to Serialisation for Pharma

GS1 Ireland Healthcare

EU Falsified Medicines Directive Delegated Act on 'Safety Features'

1. Technical characteristics of the **unique identifier (UI)** >>

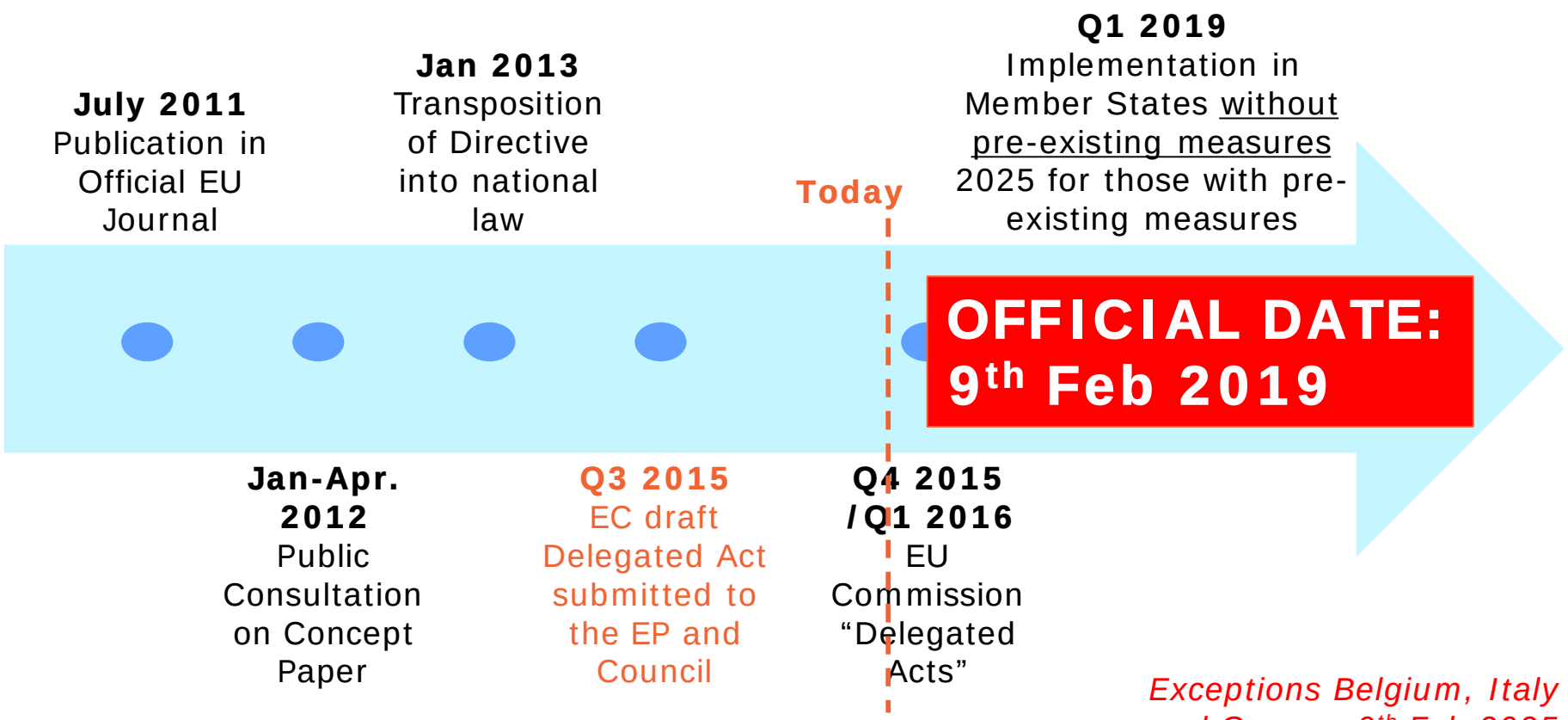
2. **Verification** of the safety features

1. Establishment, management and accessibility of the **repository system for the UI**

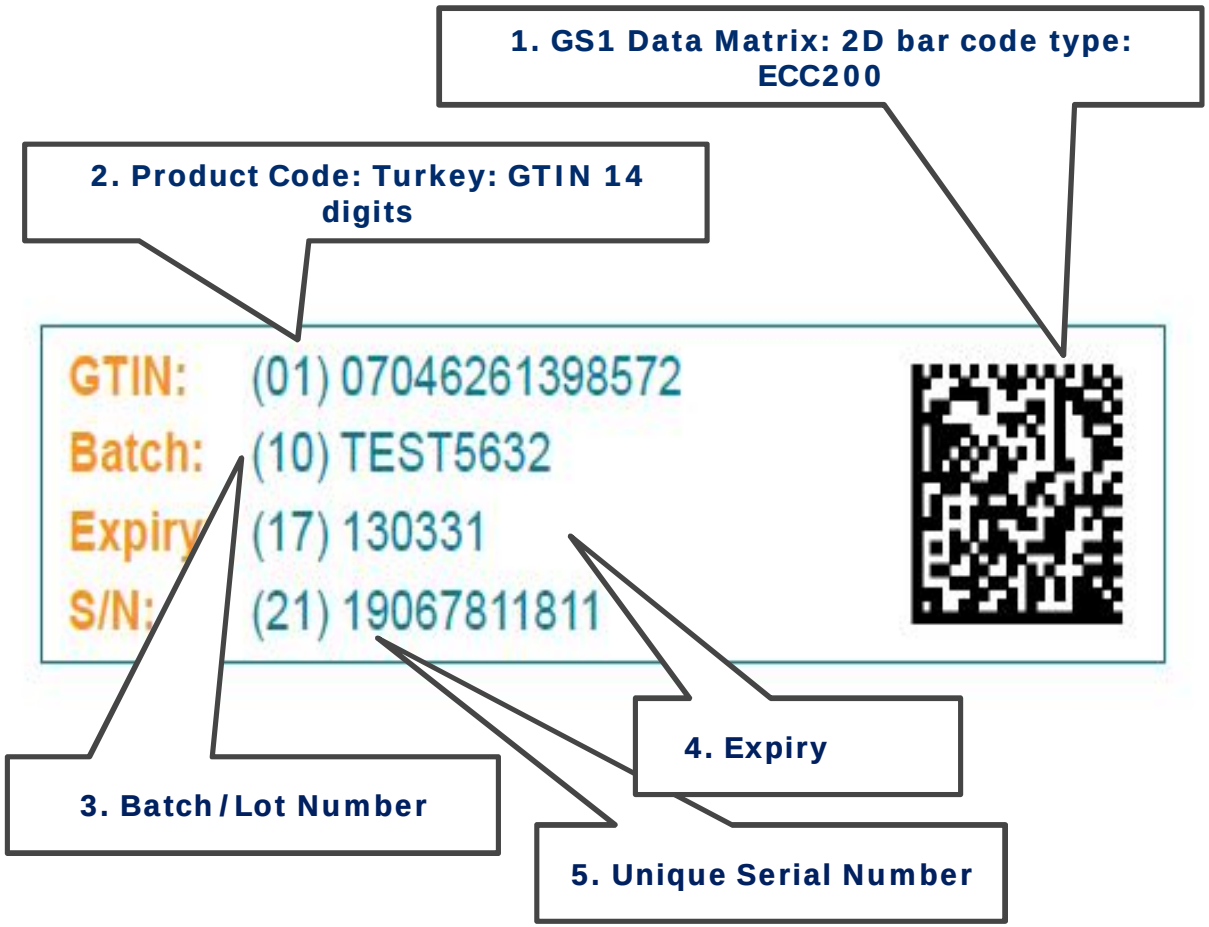
2. Lists of exceptions from bearing / not bearing the safety features

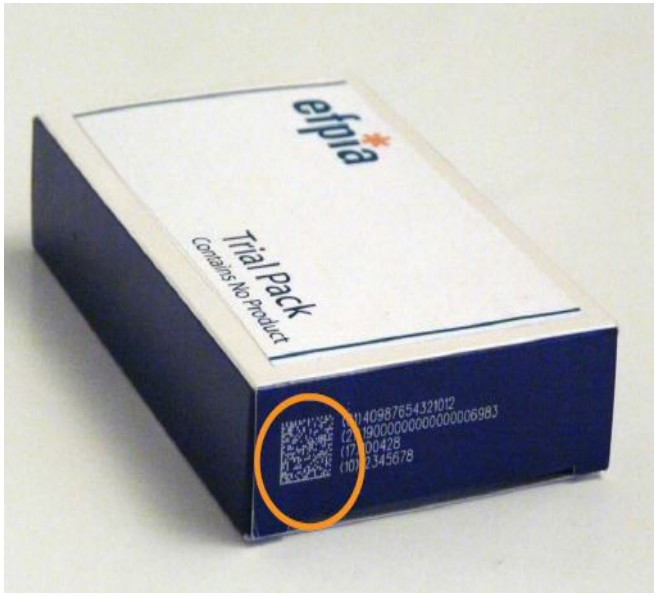
NOTE: The Act will NOT provide for:
Technical options for the anti-tampering device
(the choice of the most appropriate device will be left to the manufacturer)

EU Directive on Counterfeiting medicinal products - Timeline



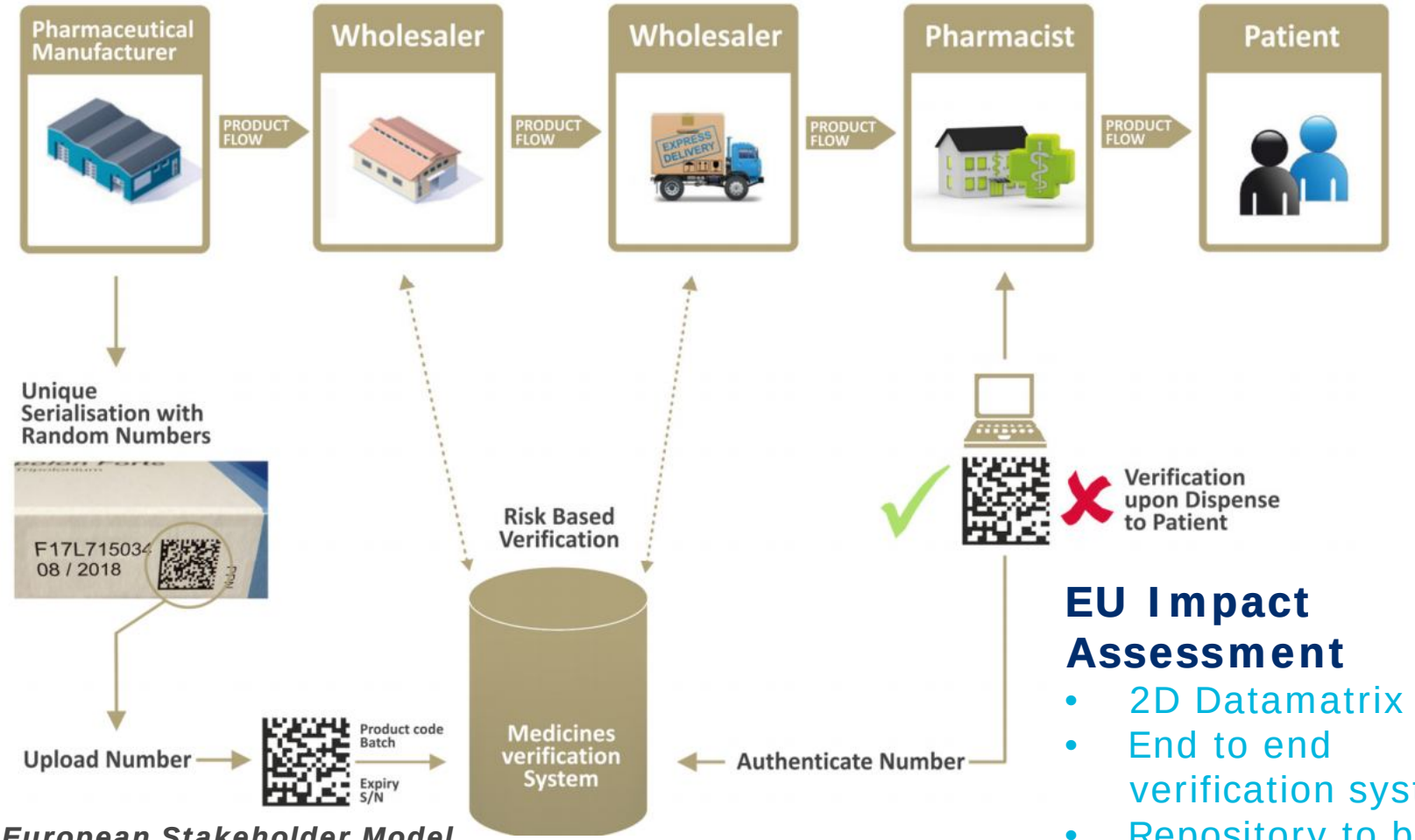
Typical Data Structure Proposed standardisation for EU Serialisation





Deadline for EU: 2019

ESM – Basic Concept
Point of dispense verification *source ESM*

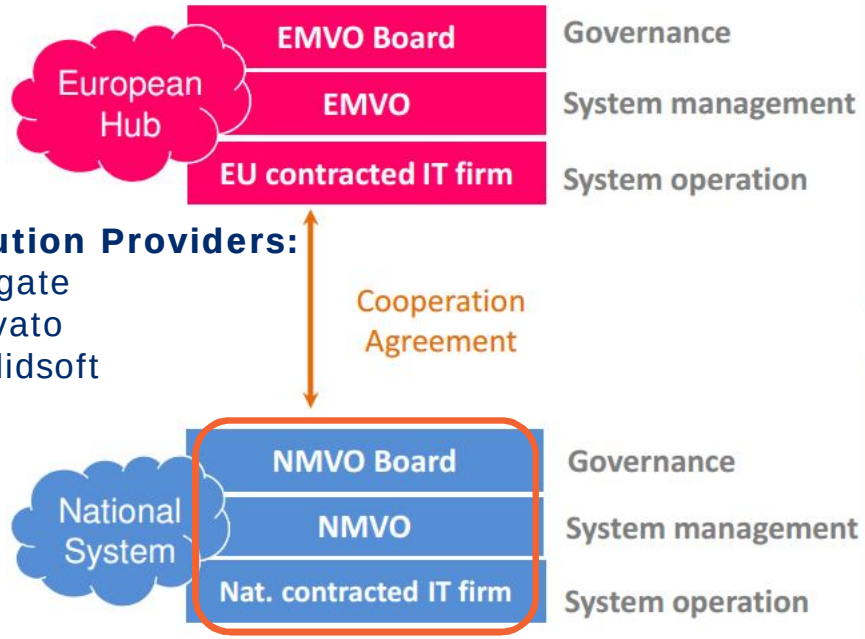


ESM = European Stakeholder Model

EU Impact Assessment

- 2D Datamatrix
- End to end verification system
- Repository to be setup and managed by stakeholders

EMVO & NMVO Governance and system management source ESM



3 Solution Providers:
- Aegate
- Arvato
- Solidsoft

EMVO

Remit

- Establish, manage and operate European Hub
- Ensure interoperability of connected systems
- Conclude agreements with NMVOs
- Set standards for the EMVS
- Manage 'national Blueprint' systems at request of national stakeholders

NMVO

Remit

- Establish and manage national system
- Ensure interoperability with European Hub
- Conclude agreement with EMVO
- Analyse exceptional events at national level

Expected to be required by Delegated Acts in combination with supervision by competent authorities

Benefits beyond Serialisation

- Assists in aggregation
- Reconciliation is a lot easier
- Recall is more effective
- Control and optimisation of processes
- PATIENT SAFETY benefits!!

Key thoughts to prepare for Serialisation

- Understand the identifiers and how they work
- Understand the 2D Datamatrix structure and the impact on your lines to move to serialisation
- Plan for the database export from your lines to the EU Repository
- Think about exception handling

GET READY for 9th Feb 2019

Overview of GS1 Standards

GS1 Ireland Healthcare

GS1 standards

GS1 standards are the global language of business …

a language for identifying, capturing, and sharing information automatically and accurately, so that anyone who wants that information can understand and use it, no matter who or where they are.

Identify: GS1 Identification Numbers

PRODUCT

GTIN®

Global Trade Item Number®

EPC*/SGTIN

Serialized Global Trade Item Number

LOGISTICS

SSCC

Serial Shipping Container Code

GSIN

Global Shipment Identification Number

ASSETS

GIAI

Global Individual Asset Identifier

GRAI

Global Returnable Asset Identifier

SERVICES AND OTHER

GSRN

Global Service Relation Number

GDTI

Global Document Type Identifier

Capture Data with GS1

BARCODES

EAN/UPC

Used on retail items that are scanned at point of sale.

GS1-128

Used on cases as well as large bulk items, such as pallets or logistics units.

ITF-14

Used on standard product groupings, such as a case of a particular product.

GS1 DataBar

Used on very small consumer items, such as loose produce.

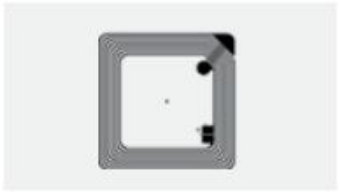
GS1 DataMatrix

Used for direct part marking of surgical instruments in the healthcare industry.

GS1 QR Code

Marketing information retrieved by a consumer from a POS product.

EPC-ENABLED RFID TAGS



HF RFID

Used for RFID systems operating in 13.65 MHz frequency.

UHF RFID

Used for RFID systems operating in 860 MHz–960 MHz frequency range.

Electronic Product Code (EPC)-enabled RFID tags carry a SGTIN or SSCC for item, case, or pallet level identification. They can be read quickly and easily without requiring line of sight and carry data that can be added to or modified as the tagged item moves through the supply chain.

SHARE DATA WITH GS1

MASTER DATA

GDSN

Global Data Synchronisation Network

The GDSN connects trading partners to the GS1 Global Registry® via GS1-certified Data Pools, enabling the immediate electronic sharing of standardised, up-to-date, accurate product information.

GLN REGISTRY

A GS1 GLN Registry is the single source of truth for accurate and up-to-date location information for entities and facilities in Ireland with their corresponding GLNs.

TRANSACTIONAL DATA

EDI

Electronic Data Interchange

EDI enables the computer-to-computer exchange of business documents between companies using a standardised format.

PHYSICAL EVENT DATA

EPCIS

Electronic Product Code Information Services

EPCIS is the standard for sharing information about the movement and status of goods in the physical world.

The benefits of GS1 standards implementation

GS1 was established by manufacturers and retailers to develop mutually beneficial standards and, for over 40 years, it has helped business communities in multiple industries to address supply chain challenges. It is a neutral not-for-profit organisation, which facilitates collaboration amongst trading partners, organisations, Government & its agencies and technology providers, leveraging standards to ensure visibility, efficiency and safety along the entire supply chain.

Visibility

Safety

Efficiency

Collaboration

GS1

International Standards Organisation

Global reach, local presence

- Not for profit, member driven
- 111 Member Organisations
- Close to 2 million member companies
- 150 countries served
- 20 sectors
- 2,000 people helping us

GS1 Ireland Advisory Services

- On-site implementation support and advice
- Implementation specification design and/or review
- Barcode Verification
- Training and Education
- Register for FREE Webinars

GS1 Solution Provider Programme

GS1 Ireland works with and accredits solution providers who are dedicated to Implement solutions based on GS1 Standards:

- To meet regulatory Requirements,
- Educate,
- And innovate

So GS1 Ireland's members can benefit from effective, scalable, interoperable solutions

SMI
SMART MANUFACTURING IRELAND

Smart Manufacturing Ireland

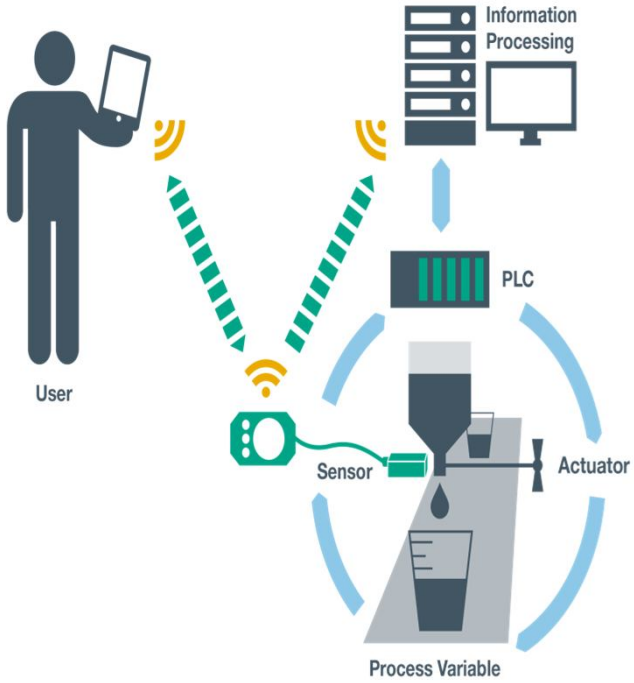
is an industry collaboration formed to help drive the adoption of Smart Manufacturing practices in Ireland and help maintain Ireland as a global leader in advanced manufacturing

GS1 Ireland · Rockwell Automation · Cisco · Hanley Automation factory automation experts · EMC² · SkillPad · Asystec Data Management Solutions

SMI Mission Statement

"To leverage the collective industry experience, technical certification, and use case solutions from the collaboration of advanced manufacturing solution partners.

- *Enabling the harnessing of the Digitalization opportunity*
- *Increasing revenue streams*
- *Improving profitability*
- *Ensuring optimized efficiency*



Key Takeaways

- Make a plan
- Talk to the experts
- Understand what compliance means for your organisation and your products
- Build a cross functional team
- Understand the IT implications and manage the timelines to being compliant
- Think about the patient safety benefits

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Key Takeaways for Software

- ✓ **Software Solutions** should be compliant with **GS1 Standards**
  - Ie: Include a field for **GTIN, GLN** and **traceability data**
  - **Review dataset** required to record product master data
  - Software needs to be capable of **interpreting data from within barcodes**
  - Software needs to be able to **resolve GTINs to material codes and hierarchies** (ie many GTINs to one material code)

- ✓ **Hardware** – new scanners should be 2D imagers

- ✓ **Products** should be labelled with GS1 compliant barcodes