Regulatory compliance using standards

Presentation to IEA Life Sciences Seminar

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Safer, more efficient care starts with a simple scan

The first scan in 1974 (45 years ago)

The very first item officially scanned for sale by its barcode was a multipack of Wrigley’s Juicy Fruit gum at Marsh Super Market in Troy, Ohio in 1974.
Patient Safety and Traceability today

State of the art medical technology VS Supply Chain Traceability from the Dark Ages
The Vision for Patient Safety

GS1 Traceability Standard

- Recall management
- Inventory management
- Purchase to pay
Regulation – a barcode for every product

Medical Devices: Unique Device Identification (UDI)
• (01) Product Code/GTIN
• (10) Batch
• (17) Expiry
• Serial number (where applicable)

Deadline for EU: May 2020
Note: FDA regulation already in place

Pharmaceuticals: Falsified Medicines Directive (FMD)
• (01) Product Code/GTIN
• (10) Batch
• (17) Expiry
• (21) Serial Number

Deadline for EU: 9th Feb 2019
Note: FMD Use and Learn period ends 31st Jan 2020 on phased basis
EU Falsified Medicines Directive
The Basics

Before FMD

Unique ID/GTIN encoded in an EAN-13

After FMD

GTIN Expiry Batch Serial#

Unique ID/ Same GTIN + additional data elements encoded in a GS1 2D Datamatrix

The Global Language of Business
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Unique Device Identification (UDI) the basics

Identify
- The Unique Identifier
  - UDI
    - DI (Device Identifier) Static Data
    - PI (Product Identifier) Dynamic Data

Capture
- The Barcode
  - AIDC
    - Machine Readable data carrier
      - Linear Barcode
      - Datamatrix
      - RFID

Share
- Product Data
  - Database
    - Device registration
  - US
    - GUDID – DI (GTIN)
  - EU
    - Eudamed- Basic UDI-DI and UDI/DI (GTIN)
# UDI in terms of GS1

<table>
<thead>
<tr>
<th>Identify</th>
<th>Basic UDI-DI</th>
<th>GMN (Global Model Number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Unique Identifier</td>
<td>« New » level of identification in the EU</td>
<td>No Application Identifier (AI) for regulated medical devices</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UDI-DI</th>
<th>GTIN (Global Trade Item Number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier (DI)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UDI-PI</th>
<th>AI (Application Identifier)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production Identifier (PI) (if applicable)</td>
<td>Application Identifier (AI)</td>
</tr>
<tr>
<td></td>
<td>• Expiration date AI(17) - e.g. 141120</td>
</tr>
<tr>
<td></td>
<td>• Batch - lot AI(10) - e.g. 1234AB</td>
</tr>
<tr>
<td></td>
<td>• Serial number AI(21) - e.g. 12345XYZ</td>
</tr>
</tbody>
</table>

*Production Identifier data will vary by medical device type and manufacturer current practice.*

<table>
<thead>
<tr>
<th>UDI-DI + UDI-PI = UDI</th>
<th>GTIN or GTIN + AI(s) = UDI</th>
</tr>
</thead>
</table>
Capture data using GS1 standards: Sample UDIs

When the UDI (DI) is a GTIN

- GTIN encoded in an EAN 13 barcode
- GTIN encoded in a GS1-128 barcode
- GTIN encoded in a GS1 DataMatrix

When UDI has dynamic data

- GTIN with Lot Number encoded in a GS1-128 barcode
- GTIN with Batch, Expiry and Serial Number encoded in a GS1 DataMatrix

Machine Readable data carrier
- Linear Barcode
- GS1 Datamatrix
Improving patient safety and traceability of infant feeds at Children’s Health Ireland at Temple Street
Special Feeds Unit – The Feeds
Based on prescription from Dieticians

A) Ready to pour feeds

B) Prepared feeds - basic to complex feeds

Very important that patient is given the right feed

Traceability is key to provide visibility
Electronic Traceability – the new process

**Before**
- Paper system, multiple manual recordings/batch
- Difficult to track
- Non-compliant to food safety standards
- 3 staff rostered/week

**After**
- GS1 Scanning App. Paperless, 2D code= one scan per movement
- Full visibility
- Traceability and compliance
- 2.5 staff rostered/week

Graphical representation:
- Feed Prep to Store room
- Dieticians place special feed order
- Multiple data capture points

Slainte Leanaí Éireann
Children's Health Ireland
@nch_info | ourchildrenshospital
Barcode identification is key to electronic traceability

Staff ID cards with unique barcode number for recording product movements

The hospital's standards Compliant serialised traceability labels

Patient ID

Not GS1 compliant yet

Standards compliant barcodes for every dispatch location
All products labelled with Serialised 2D barcode

*Titles are abbreviated or missing due to label size being limited and not to obscure any text on original product label.
Video and Case study now available!!

https://www.youtube.com/watch?v=PJKaLi1NMI4&feature=youtu.be
In Summary

• Get to know the regulatory requirements
• Traceability is an opportunity
• Design in the standard from the start – get advice
• Work with GS1 and learn from industry best practice
Resources

**Website**

www.gs1ie.org/Healthcare
- Case Studies
- News and information on upcoming training and events
- Webinars

**Newsletter**

- Subscribe for quarterly news updates and relevant announcements
  - d36.co/13CXh

**Twitter**

@GS1Ireland_HC
- Search @GS1Ireland_HC
- #GS1 #patientsafety

**LinkedIn Group**

GS1 Ireland Healthcare
- Relevant updates
- Community
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www.GS1ie.org
Key Track & Trace (GS1) projects in Ireland

National

- **Asset Registry**: National medical equipment asset registry
- **Patient ID**: IHI has a GS1 prefix
- **Instruments & Endoscopes**: 52 Hospitals
- **Haemophilia T&T**: Traceability to Patients home
- **Scan4Surgery**: Live in SJH
- **Location ID**: HSE Services Directory: Locations, Entities, Practitioners, Systems, Services
- **Procurement**: GS1 included in HSE tenders for Medical Devices
- **eProcurement**: GS1 enabling order to cash (Data and electronic messaging)
- **Automatic Tracking**: RFID tags to track Patient, Samples, Assets ...

Hospital Level

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