Agenda

• Introduction  Janice Kite, GS1 Global Office
• Case Studies
  • Manufacturer  Cyndi Poetker, Abbott
  • Distributor  Heather Zenk, AmerisourceBergen
  • Hospital  Feargal McGroarty, St James’s, Ireland
• Panel & Q&A Discussion
The GS1 System

IDENTIFY
GS1 Identification Keys & Attributes

- Product
  - Global Trade Item Number (GTIN)
  - Optional GTIN attributes such as lot number, serial number, expiration date
- Location/Legal entity
  - Global Location Number (GLN)
- Logistic unit
  - Serial Shipping Container Code (SSCC)
- Asset
  - Global Returnable Asset Identifier (GRAI)
  - Global Individual Asset Identifier (GIAI)
- Document
  - Global Document Type Identifier (GDTI)

CAPTURE
GS1 BarCodes and EPCglobal RFID

- EAN/UPC
- ITF-14
- GS1 DataBar
- GS1 DataMatrix
- EPC/RFID
- GS1-128

SHARE

- Master data
  - Global Data Synchronisation Network (GDSN)
- Transactional data
  - Electronic business messaging GS1 XML or EANCOM
- Physical event data
  - EPC Information Service (EPCIS)

Track
Trace
Authentication
Pedigree
Returns
Recalls

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GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production¹ to Point of Use²

• All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** (AI, e.g. Serial No. AI(21)), if applicable, at point of production

• Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life

• All **physical locations** are identified with the appropriate **GS1 Identification Key** (e.g. GLN) across the entire supply chain

• All **patients and care givers**, when in a care giving environment, are identified with the appropriate **GS1 identification Keys** (e.g. AI 8017; AI 8018)

• Agreed **master data** is captured and shared (e.g. via GDSN) amongst trading partners

• Agreed **transactional data** is captured and shared (e.g. via business-to-business messaging) amongst trading partners

• Agreed **event data** is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed

SO THAT:
GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production\(^1\) to Point of Use\(^2\)

**SO THAT:**

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time
- Item identification is available for use at patient bedside to ensure the Patient Rights\(^3\) are achievable
- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification
- Counterfeit products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective

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1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)...
2. The terms use or used can also mean consumed, infused, implanted, destroyed
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user
Traceability in Healthcare Phase I (TH-I)

DELCERVERED:

Global Traceability Standard for Healthcare (GTSH)

PUBLISHED 27th February 2009


GTSH Implementation Guideline

PUBLISHED 24th April 2009

Common themes

• Global Traceability Standard for Healthcare (GTSH) is a PROCESS Standard
• Definition of Traceability: both track & trace (downstream/upstream; forwards/backwards)
• Establishes the minimum model for traceability: “One up, One Down”
• In parallel with the flow of product there has to be a flow of information about the product
GTSH “One up, One down”

Information Flow

Flow of Info

Flow of Info

Flow of Info

Physical Flow

Flow of goods

Flow of goods

Flow of goods

Traceability Partner

Traceability Partner

Traceability Partner

Traceability Partner

Traceability Partner
Healthcare Traceability
Emerging Models
Pharma – Different emerging models... **US**

- **Driver:** To address counterfeiting: many actors in the supply chain, legitimate/illegal blurred
  - Numerous US States have enacted laws, e.g. Nevada, Florida
  - California most ‘notorious’ because it specifies an ePedigree Model (aka: Chain of Custody/Chain of Ownership)
  - Desire to identify and prosecute perpetrators
  - Enforcement date continuously pushed out, currently starts 2015

Could all be superseded by Federal Legislations due to be voted upon in next few weeks

Driver: Reimbursement Fraud; pharmacists claiming more than once for dispensed product

- Government developed and controlled, Centralised Track & Trace system (iTS)
- Enforcement date 2010, live 2+ years (the only live system globally!)
  - Phase 1: Manufacturers published data to MoH central database (2010)
  - Phase 2: Distributors (2012)
  - Future phases: ePrescriptions, Patient access
- ROI in ONE YEAR!
  - Reimbursement fraud eliminated
  - Examples of counterfeits being detected entering legitimate supply chain
  - Prosecutions…
Pharma – Different emerging models…Europe (1)

**Driver:** To address counterfeiting (falsified medicines), prevent them reaching the patient

- Two emerging (competing?) models: EDQM & EFPIA:
- **European Directorate for the Quality of Medicines & HealthCare (EDQM) eTACT**
  - Part of the Council of Europe; EDQM members 37 European countries, bigger than EU
  - Traceability from manufacture to the patient, ultimately given patients access to authenticate product
  - Developed and paid for by EDQM using GS1 EPCIS
  - Centralised for 37 member countries
Pharma – Different emerging models…Europe (2)

**Driver:** To address counterfeiting (falsified medicines), prevent them reaching the patient

- Two emerging (competing?) models: EDQM & EFPIA:
- Euro. Federation Pharma. Industries & Associations *(EFPIA) European Stakeholder Model (ESM)*
  - A pan-European end-to-end system enabling medicines to be verified at point of dispensing
  - Developed by the stakeholders who will use it on a day-to-day basis
  - Run on a non-profit basis; Costs to be borne by Manufacturing Authorisation Holders
  - Effective system expected in 2017
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3 Case Studies

- High level summaries
- Different points of supply chain
- Common themes
  - Implementation from receipt to patient takes time (YEARS)
  - Multi-project work programme
  - Involves all parties across the supply chain (inc. GS1 MOs)
  - Focus on solving key issues
  - All efforts have lead to improved patient safety
  - One size does NOT fit all!

http://www.gs1.org/sites/default/files/docs/healthcare/13_GS1_HC_RefBook2013_All.pdf
Implementation Reality - Traceability
AmerisourceBergen Corporation Case Study
AmerisourceBergen Corporation
GS1 Healthcare Global Conference
San Francisco, California, USA
Wednesday 2nd October 2013
AmerisourceBergen Corporation

- Publically traded $80B company
- Headquartered in Chesterbrook, PA
- 32 distribution centers throughout the US
- 25,000 SKU per distribution center with up to 75,000 SKU’s active in our network
- 750 – 1,000 manufacturer trading partners
- 60,000: pharmacy customers serviced
  - Retail, hospital, long term care, mail order, etc.
  - Next day delivery and same day delivery in some sites
Why we began implementing GS1 Standards

Drivers:

• Regulatory compliance with the state of California
• Regulatory compliance with the impending US Federal regulation
• Efficiency of doing business with our trading partners
• Data harmonization across multiple business units
What was your organisations trying to achieve?

**Goal:** Compliance with the California requirement  
(Complex data exchange is a component of this requirement)

We have been working on the public policy side since 2004, and this is on-going

Future projects are planned, e.g.
- Exception management
- Demonstrate data exchange capabilities using EPCIS
- Data harmonization
Where did you start? What benefits were realised?

We started with development and support of solution with our Executive Leadership.

We are in the process of building multi business unit master data (using GTIN and GLN).

Initial effort is 85% technology based.

To date we are too early on in our project to assess any benefits.
What did you learn? Recommendations for others?

Executive support is critical:
• Leadership must be aligned with goals, cost of project and pain points of the project
• Maintaining business focus across multiple business units

Internal Project Structure:
• Clearly define roles and responsibilities must be outlined for success

Continuous communication with trading partners is critical:
• One cannot function in a vacuum
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Case Study: 
The use of Serialised barcodes on Medication Packaging

Feargal Mc Groarty, Project Manager, 
National Centre for Hereditary Coagulation Disorders, St James’s Hospital, Ireland

GS1 Healthcare Global Conference 
San Francisco, California, USA 
Wednesday 2nd October 2013
St James’s Hospital, Dublin, Ireland

- St. James's hospital is an academic teaching hospital
- 1000 Beds
- National Specialties/Services, including
  - Haemophilia Services
- Supra-Regional Specialties/Services
- Regional Specialties/Services
- Catchment Specialties/Services
- The Hospital also focuses on 4 major cross-specialty programmes
Why we began implementing GS1 Standards

Catastrophic Event

Failure of Supply Chain- Haemophilia medication
Infection of patients with Hepatitis C and HIV due to contaminated blood products. Infected medication remained in the supply chain after recall - leading to subsequent infection

Over 70 people died in Ireland alone
What was your organisation trying to achieve?

**Goal:** Realtime track and trace including electronic recall of Haemophilia medication used for self treatment of patients at home

Improve patient medication recording compliance (budget of €50m for 200 patients)

The project was initially started in **2005**
Where did you start?

Adopt the Retail Track and Trace Model based on GS1 Standards
- Unique identification (barcode) of patient – PMGSRN
- Unique identification (barcode) of medication - Serialised GTIN
- Unique identification (barcode) of locations (Hospital/Home/Pharmacy/Transport) - GLN
What benefits were realised?

Validated Cold Chain delivery Service using Datamatrix Bar coding on medication packaging
• Since Cold Chain delivery started all products verifiably delivered between 2°C-5°C Celsius
• Documentation errors reduced from 12 to zero in the year immediately post service implementation
• € 5 Million worth of medication stock has been removed from the supply chain
• Stock rotation (based on barcoding) in 2011 saved €600,000 worth of stock
• Mock Recall identified location of all (100%) Medication within 10 minutes along with quantities of alternate stock available
• Patient smartphone App incorporating barcode scanning improves medication recording compliance and saves money
What did you learn?
Recommendations for others?

- Measures need to be implemented to ensure patient safety
- Measures need to be implemented to improve Supply Chain efficiency
- Barcodes work!
- Standardised bar-coding on packaging is the key
- Using the serialised GTIN, EPC and advanced shipping notice would dramatically improve supply chain efficiency and increase patient safety
- Technology already exists to help improve patient safety and reduce supply chain costs
- Identify a quick win (HPAC slide deck)
- Don’t reinvent the wheel!! Engage with GS1/HPAC community – Healthcare issues are local but also global!
Contact Details

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