Implementation Reality: Traceability in Healthcare

CHAIR:

Mark Davison

Blue Sphere Health

Agenda

	Session 1	Session 2
Introduction: Chair: Mark Davison, Blue Sphere Health	14:00-14:05	16:00-16:05

Traceability Today:
The GS1 Standards that enable Traceability
       Janice Kite, GS1 GO, Traceability Director   14:05-14:20   16:05-16:20
Standards Development for Event Based Traceability
Video http://www.gs1.org/healthcare/ebt_sc   14:20-14:40   16:20-16:40

Traceability Tomorrow:
How GS1 and traceability helps **3M** be a
better medical device company, Monica Kryzer   14:40-14:55   16:40-16:55

How **Novo Nordisk** use GS1 standards to build
traceability and how that helps achieve
better outcomes, Peter Egvang-Mardov & Steen Christiansen   14:55-15:10   16:55-17:10

Q&A   15:10-15:30   16:10-17:30
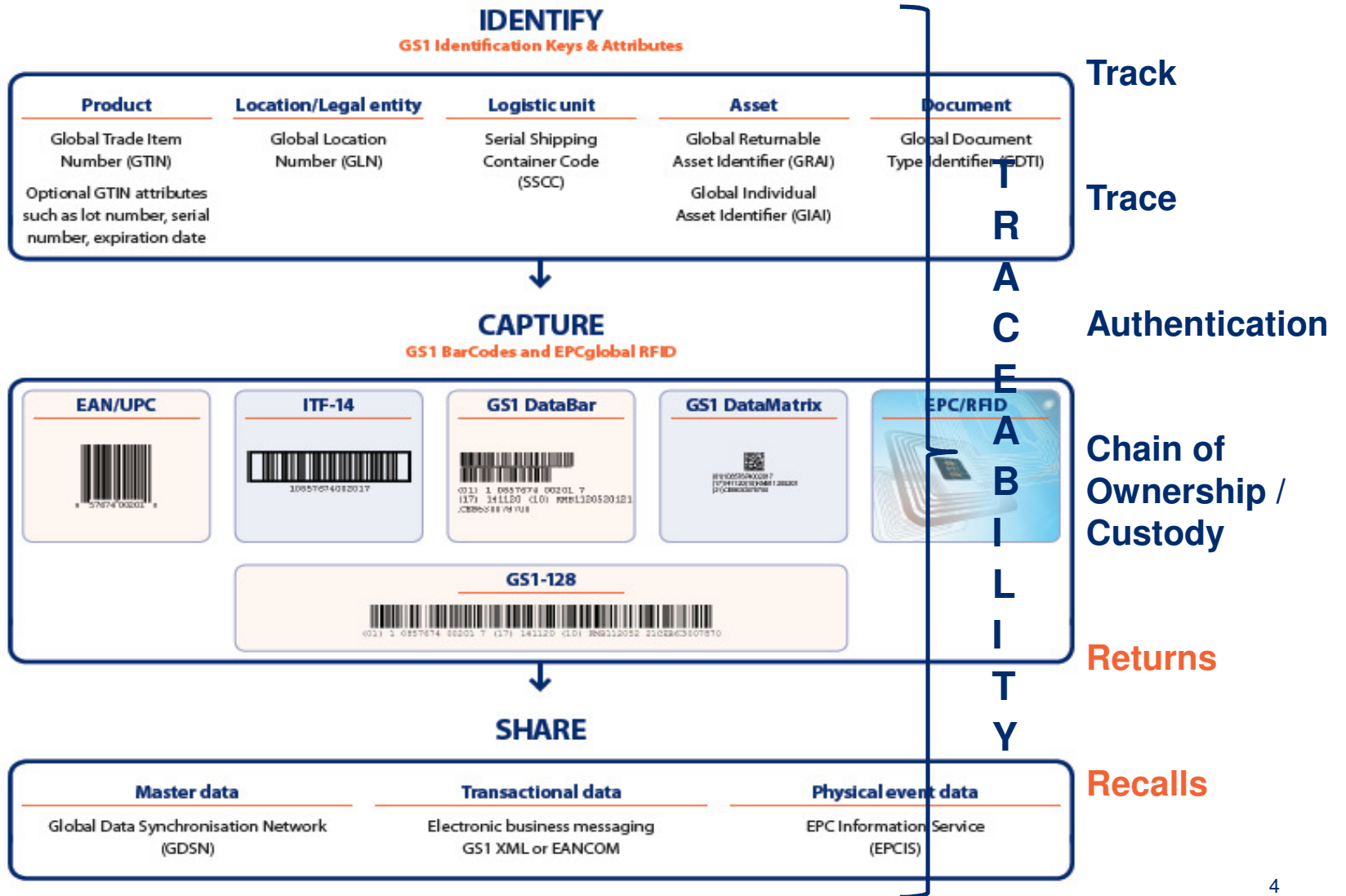
Traceability in Healthcare

Janice Kite
Traceability Director Healthcare
Global Office

The GS1 System

IDENTIFY
GS1 Identification Keys & Attributes

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

CAPTURE
GS1 BarCodes and EPCglobal RFID

EAN/UPC	ITF-14	GS1 DataBar	GS1 DataMatrix	EPC/RFID
57674 00201	10857674082017	(01) 1 0857674 00201 7 (17) 141120 (10) RN51120520121 /CEB65N67N7U8		

GS1-128

(01) 1 0857674 00201 7 (17) 141120 (10) RN0112052 21CEB63007570

SHARE

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

TRACEABILITY

- Track
- Trace
- Authentication
- Chain of Ownership / Custody
- Returns
- Recalls

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]

- 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 and appropriate **AI** (AI 8017, 8018, 8019)

- 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

SO THAT:

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

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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 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

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

Objective:

Ensure the GS1 System of Global Standards has both the process and technical standards necessary to achieve the GS1 Members Vision for Traceability in Healthcare

Approach: Two phases

TH-I - Process Standard - December 2007 to April 2009

TH-II – Technical Standards – April 2009 to date & ongoing

Traceability in Healthcare I (TH-I)

DELIVERED:

Global Traceability Standard for Healthcare (GTSH)
PUBLISHED 27th February 2009
http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf

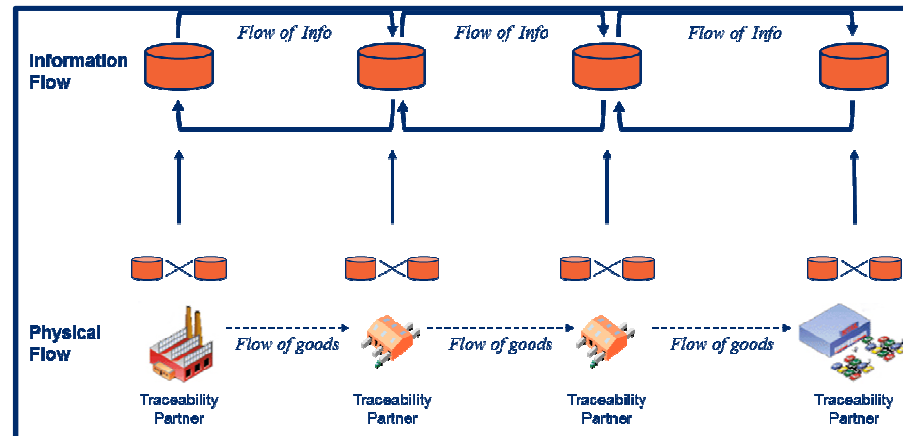### GTSH Implementation Guideline
PUBLISHED 24th April 2009
http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Implementation_Healthcare.pdf

Global Traceability Standard for Healthcare (GTSH) - **Common themes**

- PROCESS Standard

- Defines Traceability: both track & trace

- Defines foundational operational model:

  - **one-up / one-down**

  - Physical flow of product **has to be** in parallel to flow of info. about product

  - Inputs (eg receipt) must be linked to outputs (eg dispensing)

  - Parties can have varying roles

  - Business Requirements = Needs

  - Business Rules = control and/or constraints

Current Standards Development:
Event-Based Traceability with EPCIS foundation

Four dimensions of any EPCIS **event**:

- **WHAT** objects are the subject of event?

    *Individual objects (**SGTIN**) or groupings (**GTIN + Lot/batch**)*

- **WHEN** did this event take place?

    Date, time and time zone

- **WHERE** did this event take place?

    ***SGLN** of physical location & object's subsequent whereabouts*

- **WHY** did this event take place? *including...*
    - *Disposition (e.g., "expired", "recalled")*
    - *Source/Destination to indicate . . .*
        - *transfer of **ownership/responsibility/custody**,*
        - *intended party/location **endpoints** of the transfer*

Videos: http://www.gs1.org/healthcare/ebt_sc

Join: Link to Join MSWG: http://community.gs1.org/apps/org/workgroup/gsmppedsccsmswg/