Exchanging Traceability Data with EPCIS

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GS1

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EPCIS: a GS1 “Share” standard
EPCIS, a GS1 and ISO open standard

- defines interfaces for capturing & sharing data
- defines a framework data model for event data
- helps share visibility data across enterprises
- enables services & solutions for supply chain visibility
- GS1 Keys identify the “what” & “where” of visibility events...
  - ...encoded as data-carrier neutral EPCs
  - ...even when used with GS1 barcodes (instead of RFID)
- published as ISO/IEC 19987
Core Business Vocabulary (CBV)

- companion standard to EPCIS
- defines specific data values to populate EPCIS data model
- ensures a common understanding of data semantics
- anchors EPCIS events to business process context
- **critical to interoperability of EPCIS implementations**
- published as ISO/IEC 19988
EPCIS enables supply chain visibility

- **Tracking**
  *Where are the products we shipped?*

- **Tracing**
  *Where did this batch of products come from?*

- **Chain of Custody (CoC) / Chain of Ownership (CoO)**
  *Which parties had custody or ownership of these products?*

- **Inventory Management / Inventory Maintenance**
  *How many units are in stock? When does my available inventory expire?*

- **Recall**
  *Find all Product XYZ shipped from facility 4711 on 8 October 2018...*
The 4 data dimensions of an EPCIS event

• **What** objects are the subject of event?
  
  *Individual objects (GTIN + Serial Number = SGTIN)*

• **When** did this event take place?
  
  *Date, time, time zone*

• **Where** did this occur and where are the objects thereafter?
  
  *GLN of physical location*

• **Why** did this event take place?
  
  *Business step (e.g. “Shipping”) and Disposition (e.g. “in transit”)*
Egypt
Requirements to be released

**Status:** Decree on national track and trace system & Decision 29-2016 (18 April 2016)

**Scope:** only products registered as pharmaceuticals

**Requirements as applicable:**
POSTPONED deadline of 1 June 2018

New deadlines: by end 2018 T&T of at least one product and implementation plan (ie. detailed implementation timeline for printing two-dimensional barcodes on the rest of their products) for the rest

**Data Portal:** GS1 Egypt database on master data will be included in the MoH Database

**Open points/next developments:**
Updated version for Egypt Track & Trace Project Guidelines. It will be reviewed & discussed by industry prior to health agency announcement and implementation.

**Data sharing or registration methods:** EPCIS required

PP Database Dossier #: 606EGPH101004
Malaysia
Draft full T&T system

**Status:** draft requirements - announced on 5 October

**Scope:** pharmaceutical products

**Planned Requirements:**

- Phased implementation: starts in 2020 with scheduled poison products and the rest will be implemented in phases
- Primary level serialization is not required in the initial phases but will be required after full track and trace is implemented
- As of 2023: full implementation

**Data Submission Portal:** Centralised model will be used

**Open point(s)/upcoming dev.:**

- They will follow GS1 standards and follow globally harmonized approach
- They want to model their system based on Turkey since they believe that Turkey is the most successful implementation thus far

**Data sharing or registration methods:**

- **EPCIS** will be used for reporting to the central database

**PP Database Dossier #:** 458MYSPH181008
USA – DSCSA  
2015 to 2023

**Scope:** Pharmaceuticals (prescription drugs)

**Requirements as applicable:**

- Packaging level: saleable units and homogeneous cases
- Data elements: NTIN, Expiry date, lot/batch number, serial number
- Data carrier: 2D DataMatrix
- Serialisation: Nov. 2018

**Traceability Model:** full track & trace

**Data sharing:** US FDA points to EPCIS: **GS1 US Implementation Guideline:**

**Updates:**

- Product Identifiers (final):  
  [link](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf)
- Product Identifier Qs and As (for comment purposes):  
  [link](https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM621044.pdf)
- Guidance for Verification Systems requirements for drugs as part of US DSCSA.  

**Database Dossier #: 738USAPH140430**
GS1 Standards for DSCSA & Traceability
GS1 US Rx Guideline  www.GS1US.org/RxGuideline

• Describes how GS1 Standards can best be applied to pharmaceutical supply chain business processes to support traceability

• Supports collaborative supply chain traceability solutions

• Participation from over 50 pharmaceutical supply chain organisations

• Updated as necessary per requirements & industry feedback
  • V 1.0 (2012): satisfy California Pedigree regulations
  • V 1.1 (2014): align with DCSCA lot-level requirements
  • V 1.2 (2016): align with DSCSA item-level requirements
**EPCIS for Serialized Item-Level Traceability**

- Events are captured at instance-level (GTIN + Serial, SSCC)
- *Commissioning* events enable validation of serial numbers
- *Packing & Unpacking* events record packaging hierarchy
  - Aggregation of item -> case -> pallet
- DSCSA CoO transaction info integrated in *Shipping* event
- *Receiving, Dispensing, Decommissioning* events
  - record product lifecycle beyond DSCSA compliance
  - These events comprise Transaction Information (TI) & Transaction History (TH)
  - Transaction Statement (TS) is included in the EPCIS header
  - Single XML document containing all DSCSA-required information
Aggregation
Leveraging the EPCIS Aggregation Event

- Parent-Child logistical hierarchy
- Applied to a containing object and a set of contained objects
- Enables the practice of **inference**
- ADD an Aggregation (children aggregated to parent)
- OBSERVE an Aggregation (may be incomplete)
- DELETE an Aggregation (removal of subset or all children)
EPCIS events captured and shared by . . .

Party at beginning of the supply chain (e.g., manufacturer)
- Commissioning
- **Packing**
- Shipping

Intermediate parties (e.g., distributor)
- Receiving
- **Unpacking**
- **Packing**
- Shipping

Party at end of chain (e.g., pharmacy)
- Receiving
- **Unpacking**
- Dispensing
- Decommissioning
Process Flow Example
Designing a Visibility System using EPCIS

<table>
<thead>
<tr>
<th>Factory</th>
<th>Warehouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicle</td>
<td>Transport container</td>
</tr>
<tr>
<td>Container</td>
<td>Receive pallet</td>
</tr>
<tr>
<td>Pallet</td>
<td>Unload pallet from container</td>
</tr>
<tr>
<td>Case</td>
<td>Load pallet into container</td>
</tr>
<tr>
<td>Item</td>
<td>Pack cases onto pallet</td>
</tr>
</tbody>
</table>

- **Commission item SGTIN**
- **Commission case SGTIN**
- **Pack items into cases**
- **Pack cases onto pallet**
- **Load pallet into container**
- **Unload pallet from container**
Designing a visibility system using EPCIS

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps
Process Flow Example
Designing a Visibility System using EPCIS

**Vehicle**
- V1: Commission item SGTIN
- V2: Commission case SGTIN
- V3: Pack items into cases
- V4: Pack cases onto pallet
- V5: Load pallet into container
- V6: Transport container
- V7: Receive pallet

**Warehouse**
- V3: Commission pallet SSCC
- V5: Pack cases onto pallet
- V6: Load pallet into container
- V7: Unload pallet from container

The Global Language of Business © GS1 2018
Designing a visibility system using EPCIS

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps
4. Decide which business steps require visibility events
5. Model completion of each step as a visibility event
6. Decide which data to include in the visibility event
Designing a visibility system using EPCIS

1. Collect visibility goals and requirements
2. Document business process flows
3. Break each process flow into series of discrete steps
4. Decide which business steps require visibility events
5. Model completion of each step as a visibility event
6. Decide which data to include in the visibility event
7. Determine vocabularies to populate each data field
8. Document visibility events in a visibility matrix
## Visibility Data Matrix

### Designing a Visibility System using EPCIS

<table>
<thead>
<tr>
<th>Event</th>
<th>What</th>
<th>When</th>
<th>Where</th>
<th>Why</th>
</tr>
</thead>
<tbody>
<tr>
<td>V1</td>
<td>Identifiers</td>
<td>GTIN &amp; Serial (SGTIN) of item</td>
<td>24 Sept 2018, 11:27 CEST</td>
<td>Packaging line 47</td>
</tr>
<tr>
<td>V3</td>
<td>Identifiers</td>
<td>SGTINs of items into SGTIN of case</td>
<td>24 Sept 2018, 14:09 CEST</td>
<td>A-frame 21</td>
</tr>
<tr>
<td>V5</td>
<td>Identifiers</td>
<td>SGTINs of cases into SSCC of pallet</td>
<td>25 Sept 2018, 10:24 CEST</td>
<td>Palletiser 2</td>
</tr>
<tr>
<td>V6</td>
<td>Identifiers</td>
<td>SSCC of pallet</td>
<td>25 Sept 2018, 15:19 CEST</td>
<td>Dock door 11</td>
</tr>
</tbody>
</table>
Why align with EPCIS?

- EPCIS provides a standardised way of exchanging and requesting traceability event data in a way that enables the business context to be communicated.

- EPCIS is an open standard supported by an increasing number of implementations and software products.

- EPCIS and its companion Core Business Vocabulary (CBV) are designed to be applicable across multiple industry sectors.

- EPCIS and CBV are recognized as ISO/IEC standards:
  - EPCIS = ISO/IEC 19987
  - CBV = ISO/IEC 19988
What is EPCIS?

EPCIS is . . .

• an open GS1 & ISO technical standard
• an enabler for traceability solutions & services
• data-carrier-neutral, suited to GS1 DataMatrix

EPCIS is not . . .

• an out-of the box solution
• a standalone answer to visibility issues

Serialization & event-based visibility will fundamentally change supply chain precision... EPCIS will support this!
Resources: GS1 Standards & Guidelines

- EPCIS & CBV
  www.gs1.org/epcis

- EPCIS & CBV Implementation Guideline
  www.gs1.org/docs/epc/EPCIS_Guideline.pdf

- EPC Tag Data Standard (TDS)
  www.gs1.org/epc/tag-data-standard

- GS1 US DSCSA Guideline
  www.gs1us.org/RxGuideline
For further info on EPCIS...

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