Healthcare Supply Chain Integrity enabled by EPCIS

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Although counterfeits are becoming increasingly common, it is difficult for counterfeiters to fabricate a convincing information trail of the provenance of such products that lead all the way back to the manufacturer. The use of such an information trail is the basis for traceability legislation in numerous regulatory jurisdictions around the world, which aims to prevent counterfeit products from proceeding within legitimate supply chains.

Healthcare supply chain stakeholders require provision of, and secure access to, transaction and product movement information, in order to reliably document Chain of Custody (CoC) and Chain of Ownership (CoO) for supply chain security, while ensuring compliance with emerging regulations.

Event-based traceability

EPCIS is an open standard which allows businesses to capture and share supply chain information about the movement and status of goods, both within their enterprise and with their business partners. Such movements or "events" comprise four dimensions:

1. **What** products are impacted?
2. **When** did this time-stamped event occur?
3. **Where** was the product, where is it now?
4. **Why** was this observed, which process step?

EPCIS makes it possible for healthcare trading partners to satisfy regulatory requirements for Chain of Custody and Chain of Ownership, while at the same time leveraging the resulting supply chain visibility to improve operational efficiency and increase supply chain security.

GS1 EPCIS

EPCIS is a GS1 standard for capturing and communicating data about the movement and status of products, logistics units and other assets in the supply chain. It enables trading partners to capture event information about objects as they move through the supply chain, and to share this information with authorised trading partners. EPCIS defines technical standards for a data-sharing interface between applications that capture event information, and applications that need access to such information.

GS1 EPCIS, an ISO/IEC approved standard

EPCIS is published as ISO/IEC 19987.

EPCIS is data-carrier neutral

EPCIS can be used with data captured from scanned GS1 barcodes and GS1 EPC/RFID tags alike.

Benefits of open standards

Alignment with the global open standard EPCIS will lower the costs of deployment of traceability systems for trading partners and their solution providers. EPCIS is increasingly deployed in sectors such as healthcare, fresh foods, apparel, and rail, to improve efficiency in areas ranging from inventory management through loss prevention to consumer and patient safety. This, in turn, lowers adoption costs for users in all sectors through economies of scale in software solutions. EPCIS is supported by commercial implementations from major software vendors.

Multiple use cases

EPCIS caters for numerous business use cases that may be encountered by products in the supply chain, including but not limited to:

- Drop shipments
- Repackaging
- Kitting
- Recalls and withdrawals
- Returns

Custody & Ownership

The identification of source and destination provides additional information pertaining to the transfer of custody and/or ownership. For shipping events, the source field can identify the party who currently has custody or ownership, while the destination field can indicate the recipient party expected to receive either custody or ownership. For receiving events, the source field can indicate the party who previously had custody or ownership, while the destination field can identify the party that has taken custody or ownership.

"Using GS1 standards like EPCIS to support serialisation and track & trace will be key in securing the healthcare supply chain while complying with emerging regulations worldwide. This will be foundational in enabling the healthcare community to comply with the U.S. DSCSA, minimising opportunities for contamination, adulteration, diversion, or counterfeiting of pharmaceutical products."
Lloyd Mager, Global Track & Trace Lead at AbbVie

Serialised & lot-based ID

EPCIS is used to capture and share the provenance history of product instances, tracked at serial-level granularity or batch – lot level. This is a critical capability that will assist industries in migration to serialisation and track & trace.

Monitor product status

The "Disposition" field of EPCIS events can be used to indicate the status of tracked objects, such as:

- In transit
- Retail sold
- Expired
- Damaged
- No pedigree match
- Recalled

Real time updates on product and shipment can be extremely valuable to stakeholders' business intelligence. It enables trading partners to manage inventory, receive shipments, or take corrective action for exception handling, in a more proactive and efficient way.

Regulatory compliance

EPCIS will serve as an important foundation for ensuring regulatory compliance and continuity of product flow through supply chains, in healthcare for example, patients continue to receive lifesaving treatment.

Such regulations include, but are not limited to, those specified by the U.S. Drug Supply Chain Security Act (DSCSA). The same EPCIS data can be leveraged to enable traceability in multiple regulatory jurisdictions.

EPCIS enables end-to-end traceability of healthcare products and their Chains of Custody & Ownership

Acme
manufacturer

What: Acme Painkiller Extra
GTIN: 00300010123455
Serial: 10000000001

When: June 10, 2014, 15:55 EDT

Where: Acme Plant #49
GLN: 0300011111116

Why: Commissioning

Disposition: active

Smith's
distributor

What: logistics unit
SSCC: 003210112345678908

When: June 11, 2014, 17:29 EDT

Where: Smith's DC# 47
GLN: 0321011246530

Why: Shipping

Disposition: in transit

Source: Smith's DC# 47
GLN: 0321011246530
Party has Custody

Destination: University Clinic
GLN: 0399999999991
Party will have Ownership

University Clinic
provider

What: Acme Painkiller Extra
GTIN: 00300010123455
Serial: 10000000001

When: June 13, 2014, 08:22 EDT

Where: University Clinic
GLN: 0399999999991

Why: Unpacking

Disposition: in progress

GTIN: Global Trade Item Number (unique identification of products)
GLN: Global Location Number (unique identification of physical locations)
SSCC: Serial Shipping Container Code (unique identification of logistics units)

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all healthcare supply chain stakeholders, including manufacturers, distributors, healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies. GS1 Healthcare members include over 70 leading healthcare organisations worldwide.

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