The Global Language of Business

Discussion paper

RFID on Healthcare products

This non-normative document is intended as an initial high-level compass and roadmap of considerations.

Audience

This discussion paper is aimed at **manufacturers of healthcare products** (pharmaceuticals and medical devices) and hospitals which dispense those products, as well as their systems integrators and solution providers, who may be considering deployment of RFID in alignment with GS1 standards.

Objective

This discussion paper is intended to provide **guidance on how to use GS1 Standards if a manufacturer of healthcare products chooses to deploy RFID technology**. This guidance is intended to apply to any level of packaging – not only regulated levels. This document is NOT intended to encourage RFID application on healthcare products – nor to encourage serialisation of products below the lowest regulated unit.

Due to regulatory requirements, trading agreements and/or internal supply chain management processes, industry practices in deploying RFID may vary from the recommendations in this paper.

This paper does not address implementation of any specific regulatory requirements. Such requirements include, but are not limited to, the issue of regulatory triggers.

Locally applicable **regulations** (e.g., **UDI,** national traceability regulations, etc.) **should always be consulted** to ensure compliance and determine nuances which could require locally specific identification, labelling, encoding and data sharing practices.

Executive Summary

- **Most regulations on pharmaceutical traceability and medical device identification require barcodes as the primary data carrier**. A small number of these regulations allow RFID as an optional, secondary data carrier, while almost none allow RFID as the primary carrier.
- **RFID requires serialisation**.
- The SGTIN EPC is specified by GS1's EPC Tag Data Standard (TDS) to represent the combination of GTIN and Serial Number – AI(01) and (21) – on RFID tags.

Step 1:

Assess applicable regulatory requirements for product identification and marking

The first point of reference is regulations for both medical devices and pharmaceuticals.

All healthcare product identification, labelling and encoding practices will need to comply with relevant identification and data carrier regulations applicable.

Locally applicable regulations should always be examined in detail and serve as the foundation of functional requirements. This helps to ensure compliance and determine nuances which could require locally specific identification, labelling, encoding and data sharing practices.

One reason for the slow pace of adoption of RFID on healthcare products is the fact that **most regulations for traceability of pharmaceuticals and identification of medical devices require barcodes as the primary data carrier**. A small number of these regulations allow RFID as an optional, secondary data carrier, while almost no regulations allow RFID as the primary carrier.

In regulatory jurisdictions where barcodes are required as the primary data carrier, additional data carriers serve as optional carriers that are not used to satisfy regulatory requirements, instead serving a different use case (e.g., ease of scanning, inventory accuracy, etc.). In such cases, additional data carriers are essentially "invisible" to the regulator.

Note that some jurisdictions may regard the addition of a secondary data carrier (e.g., a RAIN RFID tag) as a change in labelling or packaging, automatically necessitating a NEW identifier. For more details on such "trigger" rules, market authorisation holders (MAH) should consult the locally applicable regulations.

For further details, see GS1's ***Regulatory Roadmap: Traceability of Medicinal Products*** .

Step 2:

Assess which GS1 identifiers are currently used, regardless of data carrier

GS1's portfolio of standards is often grouped into three inter-related pillars:

- Identify (focus: primary identifiers, known as GS1 "Keys", as well as supplementary information, known as “Application Identifiers” or “AIs”)
- Capture (focus: data carriers, i.e., the various GS1 barcodes and EPC Gen2 RAIN RFID tags)
- Share (focus: master data, EDI-based transactional data and EPCIS-based visibility event data, Global Data Synchronisation Network - GDSN)

It's important to **address the "Identify" aspect first**, before moving on to "Capture" and "Share".

In the context of regulated healthcare products, the proper product identifier is a Global Trade Item Number (GTIN). For product identification purposes, the **GS1 Healthcare GTIN Allocation Rules** apply. The GS1 Healthcare GTIN Allocation Rules are data-carrier-neutral and are not restricted to barcodes.

A GTIN can be used by a company to uniquely identify all of its trade items. GS1 defines trade items as products or services that are priced, ordered or invoiced at any point in the supply chain. The GTIN can be used to identify types of products at any packaging level.

A Batch/Lot number is specific to a given GTIN and identifies a grouping of products as a subset of that GTIN.

In conjunction with a GTIN, a Serial Number identifies an individual instance of a product uniquely.

For traceability of medicines or for identification of certain types/classes of medical devices, regulations almost always require serialisation

Different data carriers on the same product need to carry the same information. Supply partners can decode GS1 identifiers from any of the GS1 data carriers without having to rely on specific bilateral instructions or proprietary interpretation.

Step 3:

Encoding GS1 Identification Keys and other GS1 AIs on RAIN RFID tags

Unlike GS1 barcodes, **RAIN RFID tags require serialisation**.

A GTIN to be encoded on a RAIN RFID tag must be paired with the Serial Number – AI (21) – and encoded as an SGTIN EPC.

Different forms of the SGTIN and several other Electronic Product Code (EPC) encoding schemes, based on unique GS1 identification Keys, are **normatively specified in GS1's EPC Tag Data Standard (TDS).**

Depending on encoding needs, the specific SGTIN EPC scheme encoded on a RAIN RFID tag could be an:

- SGTIN-96 (limited serialisation capacity)
- SGTIN-198 (supports full interoperability with AI 21)
- SGTIN+ (supports full interoperability with AI 21)

Please see the latest version of **GS1's EPC Tag Data Standard (TDS)** – currently TDS 2.0 (published in August 2022) – for **detailed normative specifications** on the individual EPC encoding schemes mentioned above.

TDS 2.0, published in August 2022, simplifies support for OPTIONAL encoding of supplementary GS1 AIs (e.g., Expiry Date, Lot/Batch Number), where required. The standard also includes support for optional encoding of supplementary AIs in a different part of tag memory ("User Memory"), standardised in 2010 and in some pharmaceutical applications today.

Encoded data intended for open supply chain applications should be interoperable and consistent across GS1 data carriers. The GTIN and Serial Number, respectively encoded as GS1 Application Identifiers (01) and (21) in a GS1 barcode, should be encoded according to TDS on RAIN RFID tags as one of the SGTIN EPC schemes listed above. This is critical to ensure that the DECODING of RAIN tag data allows for the lossless re-creation of AI (01) and (21).

Considerations around downstream tagging

Product whose manufacturer barcodes include a serial number, AI (21)

Unless prohibited by applicable regulations or by the brand owner / MAH, downstream partners applying RAIN RFID tags to non-source-tagged product should encode one of the SGTIN EPC variants to ensure interoperability between GS1 barcodes and RAIN RFID tags.

NOTE that the Serial Number, AI (21) is specific to a given GTIN, AI (01) and can only be assigned by the brand owner / MAH who assigns the GTIN, or by a 3rd party acting as the agent (or CMO) of the brand owner / MAH.

The brand owner / MAH is responsible for issuing and managing each Serial Number – AI (21) for each of these products.

It is at the discretion of the brand owner whether to include supplementary "AIDC data" -- e.g., Lot / Batch number, AI (10), or Expiration date, AI (17) -- that appears in the barcoded GS1 element string on the RFID tag, as well. GS1's EPC Tag Data Standard (TDS) provides details on how to encode such information.

Product whose manufacturer barcodes do NOT include a serial number, AI (21)

Downstream partners applying RAIN RFID in the absence of a brand owner / MAH issued Serial Numbers SHALL NOT issue AI (21) corresponding to the GTIN assigned by the MAH, and SHALL NOT create SGTIN EPC encodings based on the MAH's GTIN.

This GS1 Healthcare discussion paper will be updated to incorporate new GS1 standards, as appropriate.

Takeaway:

Summary of high-level guidance on the use of GS1 identification standards where RAIN RFID is used in Healthcare

- If the product brand owner has assigned GTIN and Serial Number – AI (01) and AI (21) – at a given packaging level, these can be encoded as an SGTIN EPC
- If the product brand owner has not assigned Serial Number at a given level, this necessitates 3rd party downstream serialisation. In this scenario – without the authorisation of the brand owner and the corresponding exclusive allocation of a range or set of AI (21) serial numbers for that GTIN to each 3rd party downstream who applies serialisation– the brand owner's GTIN cannot be used.
- GS1 plans to develop guidelines to help users encode TDS-compliant data on RAIN RFID tags in cohesion with GS1 Healthcare GTIN Allocation Rules and other GS1 HC standards.
- In the absence of currently applicable regulations recognising and specifying data encoding requirements for RFID, any deployment of RFID runs the risk of misalignment with future regulations.
- This GS1 Healthcare discussion paper will be updated to incorporate new GS1 standards, as appropriate.