

The Global Language of Business

Standards and Sensors for Visibility in the Pharmaceutical Cold Chain

Whitepaper

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# **Executive Summary**

The pharmaceutical cold chain has seen rapid developments in sensor technologies. With a greater number of critical drug treatments requiring shipping and storing in uninterrupted cold conditions, from manufacture all the way to patient administration, full visibility into the product's entire journey, including problematic events like temperature excursions, helps ensure product quality and patient safety. However, there are blind spots in the cold chain. A solution could be the implementation of compatible sensor configurations and standardized data-sharing processes.

This paper will explain how GS1 Standards and sensor technologies can work together to provide visibility and interoperability for a variety of cold chain configurations and beyond. Collaboration between standards and technology can provide the foundation for an interoperable future state where full end-to-end visibility into a product's cold chain journey becomes possible.

Solutions could monitor if a product's temperature remains within the acceptable threshold and quickly deliver that assurance along the supply chain so patients can trust their medicine. From RAIN RFID\* and Bluetooth Low Energy (BLE) to low-power wide area networks (LPWAN) to Global Positioning Systems (GPS), there are myriad emerging sensor solutions, each with their own strengths and weaknesses, that can work together to create a fully visible cold chain. Datasharing processes and architecture, built on a foundation of existing GS1 Standards, are the connective tissue that holds the sensor network together.

The pillars of GS1 Standards are:

## Identify

Standardized product, location, and entity data enable consistent descriptions along the supply chain.

## Capture

Standardized data carriers and sensor technology ensure that important information is both encoded onto a product and able to be retrieved from it.

## Share

Standardized data interchange helps enable connectivity between different software solutions by building on top of data standards facilitating interoperability. While some of the sensor technologies discussed may not appear in current GS1 Standards implementation guidelines, they are increasing in prevalence in the cold chain ecosystem. Therefore, it is important to consider the various sensor technologies in achieving interoperability.

To learn more about how GS1 Standards facilitate pharmaceutical track and trace, visit our website.

To learn more about what you and your company can do to bring visibility to blind spots in the cold chain by participating in a pilot, email us at innovation@gs1us.org.

\*What is RAIN RFID?

Radio frequency identification (RFID) is a technology that enables the sharing of data encoded in RFID tags via RFID scanners. The term "RAIN RFID" specifies use of the Ultra High Frequency (UHF) band, which leverages the GS1<sup>®</sup> air interface protocol to communicate with tags.

GS1 US\* refers to "RAIN RFID" tags in this document whenever referring to UHF RFID tags. NOTE: Within the UHF RFID technology space, GS1 only endorses RAIN RFID implementations that are encoded per GS1's Electronic Product Code (EPC) standards (which is a subset of all RAIN RFID implementations).

# Today's Cold Supply Chain

As more products, such as vaccines, biologics, lab samples, or gene therapies, require special handling during transit and storage, it is becoming increasingly important to monitor them as they move through the supply chain. Alerts of problematic events like excessive force or temperature changes could help ensure the products are intact and safe for patients when they reach their destinations.

Today, shared visibility is rare. Manufacturers often lose the ability to monitor their products once they leave their facilities. Typically, data on the current state of the products is only accessible by the entity with possession during that part of the supply chain. As a result, problematic events will only be recorded by the current holder of the product during that event. Additionally, issues that occur during transit from one party to the next may not be detected at all. The lack of transparency about these events can lead to disagreements about when or where events or excursions occurred. If the event goes undetected, there is the potential for a compromised drug to be administered to a patient. At its core, the lack of transparency stems from the fact that not all parties involved have the equipment and middleware needed to collect data from the tags affixed to products. This includes the wholesale distributors, hospital systems and dispensers, and the logistics companies employed by both the manufacturers and distributors.

But improving visibility is not as simple as merely adding technology. The cold chain is a complex web of contracts between trading partners and the logistics companies they employ, which impacts what data is shared between entities and what data is obfuscated or becomes monetized. In addition, these agreements have often been in effect for many years, and the overarching business systems of pharmaceutical stakeholders can make change slow and difficult. However, the increasing number of cold chain products that require knowledge of exactly when negative events have occurred may provide the impetus for change.

For visibility across the supply chain to improve, stakeholders will need to address these data-sharing, infrastructure, and agreement issues.



## **Assumptions and Collaborator Involvement**

An initiative to implement end-to-end cold chain visibility and traceability will require not only hardware and application support, but also willing partners. Without active involvement from each of the following sectors, the value of pilot activities could be greatly diminished.

### **Product Manufacturers**

The product manufacturer or their agent would need to affix a tag utilizing the GS1 Electronic Product Code (EPC) encoding schemes that allow downstream trading partners to easily interrogate and decode the tags. Any agreed-upon technology and sensors should be documented and disclosed to the participants to promote open transparency, collaboration, and ease of use.

The manufacturer should be prepared to monitor their products in cold rooms and as possession transfers to the logistics carrier. Doing so would likely involve having readers in refrigeration units and portals at shipping locations. The manufacturer will determine the handling and storage parameters necessary to protect a product's quality and efficacy based on stability studies for the product. For example, temperature excursion tolerances would be defined by the manufacturer.

### Wholesale Distributors

Wholesale distributor involvement is essential. The goal is for the wholesale distributor to be an active participant willing to notify the manufacturer of negative events, such as any deviations over specific time or temperature thresholds. By knowing which products have been impacted by negative events along the supply chain, manufacturers can recall the right products and ensure they do not go to patients. These notifications will allow the manufacturer to act proactively with the impacted trading partner to ensure that they have adequate stock to meet patient needs.

Ideally, the wholesale distributor should implement their visibility hardware and middleware throughout their domain and should not require vendor-specific software to read and extract sensor data. This visibility would enable data capture not only from the tagged products but also from the refrigerators in which they are stored. The data captured would allow for calculating the time the product is between controlled environments as well as other key information. The snapshots, calculations, and recorded data would help provide a more complete picture of the life of the product and facilitate quick issue detection and response.

To achieve this level of visibility, the distributor would need to have systems in place at receiving docks, shipping areas, and cold rooms or refrigeration units. Hardware at these locations coupled with temperature monitoring software would allow for an almost continuous view of products and their state. Alternatively, battery-powered sensor logging tags that transmit data in an EPC-compliant way can also be used to provide temperature monitoring and visibility.

#### **Hospital Systems or Dispensers**

Having product visibility from the moment it is received until that product is dispensed at the point of care is vital for patient safety. Discussions with manufacturers have revealed that hospitals and dispensers possess this capability to some level today. It is important to promote and extend communication between these supply chain participants. During the "last mile" of the supply chain and until the eventual delivery of the product to patients, the hospitals or clinics would need monitoring equipment at receiving docks, in refrigerators, and in cabinets to capture any negative events.



(+)

### **Logistics Providers**

Having visibility during transit is critical. Typically, products are most susceptible to temperature variances and damage while in transit. If the transport is equipped to monitor and record events in real time, problematic occurrences can be reported to the manufacturer or recipient to ensure the products in question never make it to patients without further inspection.

# Essentials for Optimizing Cold Chain Visibility

Companies in a cold chain require real-time access to their product's data, from manufacture until the product is dispensed at the point of care. Since temperature excursions or other negative events can occur anywhere, end-to-end visibility would benefit all parties. Applying GS1 Standards and using Radio Frequency (RF) data carriers and sensors can enable monitoring of product conditions, movement, and transaction handoffs, creating real-time visibility that can reveal temperature excursions and reduce the impact of negative events.

By increasing supply chain visibility with GS1 Standards and currently available sensor technology, pharmaceutical companies can make more-informed supply chain decisions and mitigate the risk of products being lost, damaged, or spoiled before they reach patients.

## Identify: The Foundation of Traceability

GS1 identification standards provide organizations with structured means for creating globally unique identification keys for their products, assets, physical locations, and more. These GS1 identification keys are used to represent an object anywhere it may be referenced and act as the foundation for scalable, standardized solutions to support effective communication and efficient processes. GS1 Identification Keys are fundamental for supporting traceability and can combine with additional standards to address business needs throughout the supply chain. The GS1 Global Traceability Standard (GTS) leverages a variety of identification, data carrier, and data-sharing standards to enable companies to

precisely express the events and conditions that products encounter throughout their journey. The GTS has defined five dimensions for sharing event data across the supply chain.



Additional information on sharing information key to the pharmaceutical supply chain can be found in the Share: EPC Information Services (EPCIS) and Core Business Vocabulary (CBV) section.

Figure 1 provides an overview of the GTS data dimensions and identification, attribute, and data capture elements that can be used to support the track and trace of items in the cold chain process.

Figure 1: Recommended attributes and data storage for use in a pharmaceutical cold chain

Data Type	Description	Object to Trace	GS1 Identifier or Information to Record	Data-storing Mechanism
What	What is the object being traced?	ltem	SGTIN or GTIN®, AI (01) + Serial Number, AI (21)	Tag/barcode
What	What is the returnable object being traced (a pallet or a container)?	Item	GRAI, AI (8003)	Tag/barcode
Who	Who (party) did this action?	Legal entity	PGLN, AI (254)	Reader or data collector
Where	Where did these movements or events take place?	Physical location	SGLN, AI (254)	Reader
When	When did a movement or event that included that object occur?	Timestamp	yyyy-MM-dd'T'HH:mm:ss'Z'	Reader
Why	What business process was happening at the time of the event?	Shipping, transporting, manufacturing, etc.	Object Event	Reader
What	What movements or events took place during transportation?	Shipment	SSCC, AI (00)	Tag
Why	What incident data needs to be logged?	Force or drop	Newtons (N)*	Tag -> reader -> data collector
Where	Where did these movements or events take place during transportation?	Vehicle	GLN, AI (254) (Mobile location) Degrees, minutes, and seconds (DMS)** Latitude, longitude	GPS
Why	What sensing data needs to be logged?	Temperature	Fahrenheit (°F)***	Tag, reader, or standalone device

\* External forces applied to an object are measured in Newtons. \*\* GPS data is in Degrees, minutes, and seconds (DMS) format.

\*\* Temperature format is in Fahrenheit scale

## **Capture: Landscape of Sensor Technologies**

GS1 Standards are technology agnostic and can therefore be used in conjunction with many types of data carriers. This ensures that key cold chain identification data (product, location, entity, etc.) can be stored in the specific data carrier that best fits the relevant phase of the cold chain. Due to the complex nature of a product's journey through the cold chain, there are a wide variety of sensors that could address different use cases that arise. From more traditional 1D barcodes to QR codes to RFID tags with sensors and beyond, there are various ways supply chain data can be captured using different Internet of Things (IoT) technologies. IoT devices are capable of monitoring products to record problematic events, such as temperature excursions or excessive forces, in real time and transmit that data back to the appropriate trading partner.

While there are new sensor technologies in development that could embody multiple benefits in a single tag, currently, no one sensor is best suited for all cold chain use cases. Therefore, it is important for businesses to understand the pros and cons of each sensor option to determine what works best for their specific supply chain. By understanding how each sensor is used, businesses can work with their trading partners to ensure there is an appropriate sensor at each step of the supply chain, empowering end-to-end visibility with IoT. All the following sensor types have been used to capture cold chain information.

"GS1 Standards complement the different sensor technologies that support end-toend visibility in the pharmaceutical cold chain. The ability to capture and share event data in a standardized, predictable manner is critical for better functionality and reduces the need for stakeholders to depend on closed-loop systems."

-Gwen Volpe, Senior Director Medication Technology and Analytics, Fresenius Kabi USA

## **RAIN Radio Frequency Identification (RAIN RFID)**

Because RAIN RFID tags are passive, they are battery free, harvesting the energy from radio waves broadcast by an RFID reader to power the tag. The lack of a battery means that RFID tags can be low cost, designed for compact sizes, and are therefore ideal for low-level packaging (i.e., individual items). However, that means that data cannot be actively logged if the tag is outside of the zone of a reader or does not receive any radio wave energy from a reader. To mitigate this issue, some cold chains use visual indicators to show temperature breaches on the RFID tag that still work when it is not powered.



Figure 2: A system of tag, reader, and computer is required to log passive RFID data.

Example: MEDLOG (a subsidiary of pharmaceutical distributor Cooprofar), worked with CAEN RFID to create a temperature monitoring solution for their medicine that required cold chain conditions. The RFID solution helped ensure that the medicine was kept at the proper temperature throughout its journey to the end customer. When the RFID hardware was combined with cold chain software, it created a comprehensive solution for seamless tracking. (Data Logger)

## Active RFID

Active RFID tags are battery powered and offer a wider read range as a result. The battery addition means they are larger in size and more suitable for higher-level packaging (i.e., pallets or containers). As a result of always being powered, they are often used to provide real-time location tracking data and may incorporate sensor data.



Figure 3: Unlike passive RFID, active tags are always transmitting data.

Example: A case study from the University of Tasmania discusses how active RFID tags are important for compliance across the cold chain. Despite slow adoption, it explains how the application of active

RFID technology by a number of firms in this space has led to better return on investment (ROI) and overall improved operations. (Bertoni, et al)

#### Bluetooth Low Energy (BLE)

BLE tags are designed for low-power operation and have versions that are both battery free and battery powered, making them versatile across packaging levels. These sensors are widely used as a device positioning technology to address the increasing demand for high-accuracy indoor location services. BLE allows for mobile devices like smartphones to act as readers for data. Sensors can both respond to environmental changes in temperature and link to GPS for location data.



Figure 4: BLE tags can be read by mobile devices and data stored on the cloud

Example: Onset, a data logger and temperature monitoring company worked with Rigado's edge infrastructure solution to scale their BLE sensor solution. Data from individual loggers is shared via BLE to a Rigado gateway, where it is aggregated and processed. From there, the data is sent to the cloudbased data platform where it can be used to trigger automatic notifications based on prescribed contingencies. (Rigado)

## Low-Power Wide Area Networks (LPWAN)

LPWAN are battery powered and designed for long-range wireless communications that transmit small amounts of data (e.g., sensor information, ID) with low power use. A separate reader/base station can read many tags due to the long range. However, issues with high latency of transmission have hindered real-time data-logging efforts. Some seek to overcome this by deploying more readers for better coverage.



Figure 5: Multiple devices report back to one reader/base station due to the extended range.

Example: Sierra Wireless, an IoT solutions provider, worked with Hive-Zox International to provide real-time visibility for their cold chain by using a LPWAN monitoring solution. The LPWAN system enables an extensive sensor reach, which can be coupled with real-time data feedback to provide accurate asset tracking throughout the cold chain. This visibility ensured transparency to the trading partners that products were not compromised during their journey. (Sierra Wireless)

## **Near-Field Communication (NFC)**

NFC tags are battery free and harvest power from an NFC reader to transmit and log data. They have a very small read range, so devices require close proximity to function. All smartphone devices are equipped with NFC readers, which can be utilized for smart handheld applications to identify individuals (e.g., doctor, nurse, patient), and smart ticketing can provide stakeholders with additional information when dispensing or administering medication.



Figure 6: All smartphones are equipped with the ability to read and process NFC tag data.

Example: L&B Taspac, a New Zealand seafood processor and exporter, recently leveraged NFC technology in its cold chain monitoring program. Through its work with Emerson Cargo Solutions, L&B Taspac implemented a cargo-monitoring program that used a combination of NFC loggers and a cloud platform to ensure the safe journey of their products. Data loggers monitored the time and temperature of products while the NFC tags transmitted data using near-field communications to a mobile app. Information from each shipment could be readily tracked and shared directly from a smartphone. (Emerson)

## **Global Positioning System (GPS) and Temperature**

GPS sensors are battery powered and can be used either with a separate temperature sensor functioning alongside or, in some cases, with an embedded environmental sensor. A satellite-based radio navigation system, GPS provides geolocation and time information to a receiver anywhere on the ground. Combining GPS with other sensor capabilities (like temperature) allows the logging of where a product is and what its current state is at that location.



Figure 7: Global positioning sensors provide real-time location data and can be embedded with temperature sensing.

Example: A Bolivia-based agro-industrial logistics company partnered with Zentag, a telematics company, to use a combination of temperature and GPS sensors to track products throughout the supply chain. The temperature sensors were able to detect any deviations from the cold chain temperature while the GPS ensured accurate geolocation for the products. The combined system created a comprehensive cold chain monitoring solution. (Gurtam)

Each sensor and reader configuration has its own strengths and weaknesses. A combination of various sensor types could be used to ensure visibility from every packaging level and therefore every step in the supply chain.

The chart below summarizes the types of packaging that a product could have throughout its cold chain journey as well as the potential sensors that could be used. *"GS1 US is staying current with sensor automatic identification and data capture (AIDC) growth and making sure that GS1 Standards apply to all. GS1 Standards have a critical role to play with your sensor technology."* 

-Blair Korman, Senior Director, Digital Identification & Traceability, Johnson & Johnson



\*RAIN RFID is on the list of GS1 data carriers.

# Share: EPC Information Services (EPCIS) and Core Business Vocabulary (CBV)

## **Overview**

When it comes to cold chain management, the principal concern on supply chain leaders' minds is whether their product has been kept within the permissible temperature throughout its journey. Cold storage facilities often advertise a variety of climate control parameters, not just frozen and refrigerated. Different products have different permissible temperature thresholds, and some products may accept short deviations outside of permitted boundaries—but only for certain durations. By defining business rules for the acceptable boundaries of products and making them available through the GS1 Global Synchronization Data Network<sup>™</sup> (GS1 GDSN<sup>®</sup>) or a web resource by utilizing GS1 Digital Link, supply chain leaders can automate their cold chain exception management with EPCIS and sensorintegrated RFID tags. Leveraging GS1 Standards in the Share layer and building upon their benefits from the Identify and Capture layers could help trading partners harness the power of IoT devices and the copious volumes of data they generate. This data, when collected and shared comprehensively between trading partners, can empower artificial intelligence (AI) algorithms to perform analyses and make decisions with high speed and accuracy. Within the Share layer, EPCIS is an interface standard, meaning it is intended to be the connective tissue between disparate solutions, not a technology solution on its own. This is in recognition that trading partners will choose different vendors for technology and different types of technology to meet the needs of their respective businesses. EPCIS enables connectivity between different software solutions by building on top of data standards that enable interoperability. Enabling the visibility needed among those stakeholders requires a technology-agnostic standard allowing for solution provider choice.

## What Is It?

EPCIS is a GS1 Standard that defines a common data model and interfaces for the exchange of visibility data across open supply chains and within an enterprise. Its aim is a shared view between supply chain partners of objects' journeys. By following the standard, trading partners throughout the supply chain and their respective solutions can exchange collections of EPCIS events that can be considered snapshots of objects at moments in their journey. The common data model and interfaces enable interoperable exchange of EPCIS events.

EPCIS layers its common data model on two other key components: concrete bindings to commonly used data interchange standards (e.g., XML and JSON/JSON-LD) and use of RESTful API/SOAP API for transport of the data. These two components are commonly employed by the software providers of the modern web, helping EPCIS be more accessible to companies looking to add it to their technology stack.

The Core Business Vocabulary (CBV) is a companion standard to EPCIS that defines the vocabulary populating fields in EPCIS events to ensure common understanding among supply chain stakeholders. Industries around the globe employ these standards to gain the depth of visibility necessary for the complexities of today's supply chain management.

Note: The Implementation Guideline: Applying GS1 Standards for DSCSA and Traceability, Release 1.3, illustrates the use of EPCIS for helping the industry meet DSCSA requirements. This implementation does not support sensor data in its native state. For full sensor support, EPCIS 2.0 is recommended.

### Additions of Sensor Reports in EPCIS 2.0

A major update to the EPCIS standard, release 2.0, was published in June 2022, which added several important capabilities to the visibility data exchange standard. One of the most significant additions was a sensor-reporting component within EPCIS events. With this addition, implementations now have a standard language for expressing the measurements, metadata, business rules, and other relevant data related to sensors alongside visibility data on the journeys of objects.

This represented a significant milestone for companies looking to utilize GS1 Standards to enhance their cold chain management.

## Sensor Data Within EPCIS

## **Overview of Capabilities**

With release 2.0, EPCIS events can include sensor data as a part of event data. Inside each event, implementation can include a collection of sensor reports. These reports are flexible structures for including a variety of data points but intended as a summary of sensor readings over a period of time. For cold chain management, this means that an EPCIS event can record both the journey of temperature-sensitive items (e.g., vaccines) and a summary of sensor readings about the condition of those items over the time since the previous event. The summary of sensor readings can include several useful data points:

- Time when the readings began
- Time when the readings ended
- The average temperature
- The maximum temperature
- Standard deviation of temperature readings
- Identity of the sensor
- The unit of measure of temperature readings
- A web link to where the complete log of readings can be found

With EPCIS 2.0, sensor-integrated RFID tags can power both the visibility of objects' journeys across the supply chain as well as register the condition of those objects throughout the journey.

# Various Measurement Types, GPS Coordinates, and Other Metadata

With cold chain, temperature is front of mind for desired measurements, but EPCIS 2.0 also supports a long list of additional measurement types and units of measurement. They include pressure, humidity, force, exposure, and many others. It is also possible to express the presence and amount of chemical substances or microorganisms. Implementers may find utility in collecting sensor data of temperature along with other properties. Sensor data can also include motion in space measurements, such as GPS coordinates and altitude.

The data is not limited to only what is read by sensors. It can include alerts and errors as well as useful metadata about the sensors themselves. This metadata could be an identifier for the sensor, a link to information about how the sensor processes data or a link to business rules about the circumstances when sensor data is triggered. The added capabilities around sensor data with EPCIS 2.0 are highly flexible for the numerous use cases that can be addressed by observing the conditions of objects with sensors. EPCIS is a valuable complement to the use of sensors for cold chain management and well suited for use with RFID tags with integrated sensors as data carriers.

## Summary of Raw Sensor Data

When sensors, like temperature loggers, record sensor readings, it is often a series of measurements taken at regular time intervals. When applied to the cold chain, this leads to a great number of sensors producing hundreds, thousands, or even millions of data points to interrogate. The EPCIS standard calls these collections of data points raw sensor data. The standard can accommodate these vast collections of data points but shows a preference for providing a summary of the data instead.

Summarizing the raw sensor data into business-oriented data helps end users quickly garner answers to their ultimate cold chain questions. They can know whether a shipment of vaccines ever exceeded the acceptable upper bound for temperature during transport or how long it might have exceeded the upper bounds.

Even though the standard prefers summary data, there is an option to include a link to the raw sensor data in case users wish to interrogate the full record of observations. The EPCIS 2.0 standard incorporates sensor data in a business-friendly way and enables implementations to tune it to their preferred level of granularity.

## The Association Event and Sensor Data tied to Locations

With the addition of EPCIS 2.0, a new event type was added that adds another relevant capability for the supply chain. This event type is called the Association Event, and it can permit an EPCIS event to reflect the relationship between a physical location and one or more sensors. With the cold chain, sensors may not always be directly applied to the objects in transit along the supply chain. In many circumstances, a sensor may be integrated into a location where objects may be stored. The Association Event enables companies to receive sensor report data when objects are within a location, even if there is no explicit relationship between the objects and the sensor(s) in the location.

## Summary of Benefits of EPCIS for Cold Chain



Deviation from established temperature parameters

Solution provider choice, technology agnostic

Built on the standards of the modern web

## Conclusion/Call to Action

Developments in the pharmaceutical industry have resulted in an increasing number of drugs, vaccines, and other products that require an unbroken chain of cold conditions. To ensure patient safety, end-to-end visibility and traceability of a product's journey is crucial, but the current cold chain contains blind spots. Closing the gaps will require unprecedented collaboration among GS1 US, manufacturers, distributors, logistics partners, and healthcare providers to deploy the sensor technology and middleware needed to effectively capture and share real-time data about the state of a product at any given time or place within the cold supply chain.

Industry can leverage technology and standards they have already implemented for the benefit of cold chain by examining how they are using advanced data carriers and data-sharing standards (RFID and EPCIS, respectively). Standards must continue evolving to serve the changing needs of the pharmaceutical cold chain landscape. Enabling interoperability between standardized and non-standardized data carriers will be critical to ensuring continuous data visibility. Meanwhile, it will take the application of all three pillars of GS1 Standards to support interoperability in the emerging IoT and sensor technology landscape across all parties of the cold supply chain.

To learn more about how GS1 Standards facilitate pharmaceutical track and trace, visit our website.

To learn more about what you and your company can do to bring visibility to blind spots in the cold chain by participating in a pilot, email us at innovation@gs1us.org.

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\*If applicable

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