

Executive Summary

This white paper focuses on Healthcare supply chain Traceability, from manufacture to patient, going beyond, for example, what is currently regulated by the US 21 CFR Part 820 and ISO 13485 Quality System Regulations. It is targeted at any and all organisations and stakeholders in Healthcare, anywhere in the world, who are considering or planning implementation of traceability of medical products (pharmaceuticals and medical devices).

When selecting a traceability system regulatory compliance, patient safety and increased supply chain efficiencies are examples of key drivers and goals. These are key considerations which affect the type of model that is selected for implementation, which in turn will influence costs and return on investment. It is critical to also consider regulations and traceability partner capabilities that may constrain or determine which model is selected and implemented.

The paper considers the following traceability models one up/one down, pedigree, point of dispense authentication and distributed network track & trace. This paper also considers their benefits and limitations. It provides information about the GS1 process and technical standards that enable such traceability systems and information of medical device and pharmaceutical traceability case studies from around the world.

It concludes with GS1 Healthcare's recommendation to implement "contextually appropriate" traceability systems to make the Healthcare supply chain more efficient, safe and secure by utilising the GS1 System of Standards to identify product, capture and communicate master and transactional data and capture and share event data; incremental implementation to achieve GS1 member's Vision for Traceability in Healthcare:

Full actionable, global visibility of finished pharmaceuticals and medical devices in Healthcare from Point of Production to Point of Use

Purpose of this Document

The purpose is to provide information for entities considering or planning the implementation of traceability. It includes an overview of the GS1 System of technical Standards (to identify product, capture and communicate master and transactional data and capture and share event data), details of the GS1 Global Traceability Standard for Healthcare (GTSH)¹ and the various models that are emerging.



GS1 Standards for Traceability

There are a number of factors that determine the operational context for all organisations, such as the operational and market situation and regulations. In turn the operational context will determine which traceability model is appropriate, i.e. a “contextually appropriate” model.

Key to the incremental implementation of a contextually appropriate traceability system is the availability of GS1 process and technical standards. The ratified standards are available from the GS1 Healthcare website: <http://www.gs1.org/Healthcare/standards>.

Process Standard

- **The GS1 Global Traceability Standard for Healthcare**

The core process standard is the GS1 Global Traceability Standard for Healthcare (GTSH). It defines Traceability as “...*the ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration*”. It is complemented by the GTSH Implementation Guide².

Technical Standards

- **Auto-Identification & Data Capture (AIDC) Application Standards**

GS1 Identification Keys: numbering schemas for products, locations, patients, caregivers, and assets. GS1 Barcodes: several types of bar code, linear and 2-dimensional (2D) and Radio Frequency Identification (RFID) tags for use by GS1 members depending on the application. GTIN Allocation Rules for Healthcare: GTIN (Global Trade Item Number) provides unique identification for Healthcare Items.

- **Global Data Synchronisation Network (GDSN) for Healthcare Standard**

The GDSN enables continuous and secure global product data synchronisation and accurate product data across supply chain partners and is built around the GS1 Global Registry®, GDSN-certified data pools; the GS1 Data Quality Framework and GS1 Global Product Classification.

- **eCOM business-to-business messaging standards**

GS1 eCom provides global standards for electronic business messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners in the form of EANCOM or GS1 XML messages.

- **EPCglobal Visibility standards**

EPCglobal supports increased visibility and efficiency throughout the supply chain and higher quality information flow between organisations and their key trading partners. This is achieved through data standards and interface standards.

The GS1 System of Standards continues to develop as necessary to meet the evolution of Healthcare traceability requirements.



GS1 Standards at Work in the Healthcare Supply Chain

Figure 1 below shows the suite of GS1 Standards as they apply across the Healthcare supply chain from manufacture to Healthcare provider and how they enable traceability.

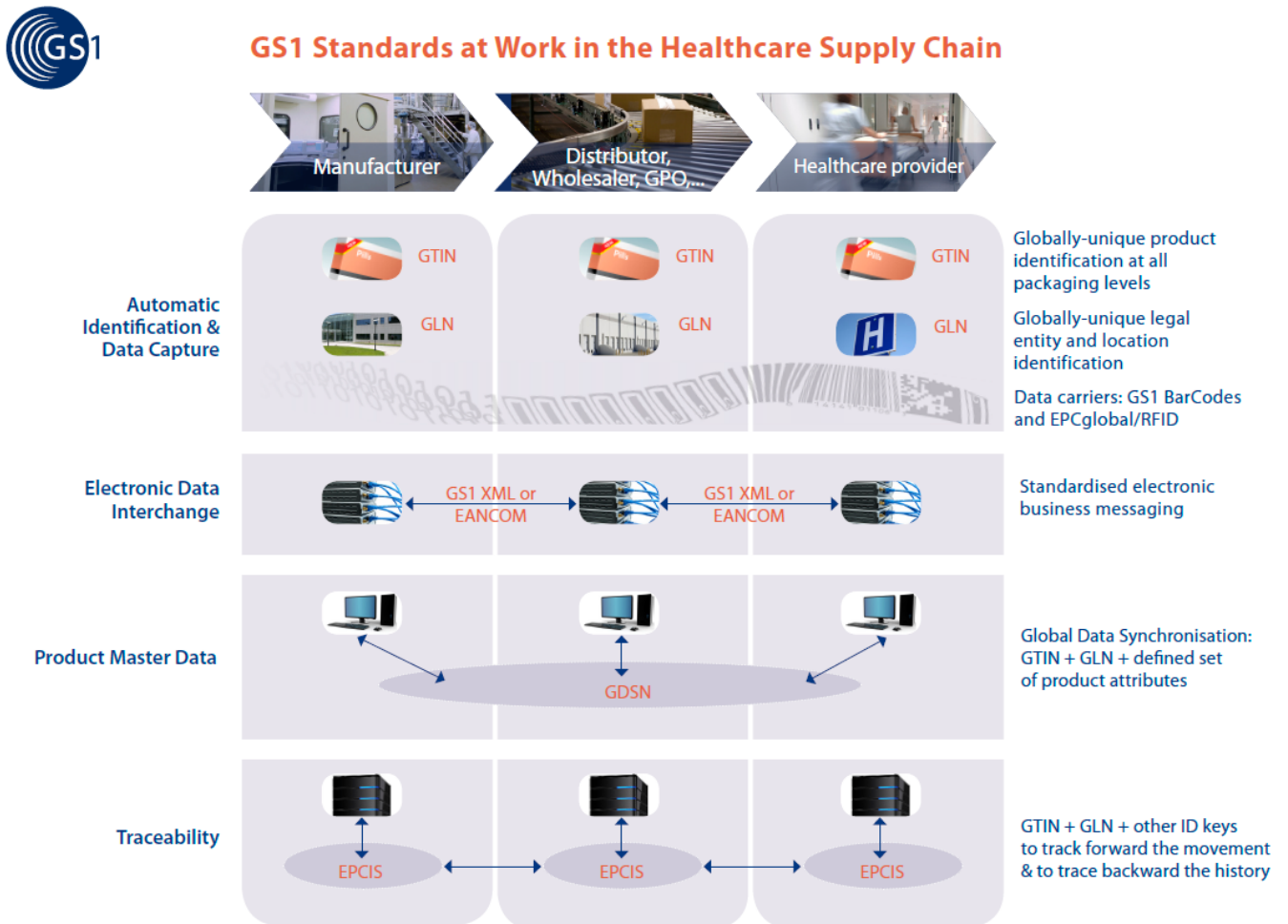


Figure 1: GS1 Standards at Work in the Healthcare Supply Chain



Traceability Models

There are currently a number of emerging models for traceability: e.g. one up/one down, pedigree, point of dispense authentication, and distributed network track & trace. There are key operational and market factors which affect the type of model that is selected, which in turn will influence costs and return on investment. It is critical to also consider regulations that may constrain or determine which model is selected and implemented. The context therefore determines which traceability model is appropriate (i.e. contextually appropriate). Below is a brief discussion of these emerging models that could be deployed to achieve the incremental implementation of contextually appropriate traceability systems.

One up, One down

The GTSH establishes the “one up, one down” model as the foundational traceability model. In this model the product moves from one party (e.g. manufacturer (supplier)) to the next party in the supply chain (e.g. Healthcare provider (buyer)): the manufacturer is “one up” from the Healthcare provider, who is “one down” from the manufacturer. In parallel to the physical flow of product is the flow of data related to that product, this is recorded and sent by “one up” party to the “one down” party who also records it. The one up, one down flow may happen multiple times before the product and data reach the end user/consumer. This model can be represented graphically as follows (Figure 2).

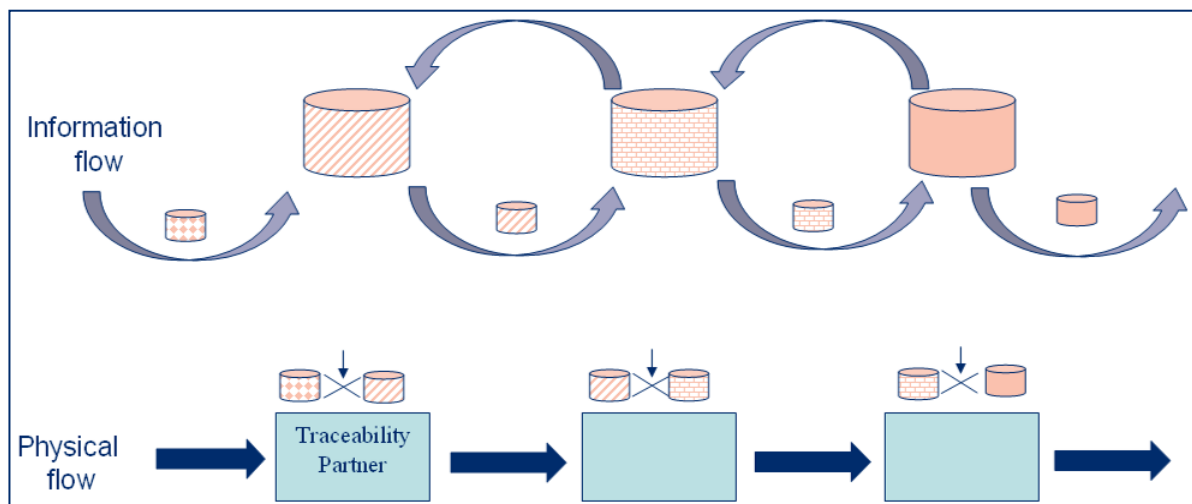


Figure 2: One up, One down Model

Due to the highly regulated nature of Healthcare, this model may already be in place for numerous stakeholders, but for those who do not have a traceability system in place, it is suggested that implementation of this foundational model should be the primary objective. It can then provide the foundation for migration to other, increasingly more sophisticated, models that are emerging, under pilot or regulated for example:



Pedigree

Pedigree means a record containing information regarding each transaction resulting in a change of ownership, change of custody or both of a given prescription drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, re-packagers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the prescription drug. A pedigree is created in a paper based form or electronic form (commonly referred to as an e-Pedigree) and should be maintained in an interoperable system, ensuring compatibility throughout all stages of distribution.

An example of e-Pedigree is the US California legislation³ scheduled to become effective in 2015.

Point of Dispense Authentication

In general authentication is the process of determining whether someone or something is, in fact, who or what it is declared to be.

The GS1 System Architecture provides the mechanism for Healthcare stakeholders to authenticate the GS1 Product Identifier (e.g. the Global Trade Item Number (GTIN) in the carrier (bar code or RFID)) through capturing data, transmitting data and communicating the results.

An example of a product identifier authentication pilot is the European Federation of Pharmaceutical Industries and Associations (EFPIA) Point of Dispense Verification Pilot⁴.

Point of dispense authentication may not be appropriate in some contexts due to, for example, the Healthcare setting (retail vs. Healthcare provider) or the type of product (e.g. medical device). In such situations, a different contextually appropriate model should be adopted.

For example, the current Turkish regulation, aimed at eliminating reimbursement fraud of pharmaceuticals, requires manufactures to apply a GTIN, lot number, expiry date and serial number to each sales pack in human readable and 2D barcode form. This information is uploaded to a central government database. When the product is dispensed at a pharmacy, the 2D barcode will be scanned and the scanned data will be uploaded to the government database signifying that the product has been dispensed.

The application of GS1 Product Identifier Authentication can enable the process of package authentication by manufacturers employing, on genuine products, an identifier in an effort to protect the product from counterfeiting.

Distributed Network Track & Trace

Looking to the future and to achieve GS1 member’s Vision for Traceability in Healthcare (below) it is likely that a distributed network trace and trace model would be required. In this model parties who may have regulated, manufactured, bought, sold, distributed, sent, received or repackaged product publish key data that is accessible by other parties authorised to view the data in order to, for example, authenticate the product identifier, establish a products pedigree or locate product for recall. Conceptually Figure 3 represents this model.

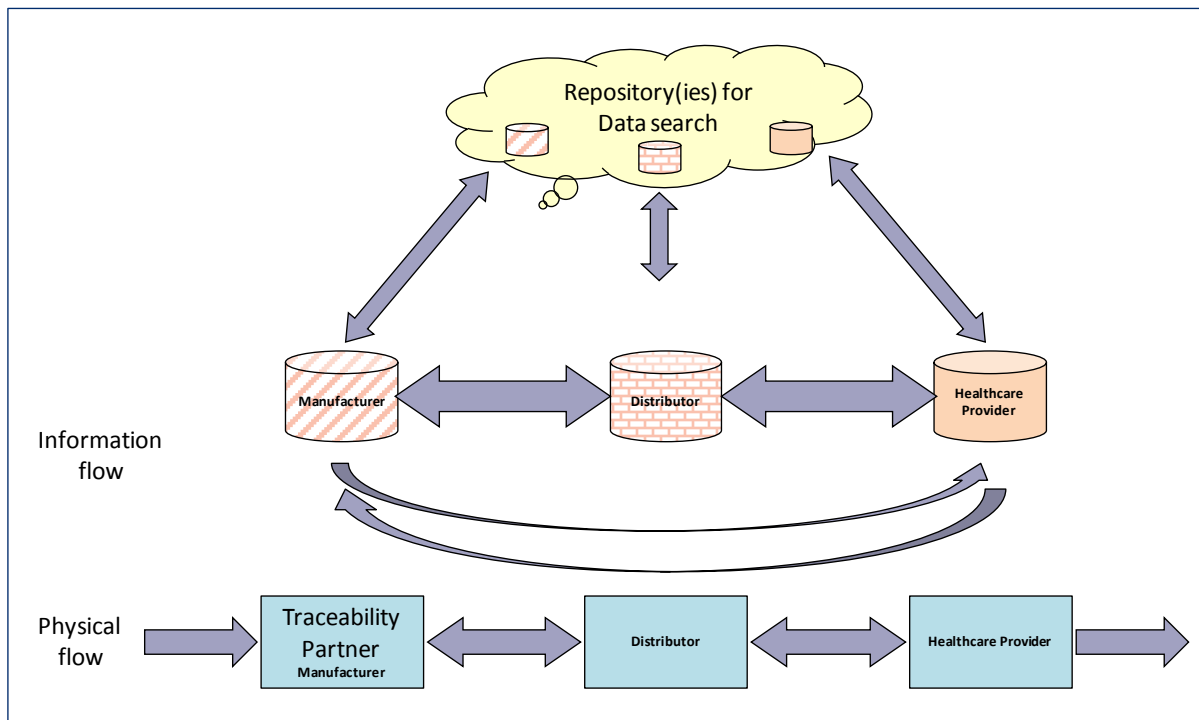


Figure 3: Conceptual Distributed Network Track & Trace Model



GS1 member's Vision for Traceability in Healthcare is a distributed model in which "Full actionable, global visibility of finished pharmaceuticals and medical devices in Healthcare is achieved from Point of Production to Point of Use". In this future model expectations are that:

- "Items can be tracked (forward / downstream) across the entire supply chain (production to use) in real time on demand
- Items can be traced (backward / upstream) across the entire supply chain (from current location back to the producer) in real time on demand
- Patients Electronic Health Records (EHRs) can be 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"

In order to achieve these goals the following must be fully established from "Point of Production to Point of Use".

- "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
- Identification remains with/on the item throughout its 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
- Agreed master data is captured and shared (e.g. via GDSN) on demand amongst trading partners
- Agreed event data is captured and shared (e.g. via EPCIS) on demand amongst traceability stakeholders"

The challenges and opportunities for all Healthcare supply chain stakeholders are how to achieve the Vision.

Map of GS1 Standards to Traceability Models

The grid in Figure 4 maps the components of the GS1 System of Standards against the models and standards discussed above. Over the last five years GS1 Healthcare has been leading efforts to develop new and enhance existing GS1 global standards to be applicable to the Healthcare sector. The global standards that have been ratified are shaded in green, those being validated for Healthcare application are shaded orange and standards that are in development are shaded in pink; check marks/ticks indicate that these standards are relevant to that particular model.

Standard	Model			
	One up, One down	Pedigree	Authentication	Distributed Network Track & Trace
Global Traceability Standard for Healthcare (GTSH)	✓	✓	✓	✓
Auto-Identification & Data Capture (AIDC) Application Standards	✓	✓	✓	✓
Global Data Synchronisation Network (GDSN) for Healthcare standard	✓	✓	✓	✓
eCOM business-to-business messaging standards	✓	✓	✓	✓
Advanced Shipping Notice (ASN)				
EPCglobal Visibility Standards - Data Standards	✓	✓	✓	
Pedigree Standard				
EPCglobal Visibility Standards - Interface Standards	✓	✓	✓	✓
EPCIS - EPC Information Services Standard				
Object Naming Service (ONS) Standard				✓
Core Business Vocabulary (CBV)	✓	✓	✓	✓
Discovery Services Standard				✓

Figure 4: Map of GS1 Standards to Traceability Models

Implementation Costs / Return on Investment (ROI)

This White Paper does not include specific cost or ROI figures related to implementing a traceability system due to complex variables in Healthcare (for example: regulations, the type of organisation, the breadth/scope of the supply chain, supply chain partner relationships, the product). As with any operational change/improvement there are associated implementation costs and the organisation should undertake an analysis of these likely costs, to secure the necessary budget / funding and to establish benchmarks that can be used post-implementation to identify return on investment / savings.



Case Studies

The GS1 Healthcare website has a library⁵ that includes an extensive and increasing number of case studies and a selected number have been published. Some examples of those related to traceability are:

- Australia: CH2 – ‘Building traceability in Australian Healthcare’
- Brazil: (ANVISA) Pharmaceutical products traceability system pilot project in Brazil
- China: ‘Shanghai Food and Drug Administration: Implementation of a post-market traceability program for implantable medical devices adopting unique device identification’
- European Union: BRIDGE Traceability report
- UK: ‘Wythenshawe Hospital implements GS1 bar coding to uniquely identify, track and trace surgical instrument trays’
- Switzerland: ‘SmartLog: a Swiss drug traceability pilot’
- USA: Premier – ‘U.S. Healthcare industry to implement common data standards to improve safety, reduce costs’

Conclusions

The need for traceability is driven by regulation and a desire to enhance patient safety. There are also other key drivers and goals for implementing a traceability system (e.g. anti-counterfeiting, tracking, tracing, supply chain efficiency etc.). Additional considerations also include operational maturity and information technology sophistication of the organisation contemplating the implementation.

These key considerations affect the type of model that is selected, which in turn will influence costs and return on investment. It is critical to also consider Regulations that may constrain or determine which model is selected and implemented. The context therefore determines which traceability model is appropriate (i.e. contextually appropriate)

GS1 Healthcare recommends the incremental implementation of “contextually appropriate” traceability systems to make the Healthcare supply chain more efficient, safe and secure by utilising the GS1 System of Standards to identify product, capture and communicate master and transactional data and capture and share event data.

Reference

¹ GTSH: http://www.gs1.org/docs/gsmpt/traceability/Global_Traceability_Standard_Healthcare.pdf

² GTSH Implementation Guide
: http://www.gs1.org/docs/gsmpt/traceability/Global_Traceability_Implementation_Healthcare.pdf

³ California Business and Professions Code, section 4034 (a)

⁴ EFPIA Product Verification Pilot Joint Final Report:
<http://www.efpia.eu/Content/Default.asp?PageID=559&DocID=8770>

⁵ <http://www.gs1.org/healthcare/library>



Glossary of Terms related to Traceability

There is a language of Traceability in Healthcare; what is meant by the key terms? Below are explanations or definitions for these terms that have been sourced largely from GS1 publications:

Application Identifiers (AI, e.g. Lot/Batch No. AI(10)). *“The field of two or more digits at the beginning of an Element String that uniquely defines its format and meaning.”* GS1 General Specifications

Appropriate GS1 Identification Keys (e.g. GTIN). *“A globally managed system of numbering used by all GS1 Business Units to identify trade items, logistic units, locations, legal entities, assets, service relationships, consignment, shipments and more. Any Identification number that combines GS1 member company identifiers (GS1 Company Prefix) with standards based rules for allocating reference numbers is a key.”* GS1 General Specifications

Chain of Custody. The objective is for Trading Partners to be able to document and produce the Product attributes, and all other Trading Partners / Traceability Partners that have had and/or currently have **physical possession** of the product.

Chain of Ownership. The objective is for Trading Partners to be able to document and produce the Product attributes and all other Trading Partners / Traceability Partners that have had and/or currently have **legal title** of the product.

Counterfeit vs. Authentic items: The World Health Organisation (WHO website; June 2010) have the following as the definition for counterfeit medical products. It is used here to both as a definition of counterfeit and, conversely, to illustrate what constitutes an authentic item: *“a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging”.*

EPCIS [Electronic Product Code Information System] *“The goal of EPCIS is to enable disparate applications to leverage Electronic Product Code (EPC) data via EPC-related data sharing, both within and across enterprises. Ultimately, this sharing is aimed at enabling participants in the EPCglobal Network to gain a shared view of the disposition of EPC-bearing objects within a relevant business context”.* EPC Information Services (EPCIS) Version 1.0.1 Specification

Identification remains with/on the item throughout its intended useful life. This refers to Business Requirement 8 in the Global Traceability Standard for Healthcare (GTSH) and aims to ensure that an item remains identified throughout its life cycle, enabling traceability, authentication or product recall.

One up, One down. In this model the product moves from one party (e.g. manufacturer (supplier)) to the next party in the supply chain (e.g. Healthcare provider/ (buyer)): the





manufacturer is “one up” from the Healthcare provider, who is “one down” from the manufacturer. In parallel to the physical flow of product is the flow of data related to that product, this is recorded and sent by “one up” party to the “one down” party who also records it. The one up, one down flow may happen multiple times before the product and data reach the end user/consumer.

Party Logistics Provider on behalf of the supplier (Patients Electronic Health Records (EHRs). *“This describes the concept of a longitudinal record of patient's health and Healthcare-from cradle to grave. It combines both the information about patient contacts with primary Healthcare as well as subsets of information associated with the outcomes of periodic care held in the EPRs’.”* GTSH Implementation Guideline

Pedigree. The GTSH defines Pedigree as: A record that traces the ownership and transactions of a product as it moves among various trading or traceability partners - from the manufacturer to e.g. the pharmacy, hospital, or other entity.”

Product recall *“Shall mean any measure aimed at achieving the return of a... product that has already been supplied or made available to consumers by the producer or distributor (EU Directive2001/95/CE General Product Safety)”.* GTSH

The legitimate supply chain *“the chain... of supply that conforms to known and established legal forms, principles and requirements; the lawful supply chain; the valid supply chain; the real, the authorized, the genuine supply chain”.* www.rxtrace.com

Traceability stakeholder [Partner]. *“Any Trading or traceability Partner involved in the traceability process e.g., Traceable Item Creator, Traceable Item Source, Traceable Item Recipient, Transporter, Brand Owner, Traceability Data Source, and Traceability Data Recipient. NOTE: The term “partner” does not imply there is a direct business relationship or partnership between parties involved in traceability.”* GTSH

Trading Partner. *“Any Supply Chain Partner that has a direct impact on the flow of goods through the supply chain. Examples include Third Party Logistics Provider, Manufacturer, Retailer, and Grower.”* GTSH





About GS1

GS1 is a neutral, not-for-profit standards organisation dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility in supply chains. GS1 is truly global with 108 Member Organisations worldwide. More than 1 million companies worldwide have adopted the GS1 System of Standards.

About GS1 Healthcare

GS1 Healthcare is a global user community consisting of all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, industry associations and regulatory authorities. 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. The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, trade organisations and other similar stakeholders who are seeking input and direction for global standards in Healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation.

For more information about the GS1 global Healthcare user group, please visit <http://www.gs1.org/Healthcare/>

