GS1 Global Traceability Standard for Healthcare (GTSH)

Implementation Guide

Issue 1, April-2009

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Log of Changes in Issue 1

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1	April-2009	Janice Kite, GS1 Global Office	Creation of new Implementation Guideline.

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1. Introduction

GS1 Healthcare is a sector focussed global user group bringing together all related Healthcare stakeholders: pharmaceutical and medical device suppliers and manufacturers, wholesalers and distributors, group purchasing organisations, hospitals, pharmacies, logistics providers, governmental and regulatory bodies and industry associations; large and small. It was formed in 2007 when the GS1 EPCglobal Healthcare and Life Sciences Industry Action Group (HLS) and the GS1 global Healthcare User Group (GS1 HUG) joined forces into one global Healthcare user group: "GS1 Healthcare".

The vision of GS1 Healthcare is to be the recognised, open and neutral source for regulatory agencies, industry 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.

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. Their work is outlined in the *GS1 Global Healthcare Roadmap* (located on the GS1 website at: gs1.org/docs/healthcare/GS1_Healthcare_Roadmap.pdf).

In December 2007, in support of the GS1 Global Healthcare Roadmap, GS1 Healthcare established the Traceability in Healthcare Work Team. The work team had an active and international membership, with representation from Algeria, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Croatia, Egypt, France, Germany, Hong Kong, India, Ireland, Italy, Netherlands, New Zealand, Norway, Sweden, Switzerland, Tunisia, Turkey, UK and US and from all healthcare stakeholders: distributors, regulatory bodies, pharmaceutical and medical device manufacturers, industry associations, hospital procurement, clinicians, academia, ministries of health and wholesalers.

This work team initially focussed on development of the *Global Traceability Standard for Healthcare (GTSH)* based on GS1's generic *Global Traceability Standard (GTS)*. The GTSH became a published standard in February 2009 and serves as a foundational standard for all stakeholders and countries to use as a starting point for identifying their specific requirements while ensuring a common approach and understanding of key principles by users around the world.

Note: The Global Traceability Standard for Healthcare (GTSH) is located on the GS1 website at: gs1.org/services/gsmp/kc/healthcare/index.html

Note: The generic Global Traceability Standard (GTS) is located on the GS1 website at: gs1.org/productssolutions/traceability/gts/

The work team's focus then turned to developing this GTSH Implementation Guideline. It is based on the GS1 System of standards (2.0) and uses the following definition as the reference definition for traceability in this document:

Traceability is 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.

Traceability is the all encompassing term that is used widely, across geographies and sectors. Because it covers both track and trace, "Traceability" is the term that will be used throughout this guideline and related documents and standards.

1.1. Business Context

Healthcare is by nature a global sector, with supply chains that often cross borders. On the other hand, healthcare is also very much local. Implementation of open, global and proven standards enable effective and efficient traceability systems around the world. Automatic identification and traceability systems based on global standards enable verification and authentication of medical products throughout the global Healthcare supply chain, making implementation faster and more effective, while improving the supply chain's safety and integrity. Some key drivers for implementing traceability are:

1.1.1. Patient Safety

Patient Safety is paramount and it is considered in anything we do in healthcare. Patient Safety is commonly represented by the "patient rights" as described below.

In the context of pharmaceutical(s)/(drug(s)) "The 5 Patient Rights" are:

1. right patient
2. right drug (e.g. a pain killer versus a anti-biotic)
3. right dose (strength (potency)) and quantity)
4. right route
5. right time

In the context of medical devices, "The 8 Patient Rights" are:

1. right device
2. right location (e.g. theatre, catheter laboratory)
3. right time
4. right condition (e.g. not recalled)
5. right procedure
6. right anatomic site
7. right patient
8. right user (user who has been trained to use this)

How does Traceability help?

Establishing a traceability system is a key enabler to achieving the majority of these patient rights. For example, drugs identified with a standard auto-identification key, e.g. GTINs, helps to assure the patient receives the right treatment.

1.1.2. Regulations / Guidance

Several countries and regions have regulated (or are considering regulating) traceability systems for healthcare products to facilitate chain of custody and/or authentication. For example:

- **Turkey** – Turkish Ministry of Health; Guidance on Implementation of Identification and Bar Coding of Medicinal Products for Human Use
www.iegm.gov.tr/its/Documents/Turkish_Drugs_Barcode_Guidance_ENG_1_1.pdf

- **US Federal Track and Trace law 21 U.S.C. 355e**

- **California Board of Pharmacy ePedigree** – California Board of Pharmacy ePedigree
www.pharmacy.ca.gov/about/e_pedigree_laws.shtml\

- **Spanish Article 87, Law 29/2006** – Spanish Article 87, Law 29/2006
  www.boe.es/boe/dias/2006/07/27/pdfs/A28122-28165.pdf

- **Brazil** – Brazil. Public Consultation No. 8, Minimum Requirements for the Definition of Traceability Mechanisms and Medicine Authenticity www4.anvisa.gov.br/base/visadoc/CP/CP[21581-1-0].PDF

  AND

  Brazilian Act issued on January 14th that established traceability of production and consumption of medicine using electronic capturing, storing and transmission of data www6.senado.gov.br/legislacao/ListaTextoIntegral.action?id=237419

- **Korea** –Guideline of Printing and Control of Barcode for Pharmaceutical Product, Korea. www.nih.go.kr/htdocs/HPSS/HPSSSE/HPSSE001.jsp

Additionally some countries are planning to issue or have issued guidance on traceability (e.g. UK "Coding for Success" dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_066082)

These traceability requirements (increasingly) vary greatly by country or region even though they have common objectives such as Patient Safety or Supply Chain safety and integrity. It is important to have standards to align these requirements into a common, global, interoperable traceability system. This guideline will assist in doing so.

1.1.3.   Supply Chain

1.1.3.1. Safety and Integrity

"Safety is... the condition of being protected against… types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable" (http://en.wikipedia.org/wiki/Safety), i.e. as embodied in the patient rights (1.1.1.) and Integrity is "…the quality or condition of being complete; pure" (http://en.wiktionary.org/wiki/integrity). A safe supply chain, therefore, is one where the potential for error and adverse events are minimised and the authentication of products is trusted e.g. authentic product, not counterfeit.

A robust traceability system is a key enabler to achieving supply chain safety and integrity. For example, scanning a product that is identified with a GTIN and that is linked to data about its history assists in confirming the product is authentic.

1.1.3.2. Efficiency

Efficiency is doing the right things correctly through the adoption of standards and the utilisation and continuous improvement of processes and systems. In the supply chain, efficiency should be achieved without compromising product safety or supply chain integrity.

An efficient supply chain can support key traceability processes such as product authentication, identification of counterfeit product or reverse logistics, e.g. returns or recalls. A more efficient healthcare supply chain could reduce errors, reduce costs for all stakeholders and enable better quality patient care.

1.2.   Purpose of this Document

The purpose of this document is to assist any/all stakeholders in the global healthcare supply chain to implement a traceability system in line with the GS1 Global Traceability Standard for Healthcare (GTSH) utilising the GS1 System of standards (2.0).

For products, in scope are all pharmaceutical products and all medical device products. Out of scope is implementation of traceability related to non-medical products supplied to Healthcare providers (e.g. food, information technology), blood and blood products.

For supply chain, the start and end points in scope are from manufacturer of finished goods, including products created in the care facility, throughout the product's intended useful life. Out of scope is implementation of traceability related to patients and healthcare professionals (HCPs) and End of Life Environmental regulations (e.g. European Waste Electrical and Electronic Equipment (WEEE) Directive)

Note: The Waste Electrical and Electronic Equipment Directive (WEEE Directive) is the European Community directive 2002/96/EC on waste electrical and electronic equipment (WEEE) which, together with the RoHS Directive 2002/95/EC, became European Law in February 2003, setting collection, recycling and recovery targets for all types of electrical goods. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0096:EN:HTML

Future versions of this guideline may extend the current scope to the out of scope areas.

1.3. Who Will Use this Document?

Any/all stakeholders in the global healthcare supply chain that want to implement a traceability system, suppliers of components or raw materials, finished goods manufacturers, distributors, wholesalers, third party logistics providers (transporters), service providers (e.g. instrument decontamination or repair providers), dispensers, institutional providers, regulators, patients and solution providers.

The target audience of this guideline is suppliers of components or raw materials, finished goods manufacturers, distributors, wholesalers, third party logistics providers (transporters), dispensers, institutional providers, patients.

In addition, this global implementation guideline can be used by GS1 Member Organisations (MOs) to support the implementation efforts of their local members. It is anticipated that this global guideline may be tailored ("localized") by some MOs, e.g. translated into the local language, or local versions developed for specific traceability priorities (e.g. plasma derivate products or surgical instrument decontamination).

1.4. How to use this document

This document should be used in conjunction with the GTSH, the Healthcare specific parts of the GS1 General Specifications and the technical standards related to the organisation's choice of identification, labelling, data capture and data exchange. Specific recommendations for which GS1 AIDC Data, GS1 Data Carriers, GS1 Application Identifiers to be used as well as key allocations rules, symbology specifications, symbol placement and data processing guidance can be found in the appropriate sections of the *GS1 General Specifications* (Section 2 for Application Standards, Section 3 for Application Identifiers, Section 4 for Key Allocation Rules, Section 5 for Symbol Specifications, Section 6 for Symbol Placement Rules, Section 7 for Data Processing)

It is acknowledged that this guideline may not be read in its entirety. But it is recommended that you read this section through to and including section 4 of this guideline; targeted reading can then focus on section 5 and the stakeholder chapter relevant to your organisation (e.g. manufacturer 5.2 or dispenser 5.5).

1.5. Structure of this Document:

The document is organised into different sections: Section 2 provides an overview of the GS1 system of standards, Section 3 covers key concepts / key principles, Section 4 covers implementation procedures, Section 5 includes separate sections for each supply chain stakeholder, section 6.0 covers selection of technologies and/or solution providers and Section 7 covers assessment of the implemented traceability system.

2.   Overview of GS1 Standards

The GS1 System is an integrated system of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. It is the most implemented supply chain standards system in the world (GS1 Website: www.gs1.org).

The GS1 System is the foundation of a wide range of efficiency-building supply chain applications and solutions. Based on GS1 Identification Keys, a common recurring set of identification keys, the GS1 System is composed of four key product areas:

Global data and application standards for bar codes that use the globally recognised GS1 Identification Keys to automatically identify things such as trade items, locations, logistic units, and assets.

Global standards for electronic business messaging that allow rapid, efficient and accurate automatic electronic transmission of agreed business data between trading partners. Based on two components: GS1 EANCOM and GS1 XML

The Global Data Synchronisation Network™ (GDSN™) is an automated, standards-based, global environment that enables secure and continuous data synchronisation, allowing all partners to have consistent item data in their systems at the same time. Global Product Classification (GPC) is a key component of GDSN, enabling effective category management.

A new global standards system that combines RFID (radio frequency identification) technology, existing communications network infrastructure and the Electronic Product Code (a number for uniquely identifying an item) to enable immediate and automatic identification and tracking of an item through the whole supply chain globally, resulting in improved efficiency and visibility of the supply chain.

Figure 2-1 GS1 System of Standards
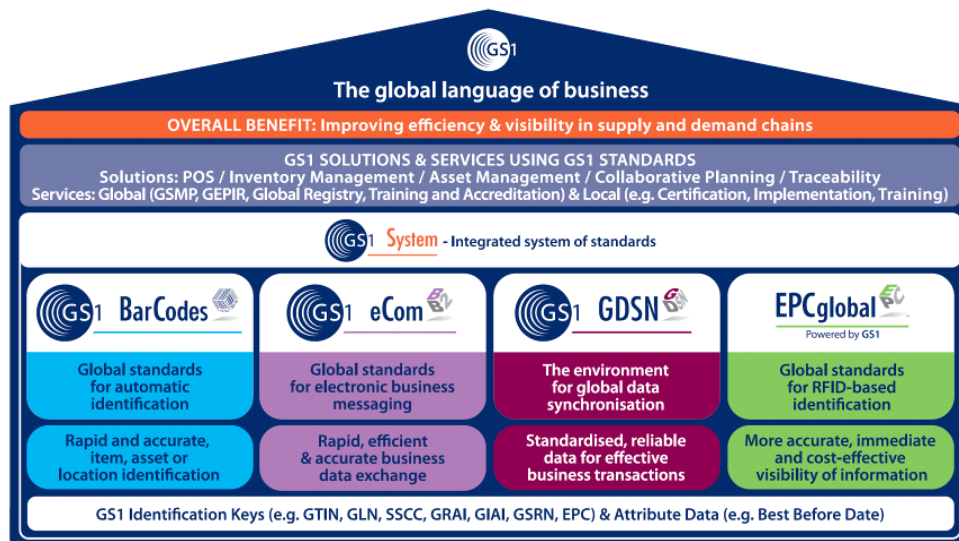
3. Key Concepts / Key Principles

External and internal traceability are needed to achieve full supply chain traceability. Internal traceability can be achieved by the organisation itself but external traceability, between trading partners, requires a common language and some previous agreement on how to track and trace, be it in terms of what to track and trace, how to identify it, what data to exchange and/or the technology to use. This is where GS1 standards play a role.

The Healthcare Industry has adopted the GTS (named GTS for Healthcare (GTSH)) in order to enable Traceability across the Healthcare Supply Chain, whatever the size of the organisation and whichever the country. The GTSH is a process standard that defines minimum data requirements for traceability for all partners and is based on using GS1 Barcodes, GS1 EPC, GS1 GDSN and GS1 eCom standards for its implementation.

Traceability can be achieved with different levels of accuracy and depth. As the Healthcare Supply Chain is diverse in terms of stakeholders, products, regulations etc… the Healthcare industry has decided to adopt the GTSH as the minimum requirement for all. It is up to each trading partner to determine if they need to go beyond the requirements documented in the GTSH and in this document because of their specific environment, notably the regulatory environment.

3.1. GS1 Identification System should be used

Unique identification of products or traceable items in general, as well as of actors and locations in particular, is a fundamental element to enable traceability across the supply chain. In order to achieve this, the Healthcare Industry has adopted the GS1 Identification system; all the Identification requirements from the GTSH are based on GS1 AIDC specifications for healthcare (refer to the Healthcare specific parts of the *GS1 General Specifications* (Section 2 for Application Standards, Section 3 for Application Identifiers, Section 4 for Key Allocation Rules, Section 5 for Symbol Specifications, Section 6 for Symbol Placement Rules, Section 7 for Data Processing).

Note: GS1 Healthcare will focus on developing a standard and/or guidance on Patient Identification in 2009.

3.2. Which technology to use: GS1 Barcodes, GS1 EPC, GS1 GDSN and GS1 eCom

Traceability can be achieved using various technologies. Given this, GS1's Traceability Standards enable each organisation to choose what is considered the most optimal solution for their operating environment. In defining key traceability principles, GS1 has developed an implementation model that links Business Needs to Supporting Technologies and GS1 Standards (Figure 3-1).

- For labelling: barcodes or RFID
- For data exchange between partners: EDI, web EDI and/or network of data bases (e.g. Electronic Product Code Information System (EPCIS))
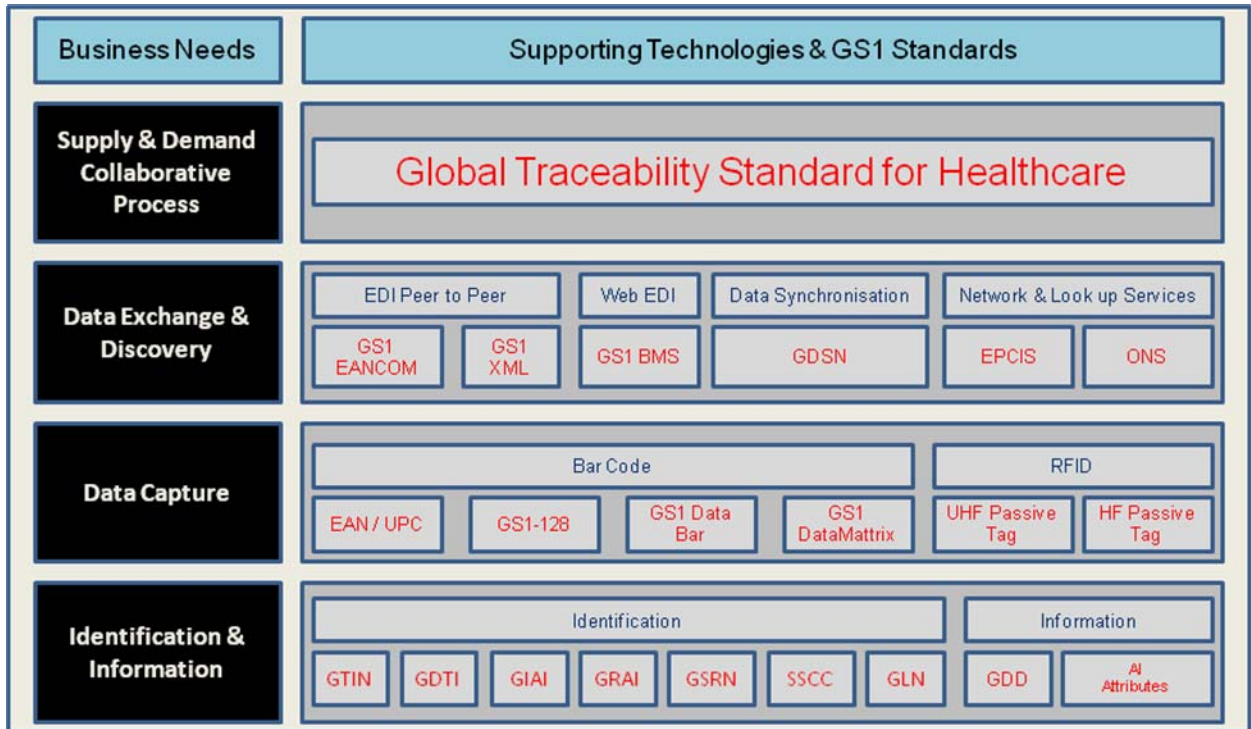
Note: Technologies for data recording depend on the internal information system(s) of the organisation (e.g. Enterprise Resource Planning (ERP), software…).

Figure 3-1 Business Needs linked to Technologies and Standards

3.3. The organisation's role in traceability

Depending on its activity, an organisation has different types of responsibility for traceability (e.g. brand owner vs. carrier).

Traceable item creators have specific responsibilities in terms of traceability. Traceable item creators are organisations that produce a traceable item. They are typically manufacturers (as they create trade items and logistic units) and 3rd party logistic organisations (3PLs), as they may create logistic units when splitting and re-creating pallets for example. Refer to Section 5 for the actors included in this healthcare guideline, the sub-sections following present specific recommendations by type of actor.

3.4. Levels of Traceable Items

In the GTSH glossary, a traceable item is "*A physical object, which may or may not be a trade item, where there may be a need to retrieve information about its history, application, or location. The level at which the traceable item is defined is dependent on the industry and degree of control required (for example within a product packaging or logistical hierarchy)… It could be tracked, traced, recalled or withdrawn. It could exist in multiple locations at the same time (for example, if identified at the trade item and batch/lot level). A traceable item may be related to another traceable item. It is the choice of the Traceability Partner which identification level (e.g. GTIN or batch/lot or serial level) to use for the traceable item.*"

It can be:

■ a trade item in general (end product, carton, pallet…),

■ batches/lots of trade items

■ individually serialized trade items

■ a logistic unit (GTSH glossary: *"An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with a Serial Shipping Container Code (SSCC); usually pallet or cartons"*)

■ a shipment

If a risk based approach is taken to determine the level of identification, item traceability could be at the GTIN-only level, GTIN+Lot level or GTIN+Serial level; see Figure 3-2.

Figure 3-2 Traceability Ladder of Precision
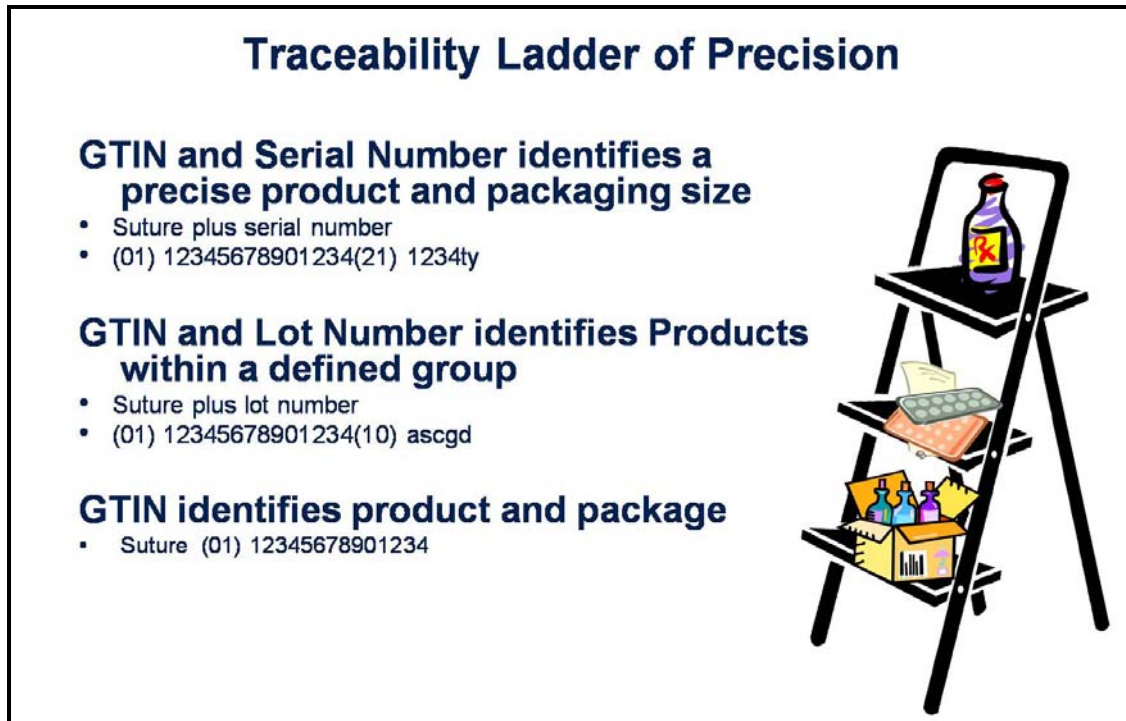
4. Implementation Procedures

Implementation of open, global and proven standards enable effective and efficient traceability systems and the GS1 System is applicable to the full range of GS1 members of any size and to all levels of organisational complexity and system sophistication, although the depth and breadth of operational implementation will vary for each organisation in line with their traceability priorities.

4.1. Traceability implementation – Project Management Methodology

GS1 has defined a project management methodology for traceability implementation: *Ten Steps to Traceability Implementation* (Figure 4-1). Following this methodology will help organisations design the tracea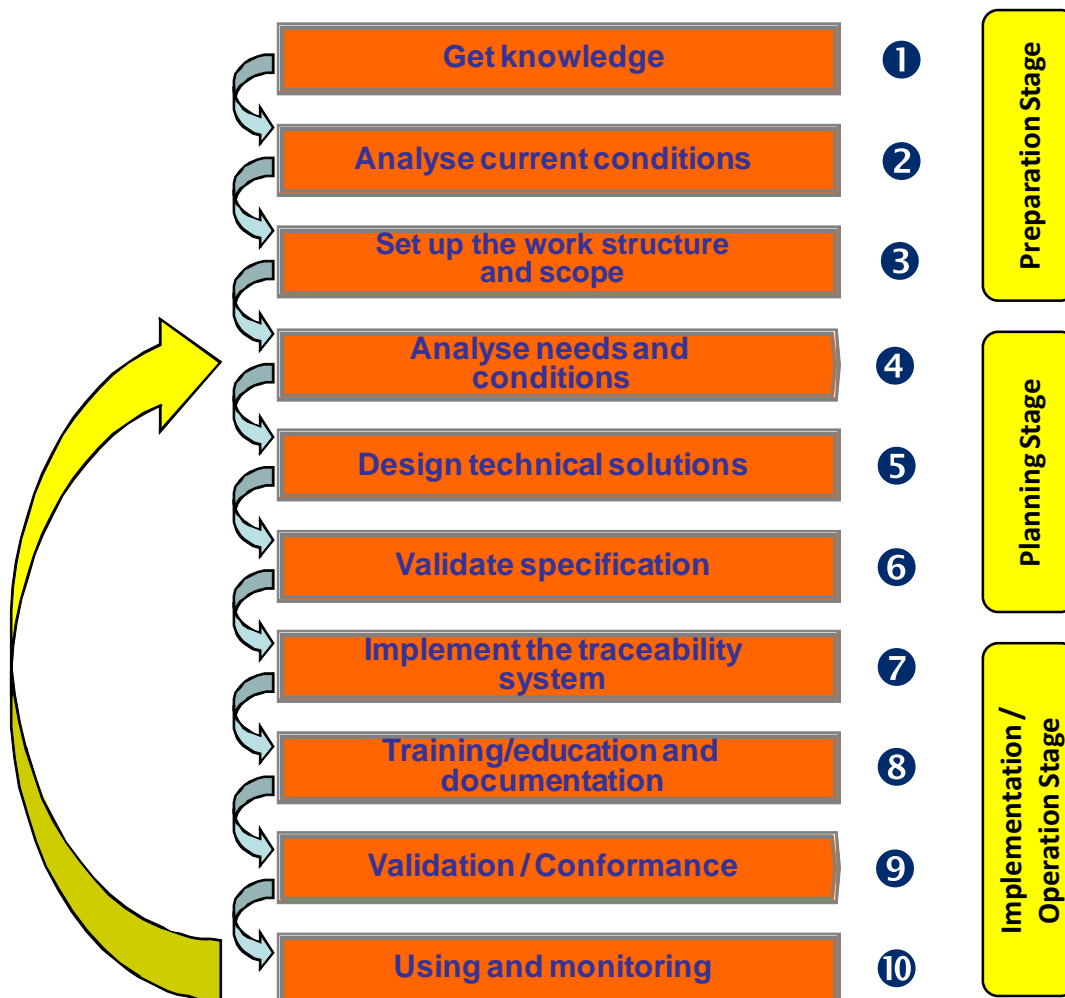bility system that meets their specific needs while being in line with global standards. It contains all the fundamental steps to ensure all important tasks have been covered, although it is accepted that the order of the steps may need to be altered to meet the needs of a specific organisation.

Detailed information on the methodology can be found in the Traceability section of the GS1 website: http://www.gs1.org/productssolutions/traceability/implementation/, in summary:

Figure 4-1 Ten Steps to Traceability Implementation

Step		Stage
Get knowledge	❶	Preparation Stage
Analyse current conditions	❷	
Set up the work structure and scope	❸	
Analyse needs and conditions	❹	Planning Stage
Design technical solutions	❺	
Validate specification	❻	
Implement the traceability system	❼	Implementation / Operation Stage
Training/education and documentation	❽	
Validation / Conformance	❾	
Using and monitoring	❿	

Preparation Stage

1. Get knowledge

TASKS	RESULTS
Contact GS1 Member Organisation Collect Information	Knowledge , including of the GTS Need for consulting?

Research, collection of data and a clear understanding of current literature needs to be undertaken to obtain an up-to-date picture of existing traceability solutions, procedures and best practices.

This will enable organisations to make the right early decisions such as choosing appropriate consulting services and enabling technologies.

The local GS1 Member Organisation (MO) can help you get the necessary knowledge and training on the traceability process, technologies and on GS1's corresponding Standards. It provides expert advice about traceability and the GS1 GTSH, as well as any existing industry specific agreements, support during your project implementation and help to identify the technology most suited to your requirements.

2. Analyse current conditions

TASKS	RESULTS
• Analyze Internal / External Conditions • Prepare Business Plan, SWOT Analysis • Make Diagnosis of what needs to be done	Go/No go decision Budget definition Senior level sponsor for project

This step is extremely important for understanding an organisation's current operating conditions and, therefore, can greatly influence future decision-making. It includes high level analysis of existing internal operational conditions (e.g. the organisation's operational capability and adaptability) and current external environmental conditions (e.g. applicable regulations (e.g. Unique Device Identification (UDI)), contractual agreements, partners' business requirements, their drivers and internal technologies).

Some well-known tools can help at this stage such as brainstorming, Strengths-Weaknesses-Opportunities-Threats (SWOT) analysis and high level business plans.

The results of this analysis enables evaluation of the problem and indicates the required resources and budget necessary to implement the solution and, ultimately, to take a go/no go decision. If a "go" decision is taken a senior level sponsor for the project should be identified and/or assigned.

3. Set up the work structure and scope

TASKS	RESULTS
• Define Responsibilities • Fix Deadlines • Determine Scope	Project Manager Steering committee Action planning 1st level of specification

Traceability is multi-disciplinary. Many departments will be involved in development and implementation of a Traceability system.

A fundamental decision to take at the beginning of this process is to define internal and external roles and responsibilities, the scope of the traceability process across the supply chain, timelines, the traceability partners involved, the traceability model boundaries, the main use cases of the traceability system (e.g. risk management, recalls etc.) and expected types of trace requests, as well as the level of required traceability (e.g. at pallet, case, SKU level).

The results of this step are the appointment of the steering committee and project manager, action planning and first level specifications.

Planning Stage

4. Analyse needs and conditions

TASKS	RESULTS
• Identify departments most concerned • Chart the organisation processes • Chart the product flow - linked with • Information flow • Apply the GTC – Check List	Chart of Traceability Flow Project Management Plan Gap analysis Functional specifications

Start by describing the physical flow of items through your supply chain. This can be done by walking though each step of the supply chain to identify the physical locations, inputs, internal processes and outputs, to identify the type of products that are exchanged between your traceability partners and to describe the logical hierarchies. Make sure you add flow of information about items to this diagram.

The results are a project plan, gap analysis and functional specifications (including supply chain links, operating and data exchange processes, relevant documents, key departments, critical control point definitions and assignment of GTSH roles).

Applying the Global Traceability Conformance (GTC) Checklist (see Section 7) can help during this analysis, enabling your organisation to compare actual conditions with intended performance.

✓ **Note:** At the time this document was published validation and/or development of the GTC to ensure it met the specific needs of healthcare had not been undertaken; but is planned for 2010.

5. Design technical solutions

TASKS	RESULTS
• Identify where to achieve traceability • Select the enabling technology • Define information system • Prepare implementation schedule	Technical specifications Description of the procedures

This step involves a number of activities:

Define and model how and where to achieve traceability along the internal process of the physical flow (stock management, production, transformation, manipulation process).

Prepare the technical specifications: select the enabling technologies for identification and the data carrier to collect, share, store and retrieve data.

Prepare detailed work breakdown structure (WBS) and time schedule of implementation. Determine the steps to implement appropriate level of identification (e.g. item or logistic units).

Define and implement EDI Messages and acquire or adapt the necessary information systems.
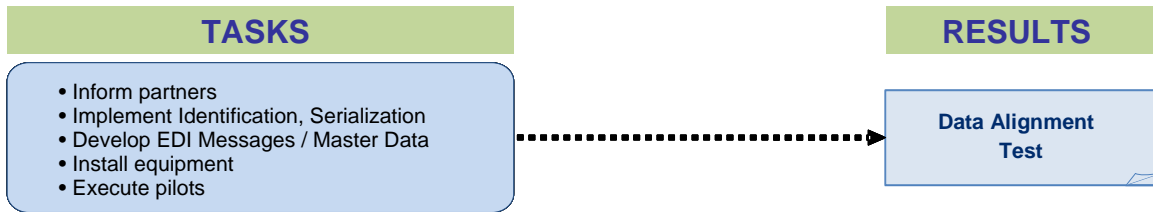
6. Validate Specification

TASKS	RESULTS
• Validate the model	Agreement between departments and partners

Validate the whole model with all parties by applying the GTC and paying attention to the capabilities of parties to fulfil the requirements for reception and delivery of goods.

Implementation / Operation Stage

7.   Implement the Traceability System

TASKS	RESULTS
• Inform partners • Implement Identification, Serialization • Develop EDI Messages / Master Data • Install equipment • Execute pilots	**Data Alignment Test**

Now implementation can start. Firstly, inform all affected supply chain partners, so they can include the results of your plan in their own traceability related projects. Implementing traceability will most probably change the way products are labelled and information is shared between traceability partners. It therefore impacts the entire supply chain.

It might be beneficial to first select a pilot project involving one partner in order to test the live procedures and technology solutions. Lessons learned from the pilot can help to improve the specifications and plan, for example:

For pharmaceuticals and medical devices it is typical for a supplier to provide traceability information to manufacturers in order to fulfil internal traceability and local market regulatory requirements. However this information is often not passed in a format conducive to sharing with downstream partners.

8.   Training, Education and Documentation

TASKS	RESULTS
• Train staff • Prepare documentation	Documentation available Staff / People involved trained

Raise staff awareness. The skills acquired through the work of the project team must not be lost once the implementation phase is finished. Training the operational traceability team and all key staff and having good documentation of the system is a substantial part of this project.
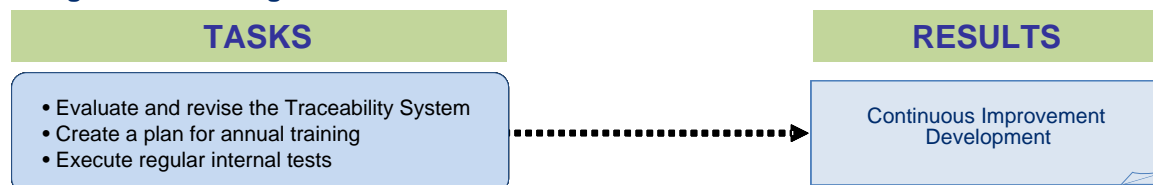
9.   Validation and Conformance

TASKS	RESULTS
• Audit the organisation • Apply the GTC	• Certification • GS1 Seal

Once the new traceability business process has been implemented by all parties, the GTC check list can be applied to validate the system and an audit can be requested to receive a GS1 seal.

Contact your local GS1 Organisation to get additional information.

10.   Using and Monitoring

TASKS	RESULTS
• Evaluate and revise the Traceability System • Create a plan for annual training • Execute regular internal tests	Continuous Improvement Development

To maintain a high quality traceability system, annual training of key staff and regular internal tests should be undertaken. Best practices recommend simulations and annual tests with traceability partners.

Based on the results of assessments, tests and trial runs and/or new tools available, evolution of regulatory landscape, existing recalls and withdrawals, the system should be evaluated and revised as necessary. If improvements are identified as the result of the periodic evaluation, then a new traceability project is required.

4.2.   The components of implementing a Traceability System

Section 6.1.3 of the GTSH states that "*The performance goal of the traceability process is for Traceability Partners to be able to retrieve information about the history, application or location of a traceable item from any point in the supply chain.*"

The necessary components are to:

A.   Plan and Organize (pre-requisite)

B.   Align Master Data

C.   Record Traceability Data

D.   Request Trace

E.   Use information

Therefore, in this guideline, it is assumed:

■   that a supply chain partner is going to fulfil traceability business requirements (BRs), as defined in Section 7 of the *GTSH V1.0*, for identifying products and locations; capturing data associated with the identified products and locations and, at the request of an extended supply chain partner, can produce the data. The product is thus a "traceable item" in the context of the GTSH.

■   that while following the GTSH is necessary for efficient data exchange with extended supply chain partners using globally interoperable standards, it is not compulsory to use the GTSH for the internal traceability processes within an organisation. However, it is recommended that the organisation explore the opportunity to harmonize internal and external traceability practices, processes and standards to reap greater benefit.

Figure 4-2 graphically shows these components:

Figure 4-2 Traceability Components

Practically the following steps should be followed:

Pre-requisite:

Step 1:   Determine how to assign, collect, share, and keep traceability data.

Step 2:   Determine how to manage links between inputs, internal processes, and outputs.

Before the physical flow

Step 3:   Create Global Location Number(s) (GLN) for your organisation using your Company Prefix (assigned by the local GS1 Member Organisation (MO)) and the GS1 GLN Allocation Rules as guidance.

Step 4:   Assign GLNs to locations in your organisation that are required for traceability. Usually, GLNs are assigned, at least, per geographical sites.

Step 5:   Assign Global Trade Item Number (GTIN) to Trade items. Trade Items are items that can be ordered by customers.

Step 6:   Assign Global Returnable Asset Identifier (GRAI) to assets that need to be traced as relevant

Step 7:   Exchange Master Data with Trading Partner. Master Data are core data elements that should be aligned between trading partners before starting to order and deliver the products. For example: GTIN, description of the product, height, weight, etc… The best practice is to use a GDSN certified data pool.

During the Physical flow

Traceable item creators (e.g. suppliers, manufacturers, institutional providers, dispensers) must:

Step 8:   Assign identification to traceable items, at the latest when physically created (for example, at the end of the production line, when creating a pallet before shipment, when compounding a drug in a pharmacy):

- If the traceable item is a trade item, a GTIN must be assigned

- If the traceable item is a batch/lot of trade items, the organisation will use the GTIN of the Trade Item and its internal batch/lot number. It is the responsibility of the brand owner to ensure the GTIN + batch/lot number is unique.

- If the traceable item is a serialized trade item: GTIN + serial number

- If the traceable item is a logistic unit: SSCC

- If a traceable item is a shipment: Global Shipment Identification Number (GSIN)

It is up to the Traceable item creator to choose the right level of identification and accuracy based on:

- Traceability applications (recalls, authentication, efficient logistics)

- Regulations

- Customer requirements

- Technology requirements (serialization is compulsory if using RFID)

Yet there must be at least one common level of traceable item between trading partners in order to ensure external traceability. Often, the common traceable item between trading partners are logistic units and batches/lots of trade items.

Step 9:   Label traceable items as soon as created (see example above). The label should remain on the product throughout its intended useful life. This means, for example, that third party logistics (3PLs)/transporters or customers should not re-label traceable items with their own label!

- If the traceable item is a trade item, the label should contain the traceable item identifier (GTIN) encoded in a data carrier (e.g. EAN/UPC or GS1 DataMatrix barcode).

- If the Traceable item is a batch/lot of trade items, the label should contain the traceable item identifier (GTIN) encoded in a data carrier (e.g. EAN/UPC) + batch/lot number + human readable information (HRI). With regard to Trade items not intended for Point of Sale GTIN and additional data can be encoded using GS1 Application Identifiers (e.g.: GS1-128).

- If logistic units: GS1 logistic label or EPC tag with SSCC

It is up to trading partner to choose the way to label the traceable items according to:

- Their environment

- Their sector/product and potential specific commercial agreement

- Pros & cons of each technology
Yet note that mass implementation today is taking place based on GS1 128 on logistic units and on trade items in Healthcare.

All stakeholders handling the goods must:

At reception and during relevant events:

Step 10:   Capture identification of the traceable item using automatic Data Capture provided by the label (barcodes, RFID…). This is of course depending on the supplier and more specifically of the creator of the item. Yet if current labels received from suppliers do not enable automatic data capture, trading partners can contact their suppliers in order to invite them to use GTSH for their own benefits (automation at the dispatch) as well as for traceability reliability (data capture by the customer on receipt).

Step 11a   Collect data from the supplier. DESADV is the best practice today. For those who want to achieve visibility at a more granular level, then EPCIS can be used in addition).

At dispatch

Step 11b   Collect internal data from dispatching step.

Step 12:   Share at least the data mentioned in the BR13 (Figure 4.4). The best practice is to use the DESADV EDI, (for those who want to achieve visibility at a more granular level, then EPCIS can be used in addition).

Step 11c: Record links between inputs and outputs

Step 13   Store all data collected and shared at reception, dispatch during the internal process as relevant. The length of time for retention of data should be in line with local regulatory requirements.

Figure 4-3 Data Elements to capture and share

Data		Supplier	Manufacturer	Distributor / Wholesaler	3PL/Transporter	Institutional Provider	Dispenser
TRADING PARTNER IDENTIFICATION:							
Traceable Item Source Identification		x	x	x	x	x	x
Traceable Item Recipient Identification		x	x	x	x	x	x
Traceability Data Source Identification		x	x	x	x	x	x
Traceability Data Recipient Identification		x	x	x	x	x	x
Date of Despatch and / or Receipt		x	x	x	x	x	x
TRACEABLE ITEM IDENTIFICATION AND DETAILS:							
When the Traceable Item is a Trade Item	Trade Item Identification	x	x	x		x	x
	Trade Item Description	x	x	x		x	x
	Trade Item Quantity	x	x	x	x	x	x
	Date of Despatch and / or Receipt	x	x	x	x	x	x
When the Traceable Item is a Batch/ Lot of Trade Items	Trade Item Identification + Batch / Lot Number	x	x	x		x	x
	Trade Item Description	x	x	x		x	x
	Trade Item Quantity	x	x	x	x	x	x
	Date of Despatch and / or Receipt	x	x	x	x	x	x
When the Traceable Item is a serialised Trade Item	Trade Item Identification + Serial Number	x	x	x	x	x	x
	Trade Item Description	x	x	x		x	x
	Trade Item Quantity	x	x	x	x	x	x
	Date of Despatch and / or Receipt	x	x	x	x	x	x
When the Traceable Item is a Logistics Unit:	Logistic Unit Identification	x	x	x	x		
	Logistic Unit Quantity	x	x	x	x		
	Date of Despatch and / or Receipt	x	x	x	x		
When the Traceable Item is a Shipment	Shipment Identification	x	x	x	x		
	Date of Despatch and / or Receipt	x	x	x	x		

Step 14 to 17 When necessary, initiate a trace request or send a response to a trace request. Trace requests are initiated when, internally, information about a traceable item, needed to achieve a specific action, is missing. For example:

- Request from a regulatory representative

- Quality incident, recall and/or withdrawal

- Checking to whom it has been delivered

- EPC network / EPCIS can be used for companies that have been using EPCIS to record information along the chain.

Otherwise, trace requests are often achieved by means of e-mails, fax or telephone.

Note: A Change Request (CR 08-000224) currently exists to standardize and automate trace requests

5. Implementation by Stakeholder

The rest of this document is divided into separate sections. Each section focuses on a particular stakeholder in the healthcare supply chain and gives examples of implementation of traceability for that stakeholder; the stakeholders included are:

■ Supplier (raw materials or components)

■ Manufacturer (finished goods)

■ Wholesaler / Distributor

■ Third Party Logistics (3PL) / Transporter

■ Dispenser (e.g. retail pharmacists, clinicians)

■ Institutional Provider (e.g. hospitals, clinics, nursing homes)

Section 10.1 of *GTSH V1.0* shows a "Fully Worked Example: Traceability in the Pharmaceutical Supply Chain", this example is reproduced below (Figure 5-1) followed by an example of Traceability in the Medical Device Supply Chain (Figure 5-2). These examples and Section 7.2.3 of the GS1 Trace I document (*GS1 Traceability Implementation, Trace I Project, Feb 2008, p89*) are drawn upon in the following stakeholder sections.

Figure 5-1 Fully Worked Example: Traceability in the Pharmaceutical Supply Chain
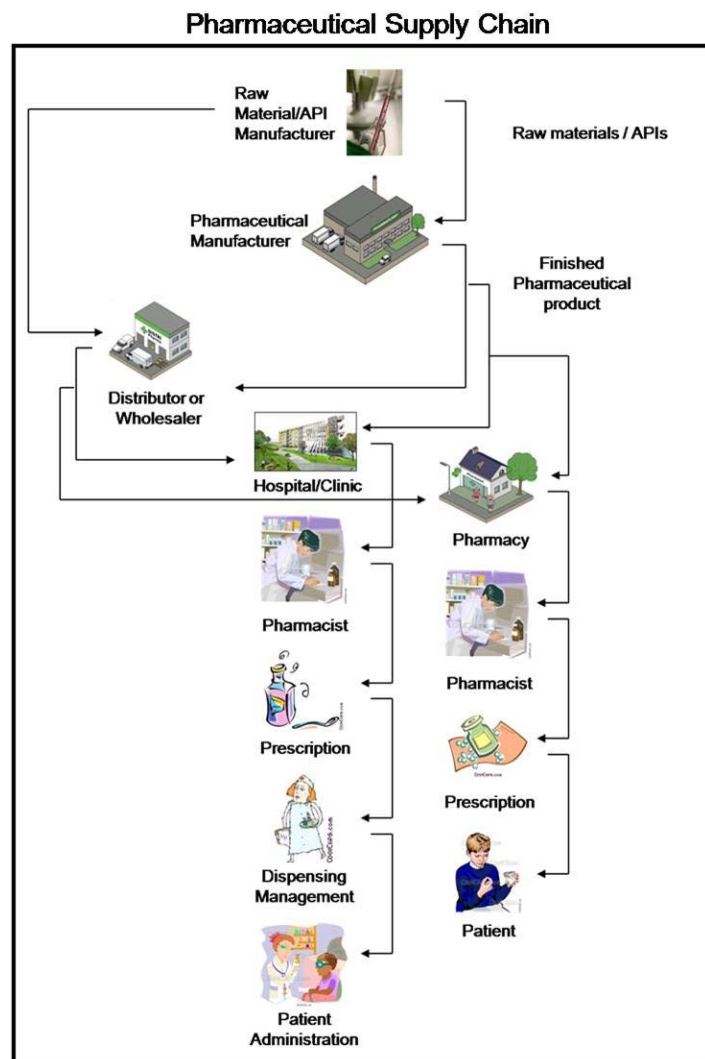
Figure 5-2 Fully Worked Example: Traceability in the Medical Device Supply Chain
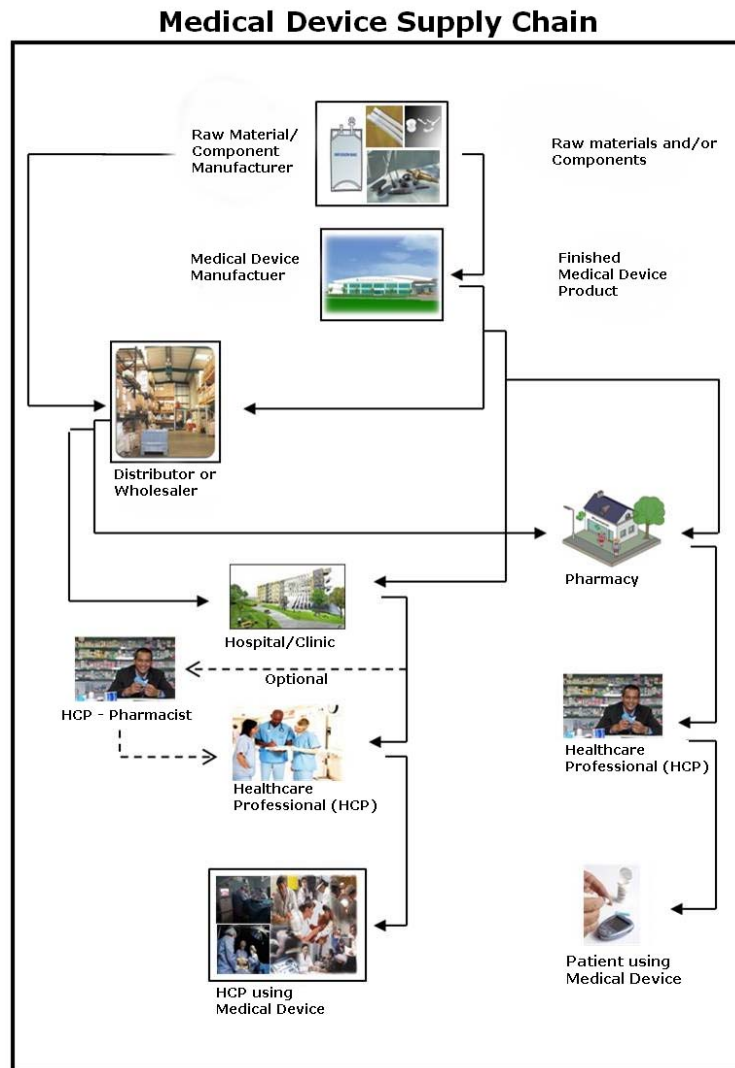
The following examples illustrate supply chains that are mature and sophisticated in terms of process and technology; practically it is more likely that a step-change approach, over a period of years, will be followed to reach this level of maturity and sophistication.

5.1.   Implementation: Supplier

Pre-Requisite Reading: You are strongly advised, at a minimum, to read Sections 1.4 (How to use this document) through to and including Section 4.2 (The components of implementing a Traceability System) of this guideline before reading further.

For the purpose of this document "Supplier" refers to supply chain partners who provide components or raw materials to the finished goods manufacturer (manufacturer).

5.1.1.   Example:

A supplier receives an order for raw materials from a manufacturer. The raw materials are packed into appropriate packaging and, as the supplier works with GS1 standards, GTINs are assigned to the packages. The packages are grouped into a carton and a GTIN is assigned to the carton.

The supplier uses the Healthcare specific parts of the *GS1 General Specifications* (Sections 2, 3, 4, 5 and 6) to determine the choice of AIDC Data and Carrier to apply to any level of Healthcare product (BRs 3 to 10). The product master data is stored in a product data base and connected with the related GTIN (BR11 to 14) (*GS1 General Specifications*, section 7).

✔ **Note:** GS1 Healthcare has developed the reference materials, which communicate the relationship of data and carrier requirements to the various healthcare products, their grouping by AIDC level of marking and the range of marking levels from direct part mark to pallet. For more information please see the GS1 Healthcare website: http://www.gs1.org/sectors/healthcare/index.html. However, as a supplier of components or raw materials to manufacturers, the choice of identification level may be determined by them to meet their traceability requirements. GS1 Upstream Integration guidance can be referenced for upstream suppliers.

Figure 5-3 Implementation: Supplier
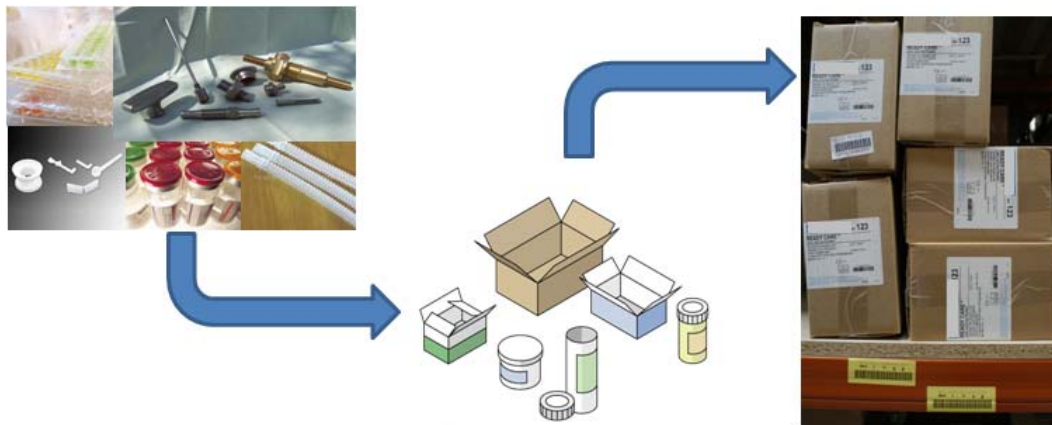
If applicable, and in order to fulfil regulatory requirements, the supplier must indicate the corresponding batch/lot number and/or expiration date in human readable form. To enable faster and accurate data capture and processing, the supplier may also encode this information in the GS1-128 or GS1 DataMatrix barcode on each packaging level.

✔ **Note:** If regulatory requirements do not exist for Human Readable Information (HRI), refer to the Healthcare specific parts of the *GS1 General Specifications* (Sections 2, 3, 4, 5 and 6) to determine whether to print HRI associated to the information encoded in the AIDC Carrier.

When the order is complete, and if the carton is one of a number of items that form a shipping/logistics unit or is on a pallet of goods, the shipping unit or pallet receives a Serial Shipping Container Code (SSCC); if the carton is the shipping unit, it may not receive an SSCC. The globally unique SSCC enables traceability of the shipping unit from leaving the warehouse until arrival at the manufacturer. In addition, the SSCC is connected with the essential information such as the GTIN.

When the material physically leaves the supplier's site, an electronic despatch advice is sent – containing the SSCC – to the customer to provide the manufacturer with the relevant information.

This example is continued in Section 5.2 Implementation: Manufacturer, Section 5.2.1 Medical Device Example and 5.2.2 Pharmaceutical Example.

5.1.2. Best Practice and/or Case Study

An extensive range of up to date case studies and best practice papers from around the world are available on the GS1 Healthcare website at:

www.gs1.org/sectors/healthcare/implementation/traceability.html

5.2. Implementation: Manufacturer

Pre-Requisite Reading: You are strongly advised, at a minimum, to read Sections 1.4 (How to use this document) through to and including Section 4.2 (The components of implementing a Traceability System) of this guideline before reading further.

For the purpose of this document "Manufacturer" refers to supply chain partners who provide finished goods to downstream partners (e.g. wholesalers, distributors, dispensers, institutional providers).

5.2.1. Medical Device Example

(Continued from 5.1.1)

A medical device manufacturer receives an order for surgical gloves from a hospital ("Institutional Provider"). The boxed gloves are packed into cartons; the cartons are grouped onto a pallet[16].

As the manufacturer works with GS1 standards GTINs are assigned to the products. The manufacturer uses the Healthcare specific parts of the *GS1 General Specifications* (Sections 2, 3, 4, 5 and 6) to determine the choice of AIDC Data and Carrier to apply to any level of Healthcare product (BRs 3 to 10). The product master data is stored in a product data base and connected with the related GTIN (BR11 to 14) (*GS1 General Specifications*, section 7).
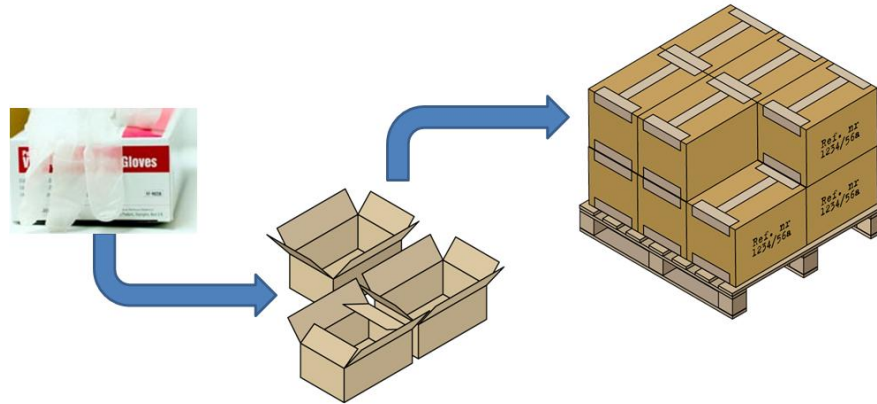
Note: GS1 Healthcare has developed the reference materials, which communicate the relationship of data and carrier requirements to the various healthcare products, their grouping by AIDC level of marking and the range of marking levels from direct part mark to pallet. For more information please see the GS1 Healthcare website at: www.gs1.org/sectors/healthcare/index.html

Figure 5-4 Implementation: Manufacturer (Medical Device Example)

In order to fulfil regulatory requirements the manufacturer must indicate the corresponding batch/lot number and expiration date in human readable form. To enable faster and accurate data capture and processing, the manufacturer may also encode this information in the GS1-128 or GS1 DataMatrix barcode on each packaging level.

✅ **Note:** If regulatory requirements do not exist for Human Readable Information (HRI), refer to the Healthcare specific parts of the *GS1 General Specifications* (Sections 2, 3, 4, 5 and 6) to determine whether to print HRI associated to the information encoded in the AIDC Carrier.

When the order is complete, a Serial Shipping Container Code (SSCC) is assigned to the shipping unit (pallet). The globally unique SSCC enables traceability of this shipping unit from leaving the warehouse until arrival at the hospital. In addition, the SSCC is connected with the essential information such as GTIN and batch/lot number.

When the material physically leaves the manufacturer's site, an electronic despatch advice is sent – containing the SSCC – to the customer to provide the hospital with the relevant information. A transport order (IFTMIN) is sent to the logistics service provider.

This example is continued in Third Party Logistics provider (3PL/Transporter)

5.2.2. Pharmaceutical Example

(Continued from 5.1.1)

A pharmaceutical manufacturer receives an order for a quantity of a branded pharmaceutical (drug) from a wholesaler/distributor. The drug is packed into cartons; the cartons are grouped onto a pallet.

As the manufacturer works with GS1 standards GTINs are assigned to the packaging at the unit level. The manufacturer uses the Healthcare specific parts of the *GS1 General Specifications* (Sections 2, 3, 4, 5 and 6) to determine the choice of AIDC Data and Carrier to apply to any level of Healthcare product (BRs 3 to 10). The product master data is stored in a product data base and connected with the related GTIN (BR11 to 14) (*GS1 General Specifications*, section 7).

✅ **Note:** GS1 Healthcare has developed the reference materials, which communicate the relationship of data and carrier requirements to the various healthcare products, their grouping by AIDC level of marking and the range of marking levels from direct part mark to pallet. For more information please see the GS1 Healthcare website www.gs1.org/sectors/healthcare/index.html

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Figure 5-5 Implementation: Manufacturer (Pharmaceutical Example)
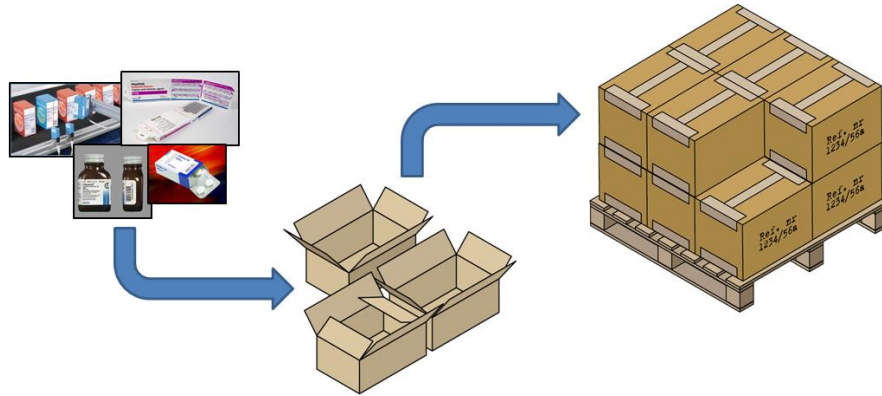
In order to fulfil regulatory requirements the manufacturer must indicate the corresponding batch/lot number and expiration date in human readable form. To enable faster and accurate data capture and processing, the manufacturer may also encode this information in the GS1-128 or GS1 DataMatrix barcode on each packaging level.

Note: Example: for controlled pharmaceutical product in California, USA, identification of an item with a GTIN only would be insufficient; this regulation6 requires serialisation – GTIN + Serial No. (from 2015)

Note: If regulatory requirements do not exist for Human Readable Information (HRI), refer to the Healthcare specific parts of the *GS1 General Specifications* (Sections 2, 3, 4, 5 and Section) to determine whether to print HRI associated to the information encoded in the AIDC Carrier.

When the order is complete, a Serial Shipping Container Code (SSCC) is assigned to the shipping unit (pallet). The globally unique SSCC enables traceability of this shipping unit from leaving the warehouse until arrival at the wholesaler/distributor. In addition, the SSCC is connected with the essential information such as GTIN and batch/lot number.

When the material physically leaves the manufacturer's site, an electronic despatch advice is sent – containing the SSCC – to the customer to provide the wholesaler/distributor with the relevant information.

This example is continued in 5.3.2 Wholesaler/Distributor

5.2.3. Best Practice and/or Case Study

An extensive range of up to date case studies and best practice papers from around the world are available on the GS1 Healthcare website at:

www.gs1.org/sectors/healthcare/implementation/

5.3. Implementation: Wholesaler / Distributor

Pre-Requisite Reading: You are strongly advised, at a minimum, to read Sections 1.4 (How to use this document) through to and including Section 4.2 (The components of implementing a Traceability System) of this guideline before reading further.

For the purpose of this document "Wholesaler/Distributor" refers to supply chain partners who are engaged in wholesale distribution of products to downstream partners, including but not limited to, manufacturers, re-packers, own-label distributors, private-label distributors, brokers, warehouses – including those for manufacturers and distributors who conduct wholesale distribution.

5.3.1. Medical Device Example

A wholesaler/distributor receives an order for catheters from a hospital ("Institutional Provider"). The boxed catheters are packed into cartons.

As the catheters were received from a manufacturer that works with GS1 standards, the boxes already carry a bar-coded GTIN which is recorded in the wholesaler's / distributor's database.

When the order is complete, a Serial Shipping Container Code (SSCC) is assigned to the shipping unit (carton). The globally unique SSCC enables traceability of this shipping unit from leaving the warehouse until arrival at the hospital. In addition, the SSCC is connected with the essential information such as GTIN and serial number.

When the material physically leaves the wholesaler's/distributor's site, an electronic despatch advice is sent – containing the SSCC – to the customer to provide the hospital with the relevant information.

5.3.2. Pharmaceutical Example
(Continued from 5.2.2)

The wholesaler/distributor has received all important shipment information in advance from their upstream supply chain partner (e.g. manufacture). They can scan the Serial Shipping Container Code (SSCC) on the pallet label and automatically match the data with the electronic information received. After completing the visual check the shipment can be moved into the wholesaler's/distributor's warehouse.

The SSCC is used to trace the original pallet within the wholesaler's/distributor's warehouse. Once the content of the original pallet is changed to fulfil customer orders, the SSCC is suspended. In addition a bar-coded expiration date supports effective warehouse management in line with the first-in-first-out (FIFO) principle, unless expiration or use by date applies, which would then take priority.

From this point onwards, tracking of the drugs leaving the warehouse must now be done at the unit level. The reference for tracking products is the GTIN and the lot number.

Figure 5-6 Implementation: Wholesaler / Distributor (Pharmaceutical Example)

The wholesaler/distributor receives an order for a quantity of a branded drug (drug) from a retail pharmacy (Dispenser). The drugs are grouped into a carton.

When the order is complete, a SSCC is assigned to the shipping unit (carton). The globally unique SSCC enables traceability of this shipping unit from leaving the warehouse until arrival at the dispenser. In addition, the SSCC is connected with the essential information such as GTINs and serial numbers.

When the material physically leaves the wholesaler's/distributor's site, an electronic despatch advice is sent – containing the SSCC – to the customer to provide the dispenser with the relevant information.

This example is continued in 5.5.2 Dispenser

5.3.3. Best Practice and/or Case Study

An extensive range of up to date case studies and best practice papers from around the world are available on the GS1 Healthcare website, here:

www.gs1.org/sectors/healthcare/implementation/

5.4. Implementation: Third Party Logistics provider (3PL/Transporter)

Pre-Requisite Reading: You are strongly advised, at a minimum, to read Sections 1.4 (How to use this document) through to and including Section 4.2 (The components of implementing a Traceability System) of this guideline before reading further.

For the purpose of this document "third party logistics provider (Transporter)" (3PL) refers to supply chain partners who receive, carry and deliver one or more traceable items from one point to another without transforming the traceable item(s). Typically only has possession, custody, or control of a traceable item, but may have ownership.

5.4.1. Example

(Continued from 5.2.1)

The 3PL picks up a shipment from a manufacturer's goods despatch point. The only number the 3PL needs to refer to is the Serial Shipping Container Code (SSCC). All information necessary for the transport (size and weight of the shipment, hazardous material etc.) connected to the SSCC was received in advance via the transport order. As soon as the time of arrival is known, the 3PL sends an arrival notice to the hospital which assists them in optimising delivery of goods.

This example is continued 5.6.1 Institutional Provider

5.4.2. Best Practice and/or Case Study

An extensive range of up to date case studies and best practice papers from around the world are available on the GS1 Healthcare website, here:

www.gs1.org/sectors/healthcare/implementation/

5.5. Implementation: Dispenser

Pre-Requisite Reading: You are strongly advised, at a minimum, to read Sections 1.4 (How to use this document) through to and including Section 4.2 (The components of implementing a Traceability System) of this guideline before reading further.

For purposes of this document "Dispenser" refers to supply chain partners who provide medical products that have been prescribed by a healthcare professional, and includes retail Pharmacists and clinicians.

Note: As a dispenser, the choice of identification level is likely to have been made upstream in the supply chain, for example, by the manufacturer. However, consideration should be given to items already in your organisations control. Perhaps they don't comply with the GTSH and a business decision is taken by your organisation to apply the appropriate identification that does comply.
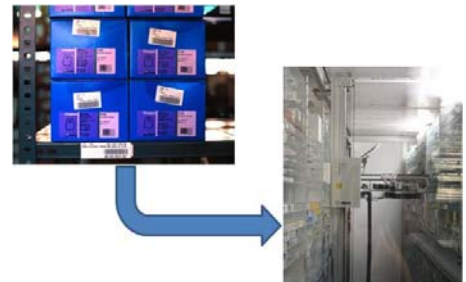
5.5.1. Medical Device Example

A prescription for a diabetes monitor is presented at the retail pharmacy by a patient. Just prior to giving the prescribed product to the patient, the pharmacist scans the GS1-128 or GS1 DataMatrix barcode on the product (that contains the GTIN and serial number). The encoded information is then related to the Electronic Patient Record (EPR). Each prescription for the patient can thus be recorded.

5.5.2. Pharmaceutical Example
(Continued from 5.3.2)

The retail pharmacy has received all important shipment information in advance from their upstream supply chain partner (e.g. wholesaler/distributor); they can scan the SSCC on the carton label and automatically match the data with the electronic information received. After completing the visual check the shipment can de-aggregated, the SSCC suspended and the units moved into the dispenser's store. In addition a bar-coded expiration date supports effective warehouse management in line with the first-in-first-out (FIFO) principle.

From this point onwards, tracking of the products leaving the retail pharmacy must now be done at the unit level. The reference for tracking products is the GTIN and the serial or batch number.

At the unit level, the combination of the encoded GTIN, serial number or batch and expiration date is essential to assure correct handling and, therefore, patient safety.

A prescription is presented at the retail pharmacy by a patient. Just prior to giving the prescribed product to the patient, the pharmacist scans the GS1-128 or GS1 DataMatrix barcode on the product (that contains the GTIN and serial number). The encoded information is then related to the Electronic Patient Record (EPR). Each prescription for the patient can thus be recorded.

5.5.3. Best Practice and/or Case Study

An extensive range of up to date case studies and best practice papers from around the world are available on the GS1 Healthcare website, here:

www.gs1.org/sectors/healthcare/implementation/

5.6. Implementation: Institutional Provider

Pre-Requisite Reading: You are strongly advised, at a minimum, to read Sections 1.4 (How to use this document) through to and including Section 4.2 (The components of implementing a Traceability System) of this guideline before reading further.

For the purpose of this document "Institutional Provider" refers to supply chain partners who prescribe or use medical products in an institutional setting, including hospitals, clinics and nursing homes.

✅ **Note:** As an institutional provider, the choice of identification level is likely to have been made upstream in the supply chain, for example, by the manufacturer. However, consideration should be given to items already in your organisations control. Perhaps they don't comply with the GTSH and a business decision is taken by your organisation to apply the appropriate identification that does comply.

5.6.1. Medical Device Example

(Continued from 5.4.1)

The hospital has received all important information, about the shipment of surgical gloves, in advance from their upstream supply chain partner (e.g. manufacturer); they can scan the Serial Shipping Container Code (SSCC) on the pallet label and automatically match the data with the electronic information received. After completing the visual check the shipment can be moved into the hospital's warehouse.

The SSCC is used to trace the original pallet within the hospital's central warehouse. Once the content of the original pallet is changed to deliver cartons to the wards, the SSCC is suspended. In addition a bar-coded expiration date supports effective warehouse management in line with the first-in-first-out (FIFO) principle.

From this point onwards, tracking of the products leaving the central warehouse must now be done at the product level. The reference for tracking these products is the GTIN and the batch/lot or serial number.

Ward

The cartons arrive at the ward (either direct from stores or (optionally) via the pharmacist) where they are temporarily stored until being required, e.g. for use with a patient. At the box, the combination of the encoded GTIN and batch/lot number is essential to assure correct handling and, therefore, patient safety.

When a healthcare professional uses the product on a patient, the GS1-128 or GS1 DataMatrix barcode on the product (that contains the GTIN and lot number) is scanned. The encoded information is then related to the Electronic Patient Health (EPR). Each product used on a patient can thus be recorded.

Figure 5-7 Implementation: Institutional Provider (Medical Device Example)

In the case where a batch/lot of surgical gloves is found to be impure, the manufacturer is forced to recall the affected batch/lot. The recall process can be affected very quickly in this example, as the relevant product data and additional data, such as batch/lot number, have been scanned and recorded at each transition point in the supply chain. The traceability of the contaminated product from the manufacturer downstream to the ward and even to the individual patient happens efficiently and effectively.

The unique and precise identification of the relevant data, the automatic data capture at each transition point in the supply chain and the electronic interchange of data play essential roles in reducing errors and saving time and cost across the supply chain.

5.6.2. Pharmaceutical Example

A prescription from a ward for hypertension medication is delivered to the hospital pharmacy by a hospital porter. As the hospital works with GS1 standards the prescription carries a bar-coded Global Document Type Identifier (GDTI) that has been related to the Electronic Patient Record (EPR).

However, as the hypertension medication was received from an upstream supply chain partner that did not work with GS1 standards, the boxes did not carry a GS1 bar-coded GTIN. Therefore, upon delivery receipt, the hospital pharmacy assigned a GTIN plus the supplier's batch/lot number, printed and applied the bar-code label and scanned the items to record the information in the hospital pharmacy database.

Just prior to despatching the medication to the ward, the pharmacist scans the GS1-128 or GS1 DataMatrix barcode on the product, to adjust the hospital pharmacy inventory, and scans the GDTI on the prescription to associate the medication to the prescription and to the Electronic Patient Record (EPR).

Figure 5-8 Implementation: Institutional Provider (Pharmaceutical Example)

5.6.3. Best Practice and/or Case Study

An extensive range of up to date case studies and best practice papers from around the world are available on the GS1 Healthcare website, here:

www.gs1.org/sectors/healthcare/implementation/

6. Selecting Technology and/or Solution Provider

Globally, and locally, through their Member Organisations (MOs), GS1 has both robust processes in place for certification of solution providers, who provide products and services that support the GS1 system of integrated global standards, and extensive knowledge of the compliant technologies. The GS1 global website also contains a wide range of related reference material www.gs1.org

Locally, your primary source of advice is the local GS1 MO. An up to date list of MOs (alphabetically or by continent) can be found on the GS1 website here: www.gs1.org/contact/worldwide.php. MOs can provide assistance in selecting appropriate technologies and/or solution providers that will assist and enable you to successfully implement your traceability system, such as:

- Checklists to help evaluate products, such as software, printers, marking

- Checklists to help evaluate providers

- IT System development / installation / Migration (from legacy to new)

- Training

Contact your local MO!

7. Assessment of Traceability System Implementation

The GS1 Global Traceability Conformance (GTC) Programme Regulation forms part of the GS1 GTC Programme which is a set of documents and procedures that are designed to compliment the GS1 Global Traceability Standard (GTS) and sector specific versions of it, e.g. the Global Traceability Standard for Healthcare (GTSH)*.

The GS1 GTC Programme Regulation presents the regulation, process and compliance criteria for each party involved in the GS1 GTC Programme.

Through a process of GS1 accredited audits, it provides formal GS1 recognition to organisations that comply with the requirements of the GTSH.

To find out more, contact your GS1 Member Organisation.

Note: At the time this document was published validation and/or development of the GTC to ensure it met the specific needs of healthcare had not been undertaken; but is planned for 2010.

8. Glossary

The glossary of the Global Traceability Standard for Healthcare (GTSH) V1.0 applies to this document. If terms used in this document are not shown in the GTSH glossary, then the definitions in the GS1 Global Data Dictionary (GDD) apply.

However, there is one term that at this time does not appear in the GTSH glossary or the GDD, it is therefore included here[17]:

Electronic Patient Record (EPR):

Also known as Electronic Medical Record (EMR), it is a record containing a patient's personal details (name, date of birth etc), their diagnosis or condition and details about the treatment/assessments undertaken by a clinician. Covers the episodic care provided mainly by one institution, typically an acute Hospital. Other healthcare providers, for example specialist units or mental health facilities, may also hold EPRs.

An Electronic Medication Administration Record ((EMAR), US) may be included in an EPR.

An EPR can feed into an Electronic Healthcare Record (EHR): 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'.