



# GS1 Standards Document

Business Process and System Requirements for  
Supply Chain Traceability

**Global Traceability Standard for Healthcare**

*Issue 1.0.0, Feb-2009*



## Document Summary

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1.0.0	Feb-2009	Mike Mowad	Convert document to issue based on draft version 0.2.1, no content changes.

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# 1. Overview

## 1.1. Business Opportunity and Business Needs

Businesses, end users and authorities in various markets around the world have an interest in establishing systems to track and trace products at various points of the supply chain. This shared interest is never more evident than for healthcare products, but the key principles can be applied to any industry sector served by GS1 that has a need to track and trace product through the supply chain.

This document is a standard because it is the definition for GS1 healthcare members (exclusive of any other definition) of what the process standard for traceability in healthcare encompasses and it shows the corresponding GS1 numbering, automatic identification data capture (AIDC) or data communication standards that must be in place for best practice applications. For example, from now on a GS1 traceability in healthcare implementation guideline will only be referred to as such if it addresses all the use cases described in the GS1 Global Traceability Standard for Healthcare.

Partners in a supply chain could use various levels of product traceability to enable business needs such as:

- To comply with regulatory requirements and guidance on recalls
- To reduce business risks above and beyond legal compliance
- Product recall and withdrawal (notably to achieve a greater degree of precision, to demonstrate control, increase efficiency and reduce the cost of product recall or withdrawal)
- To comply with a trading or traceability partner's specifications
- Efficient logistics management
- Effective quality management
- To support product and/or patient safety
- To provide information to end users and trading or traceability partners
- To verify the presence or absence of product attributes (e.g., contains latex, single use)
- Brand protection
- Product authentication and anti-counterfeit policies

## 1.2. Business Intention

The goal of this document is to create a 'GS1 Global Traceability Standard for Healthcare' using the GS1 System of standards. This is a PROCESS standard describing the traceability process independent from the choice of enabling technologies (see sections [6](#), [7.3](#) and [8](#)). It defines minimum requirements for all stakeholders, organisations and countries and corresponding GS1 Standards to be used in combination with information management tools (see section [7.1](#)).

This is a building block for developing:

- Traceability systems
- Country specific traceability user guidelines
- New GS1 standards that may be required (or leverage of existing standards)



**Note:** Refer to section [11](#).

The intention is therefore to create a foundational framework that is expected to be used by any business, organisation, large or small, and by any country in order to develop specific implementation guidelines or additional requirements. These implementation guidelines will take into consideration, for example, scope and traceable item hierarchy specific to their business needs (see sections [4](#), [7](#), [9](#), [11](#)).

This GS1 Global Traceability in Healthcare Standard will maximise use of the well-established, globally acceptable and voluntary GS1 business standards that uniquely identify a “traceable item”, describe the establishment of appropriate and effective records of events, and provide for accurate communication about the traceable item between trading or traceability partners.

This meets the core need to be able to track forward and trace back (one step up, one step down) at any point along the extended length of the supply chain no matter how many trading or traceability partners and business process steps are involved.

This may be used for benchmarking or certification of traceability systems.

### 1.3. Business Justification

Healthcare organisations require consistent traceability solutions spanning the extended supply chain regardless of country.

By defining a shared minimum requirement and showing what action is required from organisations, countries, or a group of trading or traceability partners, the GS1 Global Traceability Standard for Healthcare will enable maximum interoperability between traceability systems across the extended supply chain whilst accommodating specific business, industry sector, or national requirements.

Each partner in the supply chain will have their own objectives in terms of the use of the traceability system, the lowest level of traceable item and the data required to manage their particular trading or traceability environment and strategy. Yet partners need to work collaboratively in order to achieve the required level of traceability across the extended supply chain. Furthermore, having a proven standard-based traceability process can demonstrate that an organisation has met requirements of corporate responsibility.

The GS1 Global Traceability Standard for Healthcare will serve as a foundational standard for all countries to use as a starting point for identifying their specific business requirements. This framework will ensure a common approach and understanding of key principles by users around the world.

To demonstrate that these ideas are shared in countries around the world by businesses, legislators and regulators, here are some extracts from key reference documents:

#### Europe Building Collaboration to Facilitate Track and Trace

*“Collaboration between trading partners should be promoted continuously. Through the use of voluntary, global business standards each company involved in the supply chain can remain responsible for selecting the service provider to implement their system in an open, competitive market place. The use of voluntary, global business standards improve efficiency and drives down total supply chain costs.”*

ECR – Using Traceability in the Supply Chain to meet Consumer Safety Expectations  
ECR Europe, March 2004, Chapter 4 “Business Needs”, page 16

#### UK - Coding for Success programme

*The UK Department of Health issued a Policy Guidance Document in February 2007 in close cooperation with GS1 UK, GS1 Healthcare and ABHI (Association of British Healthcare Industries): “The Department of Health is recommending that the GS1 System should be adopted throughout the healthcare system in England [...] and presents an action plan calling for engagement in GS1 Healthcare.”*

INCLUDE REFERENCE

## Building the Business Case for Data Management

*“Since product record information can differ according to the purpose of product traceability, company, and industry, the management of this information should emphasize the importance of company and industry initiatives. However, if traceability goals and purposes are the same within an industry, it is desirable for the management method and product record information (including item code and serial number data structure of the product identification code system) to be the same.”*

Study Group on the Improvement of Product Traceability, Interim Report, April 2003  
 Ministry of Economy, Trade & Industry, Japan, Chapter 3.2 “Efforts which should be shared as much as possible”, page 11

## 1.4. Audience

The audience is all GS1 Member Organisations (MOs), the service provider community that serves them, business associations and government organisations. This includes all parts of the supply chain, for example: raw material (sometimes called “primary”) producers, processors, manufacturers, wholesalers, healthcare providers, importers/brokers and exporters, third party logistic providers, logistic providers, transporters or carriers and solution providers.

The audience includes all senior managers with executive responsibility, managers and employees working in production, quality and safety, logistics, information technology, product development, marketing, customer/patient management roles and end users/patients.

## 2. Acknowledgements

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On behalf of GS1, we would like to thank the Work Team for giving their time and expertise, together with all GS1 members and GS1 MOs that have made this document possible including.

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## 3. References

Reference Name	Description
[Ref 1] GS1 General Specifications	GS1, Version 8.0
[Ref 2] ECR – Using Traceability in the Supply Chain to meet Consumer Safety Expectations	ECR Europe, March 2004
[Ref 3] Study Group on the Improvement of Product Traceability, Interim Report,	Ministry of Economy, Trade and Industry, Japan, April 2003
[Ref 4] Coding for Success: Simple technology for safer patient care	Guidance from Department of Health, UK, February 2007
[Ref 5] EPCGlobal Healthcare & Lifesciences Track & Trace Working Group (HLS T&T)	HLS T&T Specific Business Requirements
[Ref 6] GS1 Traceability Implementation Guidelines	GS1, 2003
[Ref 7] GS1 Business Message Standards	GS1

## 4. Scope

### 4.1. Overall Business Context

Context Category	Value(s)
Industry	Global Healthcare
Geopolitical	All
Product	All pharmaceutical products All risk categories of medical device products
Process	Traceability
System Capabilities	GS1 System
Official Constraints	None

## 4.2. In Scope

The GS1 Global Traceability Standard for Healthcare includes:

- Identification of parties, items and events
- Labelling and/or marking and/or tagging of Traceable Items
- The nature and type of data to be captured and collected
- Record keeping including archiving / data storage
- Communication and sharing of information (Information can be shown at the physical level of packaging labels and printed bar-codes or captured and recorded at a data management level and communicated using e-business messaging, e.g. EDI.)
- Links identification and management
- Retrieval / search of information (The ability to track and trace a traceable item from creation to the point of sale (POS), dispensing, use or destruction, e.g. using EPCIS)

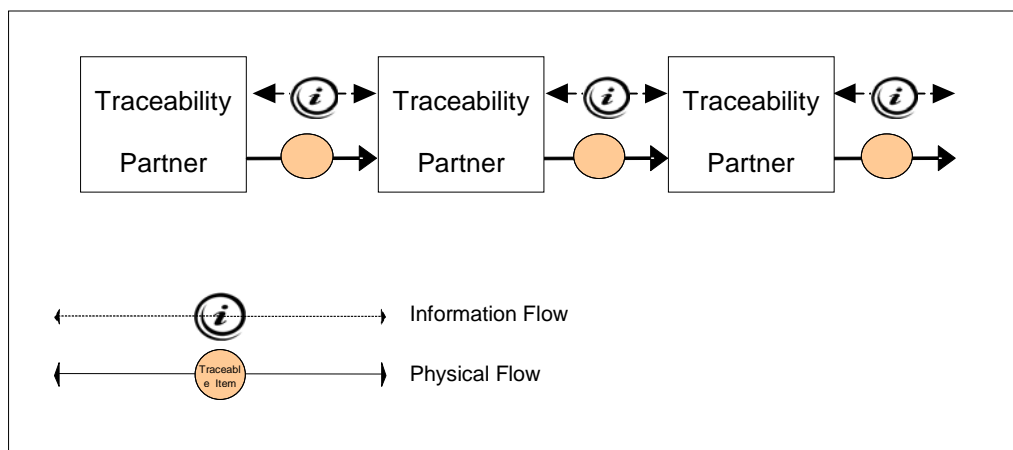
Global Healthcare where GS1 members are involved is in scope.

All pharmaceutical products and all risk categories of medical device products are in scope, for example:

- Units (e.g., hip prosthesis, batches / lots of pills)
- Trade items (e.g., a box of surgical gloves)
- Logistic units (e.g., a pallet)
- Packed and bulk products (e.g. medical gases)
- Branded Goods, private labels, generic unbranded products

**Note:** By-products, recycled products, reprocessed products, surplus stock, returns and recalls follow the same traceability process.

**Figure 4-1** Product Flow in Supply



Chain

Traceability can involve trading and non-trading partners (traceability partners), a physical flow of traceable items and information flows of traceability data. Traceability partners can be any actor in the supply chain. The physical flow can include any product from initial inputs up to dispensing to or use

by the final end user/patient. Traceability during the physical flow can also include the use of a traceable item and the destruction of any traceable item.

For example the following products may be within the scope of a traceability system:

- Any input to a pharmaceutical product, e.g. an Active Pharmaceutical Ingredient (API)
- Any individual product destined for human surgical implantation, e.g. a pacemaker
- Any item of packaging used in contact with a product, e.g. a blister pack
- Any finished manufactured product, e.g., a batch / lot of surgical gowns
- Any trade item and logistic unit, e.g., an infusion pump

#### 4.2.1. Immediate Phase

The outputs of the immediate phase are:

- To define the traceability process
- To define minimum traceability requirements for all traceability partners
- To identify existing GS1 standards and new requirements to be leveraged or developed as a priority

The principles of traceability can be applied to meeting regulatory requirements and establishing the basis for efficient product recalls and withdrawals as a priority.

#### 4.2.2. Subsequent Phases

The following topics may be addressed in subsequent phases:

- Development of new GS1 Standards required for traceability
- Use of traceability information (e.g., notification of a product withdrawal or recall)
- Exceptions
- Traceability up to the final end user/patient
- Waste
- Samples (e.g. laboratory samples or promotional items)
- Returnable assets (e.g., medical gas cylinders, orthopaedic (loan) kits)

### 4.3. Out of Scope

The process of collaborative product development and defining product specifications is not part of the traceability process. However, data deriving from this process may need to be taken into account as part of the traceability data for a product recall.

Healthcare or application specific user guidelines will need to be developed to facilitate the implementation of the GS1 Global Traceability Standard in Healthcare. The implementation process required to incorporate all participants in a supply chain traceability process standard is out of scope of the standard in itself including, e.g., training and implementation support.

## 5. General Definition

### 5.1. Initial Challenges

Organisations have different objectives and ways of implementing traceability. These differences are intrinsic to their various roles in the supply chain (e.g., manufacturer, distributor, transporter), from the diversity of products to their regulatory and business environment, and to their different strategies in terms of costs and benefits.

In many countries, some actors have limited understanding of traceability requirements and no capital to invest in traceability tools, yet products are supplied to sophisticated markets where traceability is required. This can be addressed using generic requirements for traceability using simple business processes.

Legislation generally does not specify the traceability system to be used. Most products cross geographic borders at least once in their life cycle, subjecting them to multiple, sometimes inconsistent, regulations. Supply chains have different business requirements and different expectations in terms of enabling technologies. Some do not recommend any specific automatic data capture, some recommend best practices with bar-codes and EDI, some are beginning to use RFID, and some are implementing a traceability network to be able to electronically retrieve information about products from each point along the chain, e.g. using EPCIS (Electronic Product Code (EPC) Information System (IS)).

The challenge for this Process Standard is to agree on generic healthcare requirements and on a common way to describe the traceability process irrespective of these differences.

The GS1 Global Traceability Standard for Healthcare remains a high level description of the process enabling and promoting supply chain collaboration but allowing each organisation to design its traceability system in terms of breadth, depth and precision to support its own business objective(s). This process standard is applicable to all types and sizes of organisations in any part of the extended healthcare supply chain.

### 5.2. Assumptions

The GS1 Global Traceability Standard for Healthcare is based on the use of global, voluntary GS1 business standards. The following definition is considered as the reference definition of 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*

For further examples of existing definitions, please refer to the documents listed in section [3](#).

For clarity and to assist shared understanding and wider implementation of this GS1 Global Traceability Standard for Healthcare, a Glossary of Business Terms has been identified (section 13). It is recommended that the reader studies this glossary before reading sections 6 to 12 of this document.

### 5.3. Dependencies

The following GS1 standards enable implementation of the GS1 Global Traceability Standard for Healthcare:

- Global Trade Item Number (GTIN)
- Global Location Number (GLN)
- Serial Shipping Container Code (SSCC)

- Electronic Product Code (EPC)
- Global Data Dictionary (GDD)
- GS1 XML and EANCOM e-business messages (Align and Deliver)
- Pedigree Ratified Standard (DPMS)\*
- General Specifications (data carriers)

GS1 user groups have already established a number of User Guidelines proposing the use of GS1 Standards as part of the traceability process; for examples refer to section 3 References. These provide helpful practical examples for organisations and countries that seek similar collaborative solutions.

## 6. Business Process Analysis

This analysis breaks down the traceability process. The resultant sub-processes and concepts are defined using terminology that must be understood before reading through this section; the reader should also refer to the Glossary in Section 13.

Included here in this section is:

- an explanation of internal and external traceability
- the concept of roles such as Traceable Item Creator and Traceability Data Source
- a Traceable Item Matrix to facilitate the understanding that the traceable item can exist at different levels
- a breakdown of the different responsibilities that can result due to the traceable item involving both a data flow and a physical flow which may involve different parties (Traceable Item Source and Traceable Item Recipient, Traceability Data Source and Traceability Data Recipient).

The specific Healthcare Business Requirements (BR) and Business Rules (BRU) in parenthesis (e.g., BRU 14) are detailed in section 7.

\* See announcement of 10<sup>th</sup> October 2008: "GS1 sets roadmap to state-of-the-art Global Traceability Standard for Healthcare."  
[http://www.gs1.org/docs/healthcare/Traceability\\_in\\_Healthcare\\_status\\_update\\_10\\_Oct\\_08.pdf](http://www.gs1.org/docs/healthcare/Traceability_in_Healthcare_status_update_10_Oct_08.pdf)

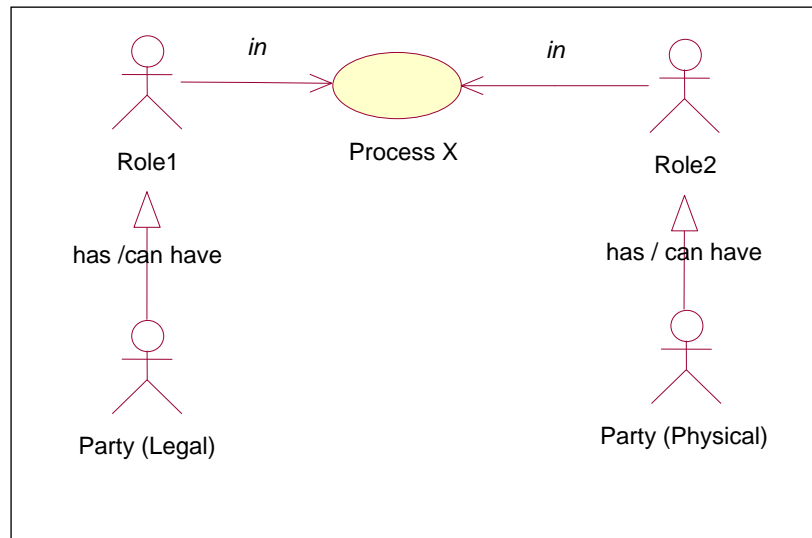
### 6.1. Business Scenario for Traceability

#### 6.1.1. Business Process Participants Descriptions

The GS1 System distinguishes between parties and roles.

- A party is a generalisation of a legal or physical entity, for example a retailer or a manufacturer.
- A role is a specific function of a party in a specific process at a specific time for example, a buyer.

A party can have more than one role. For example, the Manufacturer can act as a seller of items and also as a buyer of raw materials.

**Figure 6-1 Party Relationship**


[Figure 6-1](#) shows two parties, each of them plays a different role in the process.

**List of Parties:**

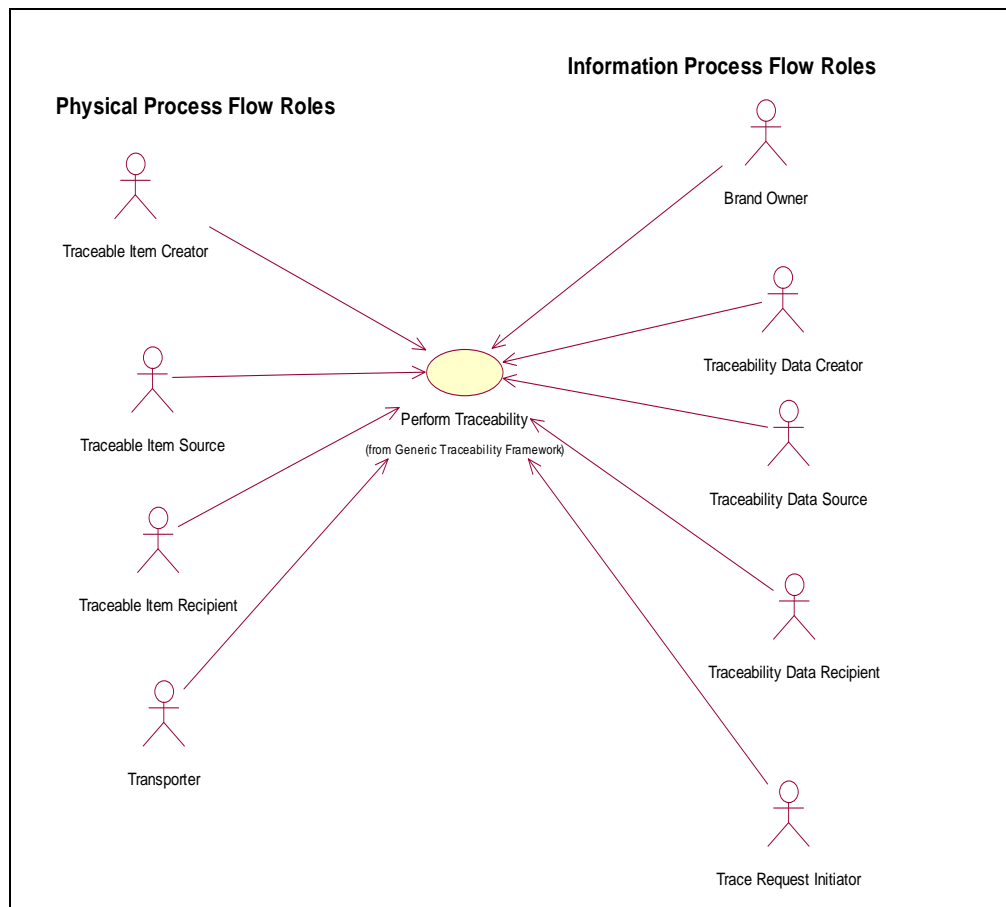
Party	Description
Carrier / Third Party Logistics Provider (3PL)	The party responsible for the delivery or shipping of the traceable item.
Processor / Manufacturer / Primary Producer / Compounder	Typically receives inputs and transforms those inputs. Examples include the pharmaceutical or medical device manufacturer, or a kit manufacturer that consolidates product from a number of suppliers, or a pharmacist (compounder) who processes APIs into a finished product, or a party that reprocesses (cleans and sterilises) surgical instruments. A supply chain may be comprised of more than one processor/manufacturer/primary producer/compounder.
Point of administration, Use or Service Operator / Provider	Has the final relationship with the patient. For example, a pharmacist, physician, nurse or healthcare provider.
Warehouse / Distribution Centre	Responsible for the handling (may transform the traceable item) and storage of the traceable item.
Authorities	The party legally mandated to protect the public interest.

The same legal entity can be more than one party. For example a Third Party Logistics Provider may also act as a Warehouse or Distribution Centre.

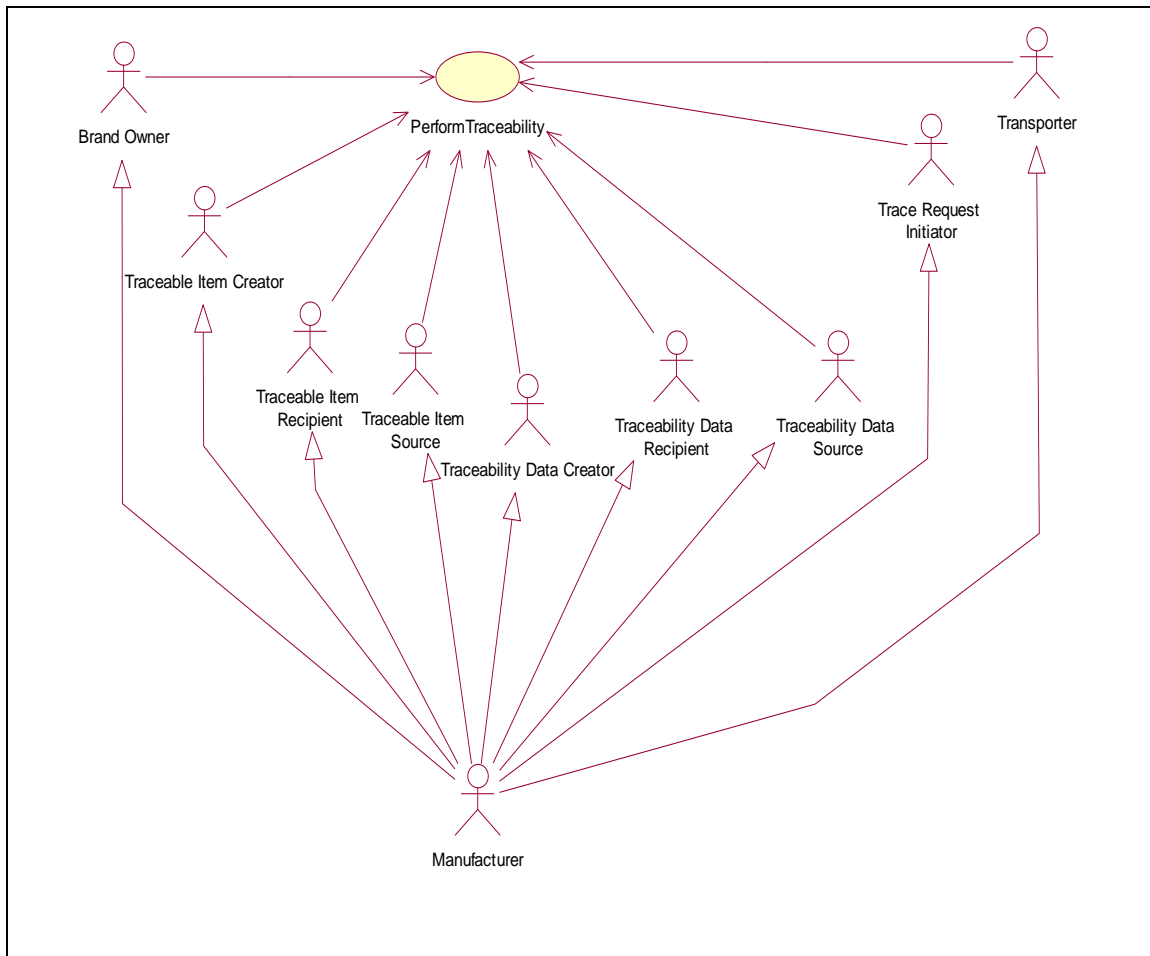
**List of Roles:**

Role	Description
Brand Owner	The party that is responsible for allocating GS1 System numbering and bar code symbols or RFID tag on a given trade item. The administrator of a GS1 Company Prefix. And / or the party that is the ultimate authority for the trade item. And / or the owner of the product specifications. And / or the party responsible for placing a trade item into commerce.
Traceability Data Creator	The Traceability Partner that generates traceability information.

Role	Description
Traceability Data Recipient	The Traceability Partner authorized to view, use, and download traceability information.
Traceability Data Source	The Traceability Partner that provides the traceability information.
Traceable Item Creator	The Traceability Partner that generates a traceable item, or makes a distinct traceable item by transformation of one or more traceable items.
Traceable Item Recipient	The Traceability Partner that receives the traceable item.
Traceable Item Source	The Traceability Partner that despatches or provides a traceable item.
Trace Request Initiator	The person who starts the trace request.
Transporter	The Traceability Partner that receives, carries, and delivers 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 and may or may not have ownership.

**Figure 6-2 Role**


[Figure 6-2](#) illustrates that parties with different roles all have a responsibility to perform traceability.

**Figure 6-3 Example Manufacturer Party Relationship**


Parties in the Supply Chain often play multiple roles in the traceability process; [Figure 6-3](#) illustrates the Manufacturer playing multiple roles.

Supply chains are complex, there is not one simple schema describing who is involved in the Supply Chain from upstream to downstream. Yet there are typical roles in all supply chains. Reference is made in this document to the five primary parties, though there may also be intermediary parties such as secondary processors.

By the time a traceable item is purchased, consumed or used, it may have gone through a number of events and transformations. Each event or transformation may have involved a number of different parties. Every party has a responsibility to manage traceability and can use the generic traceability framework to achieve this goal.

While maintaining traceability is generally the responsibility of the Traceable Item Source and Traceable Item Recipient (party with “possession, custody, or control” of the traceable item), in some instances other parties may also have responsibility. For example, an importer may never take ownership or possession of a shipment but may have a responsibility to regulatory authorities as the “person responsible” for the traceable item. Some parties that act as an agent for another party, and never take physical possession of the traceable item (such as an importer) may also be viewed by their Traceability Partners as having responsibility for traceability.

With regard to parties, we have on the one hand all Traceability Partners involved in the physical flow and / or information flow (e.g. processor, carrier, retailers), and on the other hand other parties that are

not directly involved in the supply chain process (such as certification bodies, authorities). The function or internal process often determines the level of responsibility.

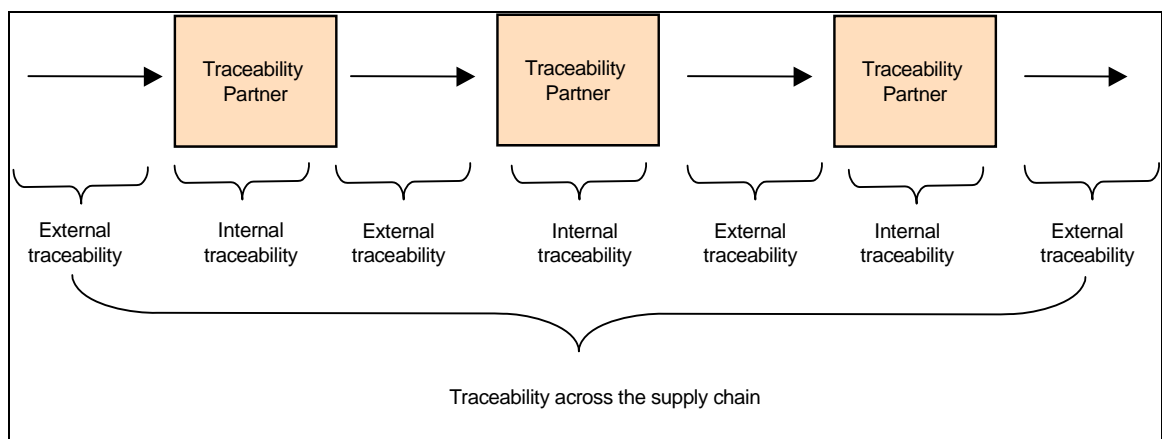
In the case of product recall, two levels of responsibility can be distinguished:

- **Primary responsibility:** Typically importers, producers, processors, manufacturers, or distributors, retailers and providers who are responsible for the specification and content of products, withdrawal and / or recall and notification. They are each responsible within the limits of the activities under their control.
- **Secondary responsibility:** Typically transporters, carriers, ship owners, storage companies, and logistics providers who work on behalf of the organisations with primary responsibility. However, those with secondary responsibility must create, capture, record and share data about their traceability activities.

## 6.1.2. Business Scenario Overview

Traceability management involves the association of a flow of information with the physical flow of traceable items. Each actor must perform different roles within the supply chain, but all actors must follow the basic agreed-to steps of the traceability process.

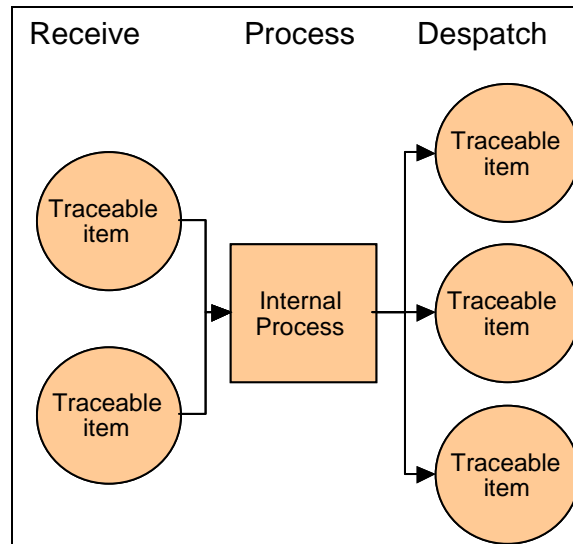
**Figure 6-4** Traceability across supply chain



In order to achieve traceability across the supply chain, all Traceability Partners must achieve internal and external traceability (BRU 10).

### 6.1.2.1. Internal Traceability

Internal traceability takes place when a Traceability Partner receives one or several instances of traceable items as inputs that are subjected to internal processes, before one or more instances of traceable items are output. The following are the relevant events in respect of collecting traceability data.

**Figure 6-5 Internal Traceability**


Every traceability partner involved in the physical flow of products receives, processes, and despatches instances of traceable items.

The following list shows the events when traceability data should be collected:

- **Receiving** is the result of a traceable item crossing the boundary from external to internal, transferring from one party to another party.
  - The traceable item received could be, for example, raw materials, packaging or finished products.
- **Internal process** is one or more sub-processes performed by the same party or without a significant involvement of other traceability partners. Each sub-process involves traceable item inputs and results in traceable item outputs. At a minimum, the internal process must consist of one of the five following sub-processes:
  - Movement
  - Transformation
  - Storage
  - Usage
  - Destruction

**Movement** is the physical relocation of a traceable item.

**Transformation** is the act of changing a traceable item, its identity and/or characteristics, e.g. as combining ingredients to make a finished product or the combination of different finished products to create a mixed pallet or reprocessing a non-sterile instrument to a sterile item. Transformation can be manufacture, production, grouping, splitting, mixing, compounding, aggregation, packing or re-packing traceable items. The act of transforming a traceable item requires specific responsibilities for the Traceable Item Creator, e.g. applying the identification to the newly created physical traceable item(s) and recording the relevant data to support the information requirements.

**Storage** is the act of holding a traceable item at a location within the Traceability Partner's organisation.

**Usage** is the act of using the traceable item and recording the traceable usage data, e.g. that a particular instrument was used on a particular patient in a hospital.

**Destruction** is the act of destroying a traceable item. For example, items returned to an organisation may be incinerated.

Depending on the internal process, the relationship between traceable Items received (inputs) and traceable items shipped (outputs) can be:

- Many to One (e.g. when raw materials and packaging are combined into a finished good)
- One to Many (e.g. when a batch of tablets stored in bulk is packed into multiple presentations)
- Many to Many (e.g. when items are repacked into new items)
- One to One (e.g. when a used surgical instrument is transformed from non-sterile to sterile)
- Many to None (e.g. when finished goods are destroyed)
- One to None (e.g. when a material is destroyed)
- None to One (e.g. when a batch of sterile water is produced)
- None to Many (e.g. when batches of “water for injection” (WFI) are produced)

**Despatching** is the transfer from one actor to another actor in the supply chain.

An organisation that is not physically handling any products but that has a legal or contractual responsibility towards the products (e.g. Brand Owner or broker) may still be involved in traceability requirements for the information flow. As an example, the Brand Owner must be able to reply to a trace request concerning the traceable item details.

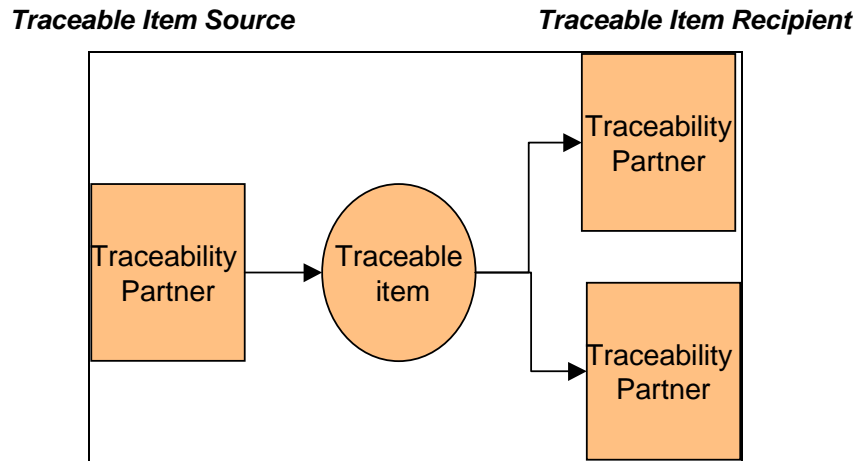
A **change of status** (e.g. quarantine or change of ownership) is also a possible event.

Every Traceability Partner has a responsibility to maintain agreed data that links input into a transformation process with the output, and that links the original and final location after movement (BRU 2, BR 14). For example, this link data could be held as quality records.

It's understood that each organisation may have its own internal process(es) to track product throughout its internal movement and / or transformation. Traceability records of movement and storage may help identify the impact of quality failure such as incorrect storage temperature or damage during transit. For those organisations that currently do not have any processes in place, or are looking to standardise their internal processes, this document recommends the use of GS1 global standards to capture the data that links inputs during a products internal life cycle.

### 6.1.2.2. External Traceability

External traceability takes place when instances of a traceable item are physically handed over from one Traceability Partner (Traceable Item Source) to another (Traceable Item Recipient).

**Figure 6-6 External Traceability**


Each Traceability Partner should be able to trace back to the direct source and be able to track forward to the direct recipient of the traceable item (one step up, one step down principle (1.2)).

A shipment may contain several levels of traceable items (e.g., logistic units each containing part of a batch / lot of units) (BRU 2, BRU 6, BRU 8). This allows the organisation, for example, to track forward and trace back at both the logistic unit level and the production batch / lot level (e.g. a batch of units split into several logistic units for different customers).

Traceability does not imply each traceability partner must hold and publish all traceability information, but the Traceable Item Source and Traceable Item Recipient must communicate and record identification of at least one common level of traceable item within their respective systems (e.g. logistic unit) (BRU 16, BRU 21). This ensures efficient information flow of data when tracking forward or tracing back.

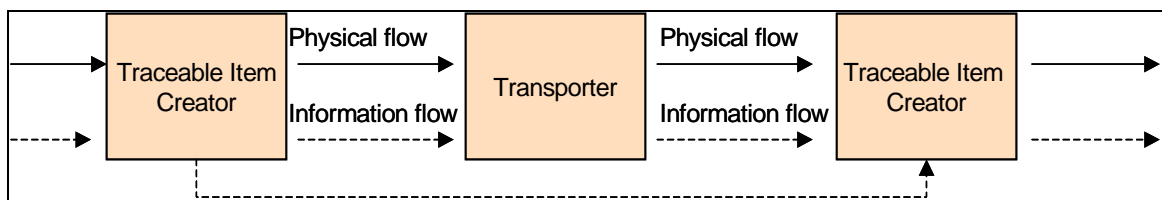
All traceable items must carry identification allocated to it and be labelled / marked / tagged at source (creation) (BR 6). This document recommends the use of a GTIN or SSCC.

The Brand Owner must ensure the true uniqueness of the identification of the traceable item (BR 7). Where sub-contractors or licensees are involved, the way to proceed to ensure the uniqueness of identification is up to the Brand Owner and depends on contractual agreements.

The identification carrier (mark / tag / label / accompanying document sometimes called "passport" or "identity card" or "Pedigree") MUST remain on or attached to the traceable item until the end of life of the traceable item. (BR 8).

### 6.1.2.3. Information Flow Links

In parallel to the physical flow, the Traceable Item Source must share information with the Traceable Item Recipient and the Traceable Item Recipient must collect this information (BRU 15, BRU 21, BRU 22, BRU 23). Traceability requirements in terms of information flow may be different for transporters and Traceable Item Creators.

**Figure 6-7 Traceable Item Creator and Transporter Information Flow**


The “One up, one down” principle between traceability partners may mean several parallel flows of data: e.g. from supplier to customer, from supplier via a Third Party Logistics Provider, from a Third Party Logistics Provider on behalf of the supplier (who would not itself have all the data about transportation / storage but would set "service level agreements / contracts" to fulfil responsibility via a third party...)

In most trading relationships, the Buyer and the Seller are the Traceability Data Recipient and Traceability Data Source, even if they are not handling the traceable items.

There is a minimum amount of data that must be recorded internally by Traceability Partners. They must maintain the minimum data elements to ensure visibility and linkage to all applicable levels. Some of these data elements must be exchanged between Traceability Partners (BR 13).

Depending on the organisation’s internal objective, the industry or the specific application of the traceability process, additional information may also need to be captured, recorded and shared. This document acts as the foundation for the business application in which additional information can be included.

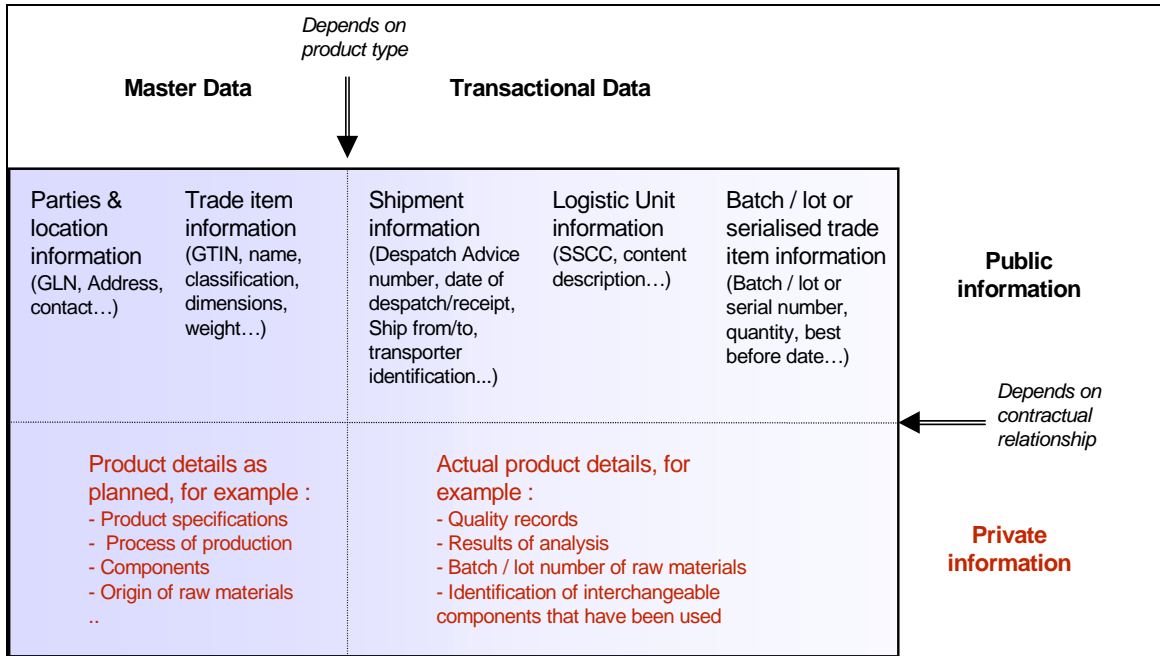
#### 6.1.2.4. Traceability Data

Traceability data includes information about (BRU 3):

- Who? Party [Identification + data elements]
- Where? Location [Identification + data elements]
- When? Date / Time
- What? Traceable item [Identification + data elements]
- What happened? Process or event [Identification + data elements]

Traceability data can be planned, expected or actual. With respect to traceability, it is usually the actual date that is relevant.

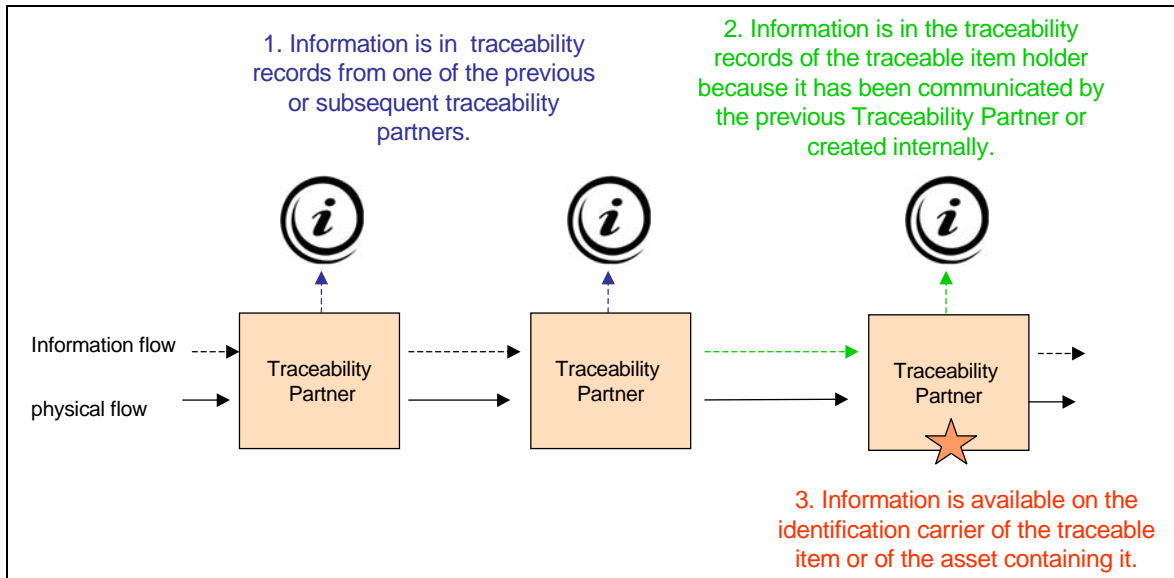
Traceability data can be master or event data (BRU 09). In the traceability context, master data is relatively consistent over time and independent from day to day physical events (e.g., name of the trade item, dimensions, country of origin of the raw material if part of the product specifications...). Event data is created during the physical flow of goods. It can only be collected when events occur (e.g., date of receipt, weight if variable...). The recommendation is to align master data, which is public (shared between traceability partners), before the physical flow begins (see section [6.1.3](#)).

**Figure 6-8 Traceability Data Matrix with Examples**


Traceability does not imply Traceability Partners must hold and share **all** traceability information, but they must all have the ability to internally search and access relevant information, and share the agreed information required without infringing the intellectual property of each Traceability Partner (BRU 14, BRU29).

The type of the traceability data impacts the appropriate solution used to record the information and later on, to conduct a trace request:

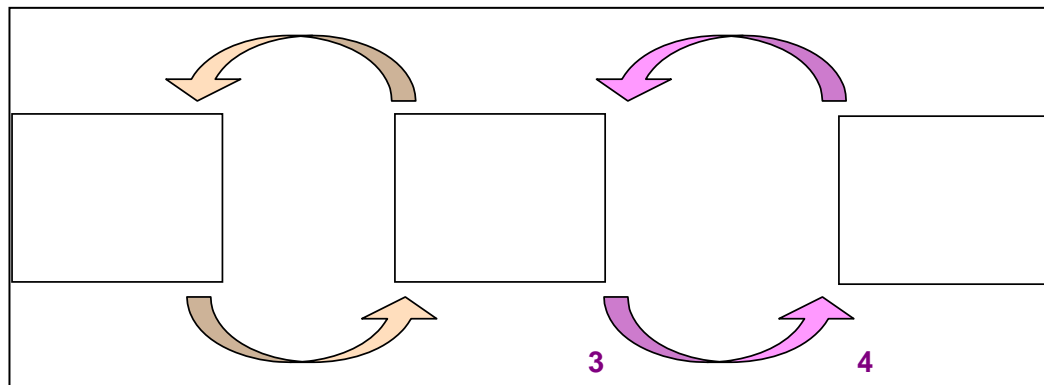
1. If the traceability data is private, it is likely to be in the traceability records of one of the previous or subsequent trading or traceability partners.
2. If the traceability data is public, it may be in the traceability records of the traceable item holders (successive traceable item sources and recipients) or published to a shared database, e.g. EPCIS.
3. If the traceability data is a key for the identification of the traceable item, it should be on the identification carrier (BR 6).

**Figure 6-9** Where is the Traceability Data?


### 6.1.2.5. Trace Request

A trace request is a formal inquiry about history, application or location of a traceable item. Any Traceability Partner can initiate a trace request (e.g. a pharmacist, a producer).

A trace request starts when a Traceability Partner is looking for information about a traceable item and this information is not available internally (BR 17, BR 18). The trace may be initiated by a Traceability Partner as a result of a request from the authorities or an adverse healthcare event.

**Figure 6-10** Trace Request


A Trace Request Initiator must contact the source of the traceable item and through a repetitive process via each link in the supply chain, the Traceable Item Creator, Brand Owner or Licensee will be contacted (BRU 17, BRU 24). The logic of the trace request is that it follows the same path as the information flow (Fig. 6.10). The Trace Request may jump a step to contact a Traceability Partner further up or down the chain in order to obtain the information more quickly.

The Traceability Data Source must reply as quickly as possible to the enquiry (BRU 25). The time period allowed may be defined in local regulations or commercial agreements.

A trace request may trigger subsequent trace requests up or down several levels of the supply chain in order to fulfil the original request (BRU 26). This fulfils the requirement often included in regulations to the effect that traceability must work “one step up and one step down” the supply chain.

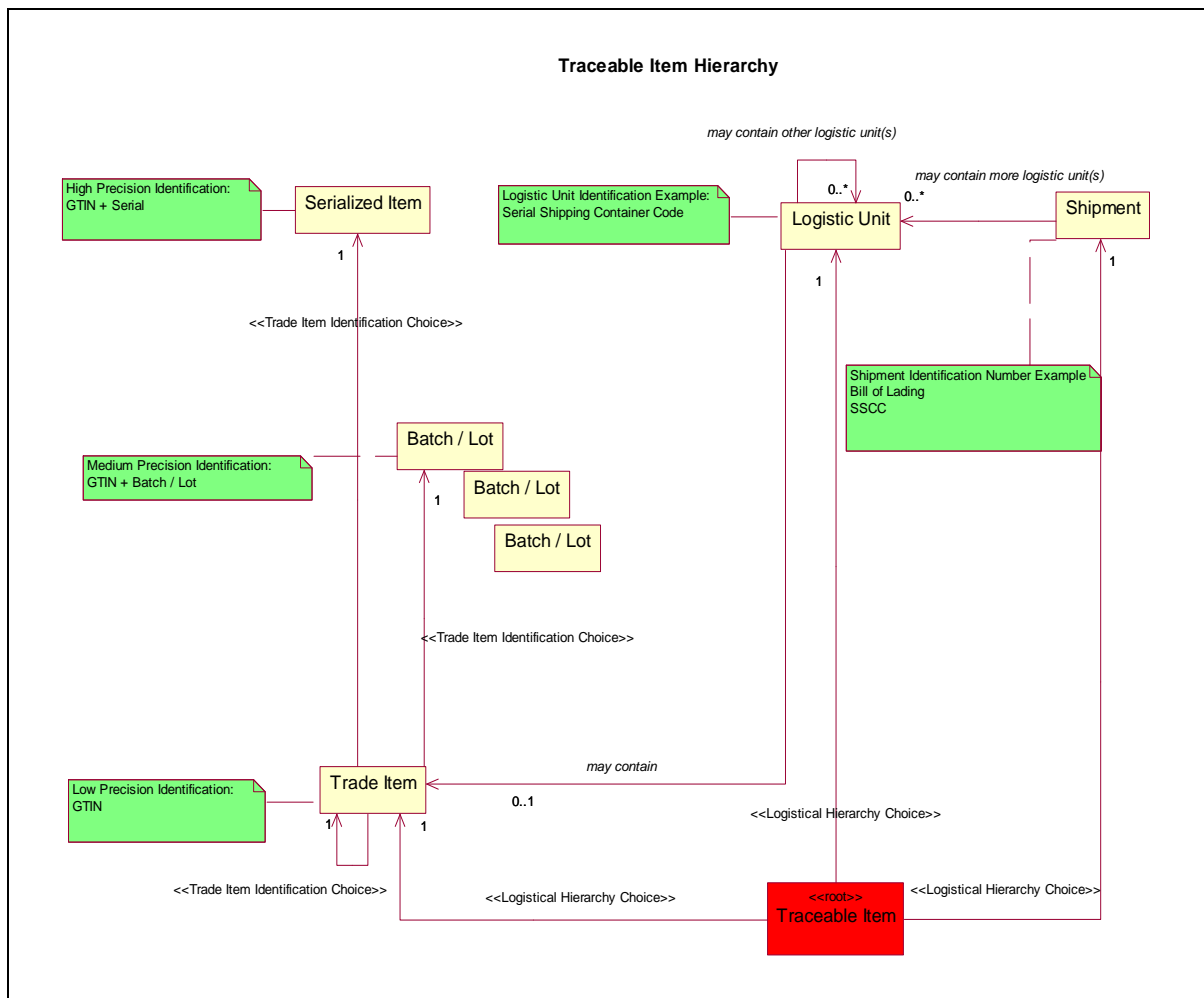
A reply may include all the data required, part of that data or may say that no information is available. There are many types of trace request; they depend on the specific business need and use of the information. For example:

- What are the ingredients of this traceable item? (e.g. inquiry about possible contaminant or allergen which is not mentioned on the label)
- Where are these traceable items located? (e.g. inquiry about the status of delivery or of product recall)
- Which traceable items have been created using this specific traceable item pallet of origin or batch of raw material? (e.g. to facilitate product withdrawal)

The relevant trace request scenario, data and messages can be precisely defined only in the context of a specific business need or application.

### 6.1.2.6. Traceable Item Hierarchy

Figure 6-11 Traceable Item Hierarchy



A traceable item is a physical object where there may be a need to retrieve information about its history, application, or location.

The level at which the traceable item is defined within a product packaging or logistical hierarchy is dependent on the degree of control required.

A traceable item may be a

- Shipment
  - May contain one or more logistics unit(s)
- Logistics unit
  - May contain other logistics unit(s)
  - May contain one or more trade item(s)
  - May be a trade item
- Trade item
  - Trade item
  - Batch / Lot of trade items
  - Serialized trade item
- Any item that traceability partners agree is a traceable item

The level of traceable item is a combination of logistical hierarchy levels and the precision of the identification.

**Here are some logistical examples:**

<u>Shipment:</u>	Truck Load, Vessel, 10 pallets of various items
<u>Logistics unit:</u>	Pallet, Container
<u>Trade item not crossing the POS:</u>	Carton, Bag
<u>Trade item crossing the POS:</u>	Consumer Unit (not usually applicable in Healthcare)

**Figure 6-12 Traceable Item Matrix**

Precision of the identification	Level in the logistical hierarchy			
	Shipment	Logistic Units	Trade Item not crossing the point of sale	Trade Item crossing the POS, Consumer unit
Unique (serialized)	Shipment Identification Number (SIN)	SSCC	GTIN + Serial number SGTIN	GTIN + Serial Number SGTIN
Specific (batch)	Not applicable	Not applicable	GTIN + Batch / Lot Number	GTIN + Batch / Lot Number
Generic	Not applicable	Not applicable	GTIN	GTIN

The GTIN is the basis for product identification. For the purpose of traceability, this may not be sufficient, requiring additional information to identify a product or grouping of products. This concept is indicated in the yellow shading in Figure 6-12.

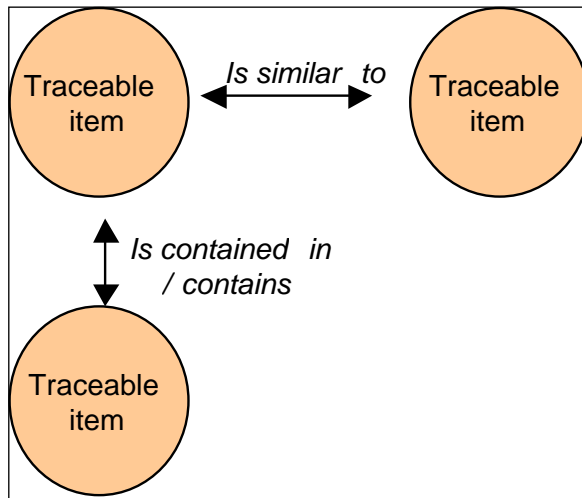
Assumptions for the traceable item matrix / hierarchy:

- Traceable items may need to be physically marked with a Batch / Lot Number to comply with legal requirements, e.g. pharmaceutical products
- Where appropriate, e.g. where product has a finite shelf life, an Expiry Date should be added
- As the level of precision required is increased it may be appropriate to identify traceable items with a Serial Number, e.g. an implantable medical device, a surgical instrument
- A Serial Number may be appropriate for items that need to be traced at this level, e.g. a medical infusion pump.

When the logistic unit is a trade item (e.g. a pallet), it is also identified with a GTIN and cumulates the corresponding identification standards from both columns "Logistic Unit" and "Trade Item not crossing the point of sale".

A traceable item may be related to another traceable item, for example:

- Is contained in
- Contains (reverse process is possible, e.g., a carton contains 50 surgical gowns)
- Is similar to
- Is composed of (reverse process is not possible, e.g. more than one pharmaceutical product is compounded to create a chemotherapy drug)
- Manufactured just before
- Manufactured just after

**Figure 6-13** Traceable Item Relationship Examples


A traceable item could exist in multiple locations at the same time. For example; the traceable item is identified at the trade item and batch level and is stored by or has been sold to many trading partners.

### 6.1.3. Current Business Scenario (“as is”)

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.

It is composed of:

#### A. Plan and Organize (pre-requisite)

**Output:** All Traceability Partners have determined how to assign, collect, share, and keep agreed traceability data. The Traceability Partners have determined how to manage links between inputs, internal processes, and outputs.

#### B. Align Master Data

**Output:** All Traceability Partners have aligned their master data.

#### C. Record Traceability Data

**Output:** Traceability Partners can identify traceable items and collect and record relevant and agreed traceability data as traceable items move across the supply chain.

#### D. Request Trace

**Output:** The traceability data is available and Traceability Partners can provide agreed, readable, comprehensive, accurate and timely information to an authorized party upon request about a traceable item.

The trace request involves communication of data that has been collected and recorded. A trace request may be initiated weeks, months or years after a traceable item has been processed, consumed or used. The types of trace request that traceability partners wish to conduct determines the traceability data that traceability partners must communicate. For example, quality records are not necessary to locate logistics units but may be relevant if the objective is to clarify the origin of a product safety problem.

## **E. Use information**

The use of the information that results from a trace request may be, for example, to resolve a quality issue or to inform traceability partners.

Example: In the case of product withdrawal or recall, a traceability partner sends a trace request upstream in order to identify the cause of the problem and to find out which traceable items may have the same problem. Then there is a downstream trace request in order to locate the products and a notification to trading partners who have received them.

The traceability system is defined as the tools and organisation necessary to implement the traceability process in a given environment, party or group of parties.

Current business scenario depicted in [Figure 6-14](#) below.

Figure 6-14 – Use Case Actor Matrix

Use Case	Plan and Organise		Align Master Data					Record Traceability Data						Request Trace			Use Information	
	1. Determine how to assign, collect, share and keep traceability data.	2. Determine how to manage links between inputs, internal processes and outputs.	3. Assign identification to the party.	4. Assign identification to physical locations.	5. Assign identification to asset as appropriate.	6. Assign identification to item.	7. Exchange Master Data.	8. Assign identification to the traceable item when it is created.	9. Apply the identification to the identification carrier on the traceable item or in an accompanying document when a transformation takes place.	10. Capture the identification of the traceable item or the asset containing it from the identification carrier when despatching and receiving the traceable item.	11. Collect all other data including traceability information from internal and external source by any method.	12. Share relevant and agreed traceability data (send information by any method).	13. Store traceability data.	14. Initiate the trace request.	15. Receive the trace request.	16. Send a response.	17. Receive a response.	18. Take action.
<b>Physical Process Flow Roles</b>																		
Traceable Item Creator	X	X	X	X	X		X	P	P	X	X	X	X	X	X	X	X	X
Traceable Item Source	X	X	X	P	X		X			P	X	X	X	X	X	X	X	X
Traceable Item Recipient	X	X	X	P	X		X			P	X		X	X	X	X	X	X
Transporter	X	X	X	X	X		X			X	X	X	X	X	X	X	X	X
<b>Information Process Flow Roles</b>																		
Brand Owner	X	X	X	X	X	P	X	X					X	X	X	X	X	X
Traceability Data Creator	X	X	X	X	X		X	X			X	X	X	X	X	X	X	X
Traceability Data Source	X	X	X	X	X		X			X	X	P	X	X	X	X	X	X
Traceability Data Recipient	X	X	X	X	X		X			X	P		X	X	X	X	X	X
Trace Request Initiator														P			P	X

**P:** The primary role responsible for the specific use case.

**X:** Designates a role involved in the specific use case.

## 7. Business Requirements and Rules Analysis

### 7.1. Business Requirements

A business requirement is a statement of need concerning the business area or business process under study. It is something that the system must do or a quality that the system must have. A requirement exists either because the type of product demands certain functions or qualities, or the client wants the requirement to be part of the delivered product.

To keep consistent with the three major activities the following abbreviations are used in the number column for the Business Requirements.

- AMD→Align Master Data
- RTD→Record Traceability Data
- RT→ Request Trace

#### Key Words

- **MUST = Mandatory** - This word, or the terms “REQUIRED” or “SHALL” means that the definition is an absolute requirement of the specification.
- **MAY= Optional** - This word, or the adjective “OPTIONAL”, means that an item is truly optional.

The Corresponding Use Case(s) should be referenced to [Figure 6-14 Use Cases](#)

Number	Business Requirement	Rationale
<i>BR 1</i> <i>(AMD)</i>	<p>Any internal or external location which needs to be traced <b>MUST</b> be globally and uniquely identified.</p> <p>This may be at a high level (warehouse location) but could be at the detail level (precise bin location) within a warehouse.</p> <p>It is the choice of the Traceability Partner which location level they uniquely identify. The minimum level is the physical site (e.g. distribution centre) identified by a Global Location Number (GLN)</p>	<p>Rationale</p> <p>For unique identification of location.</p> <p>Corresponding Standard</p> <p>GLN</p> <p>Corresponding Use Case(s): 3,4</p>
<i>BR 2</i> <i>(RTD)</i>	<p>Trading Partners <b>MUST</b> be globally and uniquely identified.</p> <p>It is the choice of the Traceability Partner which actor level they uniquely identify, e.g. the Legal Entity.</p>	<p>Rationale</p> <p>Identifying the actor to whom a trace request must be directed, will expedite the collection of the traceability information.</p> <p>Corresponding Standard(s)</p> <p>GLN and Party role list for messages</p> <p>Corresponding Use Case(s): 7, 11, 12, 14</p>

Number	Business Requirement	Rationale
<p><i>BR 3</i> <i>(AMD)</i></p>	<p>Any item, which needs to be tracked forward or traced back, MUST be globally and uniquely identified.</p> <p>This applies to any level of the Product Hierarchy for example, Consumer Unit or a traceable Item not crossing the point of sale</p>	<p>Rationale</p> <p>For unique identification of a traceable item</p> <p>Corresponding Standard(s)</p> <p>GTIN</p> <p>Corresponding Use Case: 6</p>
<p><i>BR 4</i> <i>(AMD)</i></p>	<p>Any asset, which needs to be traced forward or traced back, MUST be globally and uniquely identified.</p>	<p>Rationale</p> <p>For unique identification of the asset</p> <p>Corresponding Standard(s)</p> <p>GRAI (Global Returnable Asset Identifier) and GIAI (Global Individual Asset Identifier)</p> <p>[Ref 1] General Specifications, section 2.3</p> <p>Corresponding Use Case: 5</p>
<p><i>BR 5</i> <i>(RTD)</i></p>	<p>The identification of the traceable item MUST be assigned, at the latest, when physically created.</p> <p>When the traceable item is a trade item, the trade item identification MUST at a minimum be identified with a GTIN. For the purpose of traceability, this may not be sufficient, requiring additional information to uniquely identify a product or grouping of products such as a Batch / Lot Number or where appropriate, a serial number.</p> <p>When the traceable item is a logistic unit, it MUST be uniquely identified.</p> <p>It is the choice of the Traceability Partner which identification level to use for the traceable item</p>	<p>Rationale</p> <p>For unique identification of the traceable item</p> <p>Corresponding Standard(s)</p> <p>GTIN</p> <p>GTIN + Batch / Lot Number</p> <p>GTIN + Serial Number/ SGTIN</p> <p>Logistic Unit – SSCC</p> <p>[Ref 1] General Specifications sections 2.1, 2.2, 2.7, 2.8, 4</p> <p>Best Practice</p> <p>At minimum this information must be displayed in human readable form. For example printed on the product/label or accompanying document or electronic record.</p> <p>Corresponding Use Case: 8</p>

Number	Business Requirement	Rationale
BR 6 (RTD)	All instances of a traceable item must carry a globally unique identification directly on the traceable item or, if not possible, at least on the asset containing it or in an accompanying document.	<p>Rationale</p> <p>To carry the globally unique identification.</p> <p>Corresponding Standard(s)</p> <p>If the traceable item is</p> <p>Trade Item: GTIN</p> <p>Batch / Lot of trade item: GTIN + Batch / Lot Number</p> <p>Serialized Trade Item: GTIN + Serial Number, SGTIN</p> <p>Logistic Unit: SSCC</p> <p>Shipment: Shipment Identification Number</p> <p>[Ref 1] General Specifications section 3</p> <p>Best Practice :</p> <p>The traceable item identification should be at least one of the following:</p> <ul style="list-style-type: none"> <li>electronically held</li> <li>electronically transmitted</li> <li>machine readable on the identification carrier.</li> </ul> <p>Corresponding Use Case: 9</p>
BR 7 (RTD)	The Brand Owner MUST ensure the unique identification of the traceable item.	<p>Rationale</p> <p>The Brand Owner is the party responsible for allocating GS1 System numbering and bar code symbols or RFID tag to a given item.</p> <p>Corresponding Standard(s)</p> <p>[Ref 1] General Specifications</p> <p>Corresponding Use Case: 8</p>
BR 8 (RTD)	The identification carrier MUST remain on or attached to the traceable item <i>until the end of life of the traceable item</i> .	<p>Rationale</p> <p>For unique identification of the traceable item throughout its life cycle.</p> <p>Corresponding Standard(s)</p> <p>[Ref 1] General Specifications section 2.2</p> <p>Allocation Rules and Labelling</p> <p>Corresponding Use Case(s): 9,10</p>
BR 9 (RTD)	The identification carrier MUST remain on or attached to the traceable item when it is packed in an upper level of packaging.	<p>Rationale</p> <p>For unique identification of the traceable item throughout the packaging hierarchy.</p> <p>Corresponding Standard(s)</p> <p>[Ref 1] General Specifications section 2.1</p> <p>Allocation Rules and Labelling</p> <p>Corresponding Use Case(s): 9,10</p>
BR 10	The identification carrier MUST carry some information to link with at least one Traceability Data Source (e.g. Brand Owner, importer,).	<p>Rationale :</p> <p>This allows a traceability partner to identify a data source so that a trace request can be directed to it.</p> <p>Corresponding Standard(s)</p> <p>GS1 Logistics Label</p> <p>Corresponding Use Case: 14</p>

Number	Business Requirement	Rationale
<i>BR 11 (RTD)</i>	All Traceable Item Sources and Traceable Item Recipients MUST collect the identification of the traceable item or asset containing it from the identification carrier.	Rationale To follow the path of a traceable item Corresponding Standard(s) The GS1 General Specification includes the Application Standard for Healthcare and provides the standards for automatic identification and data capture to be used for patient safety, supply chain efficiency and traceability. Corresponding Use Case: 10
<i>BR 12 (RTD)</i>	Traceability Partners MUST agree on at least one common level of traceable item and for this common level agree on the set of consistent traceability data to be exchanged.	Rationale The traceability Partners will exchange traceable items with each other and ensure that these goods are uniquely identified to manage links between inputs, internal processes, and outputs. Corresponding Use Case(s): 8 to 13

Number	Business Requirement	Rationale
<p><i>BR 13 (RTD)</i></p>	<p>All Traceable Item Source(s) and Traceable Item Recipient(s) MUST record and MAY share the following data elements (often recorded within shipment identification documents):</p> <p>TRADING PARTNER IDENTIFICATION:</p> <p>Traceable Item Source Identification</p> <p>Traceable Item Recipient Identification</p> <p>Traceability Data Source Identification</p> <p>Traceability Data Recipient Identification</p> <p>TRACEABLE ITEM IDENTIFICATION AND DETAILS:</p> <p>When the Traceable Item is a Trade Item:</p> <p>Trade Item Identification</p> <p>Trade Item Description</p> <p>Trade Item Quantity</p> <p>When the Traceable Item is an item that traceability partners agree is a traceable item:</p> <p>Item Identification</p> <p>Item Description</p> <p>Item Quantity</p> <p>When the Traceable Item is a Batch/ Lot of Trade Items:</p> <p>Trade Item Identification + Batch / Lot Number</p> <p>Trade Item Description</p> <p>Trade Item Quantity</p> <p>When the Traceable Item is a serialised Trade Item:</p> <p>Trade Item Identification + Serial Number</p> <p>Trade Item Description</p> <p>Trade Item Quantity</p> <p>When the Traceable Item is a Logistics Unit:</p> <p>Logistic Unit Identification</p> <p>Logistic Unit Quantity</p> <p>When the Traceable Item is a Shipment:</p> <p>Shipment Identification</p> <p>FOR ALL TRACEABLE ITEMS:</p> <p>Date of Despatch and / or Receipt</p>	<p>Rationale</p> <p>These are the minimum data requirements necessary to perform traceability to manage links between inputs, internal processes, and outputs. Each industry should consider whether an extension to this generic standard is required to meet their specific data requirements. See section 11 "Implementation Considerations".</p> <p>Corresponding Standard(s)</p> <p>Business Message Standards</p> <p>Global Data Dictionary (GDD)</p> <p>EANCOM</p> <p>GS1-128 and Application Identifiers</p> <p>Best practice</p> <p>All instances of a traceable item must carry a globally unique identification.</p> <p>When a Batch / Lot Number is required to ensure traceability, this Number should be recorded.</p> <p>The product identifier (GTIN) serves as a reference to the full body of product information; examples include description, ingredients, handling requirements, product life.</p> <p>There is no need to duplicate existing records for traceability. For example, a shipment identification serves as a reference to other data elements such as « Ship from », « Ship to », « Date of despatch », « Unit of measure »...</p> <p>Examples of shipment identification:</p> <p>Bill of Lading Number</p> <p>Despatch Advice Number</p> <p>Invoice Number</p> <p>Packing Slip Number</p> <p>Container Number</p> <p>Proof of delivery</p> <p>Refer to BRU 25 for rationale and BR 6 for corresponding standards to Traceable Item identification.</p> <p>Note: The traceability Data Source and Traceable Item Source are often the same</p> <p>Corresponding Use Case(s): 12,13</p>

Number	Business Requirement	Rationale
<i>BR 14</i> (RTD)	All Traceable Item Creators, Sources and Recipients MUST record the linkage between Traceable Items created, received, processed and / or dispatched.	Rationale Traceability requires the management of successive links between what is received, produced, packed, stored and shipped across the extended supply chain. Corresponding Standard(s) Global Data Dictionary GS1 best practices used internally Corresponding Use Case: 13 Example Batches of trade items contained in a pallet Trade items used as ingredients for a finished good Pallets that have been involved for picking and creating a new pallet
<i>BR 15</i> (RTD)	The Traceable Item Source MAY have to share or make available some details and quality information about the traceable item with one or more Traceability Partners.	Rationale The Brand Owner is the party responsible for allocating GS1 System numbering and for replying to trace requests about the traceable item details. Resolving a trace request may require the Traceable Item Source to share information with the Brand Owner or other Traceability Partners. Corresponding Standard(s) EANCOM message QUALITY Corresponding Use Case: 12
<i>BR 16</i> (RTD)	The traceable item identification MUST appear in all accompanying documents or messages containing information related to the traceable item.	Rationale Ensure reliability of traceability data to avoid mistakes with manual data entry. It allows the Traceability Partner to cross check the information included in all documents. Corresponding Standard(s) None Corresponding Use Case(s): 11 To 13
<i>BR 17</i> (RT)	Any Traceability Partner MAY send a trace request to a Traceable Item Source, Traceable Item Recipient, Traceability Data Source or Traceability Data Recipient.	Rationale The trace request may be initiated by any Traceability Partner as the suspected problem can originate from anywhere in the supply chain. Corresponding Standard(s) None Corresponding Use Case(s): 14,15

Number	Business Requirement	Rationale
BR 18 (RT)	Traceability partners who wish to initiate a trace request MUST communicate to the Traceability Data Source at least one item of information from the list to help the Traceability Data Source find the information requested : Traceable item identification (or some traceable item attributes) Traceability Partners identification (or some Traceability Partners attributes) Location identification (or some location attributes) Date / Time, period of time Process or event identification (or some process attributes)	Rationale These are the minimum data requirement for the trace request. Corresponding Standard(s) None Corresponding Use Case(s): 14 To 17

## 7.2. Technical Requirements

Technical requirements are technical constraints or capabilities around business requirements (e.g. "claim reports must be sent via xml"). Technical Requirements include User Interface, Security, Performance, Quality and Backward Compatibility. As this is a *process standard* technical requirements are out of the scope of this document.

**Table 7-1** Technical Requirements

Number	Technical Requirement	Rationale
	No Technical Requirements.	Rationale Test Criteria (pass/fail) (To be used to test the resulting standard) Pass: Fail:

## 7.3. Business Rules

Business rules are statement of **fact** concerning the business area or business process under study that must survive changes to process or data. Business rules are a constraint, in the sense that a business rule lays down what must or must not be the case

Business rules define **what** must be the case rather than **how** it comes to be.

**Table 7-2** Business Rules

Number	Rule	Details
BRU 1	Traceability systems and procedures serve the purpose of meeting business, regulatory, and legal requirements by providing access to relevant party and product traceability information.	Rule Type: Definition Corresponding Use Cases: All

Number	Rule	Details
BRU 2	<p>A traceable item must be one of the following:</p> <ul style="list-style-type: none"> <li>Shipment</li> <li>Logistic unit</li> <li>Trade item</li> <li>Batch / lot of trade items</li> <li>Serialized trade item</li> <li>Any item that traceability partners agree is a traceable item</li> </ul>	<p>Rule Type: Definition</p> <p>Corresponding Use Cases: 8 to 10</p>
BRU 3	<p>Traceability data includes information about:</p> <ul style="list-style-type: none"> <li>What is it? (i.e., the traceable item)</li> <li>Who has been involved? (i.e., the traceability partner(s))</li> <li>Where did it happen? (i.e., location)</li> <li>When did it happen? (i.e., date / time, period of time)</li> <li>What happened? (i.e., process or event)</li> </ul> <p>The following information is NOT within the scope of an external traceability system:</p> <ul style="list-style-type: none"> <li>full recipes or formulas</li> <li>financial or pricing data,</li> <li>employee personal data,</li> <li>patient personal data or</li> <li>research and development data</li> </ul>	<p>Rule Type: Definition</p> <p>Rationale</p> <p>Key questions for traceability</p> <p>Corresponding Use Cases: All</p>
BRU 4	<p>Key traceability principles are:</p> <ul style="list-style-type: none"> <li>Unique identification of traceable items</li> <li>Capturing and recording traceability data</li> <li>Sharing traceability data between traceability partners</li> <li>Linking inputs through changes or processing to outputs, be that the same traceable item or a new traceable item</li> </ul>	<p>Rule Type: Definition</p> <p>Corresponding Use Cases: All</p>
BRU 5	<p>Traceability is an integral part of the business process. It is not separate from logistical processes and/or product safety / quality programs.</p>	<p>Rule Type: Definition</p> <p>Corresponding Use Cases: All</p>
BRU 6	<p>A traceable item may be related to another traceable item.</p>	<p>Rule Type: Definition</p> <p>Corresponding Use Cases: 8 to 10</p>
BRU 7	<p>Instances of a traceable item may exist in multiple locations at the same time.</p>	<p>Rule Type: Definition</p> <p>Corresponding Use Cases: 9 to 13</p> <p>Example: Drugs from the same batch that have been dispatched between several customers.</p>

Number	Rule	Details
BRU 8	There may be several levels of traceable items at the same time in one shipment with regards to the traceable item hierarchy.	Rule Type: Definition Corresponding Use Cases: 8 to 17 Example: Refer to fig 12 "Traceable Item Hierarchy"
BRU 9	Traceability data may be master data, constant across time (e.g. GTIN) or event data, changing with each case or shipment (e.g., lot / batch) or item variable information (e.g. serial number)	Rule Type: Definition Corresponding Use Cases: 13 to 17
BRU 10	All Traceability Partners must have internal and external traceability to achieve traceability across the supply chain.	Rule Type: Guideline Corresponding Use Cases: All
BRU 11	Every Traceability Partner may decide on HOW to implement internal traceability systems. It is essential that they be able to collect, record, and share the necessary information with upstream and downstream Traceability Partners in an accurate and timely manner.	Rule Type: Guideline Corresponding Use Cases: All
BRU 12	Traceability Partners use GS1 standards to ensure fast and accurate flow of information between traceability partners.	Rule Type: Guideline Corresponding Use Cases: All
BRU 13	Traceability Partners should not impose proprietary practices on other Traceability Partners.	Rule Type: Guideline Corresponding Use Cases: All
BRU 14	It is not necessary for ALL Traceability Partners to store and share ALL traceability information, but they must be able to access and share relevant and agreed information.	Rule Type: Guideline Corresponding Use Cases: 12 to 17
BRU 15	The minimum information shared between Traceability Partners should be the greater of: 1) minimum requirements defined in this GS1 Global Traceability Standard for Healthcare . 2) what is needed for day to day business transactions with traceability partners. 3) what is required by regulation.	Rule Type: Guideline Corresponding Use Case: 12
BRU 16	Each Traceability Partner must define at least one level of traceable item for each shipment.	Rule Type: Guideline Corresponding Use Case: 8

Number	Rule	Details
BRU 17	<p>The Brand Owner and / or Traceable Item Creator must know the details of the traceable item and be able to reply to a trace request.</p>	<p>Rule Type: Guideline Corresponding Use Cases: 11 to 17</p>
BRU 18	<p>A Traceable Item Source must know what has happened to the traceable item during its internal process and when, where, and to whom it has despatched the traceable item.</p> <p>Each Traceability Partner must store the data links between what is received, produced, packed, stored and shipped.</p> <p>When the Traceable Item is mixed with similar items from many locations or batches, e.g. in a grain silo, the Traceability Partner must store records of all inputs and outputs in order to provide fair estimates of where the Traceable Item has gone.</p>	<p>Rule Type: Guideline Corresponding Use Cases: 8 to 13 Example: refer to example 4 in section 10</p>
BRU 19	<p>A Traceable Item Recipient must know the Traceable Item Source that supplied the traceable item.</p>	<p>Rule Type: Guideline Corresponding Use Cases: 11 to 13</p>
BRU 20	<p>As long as a traceable item is contained within another traceable item and parent/child relationships are maintained, traceability partners MAY store only records of the movements and location of the higher level traceable item. (Refer to Business Requirement 13)</p>	<p>Rule Type: Guideline Corresponding Use Cases: 10 to 13</p>
BRU 21	<p>Traceability Partners must link physical movement of traceable items to the information movement, both between the Traceable Item Source and themselves, and between Traceable Item Recipient and themselves. This event flow of information must exactly reflect the physical movement.</p> <p>This linkage is necessary for the traceable item to be traced from point of origin or manufacture to the point of sale or use or user (if relevant). Conversely, this linkage must also ensure that product can be traced back through the supply chain.</p>	<p>Rule Type: Guideline Corresponding Use Cases: 11 to 13</p>

Number	Rule	Details
<i>BRU 22</i>	The Traceable Item Recipient may collect information from both the previous Traceable Item Source and the previous Transporter source (land, ocean, rail or air).	Rule Type: Guideline Corresponding Use Cases: 10 to 13
<i>BRU 23</i>	The Traceable Item Source may communicate information to both the Traceable Item Recipient and the subsequent Transporter (land, ocean, rail or air).	Rule Type: Guideline Corresponding Use Cases: 10 to 13
<i>BRU 24</i>	A Trace Request Initiator must contact its Traceability Partners, including the Brand Owner where appropriate	Rule Type: Guideline Corresponding Use Case: 14
<i>BRU 25</i>	The Traceability Data Source must reply as quickly as possible to the party requesting traceability information. The time period allowed may be defined in local regulations or commercial agreements.	Rule Type: Guideline Corresponding Use Cases: 16, 17
<i>BRU 26</i>	A Trace Request may trigger subsequent trace requests up or down the supply chain in order to fulfil the original request.	Rule Type: Guideline Corresponding Use Cases: 14, 15
<i>BRU 27</i>	A traceability system is only as good as its weakest link. If failure occurs at any point, traceability breaks down.	Rule Type: Guideline Corresponding Use Cases: All
<i>BRU 28</i>	Various industries, regions or countries may have additional Business Requirements beyond the generic GS1 Global Traceability Standard. These should be addressed by defining specific extensions.	Rule Type: Guideline Corresponding Use Cases: All e.g. This document is the extension for Healthcare to the GTS.
<i>BRU 29</i>	Access to and sharing of information does NOT include intellectual property of each traceability partner	Rule Type: Guideline Corresponding Use Cases: 12 to 17
<i>BRU 30</i>	Traceability Partners MAY choose a specific, key data element, e.g. purchase order number, to enable access to data and/or information related to an event of a traceable item.	Rule Type: Guideline

## 8. Structured Business Scenarios

### 8.1. Structured Business Scenario for *Perform Traceability*

The generic traceability framework is broken down into three main activities.

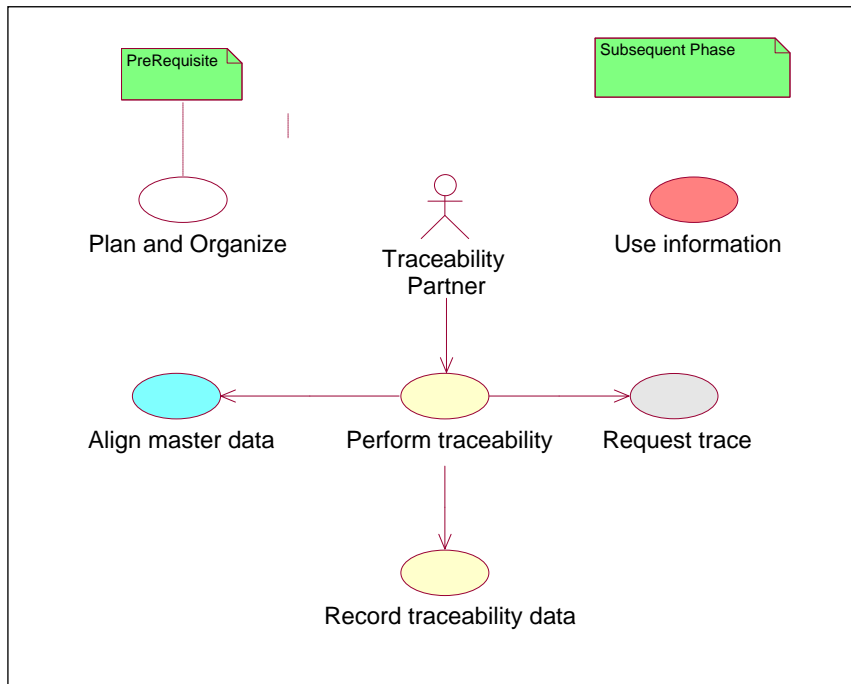
- Align Master Data
- Record Traceability Data
- Request Trace

The Plan and Organize use case is a prerequisite phase and Use Information use case is subsequent phase, and they are out of scope.

The Use Case Diagram (Figure 8.1) depicts the Traceability Partner's interaction with key processes in the traceability process. The use case diagram is a pictorial representation for Figure 6.14 Use Case Actor Matrix. They are colour coded Blue (Align Master Data), Yellow (Record Traceability Data), which is the focus here, and Grey (Request Trace). Therefore, at the highest level to perform traceability, the Traceability Partner's must Plan and Organize, Align Master Data, Record Traceability Data, Request Trace, and lastly Use Information. The Use Case Description boxes are a textual representation drilling down to the sub processes for each figure 8.1-8.4.

#### 8.1.1. Use Case Diagram: Perform Traceability

**Figure 8-1** Use Case Diagram: Perform Traceability

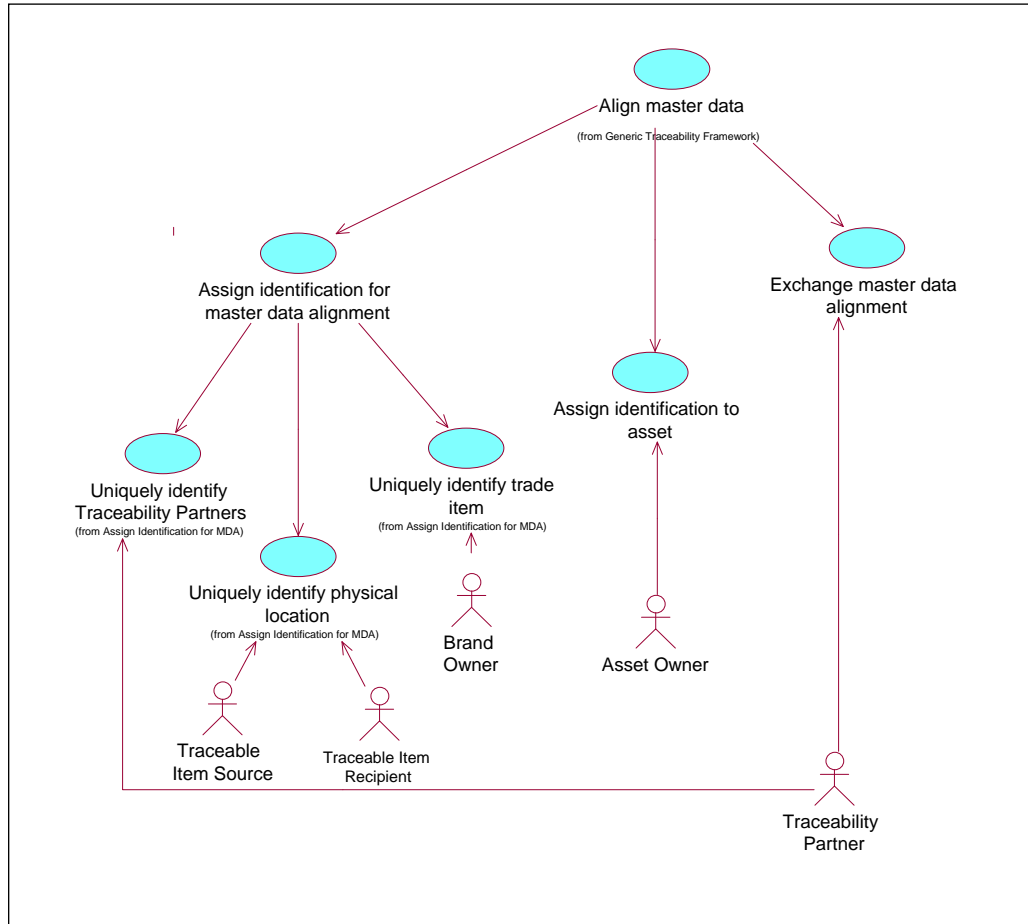


Use Case ID	UC-1
Use Case Name	Perform traceability
Use Case Description	Provides the processes involved to perform traceability.

Actors (Goal)	Traceability Partner's goal is to perform traceability. Traceable Item Creator, Traceable Item Source, Traceable Item Recipient, Transporter, Brand Owner, Traceability Data Creator, Traceability Data Source, Traceability Data Recipient, and Trace Request Initiator.
Performance Goals	The ability to track and trace items across the supply chain. At each step in the process there is basic information that needs to be collected from Traceability Data Source and kept and shared with Traceability Data Recipient. All Traceability Partners involved in the supply chain must systematically associate the physical flow of materials, intermediate and finished products with the information flow. To ensure the continuity of the information flow, each Traceability Partner must communicate pre-defined and agreed traceability data to the next Traceability Partner.
Preconditions	Traceability Partners in the supply chain have planned and organized their systems and processes to perform traceability.
Post conditions	Traceability Partners in the supply chain are able to perform traceability.
Scenario	<p><u>Perform Traceability</u> Begins when: Traceability Partner wishes to conduct future business.</p> <p>(Template Form) Continues with... Step # Primary Actor Secondary Actor (If necessary) Activity Step</p> <p>Step: 1 Actor: Traceability Partner Activity Step: Align master data</p> <p>Step: 2 Actor: Traceability Partner Activity Step: Record traceability data</p> <p>Step: 3 Actor: Traceability Partner Activity Step: Request Trace</p> <p>Ends when: The trace request initiator receives the requested information or receives the message that the information cannot be found.</p>
Alternative Scenario	No alternative scenarios
Related Requirements	Related Business Requirements contained in sub use cases.
Related Rules	Related Business Rules contained in sub use cases.

### 8.1.2. Use Case Definition: Align Master Data

Figure 8-2 Use Case Diagram: Align Master Data

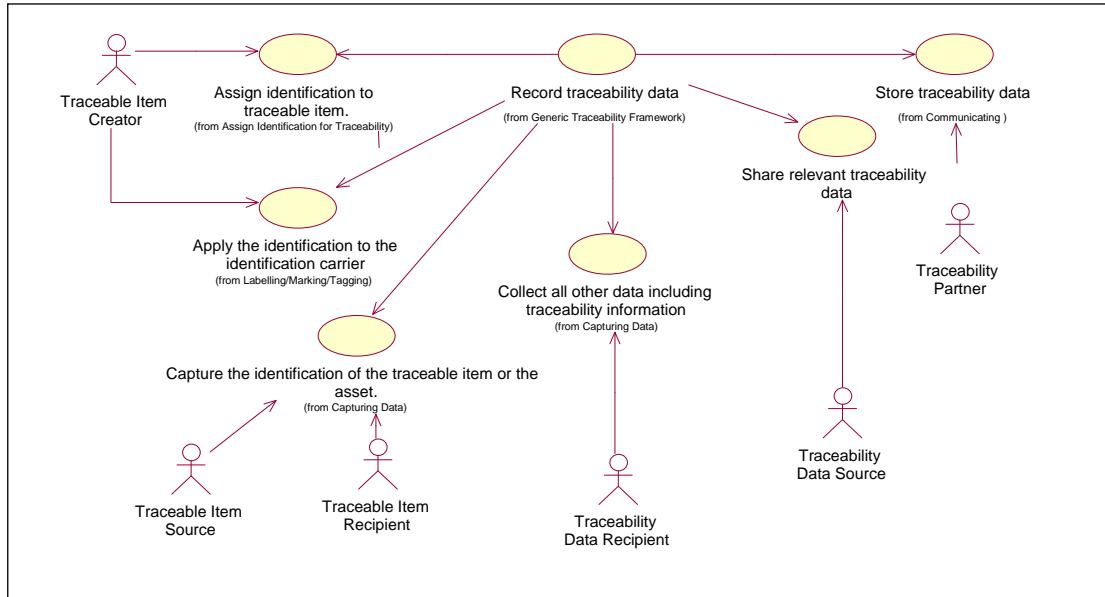


Use Case ID	UC-1.1
Use Case Name	Align master data
Use Case Description	Provides the processes to align master data.
Actors (Goal)	Traceability Partner's goal is to align master data.
Performance Goals	The ability to align master data to ensure traceability can be performed.
Preconditions	Traceability Partners in the supply chain wish to align master data.
Post conditions	Traceability Partners in the supply chain are able to exchange aligned master data.

<p>Scenario</p>	<p><u>Align Master Data</u>          Begins when: Traceability Partner wishes to align master data.</p> <p>Step: 1          Primary Actor: Traceability Partner          Activity Step: Assign identification to the party.</p> <p>Step: 2          Primary Actor: Traceable Item Source and Traceable Item Recipient.          Secondary Actor: Traceable Item Creator, Transporter, Brand Owner, Traceability Data Creator, Traceability Data Source, Traceability Data Recipient, and Trace Request Initiator          Activity Step: Assign identification to the physical locations.</p> <p>Step: 3          Primary Actor: Traceability Partner          Activity Step: Assign identification to the assets.</p> <p>Step: 4          Primary Actor: Brand Owner          Activity Step: Assign identification to the traceable item</p> <p>Step: 5          Primary Actor: Traceability Partner          Activity Step: Exchange Master Data</p> <p>Ends when: Master data alignment has been achieved.</p>
<p>Alternative Scenario</p>	<p>No alternative scenarios</p>
<p>Related Requirements</p>	<p>Business Requirements: 1-4</p>
<p>Related Rules</p>	<p>Business Rules: 1-7, 9-14, 27, 28, 29</p>

### 8.1.3. Use Case Definition: Record Traceability Data

Figure 8-3 Use Case Diagram: Record Traceability Data

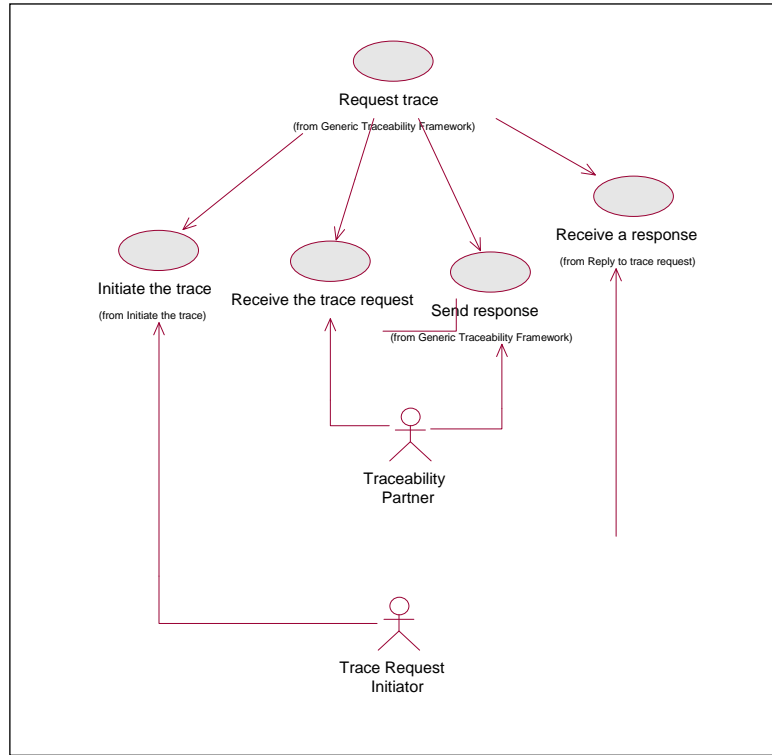


Use Case ID	UC-1.2
Use Case Name	Record traceability data
Use Case Description	Provides the processes involved to record traceability data.
Actors (Goal)	Traceability Partners can identify traceable items and collect and record relevant and, at a minimum, agreed traceability data as traceable items move across the supply chain.
Performance Goals	The ability to identify traceable items, collect and record relevant and, at a minimum, agreed traceability data as traceable items move across the supply chain.
Preconditions	Aligned master data.
Post conditions	Traceability Partners are able to fulfil a trace request.

Scenario	<p><u>Record Traceability Data</u></p> <p>Begins when: Manufacturer needs to create additional inventory, or Vendor Managed Inventory triggers inventory creation request.</p> <p>Step: 1            Primary Actor: Traceable Item Creator            Secondary Actor: Brand Owner and Traceability Data Creator            Activity Step: Assign identification to traceable item. A traceable item is a physical object where there may be a need to retrieve information about its history, application, or location. Reference section 6.1.2.5 for details.</p> <p>Step: 2            Primary Actor: Traceable Item Creator            Activity Step: Apply the identification to the identification carrier on the traceable item or in an accompanying document when a transformation takes place.</p> <p>Step: 3            Primary Actor: Traceable Item Source and Traceable Item Recipient            Secondary Actor: Traceable Item Creator, Transporter, Traceability Data Source, and Traceability Data Recipient            Activity Step: Capture the identification of the traceable item or the asset containing it from the identification carrier when despatching and receiving the traceable item.</p> <p>Step: 4            Primary Actor: Traceability Data Recipient            Secondary Actor: Traceable Item Creator, Traceable Item Source, Traceable Item Recipient, Transporter, Traceability Data Creator, and Traceability Data Source            Activity Step: Collect all other data including traceability information from internal and external sources by any method.</p> <p>Step: 5            Primary Actor: Traceability Data Source            Secondary Actors: Traceable Item Creator, Traceable Item Source, Transporter, and Traceability Data Creator            Activity Step: Share relevant and agreed traceability data (send information by any method).</p> <p>Step: 6            Primary Actor: Traceability Partner            Activity Step: Store traceability data.</p> <p>Ends when: Deliver to “Back Room” or “Back Door” (The receiving area for the final stage of the point of sale or service) or use or destruction of item or out of scope of traceability process.</p>
Alternative Scenario	No alternative scenarios
Related Requirements	Business Requirements 5-16, 19
Related Rules	Business Rules 1-14, 15-23, 27, 28, 29

### 8.1.4. Use Case Definition: Request Trace

Figure 8-4 Use Case Diagram: Request Trace



Use Case ID	UC-1.3
Use Case Name	Request trace
Use Case Description	Provides the processes involved to request a trace.
Actors (Goal)	Traceability Partner's goal is to fulfil the trace request.
Performance Goals	The data is available and traceability partners can provide agreed comprehensive, accurate and timely information to an authorized party upon request about a traceable item.
Preconditions	The Traceability Partner recorded traceability data for that traceable item.
Post conditions	Traceability Partner in the supply chain received the information on their request.

Use Case ID	UC-1.3
Scenario	<p><u>Request Trace</u></p> <p>Begins when: There is a need for trace. The information is not available internally, and the information must be requested to external traceability partner.</p> <p>Step: 1            Primary Actor: Trace Request Initiator            Secondary Actor: Traceable Item Creator, Traceable Item Source, Traceable Item Recipient, Transporter, Brand Owner, Traceability Data Creator, Traceability Data Source, and Traceability Data Recipient.            Activity Step: Initiates trace request.</p> <p>Step: 2            Primary Actor: Traceability Partner            Activity Step: Receives the trace request.</p> <p>Step: 3            Primary Actor: Traceability Partner            Activity Step: Sends a reply against the requested trace.</p> <p>Ends when: The Trace Request Initiator receives information or receives the message that the information cannot be found.</p>
Alternative Scenario	No alternative scenarios
Related Requirements	Business Requirements 17-18
Related Rules	Business Rules 1-7, 9-14, 17-19, 24-29

### 8.1.5. Activity Diagram

No Activity Diagram

### 8.1.6. Sequence Diagrams

No Sequence Diagram

## 9. Business Object Analysis

### 9.1. Business Object Life-Cycle Discussion

The purpose of this section is to identify and explain the minimum data elements required for a global traceability process standard that an organisation should plan to create, capture, record and be prepared to share agreed data elements with Traceability Partners in the supply chain. (Refer to BR13) Organisations should consider adopting these minimum data elements when selecting, designing and implementing their internal business process.

This minimum level is generic to any GS1 member company:

- Anywhere in the supply chain
- In any industry or industry sector
- In organisations of any size

There is an implicit understanding that traceability partners in the healthcare sector may need to create, capture, record and share agreed, additional information beyond the data elements defined here.

Data is created and recorded at many steps along the supply chain. It is not necessary for all of this to be exchanged with every Traceability Partner, but a minimum amount of traceability data must be exchanged to accompany the physical flow of goods. Other data should be recorded and linked within internal traceability records so that it is available to investigate and share as appropriate when a trace request is received. (Refer to section 6.1.2.4 figure 6.8 and to BRU 11)

The minimum information required, and corresponding data elements identified are as follows:

Minimum Information Required	Data Element Required	GS1 Standard
Who is my Traceability Partner?	<p>Source identification and Recipient identification for each relevant party. This includes intermediaries such as carriers or 3rd party logistics providers.</p> <p>Parties may serve as a:</p> <ul style="list-style-type: none"> <li>■ Traceable Item Source</li> <li>■ Traceability Data source</li> <li>■ Traceable Item Recipient</li> <li>■ Traceability Data Recipient</li> </ul> <p>The Traceability Data Source and Traceable Item Source are often the same. The Traceability Data Recipient and Traceable Item Recipient are also often the same.</p>	Global Location Number (GLN)

Minimum Information Required	Data Element Required	GS1 Standard
What is the Traceable Item?	<p>The level at which the traceable item is defined within a product packaging or logistical hierarchy is dependent on the degree of control required.</p> <p>The data elements required are dependent on the level of traceable item chosen as follows:</p> <p>When the Traceable Item is a Trade Item:</p> <ul style="list-style-type: none"> <li>■ Trade Item Identification</li> <li>■ Trade Item Description</li> <li>■ Trade Item Quantity</li> </ul> <p>When the Traceable Item is a batch of trade items :</p> <ul style="list-style-type: none"> <li>■ Trade Item Identification</li> <li>■ Batch / Lot Number</li> <li>■ Trade Item Description</li> <li>■ Trade Item Quantity</li> </ul> <p>When the Traceable Item is a serialised trade item :</p> <ul style="list-style-type: none"> <li>■ Trade Item Identification</li> <li>■ Serial Number</li> <li>■ Trade Item Description</li> <li>■ Trade Item Quantity</li> </ul> <p>When the Traceable Item is an item that traceability partners agree is a traceable item:</p> <ul style="list-style-type: none"> <li>- Item Identification</li> <li>- Item Description</li> <li>- Item Quantity</li> </ul> <p>When the Traceable Item is a Logistics Unit:</p> <ul style="list-style-type: none"> <li>■ Logistic Unit Identification</li> <li>■ Logistic Unit Quantity</li> </ul> <p>When the Traceable Item is a Shipment</p> <ul style="list-style-type: none"> <li>■ Shipment Identification</li> </ul>	<p>Global Trade Item Number (GTIN) Global Data Dictionary (GDD) trade item attributes</p> <p>Depending on the choice of traceable item, the traceable item identification is (refer to BR 5)</p> <p>Trade Item: GTIN Batch / lot of trade item: GTIN + Batch / Lot Number Serialized trade item: GTIN + Serial Number, SGTIN Logistic unit: SSCC and applications identifiers Shipment: Shipment Identification Number</p> <p>GS1 Application Identifiers</p> <p>Note: as of July 2005, SGTIN only exists for RFID technology using EPC. As bar code solutions a combination of GTIN plus serial number can be found as appropriate counterpart (e.g. GS1 DataMatrix or GS1-128).</p>
Where was it shipped from or shipped to?	Best practice or specific extensions of traceability requirements: "ship from" or "ship to" identification	GLN
When did I receive / despatch it?	Date of receipt and / or date of despatch as relevant depending on the role of the party	EDI DESADV



**Important:** In order for traceability to be effective along the supply chain, and the above data elements to be truly useful, each Traceability Partner must practice internal traceability. This requires that each Traceability Partner establishes and records linkages between inputs and outputs (BR 14, BRU 6, BRU 10). While outside the scope of this GS1 Standard, internal traceability best practices are available at, for example, [ref 2] Chapter 6 of *ECR – Using Traceability in the Supply Chain to Meet Consumer Safety Expectations*.

**9.1.1. State Diagram(s)**

No State Diagram.

**9.1.2. Business Object relationship discussion**

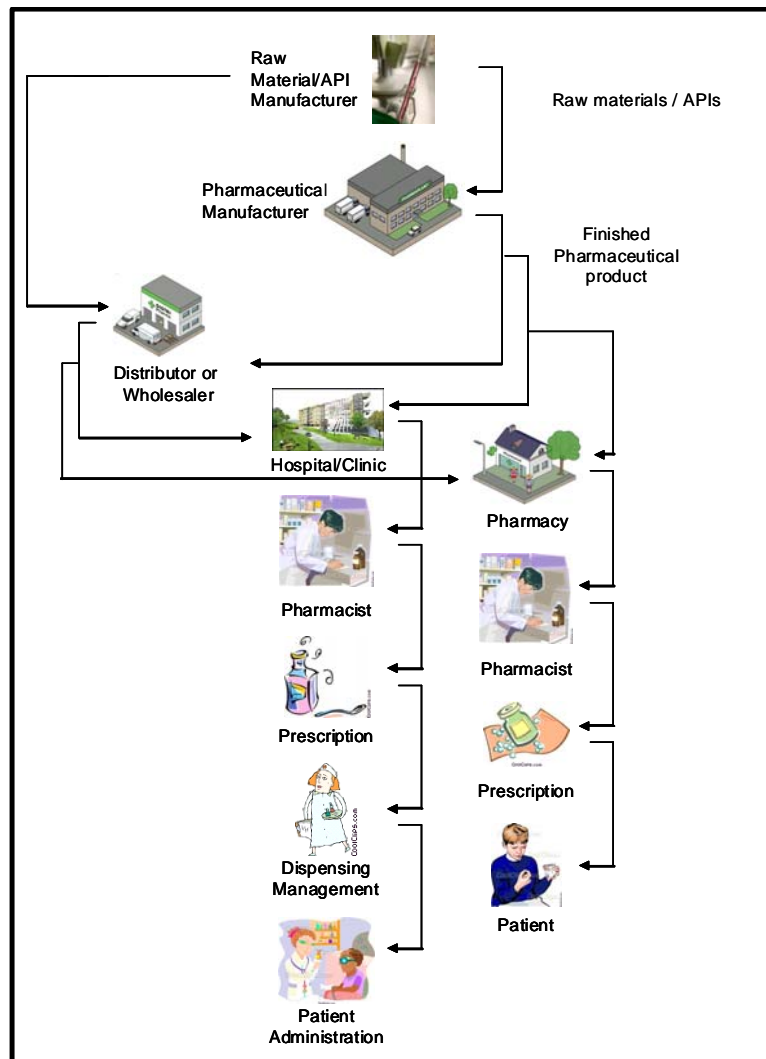
No Business Object relationship discussion

**10. Conceptual Solution (Examples)**

**10.1. Fully Worked Example: Traceability in the Pharmaceutical Supply Chain**

This example is based on a high level, typical Pharmaceutical Supply Chain from raw materials or APIs through either a hospital pharmacy or retail pharmacy to the patient and the actions / roles defined in this Business Requirement Analysis Document Section 6. The purpose is to show how the GS1 Global Traceability Standard for Healthcare and GS1 best practices can be used to establish a robust scheme for traceability in the Healthcare sector.

**Figure 10-1** The Pharmaceutical Supply Chain



**Table 10-1** Traceability in the Pharmaceutical Supply Chain

<b>1. Who are the Traceability Partners?</b>	Industry Sector: Healthcare: Pharmaceuticals Traceability Partners: Raw Material/API Manufacturer, Pharmaceutical Manufacturer, Pharmaceutical Wholesaler, Pharmaceutical Distributor, Hospital, Hospital Pharmacist, Retail Pharmacist, Patient
<b>2. What is the business need?</b>	<ol style="list-style-type: none"> <li>1. Patient Safety</li> <li>2. Product traceability in a complex, global supply chain</li> <li>3. Quality management</li> <li>4. Product safety and to support withdrawal or recall</li> <li>5. Global supply chain logistics efficiency</li> <li>6. Legal compliance with national, regional or global regulation</li> <li>7. Brand protection, product authentication and reduction in risk of counterfeit or fraud</li> </ol>
<b>3. Description of the physical flow of product.</b>	<p>The physical flow of goods in the Pharmaceutical supply chain is described in the schema shown above (one organisation may manage several steps):</p> <ul style="list-style-type: none"> <li>■ <b>Raw Material/API Manufacturer:</b> Responsible for the production and delivery of raw materials or APIs: record keeping should include manufacturing processes.</li> <li>■ <b>Pharmaceutical Manufacturer:</b> Responsible for receiving the raw material/APIs and for the production, manufacture, inventory management and dispatch of pharmaceutical product. As well as record keeping of appropriate information about manufacturing processes, what is received and what is dispatched.</li> <li>■ <b>Pharmaceutical Wholesaler:</b> Responsible for receipt, storage, inventory management and dispatch of pharmaceutical product, as well as re-packing and re-labelling as required. Plus record keeping of appropriate information about what is received, re-packaged, relabelled and what is dispatched.</li> <li>■ <b>Pharmaceutical Distributor:</b> Responsible for receipt, storage, inventory management and dispatch of pharmaceutical product, as well as re-packing and re-labelling as required. Plus record keeping of appropriate information about what is received, re-packaged and relabelled and what is dispatched.</li> <li>■ <b>Hospital Pharmacy/Pharmacist:</b> Responsible for receipt, storage, inventory management and dispensing of pharmaceutical product, as well as compounding, re-packing and re-labelling as required. Plus record keeping of appropriate information about what is received, compounded, re-packaged or relabelled and what is dispensed.</li> <li>■ <b>Healthcare Professional (e.g. Doctor/Nurse):</b> Responsible for administering the pharmaceutical product to the patient, as well as record keeping of appropriate information about what is administered.</li> <li>■ <b>Retail Pharmacy/Pharmacist:</b> Responsible for receipt, storage, inventory management and dispensing of pharmaceutical product, as well as re-packing and re-labelling as required. Plus record keeping of appropriate information about what is received, re-packaged or relabelled and what is dispatched.</li> <li>■ <b>Hospital Patient:</b> Responsible for taking the prescribed pharmaceutical product.</li> <li>■ <b>Domestic Patient:</b> Responsible for taking the prescribed pharmaceutical product. May be responsible for the receipt and storage of pharmaceutical product and may also be responsible for recording information about receipt, storage and administration of pharmaceutical product.</li> </ul>

<b>4. What is the “traceable item”?</b>	<ol style="list-style-type: none"> <li>1. Raw Material / API</li> <li>2. Compounded Product</li> <li>3. Finished Goods by GTIN</li> <li>4. Packaging materials as production inputs by Batch / Lot Number</li> <li>5. Finished goods by Batch / Lot Number</li> </ol>
<b>5. Traceability Partner “Roles”</b>	<p>The key roles performed for traceability in the Pharmaceutical Supply Chain are listed below (one trading or traceability partner may perform several roles):</p> <ol style="list-style-type: none"> <li>1. Traceable Item Creator (e.g. Raw material / API manufacturer)</li> <li>2. Traceable Item Source</li> <li>3. Traceable Item Recipient</li> <li>4. Transporter (e.g. third party logistics provider)</li> <li>5. Brand Owner</li> <li>6. Traceability Data Creator</li> <li>7. Traceability Data Source</li> <li>8. Traceability Data Recipient</li> <li>9. Trace Request Initiator</li> </ol> <p>The Pharmaceutical supply chain is usually required by regulation to manage the supply chain within strict Regulatory, Customs and Excise controls and this may establish additional roles, data and business requirements.</p>
<b>6. Traceability data to create, capture and record</b>	<p>Minimum data attributes to create / capture / record as appropriate at each step include data described in BR 11 and documentation required by international and/or local regulation</p> <p>Additional categories of information to create, capture and record based on supply chain roles includes:</p> <ol style="list-style-type: none"> <li>1. <b>Pharmaceutical Manufacturer:</b> Physical samples should be retained / analysed.</li> <li>2. <b>Distribution:</b> Receipt, storage, inventory management, dispatch, rework</li> <li>3. <b>Pharmacist:</b> Receipt, storage, inventory management, compounding and dispensing</li> </ol>

<p><b>7. Enabling technologies and GS1 “best practices” to consider</b></p>	<p>Section 6, <u>Business Process Analysis</u>– describes the roles and the activities carried out by each traceability partner throughout the supply chain. Enabling technologies are available to support the use of GS1 e-business standards, together with traditional methods, meeting the needs of organisations both large and small.</p> <p>Some of the choices of GS1 standards available in the Pharmaceutical Supply Chain are identified in the GS1 Healthcare Traceability Guideline as follows (refer to Glossary) :</p> <ul style="list-style-type: none"> <li>■ Global Location Number (GLN)</li> <li>■ Global Trade Item Number (GTIN)</li> <li>■ Serial Shipping Container Code (SSCC)</li> <li>■ Application Identifier (AI)</li> <li>■ Global Returnable Asset Identification (GRAI)</li> </ul> <p>Some of the enabling technologies for larger, more automated systems include:</p> <ol style="list-style-type: none"> <li>1. Bar code – linear and 2D symbologies to apply asset identification (EAN/UPC 13 - bottles, ITF14 - cases, GS1-128 – pallets / full shipping containers, 2D – serial number identification)</li> <li>2. Electronic Data Interchange (EDI) and internet based messaging (XML)</li> <li>3. RFID – electronic tag, Electronic Product Code (e.g. to secure and identify shipping containers)</li> <li>4. Fixed and hand held Bar code and electronic scanners, Radio frequency local area networks, interfaces to Enterprise Resource Planning (ERP) Systems</li> <li>5. Small and medium sized enterprises (SMEs) can achieve all the required steps by reference to human readable information on labels, accompanying shipping documents, buying specifications and purchase orders and other conventional business records.</li> </ol>
<p><b>8. How do Traceability Partners assign identification to the traceable item using GS1 “best practice”?</b></p>	<p>Pallet shipments:</p> <p>Serial Shipping Container Code (SSCC) allocated by the manufacturer, wholesaler or distributor. When bar coded, the SSCC is represented in a GS1-128 symbol. The AI (00) indicates that the data field contains an SSCC.</p> <p>The container may have several sections, each identified with batch numbers.</p> <p>The mandatory AI is (00) – Serial Shipping Container Code (SSCC).</p> <p style="text-align: center;"><b>Serial Shipping Container Code (SSCC) bar coded in GS1-128 symbol</b></p> <div style="text-align: center;"> </div> <p>Finished Pharmaceutical Products: (Also refer to GTIN Allocation Rules for Healthcare)</p> <p><u>A. Trade items crossing the point of sale (e.g. bottle, box containing blister packs):</u></p> <p>These must be identified with a GTIN and bar coded with EAN/UPC symbol for scanning at point-of-sale. Some countries, including EU member states, require the allocation of a Batch / Lot Number to each consumer unit created during the filling process. This information may be displayed in human readable form.</p>

	<p>Traceability Partners should refer to the GS1 General Specification, Section 2 Application Standard For Healthcare to select their AIDC data and carrier choices. The application standard identifies three different levels of marking for regulated healthcare products (normal, enhanced and highest); and, provides three options for carrier selection (preferred options, options in addition to a barcode and other acceptable options).</p> <p><u>C. Logistic units (pallets)</u></p> <p>Identification and traceability of pallets is ensured through the allocation of a Serial Shipping Container Code (SSCC). Any pallet, independently of its type (mixed or uniform), needs to carry an SSCC allocated by the filler/packer. A new SSCC must be allocated every time a new logistic unit (pallet) is created.</p> <p style="text-align: center;"><b>GS1 Logistics Label</b></p> <p>Based on feedback from AIDC AppStd Team:  REPLACE LABEL with two new labels:</p> <ul style="list-style-type: none"> <li>• one for trade items with GTIN, lot and expiry</li> <li>• and one for logistics label only using SSCC Excluding AI02 and AI37</li> </ul> <p>EAN.UCC should be changed to GS1  (Best before should be expiry)</p>
<p><b>9. How do Traceability Partners apply the identification carrier?</b></p>	<p>The identification carrier (e.g., linear or 2D bar code; RFID electronic tag) is applied at source when the finished goods are created or shipped.</p> <p>Bulk goods can be managed using traditional methods such as unique identification of bulk transport container linked to purchase order, invoice, accompanying shipment documentation, correspondence, e-business messages.</p>
<p><b>10. How do Traceability Partners collect the identification of the traceable item?</b></p>	<p>The identification carrier can be scanned to automatically capture data when it is in the form of a bar code and / or RFID tag.</p> <p>The data is also available in</p>
<p><b>11. How is other relevant data collected?</b></p>	<p>Other data is held in the form of physical Pharmaceutical samples, with accompanying records created through scientific analysis, held in traditional organisation archives.</p>
<p><b>12. How is relevant data shared?</b></p>	<p>Data is shared through traditional correspondence, e-business messages including fax, email, EDI, XML, data synchronisation and through personal telephone and face to face communication.</p>
<p><b>13. How is data recorded?</b></p>	<p>Data is recorded in electronic databases, on shipping and customs documentation, in organisation paper based records.</p>

<b>14. Managing a “Trace request”</b>	<p>A “Trace Request” may arise as a result of several scenarios, e.g. perhaps as a result of an adverse event. At this moment, especially for Pharmaceuticals, it is important for the pharmacist to obtain and secure a sample of the defective product. The sample of the Pharmaceutical product may be required to conduct analyses of the product for comparison with records and to identify any foreign materials the bottle may contain.</p> <p>From the physical bottle and label all the key minimum data required to trigger a trace request can be obtained including:</p> <ol style="list-style-type: none"> <li>1. Brand name and product description</li> <li>2. Supplier name and contact address</li> <li>3. Batch / Lot Number (sometimes including a serial number)</li> </ol> <p>The pharmacist can identify and contact the supplier and investigate the nature, impact and resolution required for the specific problem identified.</p>
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Application Identifiers / Data Attributes recommended for the Healthcare GS1-128 Pallet Label are defined below:

Application Identifier (AI) or Header	Data Attributes
Header	Organisation name, corporate logo and GLN number of the producer
Header	Product Description, e.g. Brand / Quality / Age Ref/ Size / number in case / % ABV)
(00) (Mandatory)	Identification of a logistic unit – Serial Shipping Container Code (SSCC)
(02) (Strongly Recommended)	Identification of a trade item, i.e. the case of bottles (Global Trade Identification Number - GTIN)
(37) (SR)	Count of trade items contained in a Logistic Unit, i.e., number of cases on the pallet
(10) (SR)	Batch / Lot Number
(15) (SR)	Minimum Durability Date (quality) (YYMMDD), i.e., Best Before Date if it appears on the label on the packaged goods

## 11. Implementation Considerations

Please refer to the GS1 User Guidelines for Implementing Traceability in Healthcare.

## 12. Test Scenario Summary

For Conformance and Certification, please refer to the [GS1 Global Traceability Conformance Programme \(GTC\)](#). The GTC defines essential elements for the development of best practice Traceability.

## Glossary of Business Terms

Term	Description
Actor	An actor is a role that a user plays with respect to a system.
Agreement(s)	Arrangement(s) undertaken by and legally binding on parties.
Application Identifier (AI)	The field of two or more characters at the beginning of an Element String that defines its format and meaning.
API	Active Pharmaceutical Ingredient
Apply	Physically mark or attach
Assign	Designate or allocate.
Asset	Can be an item that is procured/purchased and depreciated. Examples could be "bulk container", "returnable container" NOT: a disposable item; an item on consignment (Reference Business Requirement 6)
Authentication (Pharmaceuticals)	Track and trace in the pharmaceutical supply chain is a series of product authentication steps. The authentication step is a process that permits attribute(s) of a packaging component to be verified, through the use of a data carrier on the packaging component, by means of an electronic transmission. The electronic transmission transfers data from a sender to a recipient. The transfer may use an electronic technique to protect the transmitted information. Upon verifying the electronic data, the recipient communicates back a passing or failing message to the original sender thereby ensuring the sender as to the genuineness of the drug product. The complete process of capturing data, transmitting data, verifying data, communicating the results back is known as product authentication.
Batch / Lot	The batch or lot number associates an item with information the manufacturer considers relevant for traceability of the trade item. The data may refer to the trade item itself or to items contained.
Batch Number / Lot Number	Reference number assigned by manufacturer to a series of similar products or goods produced under similar conditions.
Brand Owner	The party that is responsible for allocating GS1 System numbering and bar code symbols on a given trade item. The administrator of a GS1 Company Prefix. And / or the party that is the ultimate authority for the trade item. And / or the owner of the product specifications. And / or responsible for placing a traceable item into commerce.
Broker	A person or an entity whose activity involves the broker entering into a contract with a person or entity whereby the broker receives a commission for any business he brings to the person or company calculated as a percentage of the transaction between that entity and a third party. However, the broker normally does not actually take physical control of the goods

Term	Description
Business Requirement	Is a statement of <u>need</u> concerning the business area or business process under study. It is something that the system must do or a quality that the system must have. A requirement exists either because the type of product demands certain functions or qualities, or the client wants the requirement to be part of the delivered product.
Buyer	An entity that purchases the product from the Brand Owner or its agent.
Collect	Gather required information by any means.
Composing	Means that an item/product is composed of other items/products (See 6.1.2.6., & Figure 6.13), e.g. a cake is composed of sugar, eggs etc, reverse process <b>is not</b> possible
Compounder	A pharmacist, in a hospital or retail pharmacy, that creates/manufactures pharmaceutical product from compounding other pharmaceutical ingredients. Compounded product would be deemed a new product and require new identification (See GTIN Allocation Rules in Healthcare)
Consumer	The end user of a trade item or a service.
Consumer Unit	The trade item intended to be sold to the end consumer.
Contained in	Means that there is an upper level of packaging and that the lower level item can be removed (See 6.1.2.6., & Figure 6.13), e.g. a carton contains 50 T-shirts, reverse process <b>is</b> possible
Container	The material employed in the packaging of a product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary and transportation containers are not intended to be in direct contact with the product.
Contract	Document/message evidencing an agreement between the seller and the buyer for the supply of goods or services; its effects are equivalent to those of an order followed by an acknowledgement of order.
Counterfeit (medical product) <i>World Health Organisation (WHO) Definition November 2008</i>	<p>A medical product is counterfeit when there is a false representation in relation to its identity<sup>7</sup> history or source<sup>8</sup>. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct the<sup>9</sup> or with the wrong components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.</p> <p>Quality defects or [Good Manufacturing Practice/Good Distribution Practice] non-compliance in legitimate, authorized medical products should not be confused with counterfeiting.</p> <p><i>7 e.g. any misleading statement with respect to name, composition, strength, or other elements</i></p> <p><i>8 e.g. any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorisation holder</i></p> <p><i>9 this refers to ingredients or any other component of a medical product</i></p>
Distribution	The division and movement of products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage establishments.

Term	Description
End of Life	Definition of “end of life” is dependent upon the industry and/or product. In healthcare it could be when surgical gloves are used and then disposed of or when insulin is injected or a single use instrument is used once.
End to End	From finished goods to end of life of product, including products created within a healthcare facility but excluding environmental disposal, e.g. European Union (EU) Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC and 2003/108/EC
EPCIS	Electronic Product Code (EPC) Information System (IS):
Event	Is an occurrence of a process in a specific time or a period of time.
Event data	<p>An event has four dimensions:</p> <ul style="list-style-type: none"> <li>- What: what physical objects were involved (GTIN)</li> <li>- When: when the event took place (timestamp)</li> <li>- Where: where the event took place (Location identifier (GLN))</li> <li>- Why: what business step was being carried out</li> </ul> <p>See also “Transactional data”</p>
Expiry Date	The date given on the individual container (usually on the label) of a product up to and including which the product is expected to remain within specifications, if stored correctly. It is established for each batch/lot by adding the shelf-life to the date of manufacture.
Extended (as in Extended Supply Chain)	<p>Extended indicates that whatever the readers view of what constitutes the “supply chain” Traceability goes beyond that view.</p> <p>Extended implies both upstream and downstream supply chain, e.g. from source material (e.g. seed to grow wheat) through manufacture (making bread) to consumption or use (e.g. eating the bread) to destruction (e.g. composting stale bread).</p> <p>Usually what constitutes the “supply chain” depends on the individual’s perspective, e.g. for a manufacturer, the supply chain may be raw materials to delivery of finished goods or for a nurse, for pharmaceuticals, may be from pharmacy to consumption by the patient.</p>
External Traceability	External traceability takes place when instances of a traceable item are physically handed over from one traceability partner (traceable item source) to another traceability partner (traceable item recipient).
Forwarding Agent	A person or entity engaged in providing, either directly or indirectly, any service concerned with clearing and forwarding operations in any manner to any other person and includes a consignment agent.
Global Location Number (GLN)	The GS1 Identification Key used to identify physical locations or legal entities. The key is comprised of a GS1 Company Prefix, Location Reference, and Check Digit.
Global Trade Item Number (GTIN)	The GS1 Identification Key used to identify trade items. The key is comprised of a GS1 or U.P.C. Company Prefix followed by an Item Reference Number and a Check Digit.
Global Returnable Asset Identifier (GRAI)	The GS1 Identification Key used to identify Returnable Assets. The key is comprised of a GS1 Company Prefix, Asset Type, Check Digit, and optional serial number.
GS1 System	The specifications, standards, and guidelines administered by GS1.

Term	Description
Homogeneous Pallet	Homogeneous Pallet is composed of identical products (identified with the same item identification (GTIN)) originating from the same Batch / Lot.
Identification	Refer to GLN and GTIN
Identification Carrier	Mark / tag / label / accompanying document sometimes called “passport” or “identity card” or “Pedigree” in some industry sectors
International Medical Products Anti-Counterfeiting Taskforce (IMPACT)	<p>Responding to the growing public health crisis of counterfeit drugs, in February 2006, the World Health Organization launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). At its core, IMPACT aims to build coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe. IMPACT is a partnership comprised of all the major anti-counterfeiting players, including: international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities.</p> <p><a href="http://www.who.int/impact/impact_q-a/en/index.html">http://www.who.int/impact/impact_q-a/en/index.html</a></p>
Intellectual Property (IP)	<p><b>Copyright</b> protects material, such as literature, art, music, sound recordings, films and broadcasts.</p> <p><b>Designs</b> protect the visual appearance or eye appeal of products.</p> <p><b>Patents</b> protect the technical and functional aspects of products and processes.</p> <p><b>Trade Marks</b> protect signs that can distinguish the goods and services of one trader from those of another.</p> <p>Also covers trade secrets, plant varieties, geographical indications, performers rights and so on. Often, more than one type of IP may apply to the same creation. (Ref.: <a href="http://www.ipo.gov.uk/whatis.htm">http://www.ipo.gov.uk/whatis.htm</a>)</p>
Intermediate Product	Partly processed product that must undergo further manufacturing steps before it becomes a bulk finished product.
Internal Process	A series of actions, changes or function(s) within an organisation or an organisation that brings about a result.
Internal Traceability	Internal traceability takes place when a traceability partner receives one or several instances of traceable items as inputs that are subjected to internal processes, before one or several instances of traceable items are output.
Link	Recording the information necessary to establish the relationship to other relevant information.
Location	<p>A place where a traceable item is or could be located.</p> <p>[ISO / CD 22519] A place of production, handling, storage and / or sale.</p>
Logistic Unit	An item of any composition established for transport and/or storage that needs to be managed through the supply chain. It is identified with SSCC.
Logistics Provider (including Third Party Logistics Providers (3PLs))	<p>A logistics provider is a person or entity that provides logistics services for part or all of the supply chain management functions for other entities (manufacturers or suppliers). Third party logistics providers are typically specialized in integrated warehousing and transportation services that can be customized according to the demands and delivery requirements of their customers. A logistics provider does not hold proprietary rights over the product they store or distribute.</p>

Term	Description
Master Data	<p>Master Data describes each item and party involved in supply chain processes. Master Data is defined as data having the following characteristics:</p> <ul style="list-style-type: none"> <li>Permanent or lasting nature</li> <li>Relatively constant across time, not being subject to frequent change</li> <li>Accessed / used by multiple business processes and system applications.</li> <li>Can be either neutral or relationship dependent.</li> </ul>
Medical Device	<p>Any instrument or article that can be used to diagnose, prevent, monitor, treat or alleviate diseases or other conditions (including pregnancy) and which does not - like a medicine - achieve its principal action by direct pharmacological, immunological or metabolic means (Note: definition can be specific to regulatory agency).</p>
Mixed Pallet	<p>Mixed Pallet is composed of one or more different products (identified with different item identification (GTIN)).</p>
Party	<p>A Party (or) Location is any legal or physical entity involved at any point in any supply chain and upon which there is a need to retrieve pre-defined information. A Party is uniquely identified by a Global Location Number (GLN).</p>
Pedigree	<p>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.</p>
Process	<p>A series of actions or steps towards achieving a particular end. Examples of common processes include Production, Transformation, Quality Control, Storage, Transportation, Movement, Recycle, Return, Packing, Receiving, Traceability.</p>
Quality System	<p>An appropriate infrastructure, encompassing the organisational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality.</p>
Quarantine	<p>The status of products isolated physically or by other effective means while a decision is awaited on their release, rejection or re-processing.</p>
Recall	<p>Shall mean any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor (EU Directive 2001/95/CE General Product Safety)</p>
Record	<p>Act of creating a permanent piece of information constituting an account of something that has occurred.</p>
Sampling	<p>Operations designed to obtain a representative portion of a product, based on an appropriate statistical procedure, for a defined purpose, e.g. acceptance of consignments or batch release.</p>
Seller	<p>The party selling the traceable item to a buyer.</p>
Serial Shipping Container Code (SSCC)	<p>The GS1 Identification Key used to identify logistics units. The key is comprised of an Extension digit, GS1 Company Prefix, Serial Reference, and Check Digit.</p>

Term	Description
Serialized Global Trade Item Number (SGTIN)	SGTIN is a method of identifying items at the unit or retail level as well as at the case and carton levels. It is composed of a GS1 assigned Company Prefix & Item Reference (GTIN), combined with a Serial Number. Where GS1 bar codes have traditionally been used, the SGTIN specification combined with an RFID tag can give visibility beyond the Item Reference right down to the exact serial number of the item.
Share	Act of exchanging information about an entity or traceable item with another Traceability Partner.
Shelf life	The period of time during which a product, if stored correctly, is expected to comply with the specification as determined by stability studies on a number of batches/lots of the product.
Shipment	An item or group of items delivered to one party's location at one moment in time that have undergone the same despatch and receipt processes.
Shipper	Party responsible for the shipment of goods.
Storage	The storing of products up to the point of use or onward distribution
Store Data	Keeping information available by any method.
Supplier	The party that produces, provides, or furnishes an item or service.
Traceability	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 Data	Any information about the history, application or location of a traceable item. This may be either master data or event data.
Traceability Data Creator	The Traceability Partner that generates traceability information.
Traceability Data Recipient	The Traceability Partner authorized to view, use, and download agreed traceability information.
Traceability Data Source	The Traceability Partner that provides the agreed traceability information.
Traceability 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. <b>NOTE:</b> The term "partner" does not imply there is a direct business relationship or partnership between parties involved in traceability
Traceable Item	<p>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 level).</p> <p>A traceable item may be related to another traceable item.</p> <p>It is the choice of the Traceability Partner which identification level (e.g. GTIN or Lot/Batch or serial level) to use for the traceable item.</p> <p>See also definition for process</p>
Traceable Item Creator	The Traceability Partner that generates a traceable item, or makes a distinct traceable item by transformation of one or more traceable items.
Traceable Item Recipient	The Traceability Partner that receives the traceable item.
Traceable Item Source	The Traceability Partner that despatches or provides a traceable item.

Term	Description
Trace Request	A formal inquiry about the history, application, or location of a traceable item. A request can trigger subsequent trace requests up or down the supply chain in order to fulfil the original request
Trace Request Initiator	The person who starts the trace request and requires a response from the Traceable Data Source.
Tracing	Tracing is the capability to identify the origin and characteristics or history of a particular traceable item upstream based on criteria determined at each point of the supply chain by reference to records held about it. Trace or Tracing backward or ascending traceability
Tracking	Tracking is the capability to locate or follow the path of a particular traceable item downstream based on criteria determined at each point of the supply chain by reference to records held about it. Track forward or descending traceability
Trade Item	Any item (product or service) upon which there is a need to retrieve pre-defined information and that may be priced, or ordered, or invoiced at any point in any supply chain.
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.
Transactional Data	Information necessary for the business process being executed. For example, Item codes and ordered quantities are transactional as these are mandatory fields within a purchase order: and, may vary by purchase order. See also "Event data"
Transformation	A change to the nature of a traceable item that changes the identity and/or the characteristics of the traceable item. The act of changing the item such as combining ingredients to make a finished product or case picking to create a new pallet. Transformation can be production, aggregation, grouping, splitting, mixing, compounding, packing and repacking traceable items.
Transit	The period during which products are in the process of being carried, conveyed, or transported across, over or through a passage or route to reach the destination.
Transporter	The Traceability Partner that receives, carries, and delivers 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.
Wholesaler	Any person or organisation that is engaged in wholesale distribution of products, 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.
World Health Organisation (WHO)	WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.
Withdrawal	Shall mean any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer[/end user] (EU Directive 2001/95/CE General Product Safety)

## 13. Summary of Changes

Change	BRAD Version	Associated CR Number
<ul style="list-style-type: none"> <li>• Document for Healthcare based on Global Traceability Standard</li> <li>• Completion of Traceability Work Group Public Review</li> <li>• Posted for eBallot</li> </ul>	0.2	CR 08-000201
<ul style="list-style-type: none"> <li>• Acknowledgement section replaced Sabine Klaeser with Bettina Bartz from GS1 Germany</li> <li>• Section 5.3 Added "GS1" to XML</li> <li>• Figure 6-1 corrected "process" Typo</li> <li>• Section 9.1               <ul style="list-style-type: none"> <li>○ Replaced "GS1-128 Application Identifier" with "GS1 Application Identifiers"</li> <li>○ Added revised note Note: as of July 2005, SGTIN only exists for RFID technology using EPC. As bar code solutions a combination of GTIN plus serial number can be found as appropriate counterpart (e.g. GS1 DataMatrix or GS1-128)."</li> </ul> </li> </ul>	0.2.1	Errata Changes