The Global Language of Business

Traceability in Healthcare

Traceability in Healthcare

A key driver in the Healthcare sector for

- Patient Safety
- Preventing counterfeiting
- Enabling correct patient records
- Enabling effective product recalls
- Traceability down to the patient
- Enabling regulatory compliance
- Enhancing business processes (e.g. inventory management, optimized supply chain efficiency, eProcurement)

Complexity

Many advantages**, BUT**

- Traceability is complex, multi-sectorial and cross border, but it is not always recognized as such
- Traceability is becoming a necessity, but one that is addressed by an endless number of isolated solutions
- GS1 Standards can help…

GS1 Members Vision for Traceability in Healthcare

Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

- All authentic **items** are identified with the appropriate **GS1 Identification Keys** (e.g. GTIN) and appropriate **Application Identifier** ((AI), e.g. Serial No. AI(21)), if applicable, at point of production
- Supply chain identifiers are associated with the patient and remain with/on items throughout their intended useful life
- All **physical locations** are identified with the appropriate **GS1 Identification Key** (e.g. GLN) across the entire supply chain
- All **patients and care givers**, when in a care giving environment, are identified with the appropriate GS1 identification Keys and appropriate **AI** (AI 8017, 8018, 8019)
- Agreed **master data** is captured and shared (e.g. via GDSN) amongst trading partners
- Agreed **transactional data** is captured and shared (e.g. via business-to-business messaging) amongst trading partners
- Agreed **event data** is captured and shared (e.g. via EPCIS) amongst trusted traceability stakeholders, based on data sharing/security policies

SO THAT:

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed

GS1 Members Vision for Traceability in Healthcare

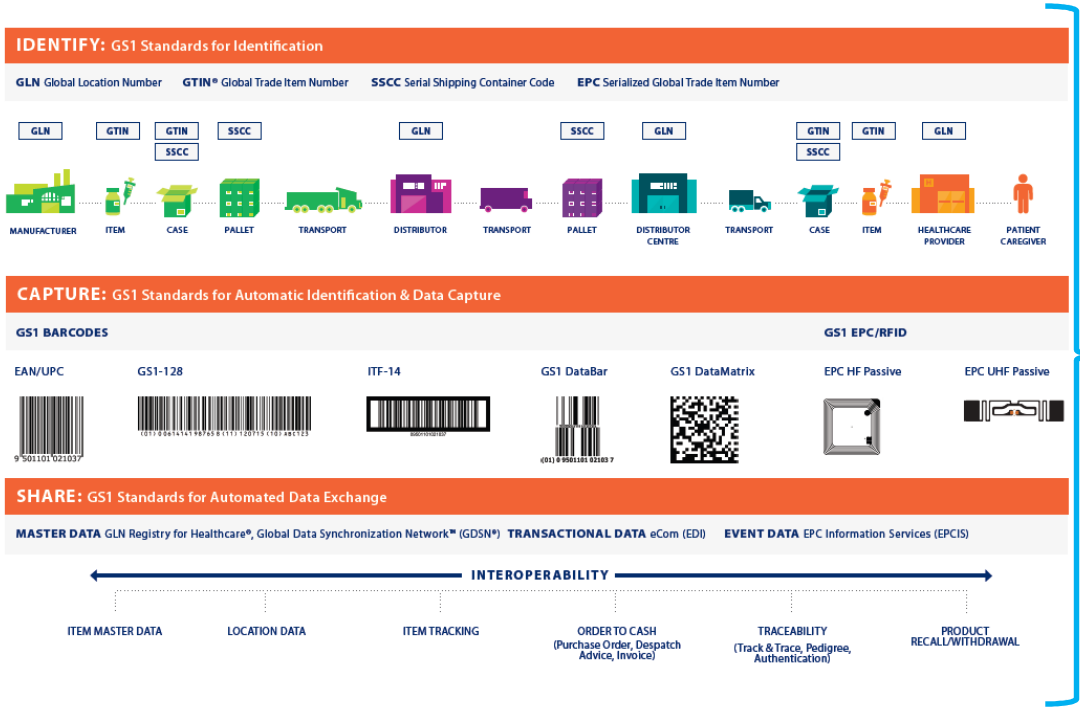
Full, End to End, actionable visibility of finished pharmaceuticals and medical devices in healthcare globally, from Point of Production[1] to Point of Use[2]

SO THAT:

- Items can be **tracked** (forward / downstream) across the entire supply chain (production to use) in real time
- Items can be **traced** (backward / upstream) across the entire supply chain (from current location back to the producer) in real time
- Item identification is available for use at patient bedside to ensure the Patient Rights[3] are achievable
- Patients Electronic Health Records (EHRs) are updated with agreed traceability information, including Care Giver identification
- Counterfeit products are detected when entering the legitimate supply chain
- A **product recall** would be fast, efficient and effective

1. The terms production or producer can also mean commercially available, manufacture(r), creation(or), compounding(er)…
2. The terms use or used can also mean consumed, infused, implanted, destroyed
3. Pharmaceuticals (5): Right patient, right drug, right dose, right route, right time. Medical Devices (8): right device, right location, right time, right condition, right procedure, right anatomic site, right patient, right user

GS1 Global System of Standards Enables Traceability



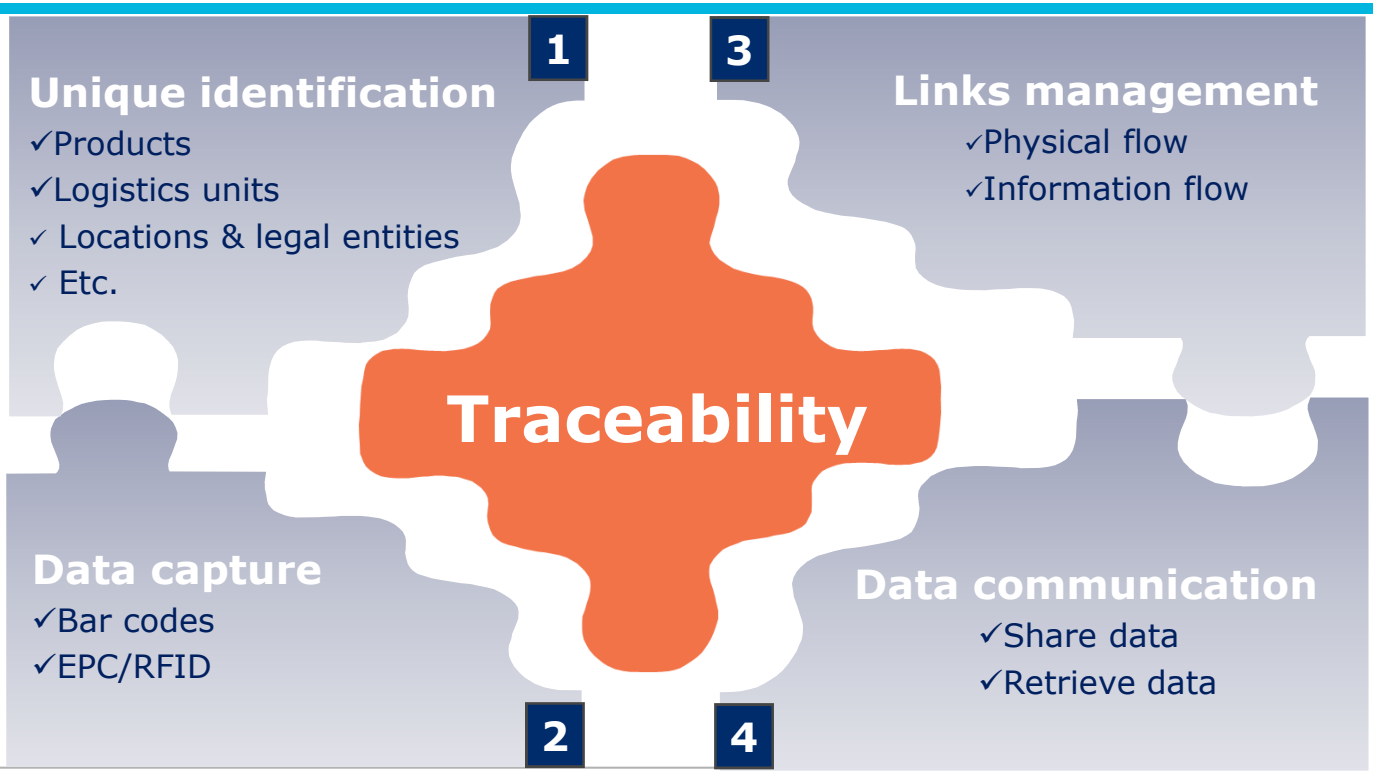
Traceability – a definition

"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/Visibility

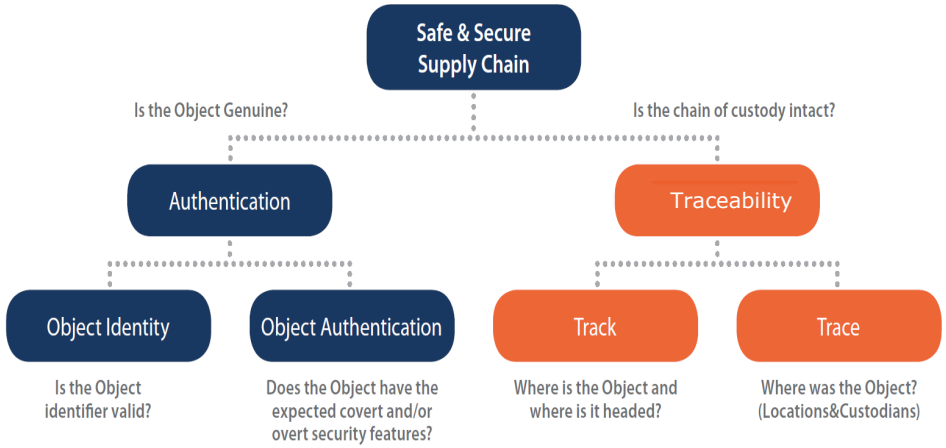
- Where is the product now?
- Where has it been? Who owned it?
- When has it been shipped/delivered/received?

Building blocks for traceability



Different approaches

- Can the product identification features be verified?
- Can the product be tracked to where it is – or traced from where it has been?



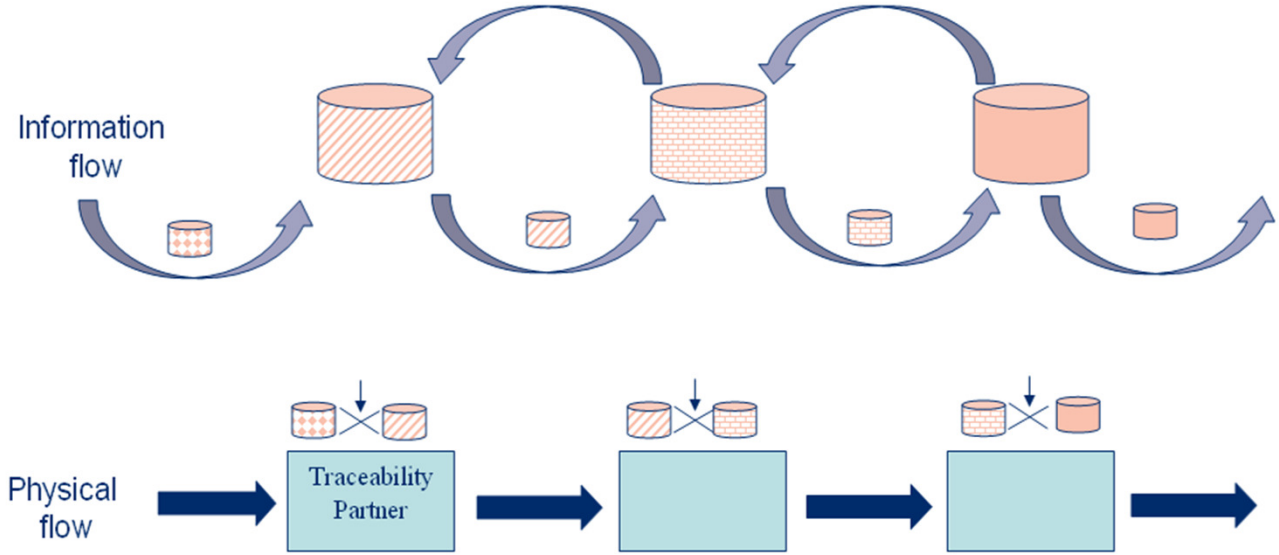
Traceability across borders

Regulatory bodies need to address Public Health issues – one important being counterfeiting of drugs

Ensuring supply chain security and visibility can help to address this - deviations from a global harmonised approach make implementation much more costly and complex than with global data standards

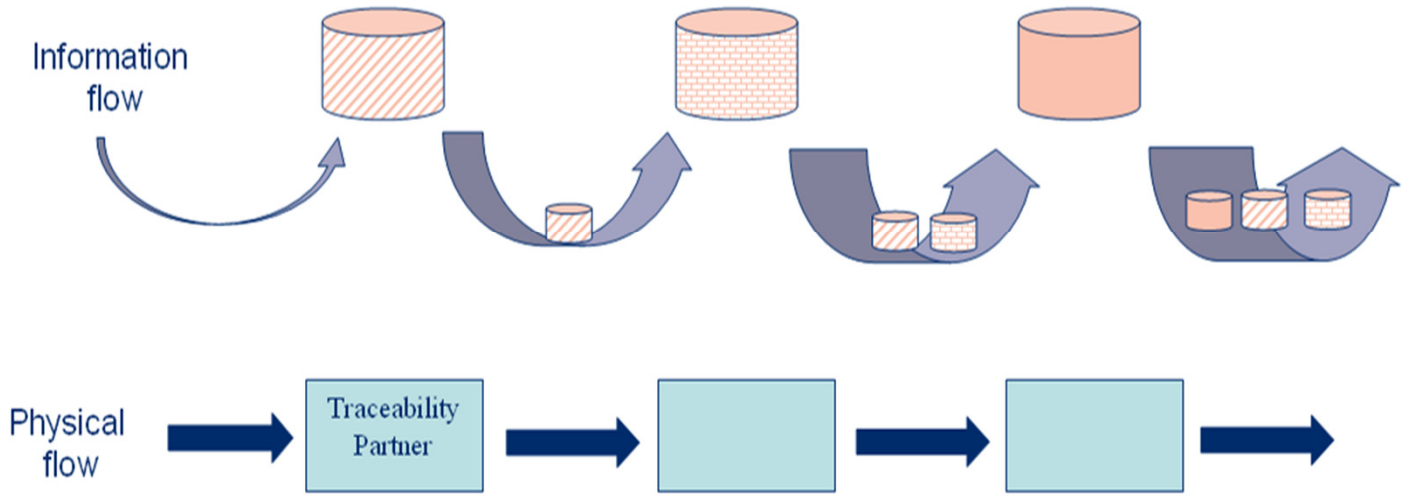
1. One up, one down

- Point-to-point information sharing for day to day operations
- Other data on request when necessary to previous actor



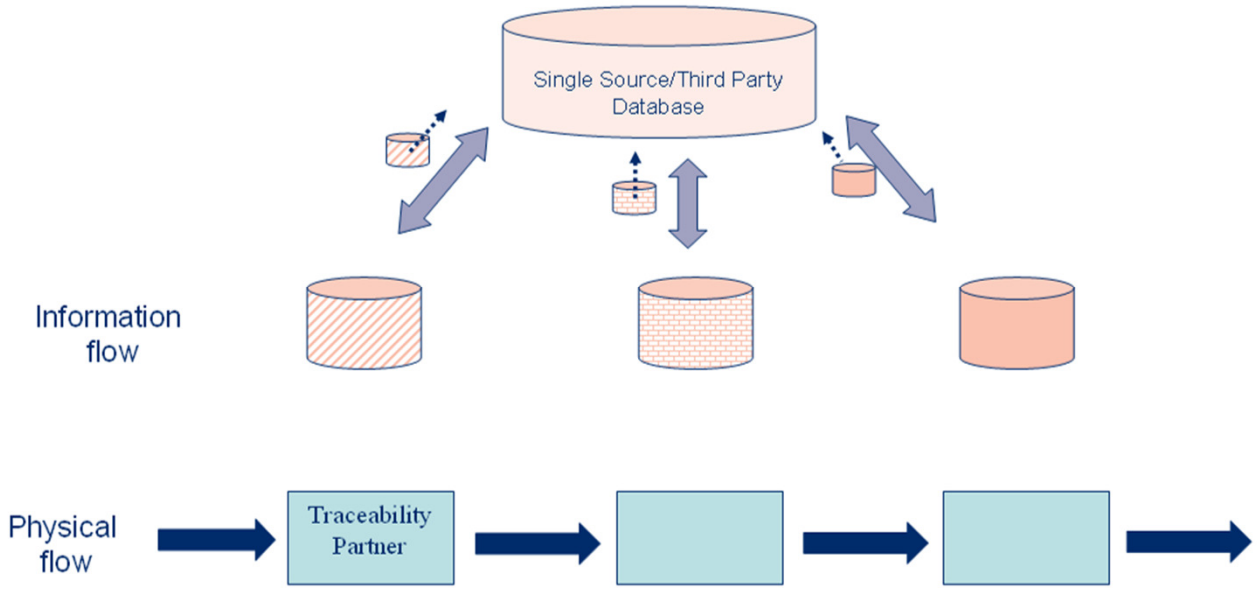
2 - Cumulative Tracking
(e.g., former California ePedigree)

Traceability data received from all previous upstream chain sources **plus** its additional traceability data, available to the next downstream supply partner.



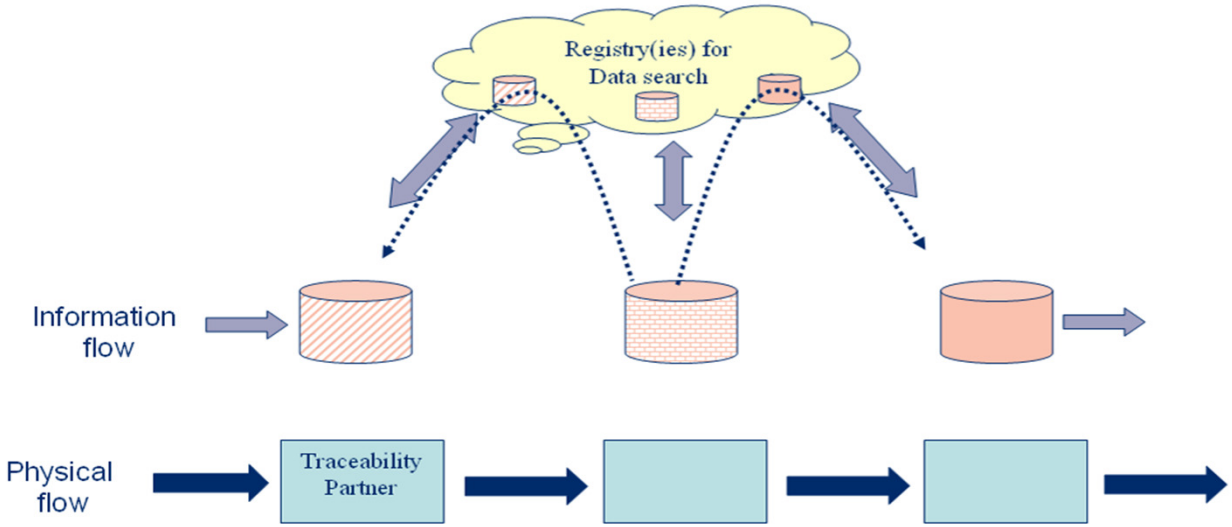
3 - Central Database

The traceable item source makes its traceability data available (e.g. publishes the data) to a central repository/database maintained by a Third Party/regulatory body.



4 – Distributed Model

Traceability identification keys available in a registry to enable traceability data search - information can be stored anywhere as the registry provides the link and data search mechanism.



EPCIS – sharing information on events

WHAT objects are the subject of event?

Individual objects (SGTIN) or groupings (GTIN + Lot/batch)

WHEN did this event take place?

Date, time, time zone

WHERE did this event take place?

GLN of physical location & object's subsequent whereabouts

WHY did this event take place?

Business step, Disposition, Source/Destination info

All captured in an EPCIS repository

APEC Roadmap for Global Medical Product Integrity and Supply Chain Security

- 5 year project (Jan. 2013 - Dec. 2017)
- APEC sponsors:
  - APEC Life Sciences Innovation Forum
  - APEC Regulatory Harmonization Steering Committee

- Objective:
  - examine current practices and regulatory requirements
  - develop recommendations to regulators
  - develop training programs which will be made publically available through the APEC website
- **Track & Trace Work Group** (TTWG) has 10 work streams

TTWG –Recommendations

- Six Recommendations supporting the APEC goals of regulatory harmonisation and of 10% reduction of supply chain cost:
- All three overarching Recommendations apply irrespective of the geography, economy or regulatory issue being addressed :
  - 1st Recommendation: define clear objective to be achieved
  - 2nd Recommendation: collaborate with stakeholders
  - 3rd Recommendation: recommend the use global data standards (GDS)
- All three secondary-Recommendations apply over time as traceability systems are incrementally implemented:
  - Identify
  - Capture
  - Share

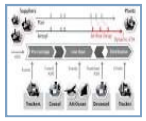
First Recommendation

Define clear objectives to be achieved

The solution required by a regulation should be based on the regulatory objective to be achieved

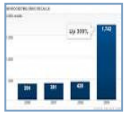
What issue is being addressed?

Drivers



Supply Chain Visibility

Product Protection



Recall Improvement

Returns, Shipment accuracy and efficiency

Reimbursement

The dilemma created by lack of clear objectives

- Strategic alignment of stakeholders may not occur – differing interpretations and implementation
- Missed opportunity to leverage global learnings
- Unclear what the solution is addressing and if it will work – too onerous / costly? not addressing the issue?
- Processes become complex
- Timelines may extend
- Costs can increase

Clear objectives will facilitate the achievement of regulatory needs and costs can be minimized

Defining clear objectives

- Provides stakeholders certainty so able to focus on task rather than being sidetracked by ambiguity
- Supports development of common approaches/standardisation to issue being addressed
- Leverages committed industry stakeholders who possess the skill, creativity, dedication and tenacity to create appropriate solutions to address the issue

Second Recommendation

Collaborate with stakeholders

A collaboration of the drug supply chain partners and regulators should define the implementation approach (i.e. timing and phasing) and governance model, including data management and privacy.

Collaboration should be ongoing due to the changing and/or evolving nature of the situation.

The dilemma created by lack of collaboration

- Strategic alignment of stakeholders across geographic networks does not occur
- Multiple economies facing common challenges create different approaches for a shared supply chain network

- Disparate and proprietary solutions are implemented
- Processes become very complex
- Timelines extend
- Costs increase

Without dialog & collaboration, health care costs rise and the patient needs are not met

Third Recommendation

Recommend the use of global data standards (GDS)

The use of global data standards would enable global interoperable product identification, capture and sharing of data. This may support efficient and cost effective management of the pharmaceutical supply chain globally. This may also facilitate harmonised implementation of regulatory requirements.

Support the objective of APEC to achieve regulatory harmonization

APEC Ministerial Statement

" We recognized the contribution that global data standards can make to enhancing supply chain efficiency, and welcomed ABAC's contribution in this area. As APEC economies further develop data standards frameworks, we encourage officials to explore what more can be done to facilitate **mutual compatibility amongst data standards frameworks, and the compatibility of economies' frameworks with the use of global data standards. "**

All training material at
http://www.nifds.go.kr/apec/SupplyChain/APEC_SupplyChainToolkit_170317.pdf

The dilemma created by lack of Global Data Standards

- Multiple economies facing common challenges create different approaches for identification and data exchange

- Disparate and proprietary solutions are implemented and expensive to maintain
- Internal applications that serve several geographic networks require complex logic
- External systems can not be shared across regional boundaries
- Processes become very complex
- Costs increase

Without Global Data Standards, health care costs rise and time to deliver product to the market increases

Measuring the impact of deviations from global data standards

- External serial numbers for China
  - Issue: External serial number must be uploaded and downloaded
  - Solution: Up/download program for serial numbers, adaptations with mapping tables for data structure (CN-product code did not fit in data structure)
  - Effort: Development and testing of up/download program; app. ½ year effort (1.3 man year, 250'000 US$); ongoing effort to download and upload numbers; stock level of serial numbers must be monitored
- Linear barcode on carton level for China
  - Issue: linear barcode can not be printed online in required quality, size and speed at packaging line
  - Solution: Usage of preprinted (serialized) packaging material
  - Effort: 2 step production process increases lead time, stock monitoring of packaging material needed. Exception process compared with normal production: Shanghai production implemented local solution, but is not capable for group supply anymore

Driven by many regulations worldwide

- From Turkey to Argentina, South Korea, USA, Europe, Saudi-Arabia and many other MEMA countries
- Different data base models, but all with the basic data elements

Product Identifier (GTIN)

Serial Number

Expiry date

Lot/Batch number

Healthcare

Turkish Pharmaceutical Track and Trace System (ITS)

ITS was the first successful application of a "Pharmaceutical Track and Trace System" in the world and is designed to track the location of every drug unit to ensure the reliable supply of drugs to patients.

Challenge

To ensure and guarantee the reliable supply of legitimate drugs to patients in Turkey. Like most countries, this supply was put at risk by illegal activities that could seriously impact public health and safety.

Approach

Turkey developed a Pharmaceutical Track and Trace System and built a centralised repository to monitor drug movement throughout the supply chain. With this central management system in place, the ITS can track and trace a drug from the point of manufacture to the point of dispense by leveraging GS1 identification keys, attributes and barcodes.

Results

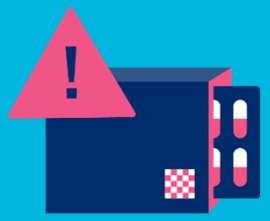
Reliable and safe supply of drugs to patients

Enhanced ability to combat illicit drug sales, barcode scams and theft

More than
$1 billion
in annual savings

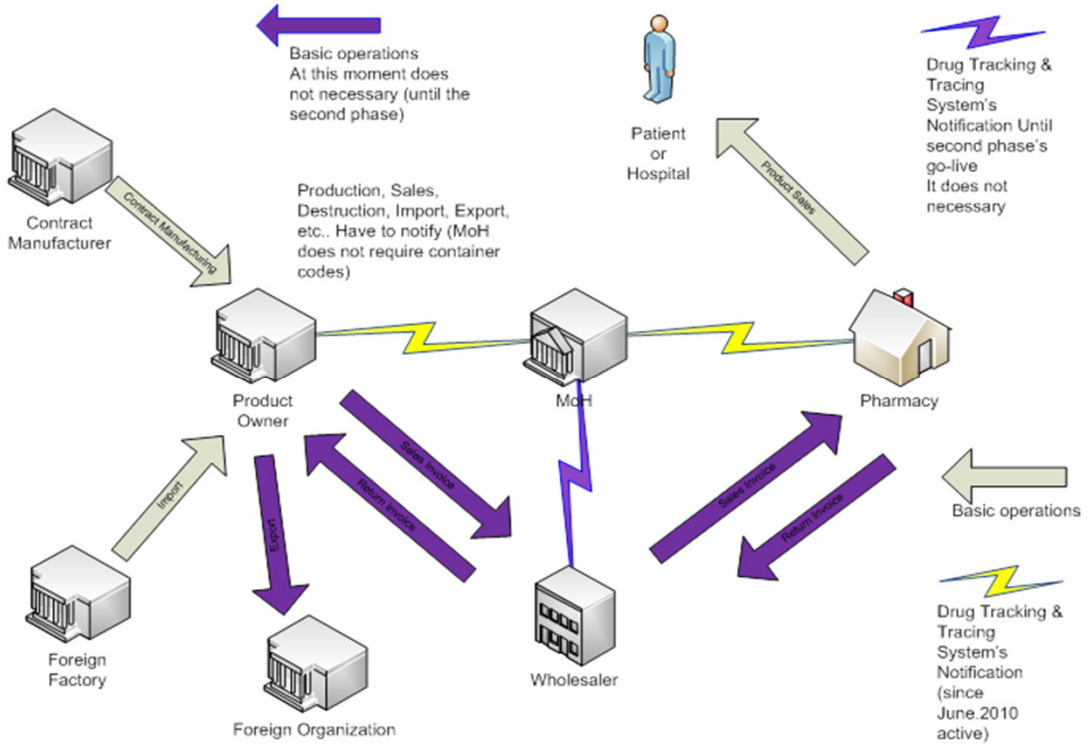
More than
45 million
daily transactions through ITS

Response time is 0.02 seconds per transaction



Sophisticated and efficient recall management

Turkey – ITS system

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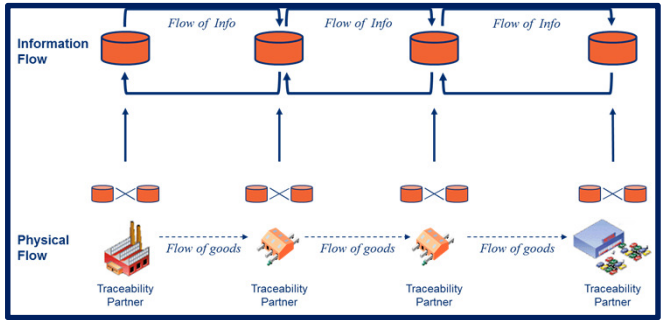
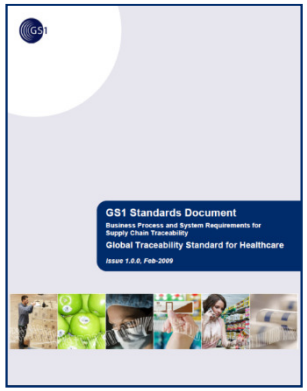
Global Traceability Standard for Healthcare (GTSH) - Common themes

- PROCESS Standard
- Defines Traceability: both track & trace
- Defines foundational operational model:
  - one-up / one-down
  - Physical flow of product **has to be** in parallel to flow of info. about product
  - Inputs (e.g. receipt) must be linked to outputs (e.g. dispensing)
  - Parties can have varying roles
  - Business Requirements = Needs
  - Business Rules = control and/or constraints



Traceability in Healthcare Phase I



Global Traceability Standard for Healthcare (GTSH)

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Standard_Healthcare.pdf

GTSH Implementation Guideline

http://www.gs1.org/docs/gsmp/traceability/Global_Traceability_Implementation_Healthcare.pdf

GTSH Implementation Guideline

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

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

For supply chain, the start and end points in scope are from manufacturer of finished goods, including products created in the care facility, throughout the product's intended useful life.

Implementation of Traceability System - Common Themes

- Implementation from manufacturer to patient takes time (YEARS)
- Multi-project work programme
- Involves all parties
- Focus on solving key issues
- All efforts have lead to improved patient safety
- One size does NOT fit all!

Traceability Adding Value…

"Added Value" – a business term

There are four key areas of "Added Value":

- Reduce exposure to risk
- Manage and reduce costs
- Increase effectiveness
- Create new opportunities

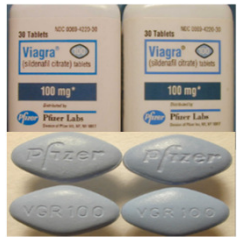
Specifically, Traceability can **assist** an organisation to…

1. Reduce exposure to risk

- Assist in: Meeting regulatory requirements
- Assist in: Product Quality and Safety Management
- Assist in: Providing an additional Anti-counterfeiting tool (e.g. product identifier authentication)
- Assist in: Identifying expired product; managing inventory
- Assist in: Making Recalls and/or Withdrawals faster, more accurate and efficient

= Increased Brand protection?

= Increased Patient Safety?



2. Manage and reduce costs

Assist in:

- Optimization of the supply chain
- Operational Planning
- Waste management
- Sustainability
- Efficient logistics

= Return on Investment (ROI)

= Reduce operating costs

3. Increase effectiveness

Assist in:

- **Brand Protection**
- Increased inventory management
- Improving hospital operational processes

4. Creates new opportunities

Visibility means

Increased Brand protection
Increased Patient Safety
Return on Investment
Reduce operating costs
Enhanced Customer Service
Enhanced Patient Experience

And a word on blockchain

What is blockchain?

The word “Blockchain” is used in a variety of ways:

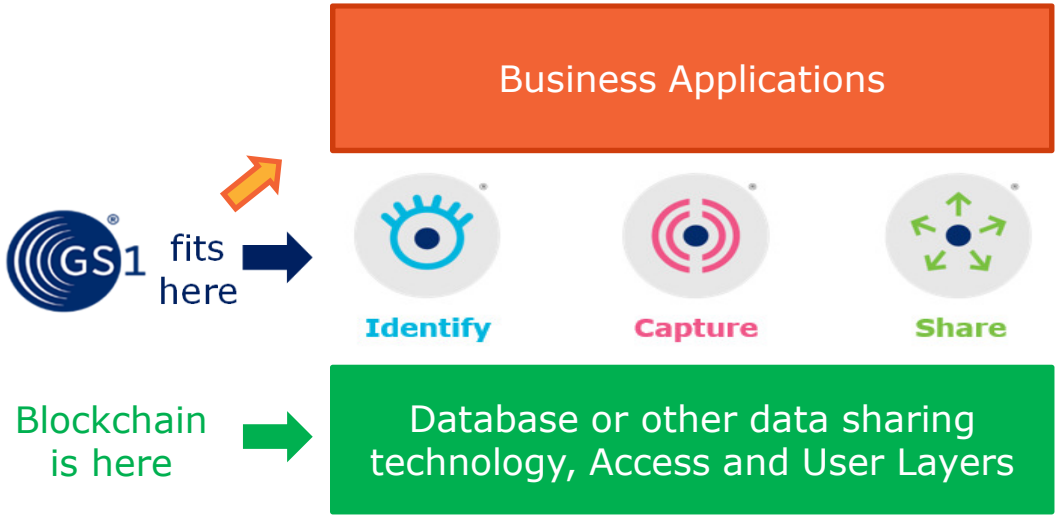
- To refer to technologies that are, basically, “shared ledgers” of data
- As the name of algorithms that help achieve decentralized consensus which validate entries on a ledger
- To refer to a deployed shared ledger system: e.g. “the blockchain”
- A general purpose magic word.

Why is blockchain exciting? Data Sharing.

Most of the excitement about blockchain is really just excitement about the possibility of sharing data across company lines.

- For some entire industries, this is an unfamiliar concept.
- For industries where data sharing is familiar and interesting, blockchain presents an interesting way to discuss it…and to raise awareness of the need for data sharing across organisational silos.

Where does GS1 fit…
and where does "blockchain" fit?



- Track & Trace, Anti-counterfeit
- Order-to-cash processes
- Electronic commerce

- Standardized identifiers
- Transaction data
- Visibility event data
- Master Data

- Oracle, IBM, Microsoft, Teradata, etc.
- Amazon, Google, Bluemix, etc
- EDI Networks, VANs, data pools
- Enterprise Access and User Layers

Blockchains are shared, secure, distributed ledger that allows for the exchange of data between parties
GS1 facilitates standards for data and some business applications

GS1 Healthcare aims for harmonization of regulatory requirements across the world

- A global standardized system is needed for **“unique” identification numbers** to ensure world-wide supply chain compatibility.
- **The result:** Prevent counterfeit drugs entering the market, gain efficiency, have the right product in the right place at the right time, more effective recalls and more…

Thank you
Asante
Shukran
شكرا لك
謝謝您
ขอบคุณ
Cảm ơn bạn
Merci
Obrigado
Gracias
Grazie
Danke
Mange tak

Contact Details