



The Global Language of Business

An Overview of Track & Trace using Global Standards

GS1 Malaysia Berhad



GS1 – A global standards organisation



1 million

Over 1 million companies worldwide use GS1 standards

150 countries

25 industries Served across 150 countries

6 billion

Barcodes scanned more than 6 billion times per day globally

114 MOs

114 Member Organisations around the world

GS1: The Global Language of Business



GS1 is a **neutral, not-for-profit standard organisation** driven by its users, that facilitates collaboration amongst trading partners, to create more efficient, safer and sustainable value chains through global standards.

GS1 is both global and local



GS1 Global Office

Identification, creation, development and maintenance of standards and our foundational architecture, coordination with other international bodies, development of training programmes...

GS1 Member Organisations

Local offices in 114 countries / regions around the globe.
Implementation of standards, local regulatory adjustments, community management and relationship management with local governments and regulatory agencies...

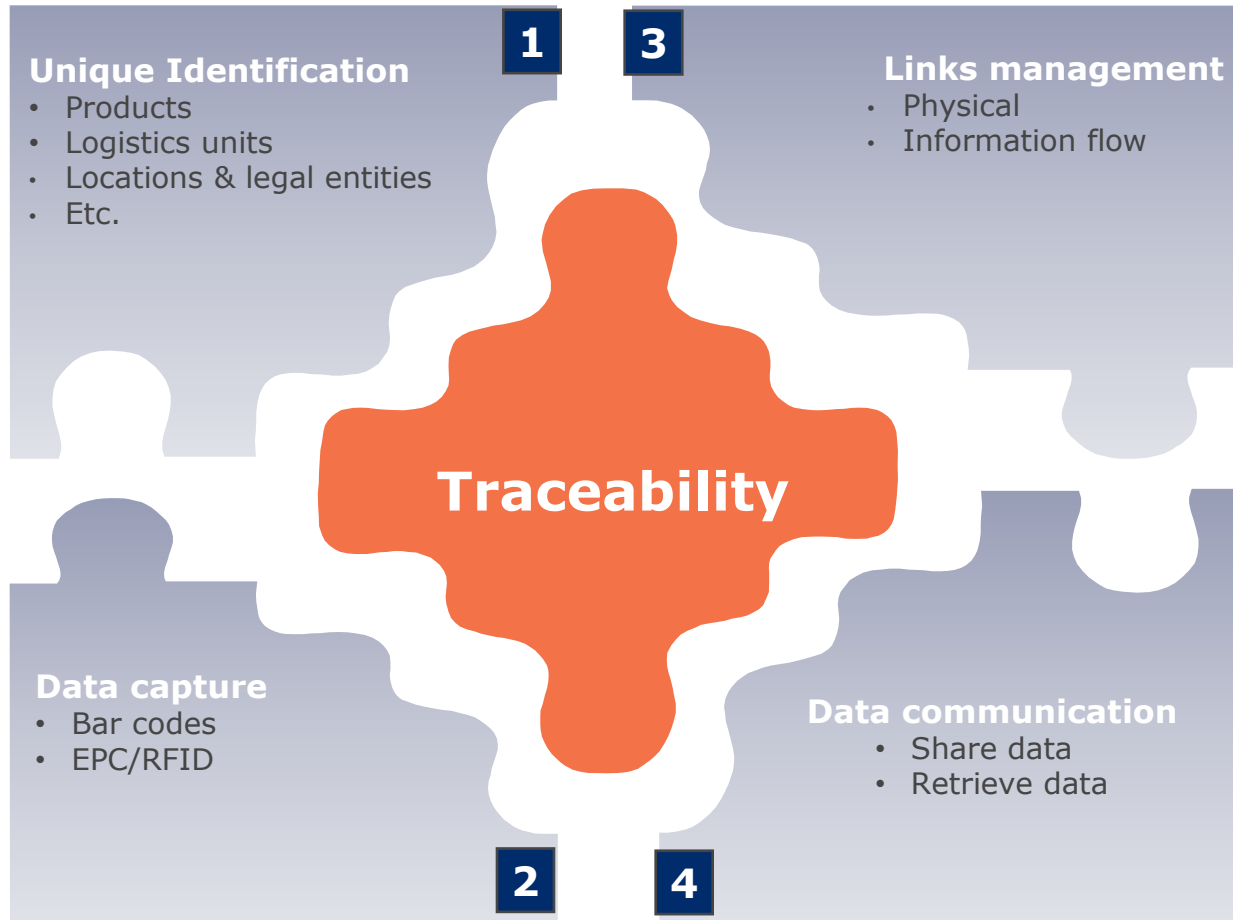
Traceability – A Definition



“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”.

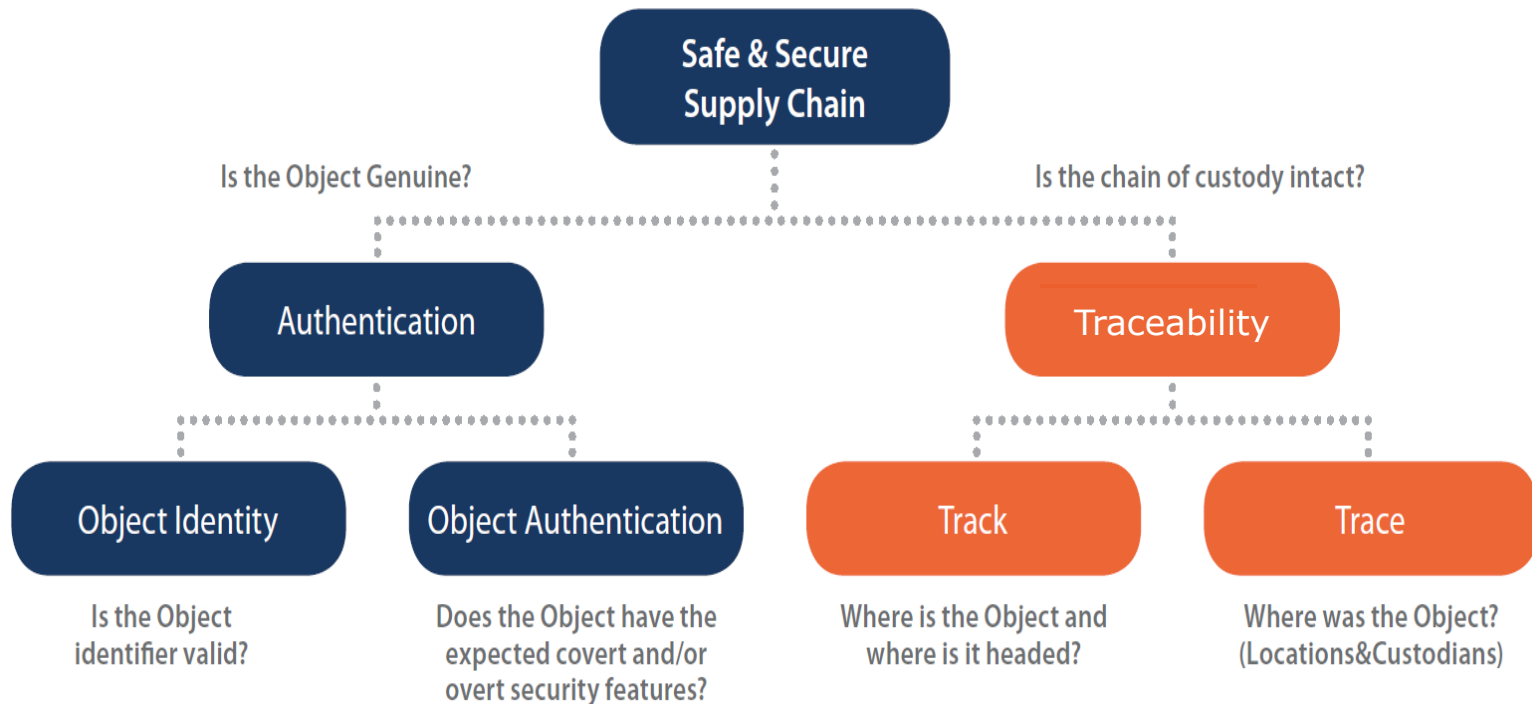


The traceability “building blocks”



Different approaches

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



GS1 Standards for Traceability



- The use of GS1 global standards enables **worldwide interoperable product identification**
- It can also facilitate the **harmonised implementation of regulatory requirements**
- Around **70 economies** are requiring or allowing the use of GS1 standards to implement healthcare requirements

GS1 Global System of Standards Enables Traceability



**T
R
A
C
E
A
B
I
L
I
T
Y**

Track

Trace

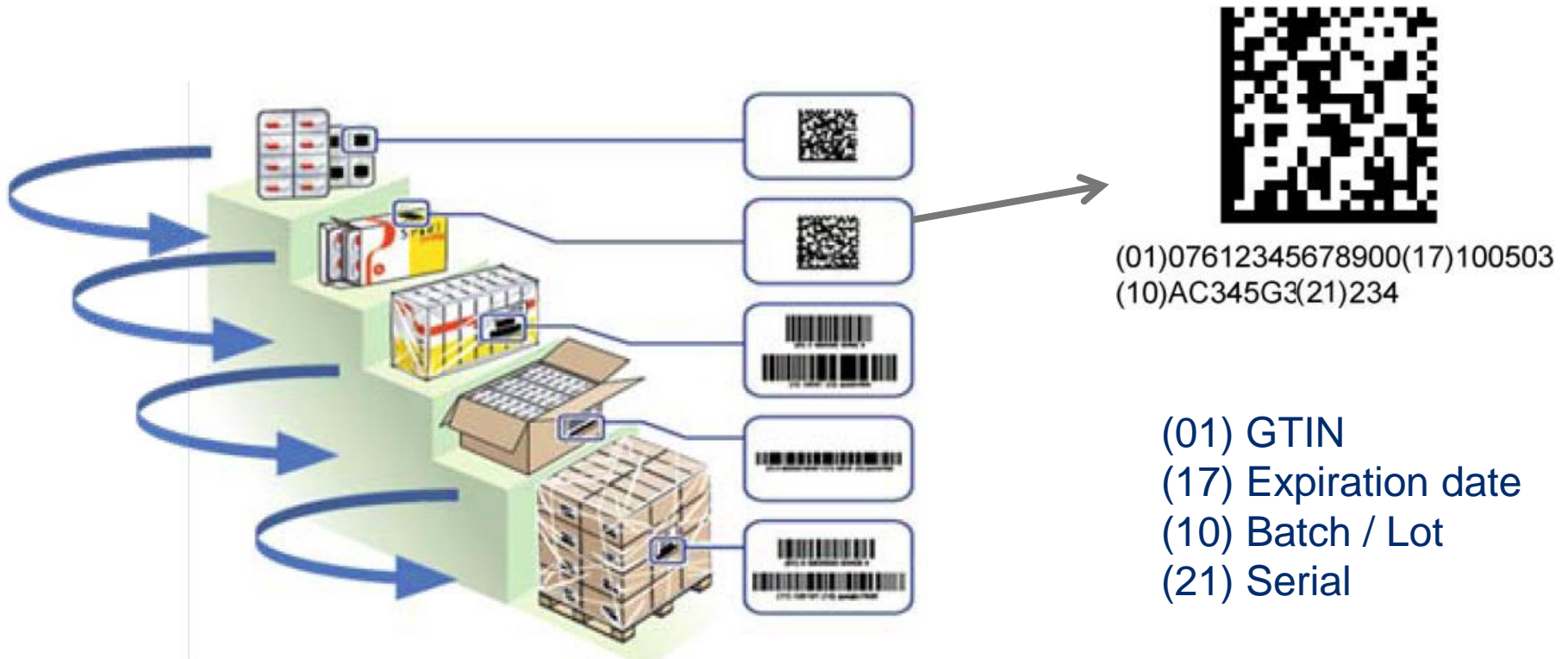
Authentication

Chain of Custody / Ownership

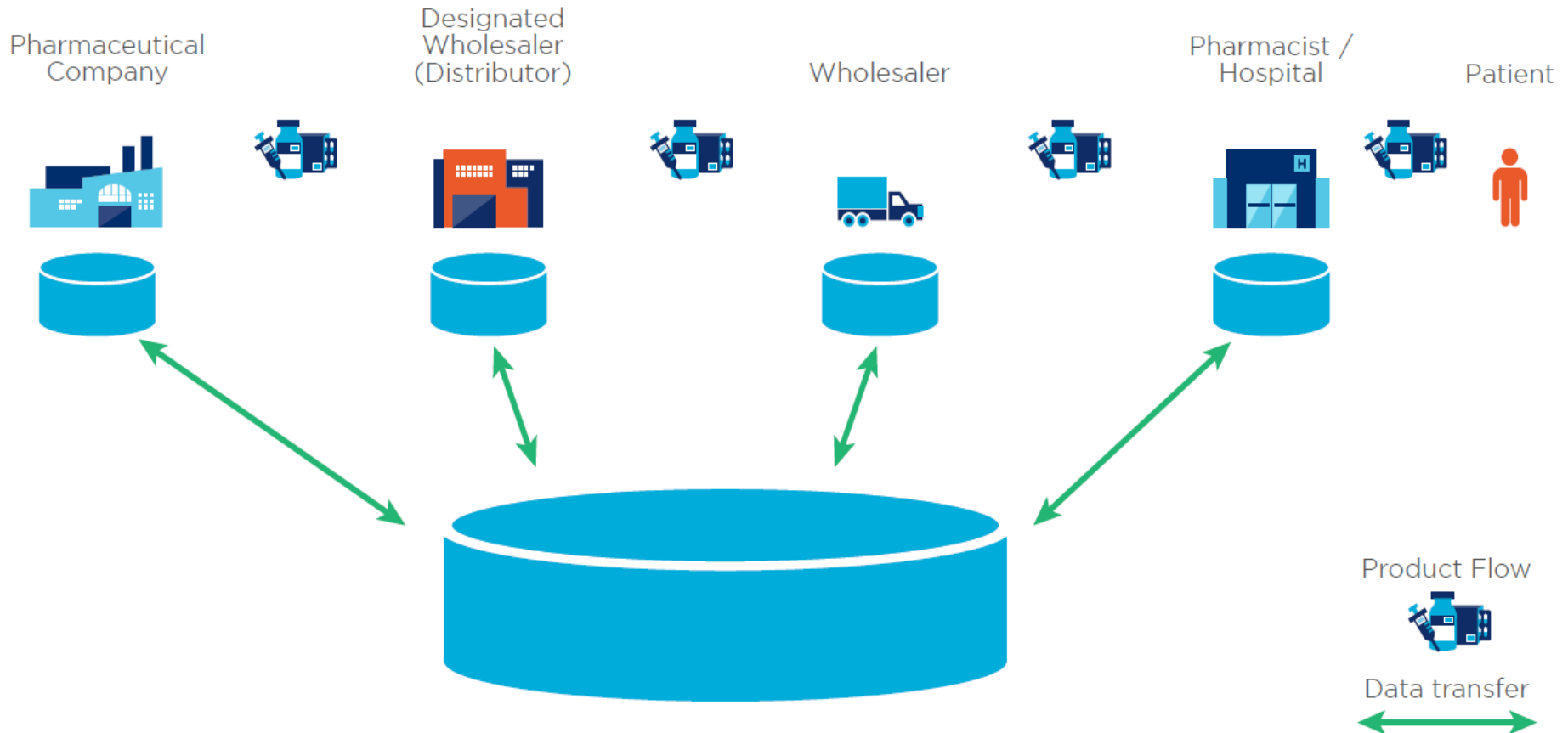
Returns

Recalls

The Foundation of Track and Trace Using GS1 Standards - Aggregation



Track & Trace - Centralised system



Global trend: IDENTIFY

4 identification attributes



Product Identifier (GTIN)

Serial Number

Expiry date

Lot/Batch number

Limit to the number of data elements encoded in the bar code.

Global trend: CAPTURE Use of GS1 DataMatrix



(01) 10222222333334(17) 091231(10) A1345B(21) 1234

Item Identifier

Expiration Date

Batch Number

Serial Number



(01)07612345678900(17)100503
(10)AC3453G3(21)1234

Global trend: SHARE

Different type of data for traceability



Master Data - GDSN refers to data that is associated with the product



Transactional Data - EDI refers to data that is shared between two trading parties in the sale/purchase process.

Event Data - EPCIS refers to activities that a product goes through as it moves through the supply chain. An event has four dimensions.



UDI & GS1 Standards

UDI

Unique Device Identification

...is enabled by GS1 Standards !!

...GS1 Global is the **first accredited UDI issuing agency by the US FDA and EU.**

UDI information is submitted to FDA's Global Unique Device Identification Database (GUDID) and EU's European Database on Medical Devices (EUDAMED)

NOTE: While GS1 Global is the issuing agency, GS1 MOs are referred to as agents to issue UDI for subscriber members.

Unique Device Identifier (UDI)

What is UDI?

Identifier/code on device label and packaging or, on the device itself.

UDI = Device Identifier (DI) + Production Identifier/s (PI)

- DI (static) – specific to a device version or model.
- PI (dynamic) – one or more currently used information for control/production identifiers,
e.g. *lot/batch number, serial number, manufacturing date, expiration date.*

The UDI must appear on the label in a human readable format, as well as in a manner that can be read by automatic identification and data capture (AIDC) technology.

UDI in GS1 terms

| | |
|--|---|
| <p>UDI Unique Device Identification</p> | <p>GS1 Standards Product Identification</p> |
| <p>DI Device Identifier (DI)</p> | <p>GTIN Global Trade Item Number</p> |
| <p>PI Production Identifier (PI) (if applicable)</p> <p><i>Production Identifier data will vary by medical device type and manufacturer current practice.</i></p> | <p>AI Application Identifier (AI)</p> <ul style="list-style-type: none"> • Expiration Date AI(17) - e.g. 141120 • Lot/Batch AI(10) - e.g. 1234AB • Serial Number AI(21) - e.g. 12345XYZ |
| <p>DI + PI = UDI</p> | <p>GTIN or GTIN + AI(s) = UDI</p> |

How a GTIN is put together:

<Country Prefix> + <Company Prefix> + <Running No>
+ <Check Digit>



More than 85% of products in US FDA GUDID carry GS1 as UDI primary DI

| US FDA GUDID Analysis | | | |
|---|------------|------------------|--------------|
| Total Number of Unique Primary Devices Currently Listed in GUDID | | 1,335,933 | |
| Total Number of Devices by Issuing Agency <i>(DI from agency either Primary or Secondary)</i> | GS1 | 1,142,813 | 85.5% |
| | HIBCC | 192,968 | 14.5% |
| | NDC\NHRIC | 97 | 0.0% |
| | ICCBBA | 55 | 0.0% |

HIBCC - The Health Industry Business Communications Council®

ICCBBA - International Council for Commonality in Blood Banking Automation

NDC - National Drug Code

The GS1 Traceability Standard



The Benefits of Safe, Efficient and Traceable Healthcare Products

- Healthcare products that are safe to use, prevent counterfeiting.
- Prevents resale of Healthcare Products meant for single or exclusive use.
- Expedites recalling of Healthcare Products.
- Prevents sale of expired Healthcare Products.
- Prevents shortages of Healthcare Products.
- Provide quality and accurate data for insurance claims.
- Provide statistics to develop policies on Medicine and Medical Device Use.
- Enables pharmacovigilance and strategic planning.
- Ensures that the **Correct Medication** is **administered Correctly** to the **Correct Patient**, at the **Correct Dosage** and **Correct Time**, and can be easily traced due to its **Correct Documentation**.

Regulatory Developments



Pharma – World* – an ever growing number of coding & serialisation requirements

Australia

Serialisation + DataMatrix on blood products: 1 Jan. 2018
Medicines labelling: GTIN + DataMatrix: 1 Sept. 2020
TGA pharma 'standard' development - consultations

China

eCode and GTIN to be both allowed
Drug traceability standards released April 2019
Sept 2019 standards for comments
Implementation in 2022
? Distributed model: NMPA/Stakeholders
Vaccines: Regulation Dec 2019, implementation March 2020

Chinese Taipei

Secondary pack.: GTIN + Exp.+ Batch# +Serial#
GS1 DataMatrix
Identification: Jan. 2018
Serialisation: Jan. 2019
Registration for reporting: Jan. 2020
? Release final requirements

India

For export:

Since 2013:

Secondary pack.: GTIN + Exp. + Batch# + Serial#

GS1 DataMatrix

Reporting & Aggregation: 1 April 2020

DAVA portal on hold, discussion on re-design

Indonesia

Secondary pack.: GTIN + Exp. + Batch# +Serial#

GS1 DataMatrix or QR code

Primary and tertiary levels requirements

Aggregation mandatory

Japan

Secondary pack.: GTIN + Exp.+ Batch# **or** Serial#

GS1 DataBar

Deadline: March 2021

Pharma – World* – an ever growing number of coding & serialisation requirements

Kazakhstan

Pilot announced
2020/2012: voluntary labelling
2023/2024: mandatory labelling

Malaysia

Requirements for track & trace under development
Full T&T: 2023

Pakistan

Regulation now aligned with GS1
No AI 240, primary removed
Implementation deadline extended to 6 years
Punjab Government aligns with GS1 standards

Russia

Secondary: DataMatrix, GTIN + Serial# + crypto (AI(91) AI(92))
Tertiary: GS1 128, SSCC or sGTIN
Aggregation required
Reporting: Labelling Information System (LIS)
1 July 2020: Full track and trace

Singapore

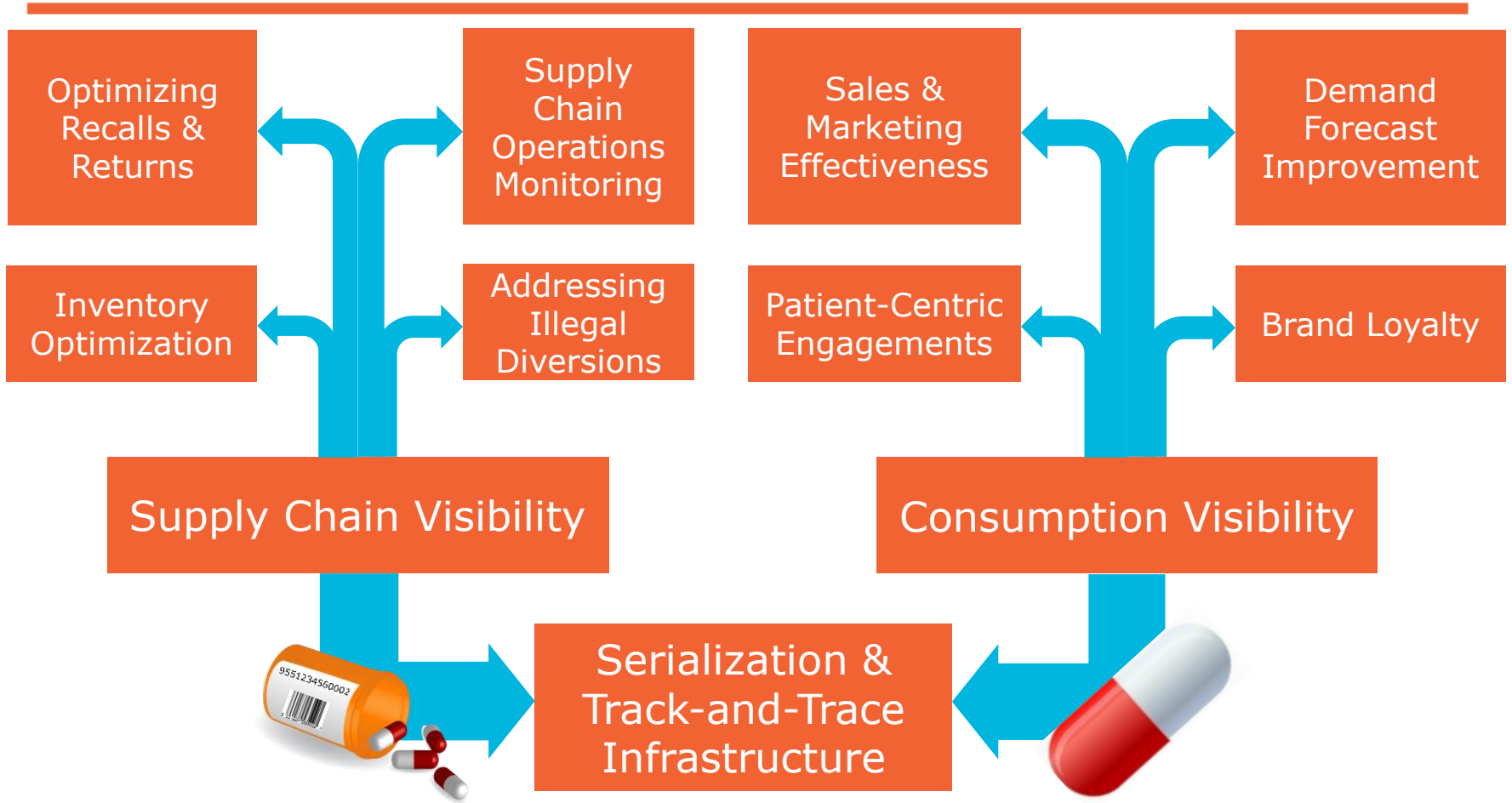
Consultation: use of e-PIL on prescription drugs
QR code?
voluntary possible pilot for companies

South Korea

Secondary: GTIN + Serial# + Expiry + Lot#
DataMatrix
All products serialised by end 2015
Aggregation voluntary by 2016
Reporting by 1 July 2016

Also,
Ukraine, Kyrgyz Republic, Mongolia, Sri Lanka, Vietnam, Cambodia

Driving Value Beyond Compliance through Track & Trace



Step by Step Implementation Guide



The Global Language of Business

GS1 standards make it possible to achieve end-to-end supply chain traceability

| Harvesting | Manufacturing | Shipping | Transporting | Receiving | Selling |
|--|--|---|---|--|--|
| <p>Location identification: Harvesting location GLN: 9504000219901-PL-A023</p> <p>Case-level identification: GTIN: 09504000219109 Batch/Lot: B20171202-1 Attributes Production date: 2017-05-22</p> <p>Who (GLN) 9504000219900 What (GTIN) 09504000219109 (Batch/Lot) B20171202-1 (QTY) 200 Where (GLN) 9504000219901 (GLN extension) PL-A023 When 2017-05-22T13:15:00+05:00 Why Harvesting</p> | <p>Location identification: Processing location GLN: 9501101530911</p> <p>Case-level identification: GTIN: 09501101530003 Batch/Lot: AB-123 Attributes Expiration date: 2017-12-02</p> <p>Who (GLN) 9501101532007 What (GTIN) + (Batch/Lot) + (QTY) (Ingredients) What (GTIN) 09501101530003 (Batch/Lot) AB-123 (QTY) 500 Where (GLN) 9501101530911 When 2017-07-14T23:20:00+01:00 Why Manufacturing</p> | <p>Location identification: Outbound staging area GLN: 9501101530928-05-5</p> <p>Batch identification: SSCC: 395011015300022013 Contents 20 cases of GTIN: 09501101530003 Batch/Lot: AB-123 Expiration date: 2017-12-02</p> <p>Who (GLN) 9501101532007 What (SSCC) 395011015300022013 What (GTIN) 09501101530003 (Contents) (QTY) 20 Where (GLN) 9501101530928 (GLN extension) 05-5 When 2017-08-02T09:12:00+01:00 Why Shipping</p> | <p>Location identification: Loading dock GLN: 9501101530928-09-15</p> <p>Pallet identification: SSCC: 395011015300022013 Truck identification: GIAI: 950400022011-501-BK</p> <p>Who (GLN) 9504000220006 What (GIAI) 950400022011-501-BK (Truck) What (SSCC) 395011015300022013 Where (GLN) 9501101530928 (GLN extension) 09-15 When 2017-08-02T10:15:00+01:00 Why Transporting</p> | <p>Location identification: Inbound staging area GLN: 9504000221902-15-3</p> <p>Pallet identification: SSCC: 395011015300022013 Contents 20 cases of GTIN: 09501101530003 Batch/Lot: AB-123 Expiration date: 2017-12-02</p> <p>Who (GLN) 9504000221903 What (SSCC) 395011015300022013 What (GTIN) 09501101530003 (Contents) (QTY) 20 Where (GLN) 9504000221102 (GLN extension) 15-3 When 2017-08-02T12:12:00+01:00 Why Receiving</p> | <p>Location identification: Store GLN: 9504000221805</p> <p>Consumer unit identification: GTIN: 9501101530010 Batch/Lot: AB-123 Attributes Expiration date: 2017-12-02</p> <p>Who (GLN) 9504000221805 What (GTIN) 9501101530010 (Batch/Lot) AB-123 (QTY) 2 Where (GLN) 9504000221805 When 2017-08-12T11:34:00+01:00 Why Selling</p> |

Harvesting:

The producer harvests the crop and packs it into cases. Each of the cases gets a label with GTIN + batch/lot ID, and the related data is recorded.

Manufacturing:

The manufacturer transforms ingredients into final products. After that, the manufacturer packs the products into cases. To maintain traceability, the inputs and outputs of the process are recorded on batch/lot level.

Shipping:

The warehouse department picks the goods and packs them onto pallets. To maintain traceability the warehouse records the links between product IDs (GTIN + batch/lot ID) and pallet IDs (SSCC). Subsequently, the pallets are moved to the outbound staging area to be collected by the carrier.

Transporting:

The carrier arrives and loads the pallets onto the truck. The driver uses his mobile device to identify each of the pallets. The link between the pallets and the truck is recorded. Now, by tracking the truck, pallets and goods can also be tracked.

Receiving:

The pallets arrive in the retail distribution centre. The incoming goods department inspects the received goods by scanning the SSCCs on the pallet label and compares the data against the pre-registered information in the system. When all checks are correct, the goods will be marked as available in the inventory management system.

Selling:

The products have arrived at the store and placed on the shelves. A consumer has decided to buy two products. At the checkout, the clerk scans the barcode on the products. The system automatically checks the expiry date, the GTIN and the batch/lot ID are registered. The sales are recorded.



Scan to get a copy

GS1 identifications keys used:
GTIN: Global Trade Item Number
GLN: Global Location Number
SSCC: Serial Shipping Container Code
GIAI: Global Individual Asset Identifier

Useful Information



Why GS1 Matters to Everyday Business
(VIDEO)



Brand Protection & Business Integrity
through Product Identify Governance
(VIDEO)



The Threat of Unauthorised Numbers to
Product Identity Governance

GS1 Malaysia Berhad

Wisma FMM, No. 3, Persiaran Dagang,
PJU9, Bandar Sri Damansara
52200 Kuala Lumpur



Contact Us

| | |
|----------------------------|-----------------------|
| Membership enquiries: | membership@gs1my.org |
| Product Listing enquiries: | databank@gs1my.org |
| Payment enquiries: | payment@gs1my.org |
| General enquiries: | gs1malaysia@gs1my.org |

WhatsApp

+6014-3933 228, +6011-1616 8228

Website: **<http://www.gs1my.org>**