34thGlobal GS1 Healthcare Conference 2018 BANGKOK

UDI
current situation of Japan

Centara Grand at CentralWorld

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PMDA

A member of IMDRF UDI WG

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This presentation includes personal opinion ,so that, some may not represent the PMDA opinion

History of GHTF and IMDRF activities

History of UDI Guidance

2007 Oct GHTF UDI WG
2012 GHTF disband and IMDRF started
2013 Dec IMDRF Guidance document established IMDRF/WG/N7FINAL:2013

Since the Guidance document has been established , during those 3 years ,especially USA Industry group was trying to implement the UDI system and found the needs of implementation guidance for the UDI system.

Current Activities

2017 Dec IMDRF NWI for Application Guide for UDI system
2018 July IMDRF UDI system Application Guide: Public comment IMDRF WG(PD1)/N48
20192019 Mar Expected to be a final document

History of GHTF and IMDRF activities

Back Ground

Find Benefit to use tool for Uniquely identify the Product

1. Traceability

a) record for distribution and inventory control

b) record at healthcare site

c) for safety corrective action

2. Identification

a) identify the device in any use distribution and use

b) identify the product for adverse event reporting

3. Adverse Event Reporting and Field safety Corrective Action

4. Prevention or reducing Medical errors

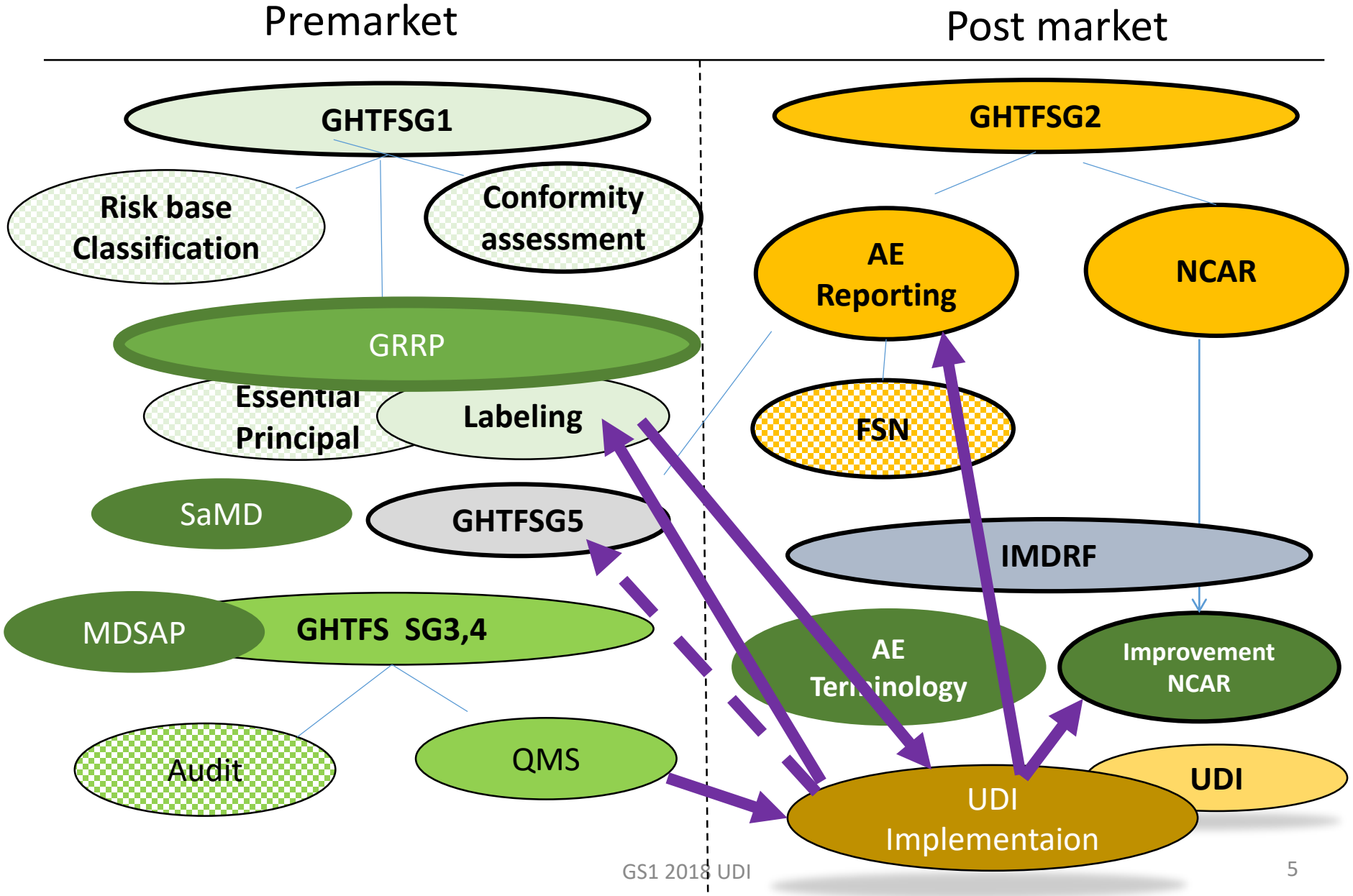
5. Documentation

a) Patient record

b) Incident Report

c) Distribution warehouse inventory control etc.

IMDRF Documents



IMDRF Guidance Document Summary And Current IMDRF Activities

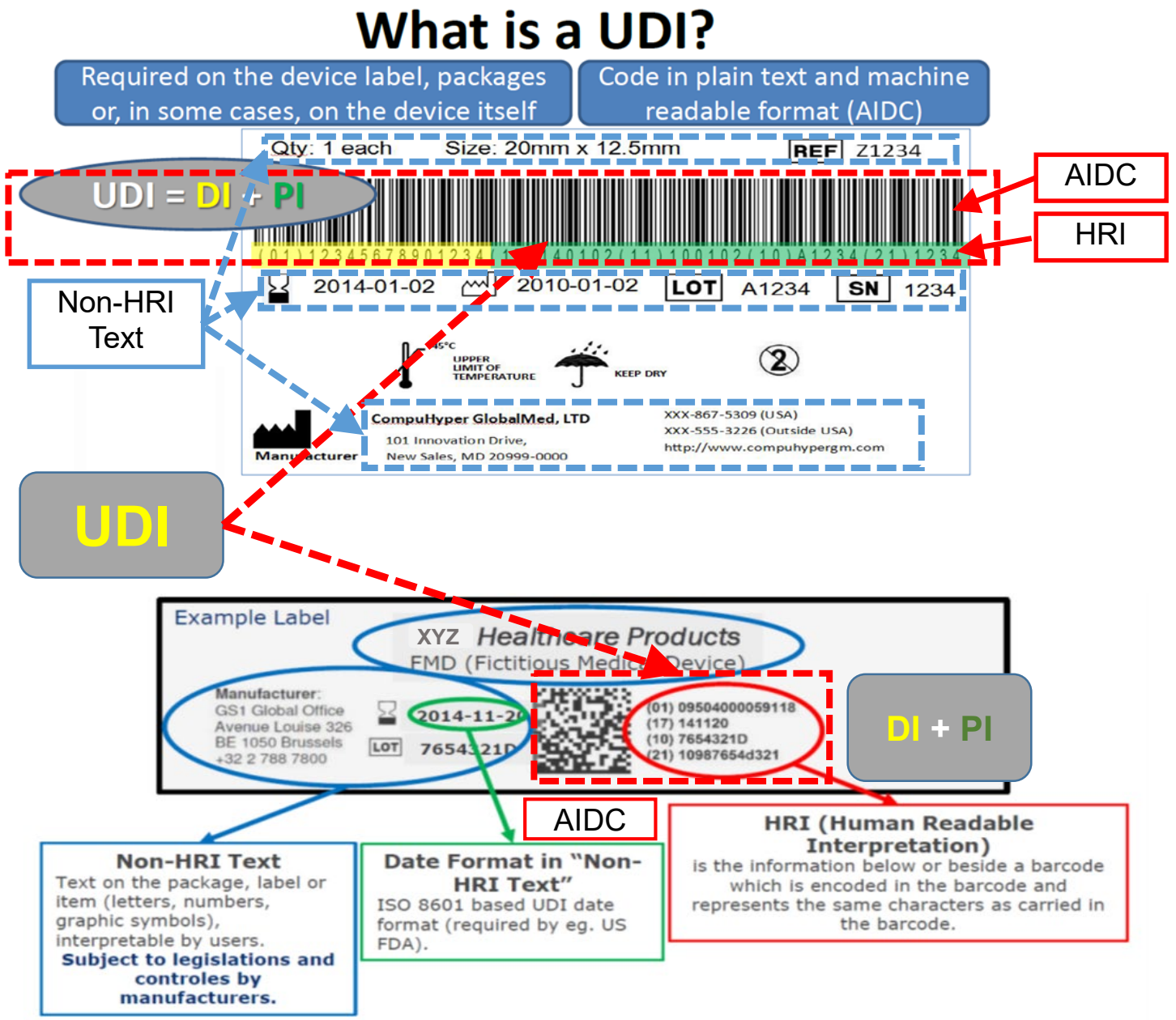
1. IMDRF N7

- Define UDI System
- UDI system is UDI and UDID
- UDI is UDI-DI and UDI-PI and define those
- UDI carrier (AIDC and HRI) and AIDC format
- UDID elements are the common data for each jurisdiction
- Fundamental requirements for UDI
- Where to print or mark UDI (device it self and package)
- UDI-DI is the key to access UDID

2. IMDRF N48

- Describe the responsibility of each stakeholders
  Regulators, Manufacture (including, labeler) and Issuing agency/ entity
- Details explanation about how to do
  Direct mark to the device itself and package
  specially for Direct marking, Kit, Software, Configurable,

IMDRF Guidance document Summary



Summery of Barcode Implementation in Japan

1980s

Start using GTIN-13 and marking with EAN

1999

Guideline (Industry Group)

Barcode were changed from EAN or ITF to GS1-128

2007 GHHTF stats considering UDI

2008

March 2008 MHLW issued "Guideline for Barcode Labeling of Medical Devices" Notification MHLW # 0328001

Notification MHLW # 0328001

Scope: Medical devices for Reimbursable Devices(Materials)

Purpose : Secure traceability, Inventory Control, Reimbursement

Now including Medical devices other than Materials

Most packages are marked with GS1-128

2012 FDA regulation

2013 IMDRF published N7

FDA-2011-N-0090 guidance(draft)

2020 IMDRF will be published N48

97.7% for primary package are labeled by GS1 (as of 2017 survey by GS1)

IMDRF Guidance Document and Summary of DB in Japan

Comparison with IMDRF UDID data element

● Information are provided by Package insert DB

UDID Element Comparison(2018)				
FDA		IMDRF	MDD	JAPAN
✔	1	UDI-DI	✔	✔
✔		Q7Typer package configuration	✔	✔
✔		GS1,HIBICCS	N/A	(GS1)
✔	2	UoU	✔	✔
✔	3	Manufacturer's Name	✔	✓ (MAH)
✔	4	Manufacturer's Address	✔	●
✔	5	Customer service information	✔	●
N/A	6	Authorized Rep's Name	✔	●
N/A	7	Authorized Rep's contact info.	✔	●
✔	8	GMDN	✔	✓ (JMDN)
✔	9	Brand Name	✔	✔
N/A	10	Software version	N/A	
✔	11	Device model or version	✔	●
✔	12	Reference and/or catalogue #	✔	(✔)
N/A	13	How the device is controlled	N/A	●
✔		S/N , lot ,batch (yes or NO)	✔	N/A
✔	14	Clinical size	✔	✔
✔	15	Additional product description	✔	●
✔	16	Storage conditions	✔	●
N/A	17	Handling Conditions	✔	●
✔	18	Labeled as single use?	✔	●
N/A	19	Packaged sterile?	✔	●
✔	20	Need for sterilization before use?	✔	●
N/A	21	Restricted number of use	✔	●
✔	22	License and /or marketing authorization #	✔	✔
N/A	23	URL information	✔	●
N/A	24	Critical warnings or contradictions	✔	●
✔		Latex?	✔	●
N/A		DEHP?	N/A	●
✔		MRI compatible?	N/A	●
✔	25	Date of discontinue	N/A	✔

Japan brief history about Bar code system

JFMDA: Japan Federation of Medical Devices Associations
MEDIS-DC: Medical Information System Development Center

1999 UCC/EAN-128 Implementation Guideline (JFMDA)

2000 MDIS-DC established

2001 Medical devices for Reimbursable Devices (Materials) use DB and Bar code

2007 GHHTF stats considering UDI

2008 MHLW issued "Guideline for Barcode Labeling of Medical Devices" Notification MHLW # 0328001

2012 FDA regulation

2013 FDA-2011-N-0090 guidance(draft)
IMDRF published N7

Japan Current situation (share with you)

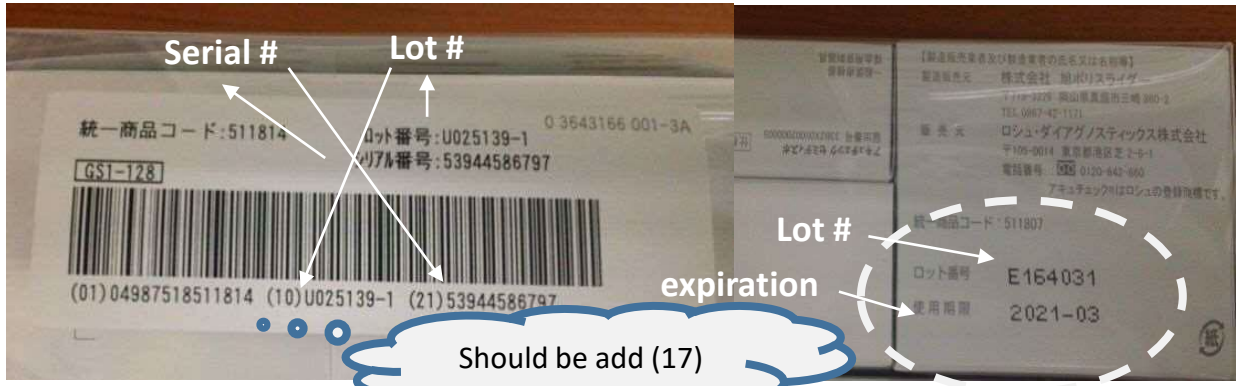
Japan Current situation (from the experienced country)

Nothing on the outer Highest package

Even on the lowest package

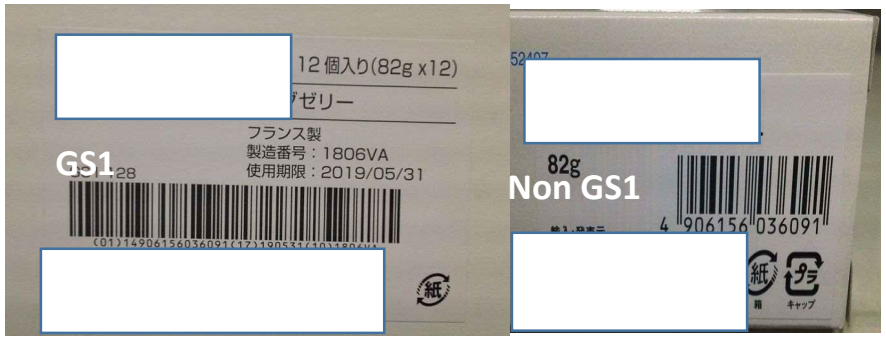
No indication about effective date even the label indicated

Lot # is different

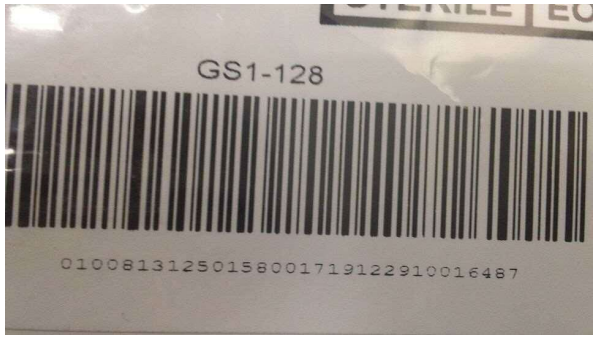


Original MFR information is uncertain but Importer put the right Tag on the package,
Then distributor or Marketing authorization Holder put Bar cord according to their control way.

Different code on The lowest package

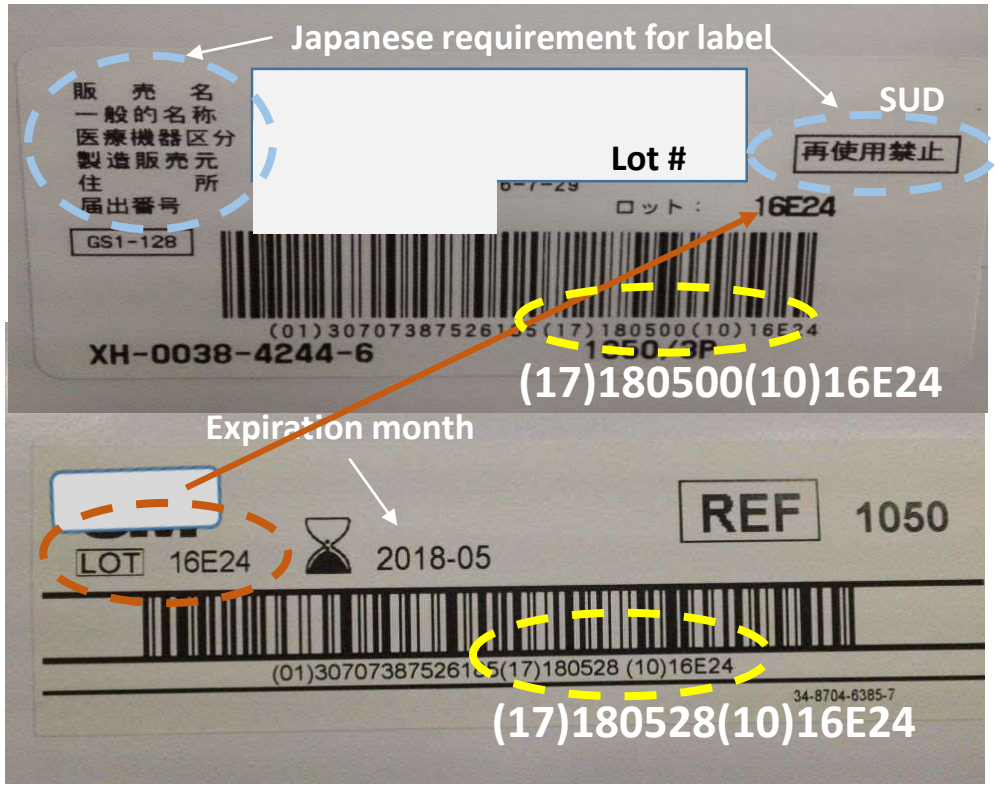


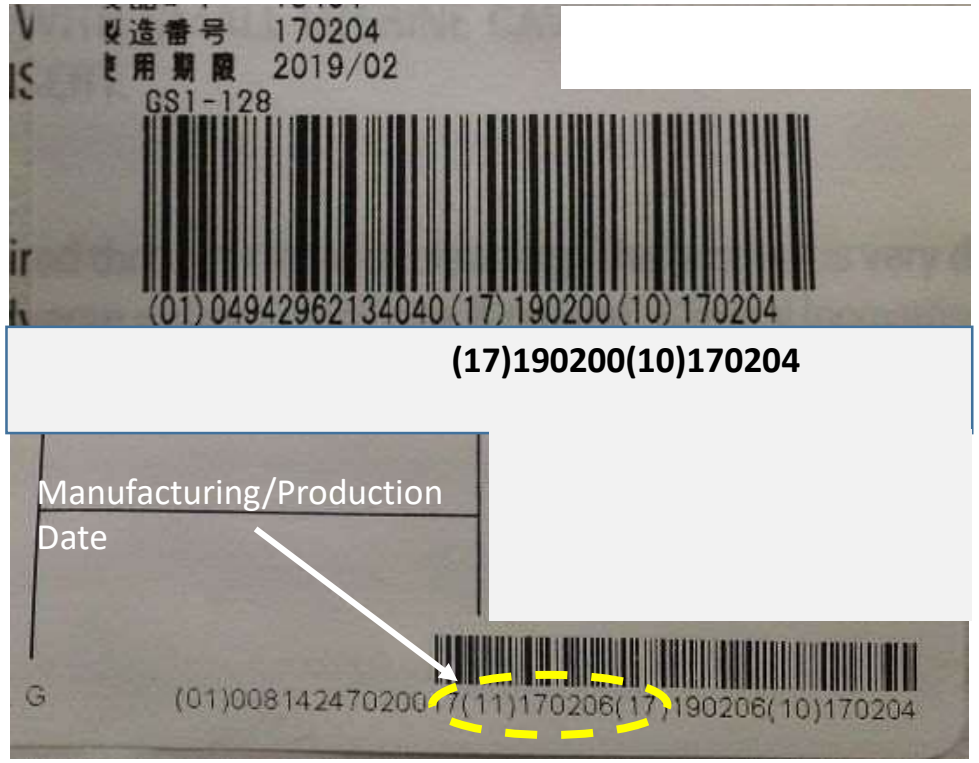
Manufacturer do not follow the rule



Japan Current situation (share with you)

Two barcodes are on one package and Different expiration information indication





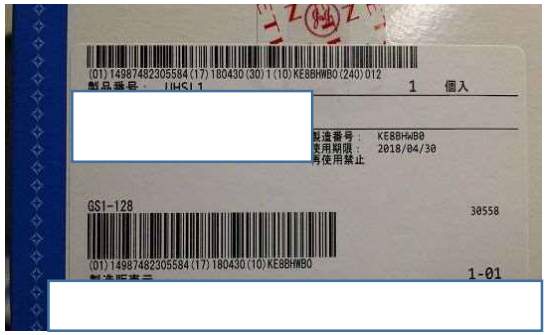
(11)170206(17)190206(10)170204

Two Barcode are on the package, one is original ,manufacturer and top one is MAH put label on the package.
And (17) expiration date is different. Should be same as original one.

(11) Manufacturing date is indicated on original label,
but at the imported time omit this and also put expiration month only.

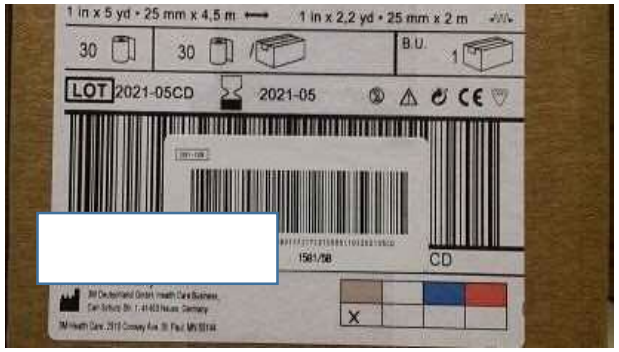
Japan Current situation (share with you)

Two barcodes are on one package and Different information indication



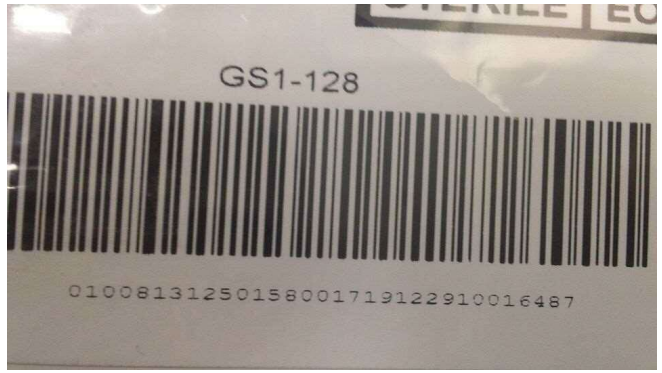
Manufacturer do not follow the rule
Two different barcode son the same label.
Make confusion at the time of reading barcode.

Original one lot #2021-05CD expiration 2021 May 28
New label lot # 202105CD expiration date 2021 May 31



Two barcodes are placed on the other barcode, machine can recognized both code.

Is this GS1-128?



Many Barcodes are on the label

Japan Current situation (share with you)

Hospital Use: In the theatres

Tokai University Hospital

Most of reimbursable medical materials have source marked GS1 barcodes on the primary packages. The marking ratio is 97.7% in 2017 (MHLW survey).
Several hospitals have started to scan the GS1 barcodes to ensure the accurate use of medical materials and the traceability.

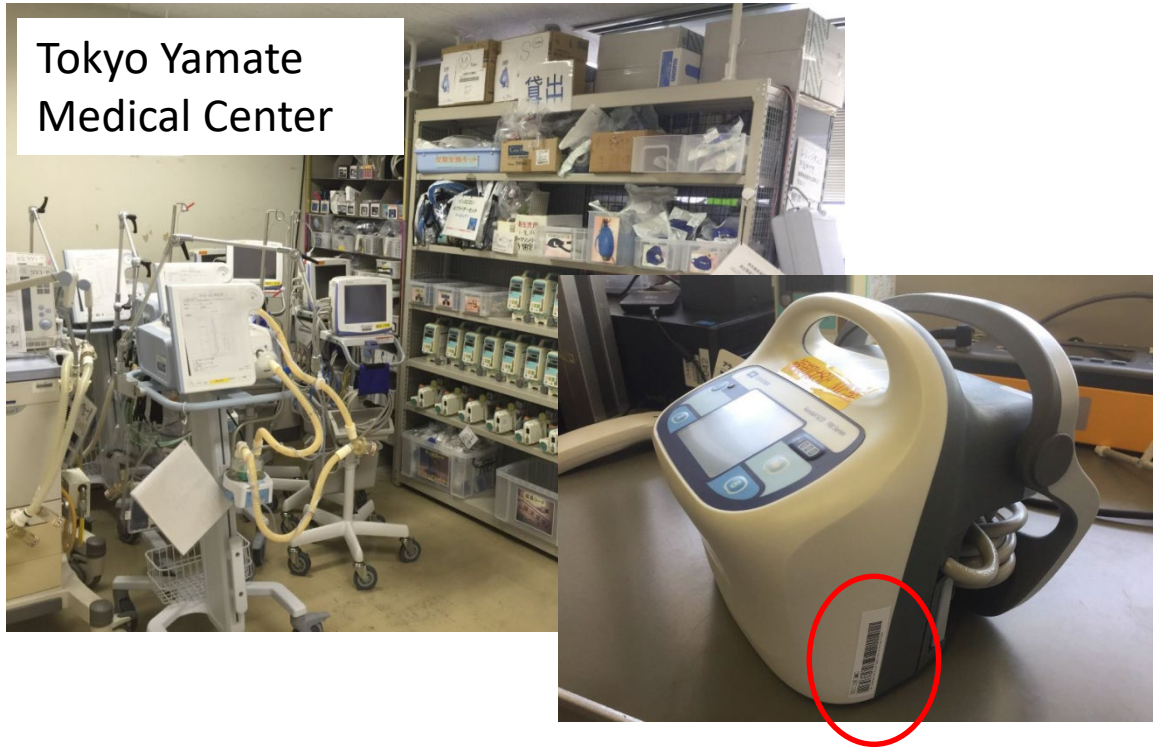
Shizuoka Cancer Center

Capturing the accurate products
Checking the expiration date
Capturing the actual and accurate cost
Automatic registration for reimbursement

Japan Current situation (share with you)

Source GS1

Hospital Use: management of medical device

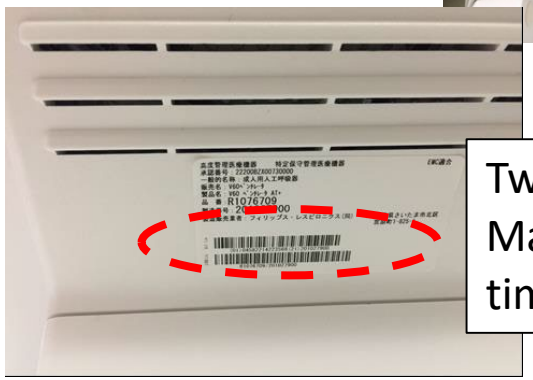


Around 20% of MDs for lending in the hospital have GS1 barcodes on the device itself.
They decided to use the source marked GS1 barcodes instead of in-hospital barcodes for the management.

However some barcodes have problems.

Low printing quality
It can not be read.

Marked on the back
It can not be scanned.



Two barcodes
Make confusion at the time of reading barcode.

Japan Current situation (share with you)

Where is the issue existed

Manufacturer

- Follow the GS1 rule
  - Readable barcode (avoid confusion)
- Understand the reasons to use barcode
  - Traceability, keeping record, keep uniqueness,
- One package has just one UDI barcode and nothing other similar code on it.
- Think about DB and its information
  - DI is the key to UDID
  - Distributors, healthcare providers are using those data

MAH(Marketing Authorization Holders)

Including Importers

- UDI PI information on the package should be same as manufacture labeled on the package.

Distributors/Retailer

- Follow the GS1 rule and do NOT modify any UDI barcode or similar one
- Do NOT open the package if it is the lowest package. And make sure UDI should appear on the package.

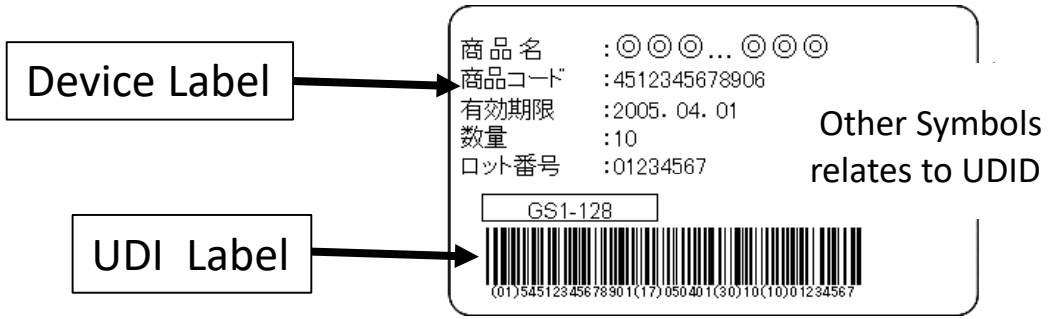
Lots of new labels are placed and the contents of the information required to UDID is different from the original one.
Means imported goods should be the same information for PI portion. (e.g. expiation information)

Japan Current situation (share with you)

Where is the issue existed(continue)

SPD(Supply, Processing, Distribution)or Distribution Center

- Follow the GS1 rule
  - Readable barcode (avoid confusion)
- Understand the reasons to use barcode
  - Traceability, keeping record, keep uniqueness,
- DB information is responsible by MAH
  - Do not create or add any UDI label
  - In case create some label, consider not make confusion for the distribution and UDI system
- Do NOT open the package if it is the lowest package. And make sure UDI should appear on the package.



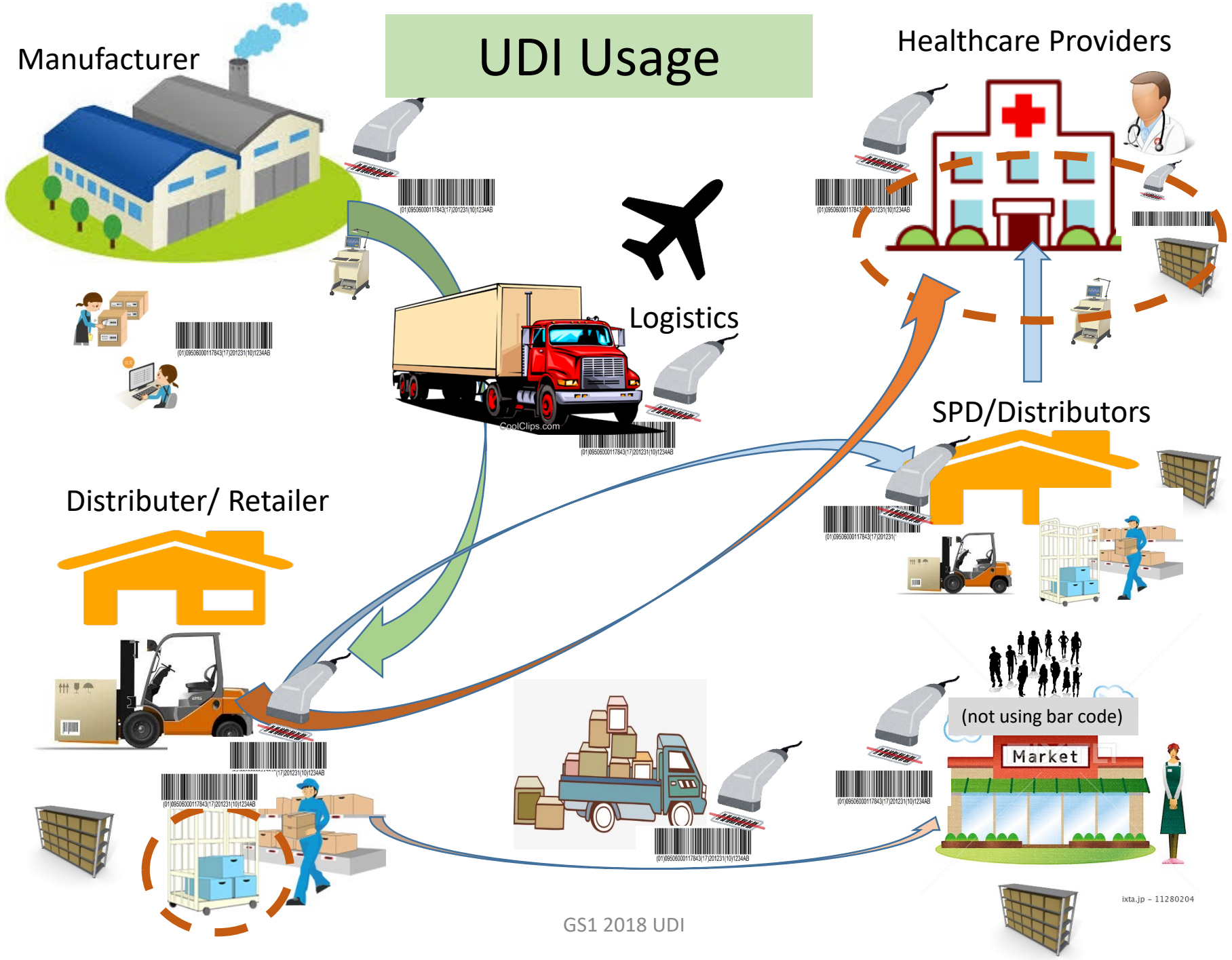
Healthcare Providers

- Use original UDI
- Preferable create less Hospital use bar code for her inventory control
- Hope to use UDI for the Hospital record keeping

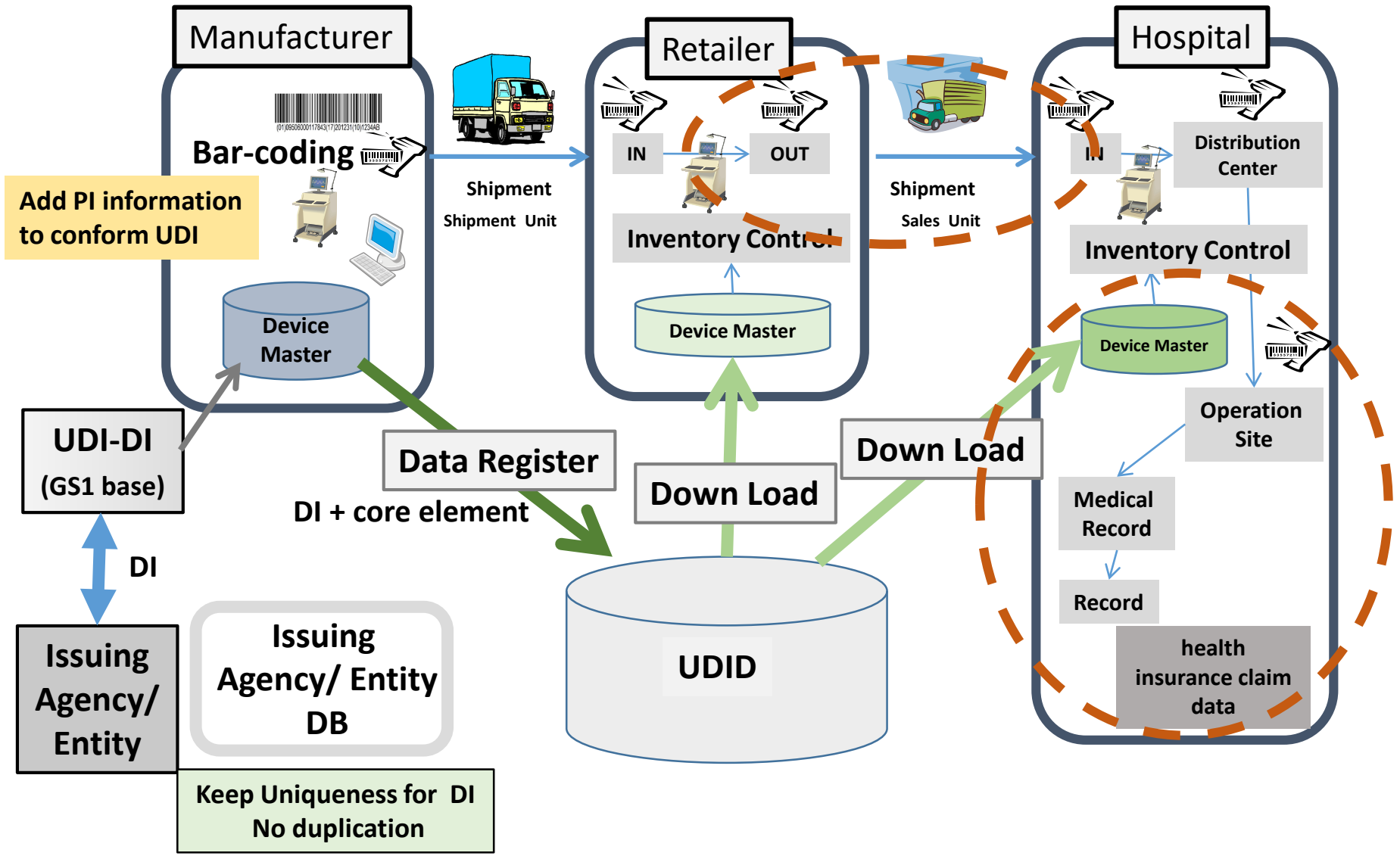
General concern

- **<u>Device Label rule and UDI label</u>**
  Different type of Device Label are used and the contents of the Device Label are including UDI label (bar code and HRI)
- No overlap the UDI information ,specially for imported medical devices package besides device it self.
- PI information should be same as
- original manufacturer assigned

UDI Usage


Manufacturer
Healthcare Providers
Logistics
SPD/Distributors
Distributer/ Retailer
(not using bar code)
Market
CoolClips.com
ixta.jp - 11280204

Structure of overall UDI System



Take to your home

- ✓ UDI is the name of barcode using Medical Devices which is regulated in each jurisdictions. and not for consumer goods.
- ✓ UDI System is composed with UDI and UDID
- ✓ In case DI part has to be changed in some reasons, DO NOT change PI portion.
- ✓ Avoid confusion about Device label and UDI label
- ✓ Responsibility of assigning DI and PI is the manufacturer or authorized entity approved by the regulation
- ✓ Use UDI through the life of the product

Thank You Very much

Khob khun krab