

# **Implementation of GHTF UDI Principle in Medical Device Tracing System**

A Case of UDI Pilot Project in Shanghai China

Prof. YAN, Liang

Senior Advisor of Institute for Food and Drug Safety  
Former Director of Legal Affairs FDA Shanghai China

2010 11 10 GS1 Healthcare Singapore

# AGENDA

- 1. Challenge on record and poor traceability.**
2. UDI code + Nomenclature code is a solution
3. How to keep ID “Unique” and the traceability Model
4. The UDI case we adopting in Shanghai city China



# Current Device Identification

Business Name	Item Number Type	Item Number
<b>BD</b>	<b>Mfg Catalog Number</b>	<b>329461</b>
<b>BD</b>	<b>GTIN</b>	<b>00382903294619</b>
<b>BD</b>	<b>GTIN</b>	<b>30382903294610</b>
<b>BD</b>	<b>GTIN</b>	<b>50382903294614</b>
<b>Cardinal Health</b>	<b>PV Order Number</b>	<b>BF329461</b>
<b>Owens &amp; Minor</b>	<b>PV Order Number</b>	<b>0722329461</b>
<b>Owens &amp; Minor</b>	<b>PV Order Number</b>	<b>0723329461</b>
<b>American Medical Depot</b>	<b>Vendor Catalog Number</b>	<b>777127217</b>
<b>American Medical Depot</b>	<b>Vendor Catalog Number</b>	<b>777127218</b>
<b>Government Sci Source</b>	<b>Vendor Catalog Number</b>	<b>FSC1482679CS</b>
<b>Government Sci Source</b>	<b>Vendor Catalog Number</b>	<b>FSC1482679PK</b>
<b>Alliance Joint Venture</b>	<b>Vendor Catalog Number</b>	<b>888021932</b>
<b>Thomas Scientific</b>	<b>Vendor Catalog Number</b>	<b>8938M25</b>
<b>Thomas Scientific</b>	<b>Vendor Catalog Number</b>	<b>8938M28</b>
<b>VWR International</b>	<b>Vendor Catalog Number</b>	<b>BD329461</b>



# Healthcare Data errors in healthcare

<b>Data error</b>	<b>% of total</b>	<b>Manu- facturer</b>	<b>Distributor</b>	<b>GPO</b>	<b>Healthcare provider</b>
<b>Missing Middle Levels of Packaging</b>		<b>15-20%</b>	<b>1-4%</b>	<b>20-25%</b>	<b>15-25%</b>
<b>Hard “Packaging Quantity” Errors</b>		<b>1%</b>	<b>1%</b>	<b>2%</b>	<b>2-5%</b>
<b>Unit of Measure Confusion/Misuse</b>		<b>2-6%</b>	<b>1-3%</b>	<b>2-5%</b>	<b>Unknown</b>
<b>Missing Packaging—not Middle Level</b>		<b>3-8%</b>	<b>3-8%</b>	<b>3-7%</b>	<b>5%</b>
<b>Manufacturer Name Problems</b>		<b>NA</b>	<b>2-5%</b>	<b>1-4%</b>	<b>30%</b>
<b>Obsolete Products</b>		<b>1-4%</b>	<b>2-5%</b>	<b>1-8%</b>	<b>5-15%</b>
<b>Missing Product Brand Names</b>		<b>2-5%</b>	<b>5-10%</b>	<b>5-10%</b>	<b>20-25%</b>
<b>Incomplete Item Descriptions</b>		<b>5-15%</b>	<b>3-12%</b>	<b>5-15%</b>	<b>10-20%</b>
<b>Wrong Customer Unit Prices</b>		<b>Unknown</b>	<b>1-2%</b>	<b>NA</b>	<b>1-2%</b>
<b>Customer Paid More Than Lowest Contract Price</b>		<b>NA</b>	<b>Unknown</b>	<b>NA</b>	<b>3-6%</b>

*Source: US Department of Defense Study*

**What is the basic element of information  
whether discussing on  
information flow or phisical flow  
for supply chain control**

---

1. One is the product UDI code
2. Other is Nomenclature code

# AGENDA

1. Challenge on device record and poor traceability.
2. **UDI code + Nomenclature code is the solution of control**
3. How to keep ID “Unique” and the traceability Model
4. The UDI case we adopting in Shanghai city China

# Two Code solution for supply chain

(1) Code of Article ID ; (2) Code of product nomenclature

Two Code must be on the device label and primary package.

12345 →  
CAR ID



CAR ID LINK OWNER ID



# AGENDA

1. Challenge on record and weakness of traceability.
2. UDI code + Nomenclature code is a solution
3. **How to keep ID “Unique” and the traceability Model**
4. The UDI case we adopting in Shanghai city China

GHTF/SC/NX:2009



**GHTF Discussion Paper**

(in view of preparation of a draft guidance on)

**UDI for Medical Devices**

**Title: Unique Device Identification (UDI) System**

**Authoring Group: GHTF SC UDI AHWG**

**Proposed by the Global Harmonization Task Force for Public Consultation**

**Deadline for comments: 31 March 2010**

**Address for submitting comments: [mail box: entr-cosm-med-dev@ec.europa.eu](mailto:entr-cosm-med-dev@ec.europa.eu)**

**Expectations from this consultation phase/invitation for public comments:**

**Part A: Comments on the UDI system:**

Comments/suggestions are invited on the chapters of this discussion paper; in particular the UDI system including the UDI code, carrier and placement, the UDI Database; How such a system would or could be used by manufacturers, regulators, purchasers, and/or final users? More globally, what could be the governance and economic model of a single UDI system worldwide?

**Part B: Comments on the concept of UDI Database(s):**

- What is your vision on how (a) UDI Database(s) could be designed and implemented in the short term worldwide? Who are the different types of users?
- What are the key elements of UDI Database(s) administration?
- How will the UDI Database(s) articulate/interact with other existing entities or international standardisation organizations.

Disclaimer: No prejudice/preference towards a single global physical database versus the interconnection of regional data bases is anticipated in this consultation document.

**Date:** November 12, 2009

Roland Rotter, GHTF Chair

Copyright © 2009 by the Global Harmonization Task Force

## GHTF UDI

Aug. 25 - 26th  
2009

GHTF Public  
Consultation for  
UDI, Deadline for  
comments on  
Mar. 31th 2010

Only Adopting  
International  
Coding Standard  
to keep "Unique"

# UDI - Unique Device Identification

## How Keeping Unique:

- Unique requirement must be considered **on global scope**
- **Only International standard. GS1 coding system or HIBCC system** is adopted in supply chain to keep Unique. **(How AIDC)**
- Using distributor 's or hospital own coding standard will not meet Unique principle on global market.

# GS1 EAN/UCC-128 Code Structure



National Code

Product Code

Manufacturer Code



Date of Manufacture or Expiration

Lot / SN

# H BOC Code Structure



+ H739451544V035

Manuf act ur er Code

Pr od uct Code



+ 08060X03053185R

Expi r at i on Dat e

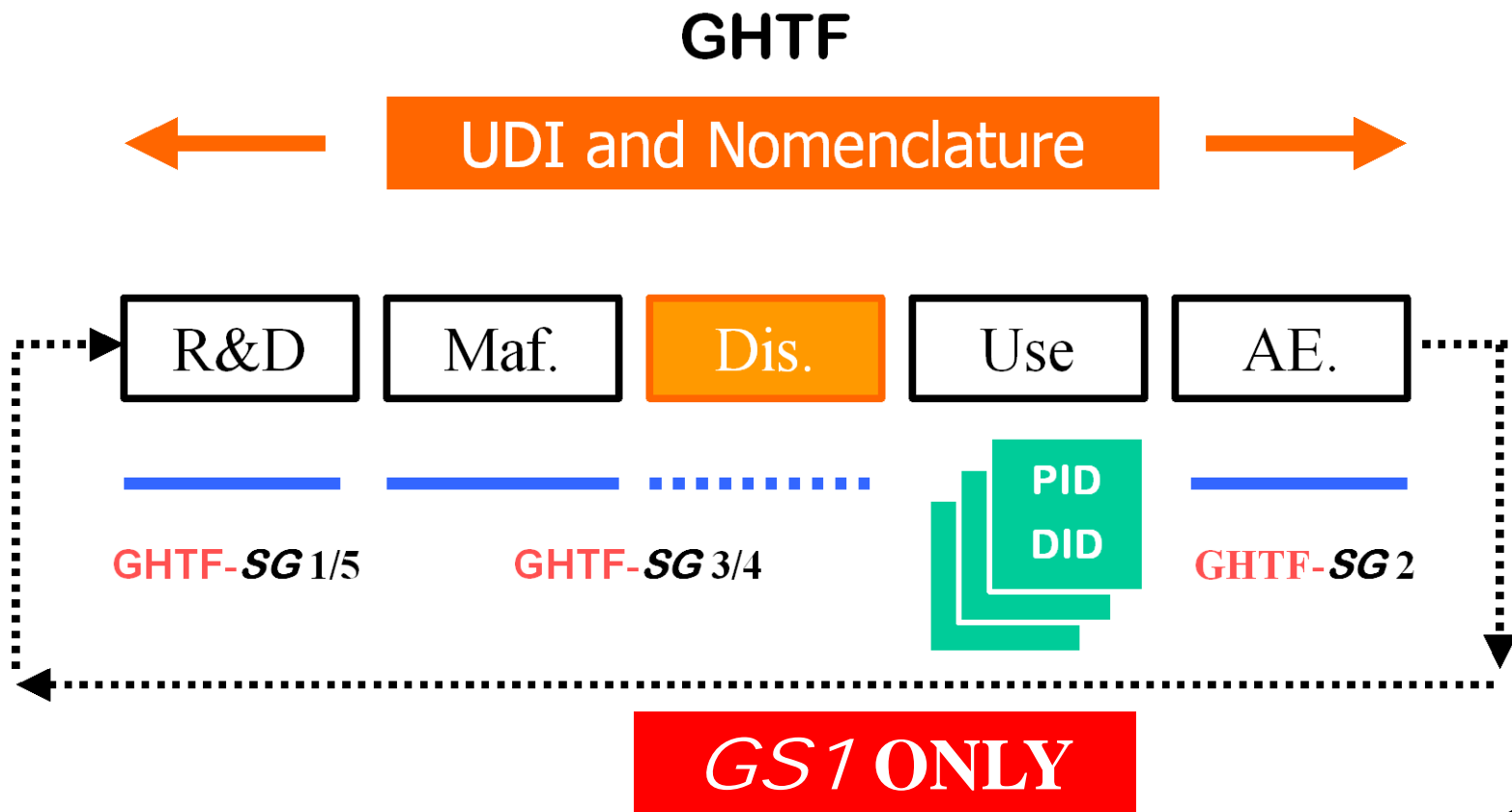
Lot / SN

**What is the basic elements  
if  
We discuss the traceability**

---

1. One is the product UDI code
2. Other is Nomenclature code
3. The HOPITAL management

# UDI and Nomenclature issue relating to whole management of MD. Not only in supply chain





# Healthcare Traceability – a business process



## The global language of business

**OVERALL BENEFIT:** Improving efficiency & visibility in supply and demand chains

### GS1 SOLUTIONS & SERVICES USING GS1 STANDARDS

Solutions: POS / Inventory Management / Asset Management / Collaborative Planning / Traceability

Services: Global (GSMP, GEPIR, Global Registry, Training and Accreditation) & Local (e.g. Certification, Implementation, Training)



**System** - Integrated system of standards



Global standards  
for automatic  
identification

Rapid and accurate,  
item, asset or  
location identification



Global standards  
for electronic business  
messaging

Rapid, efficient  
& accurate business  
data exchange



The environment  
for global data  
synchronisation

Standardised, reliable  
data for effective  
business transactions



Global standards  
for RFID-based  
identification

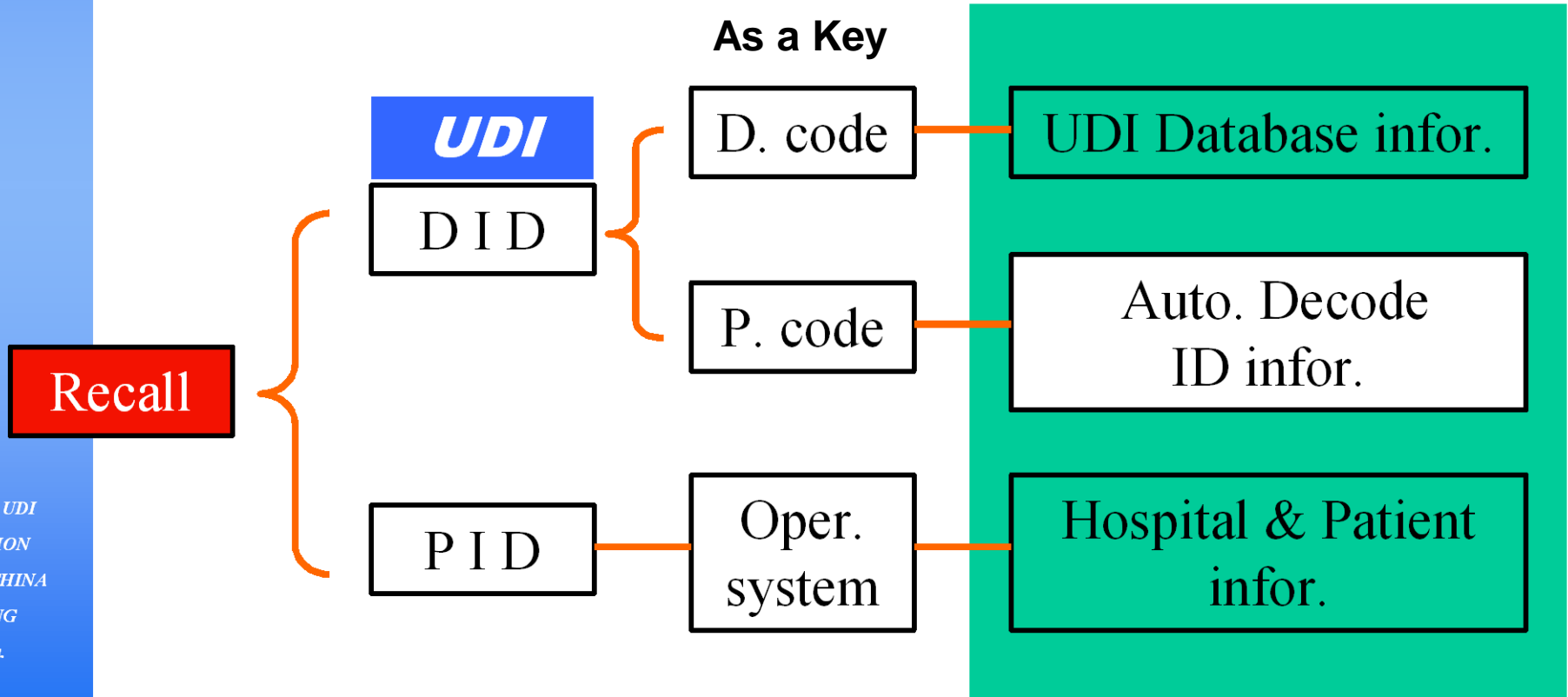
More accurate, immediate  
and cost-effective  
visibility of information

GS1 Identification Keys (e.g. GTIN, GLN, SSCC, GRAI, GIAI, GSRN, EPC) & Attribute Data (e.g. Best Before Date)



# **TRACEABILITY** discussion

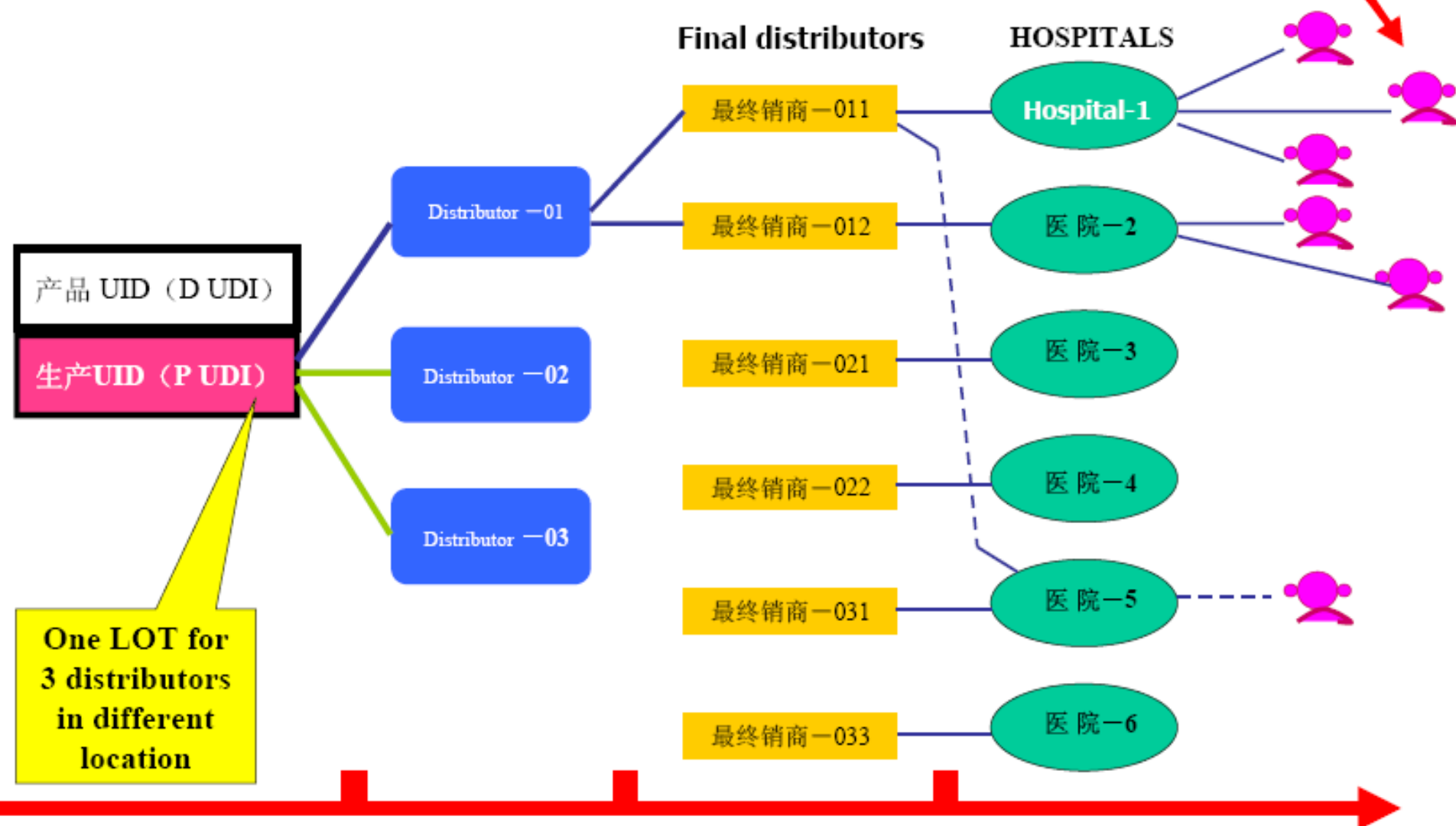
ADR. Report



# The Flow Path of UDI Dynamic information

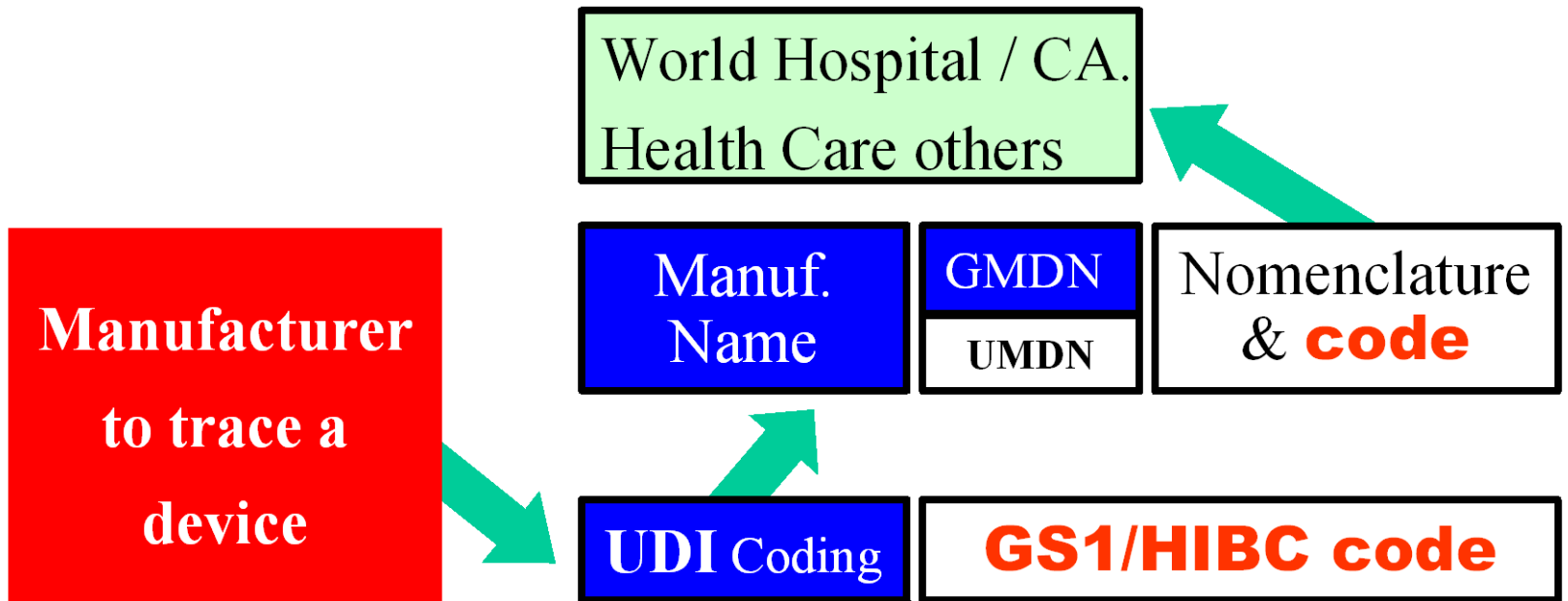
$$PID + UDI \text{ (DUDI+PUDI)} = EHR$$

*Only scanning UDI (Dynamic section) at the place of Hospital that can relating to PID*



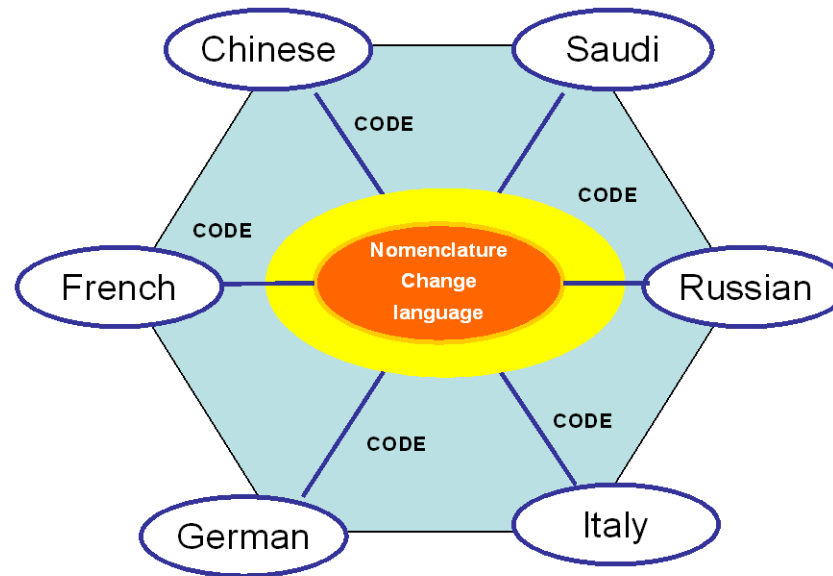
## Based on “UDI” and “GMDN” Establish a Worldwide Vigilance System

- ▶ When event really happened, where they are ?
- ▶ Using IT system to search the device UDI .
- ▶ High risk device is the first target to using UDI.



## 全球范围的命名系统作为各国语言交换平台

- Language changing use device **Nomenclature Number**
- Nomenclature works with UDI for tracing the Device



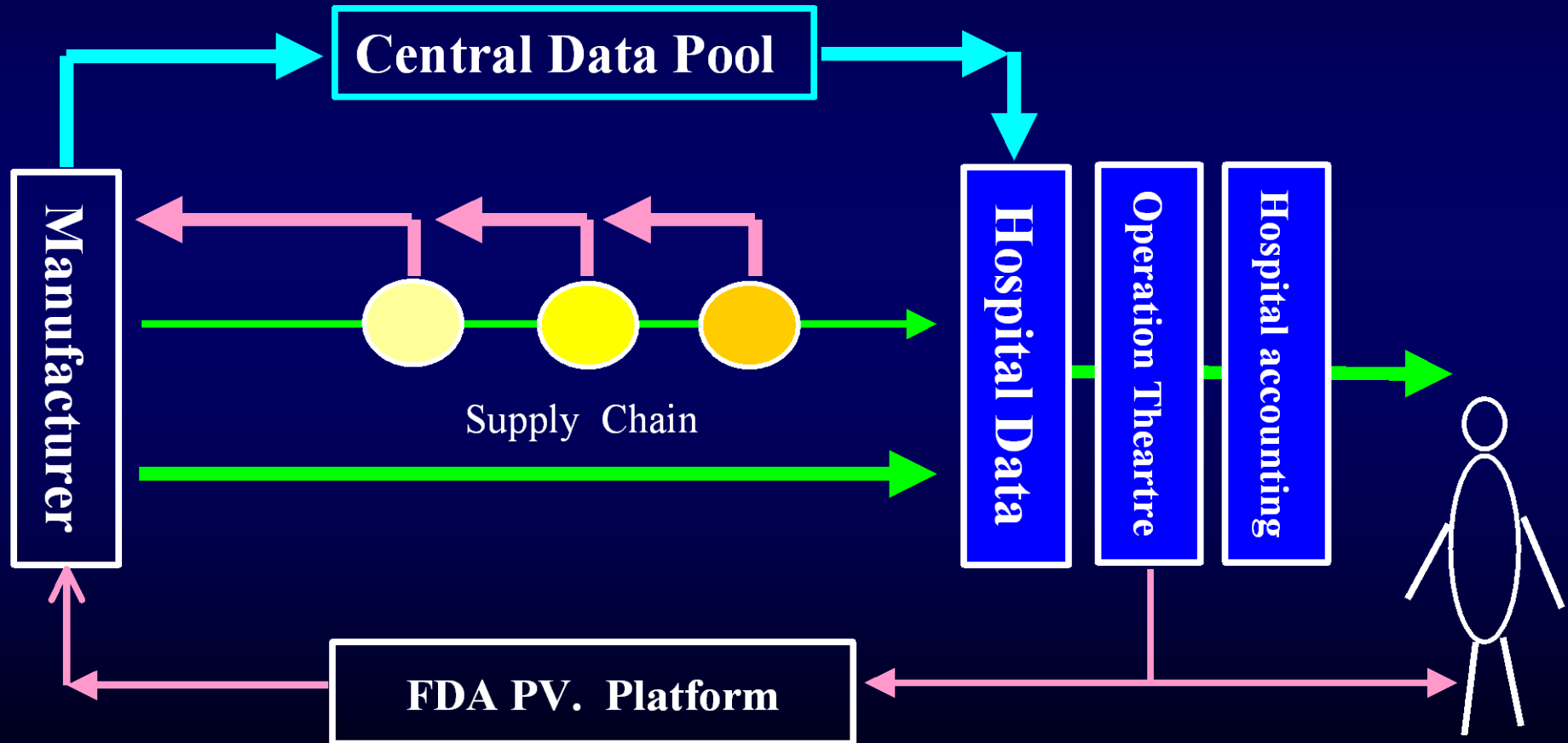
Asian Harmonization Working Party  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA



# AGENDA

1. Challenge on record and weakness of traceability.
2. UDI code + Nomenclature code is a solution
3. How to keep ID “Unique” and the traceability Model
4. **The UDI case we adopting in Shanghai city China**

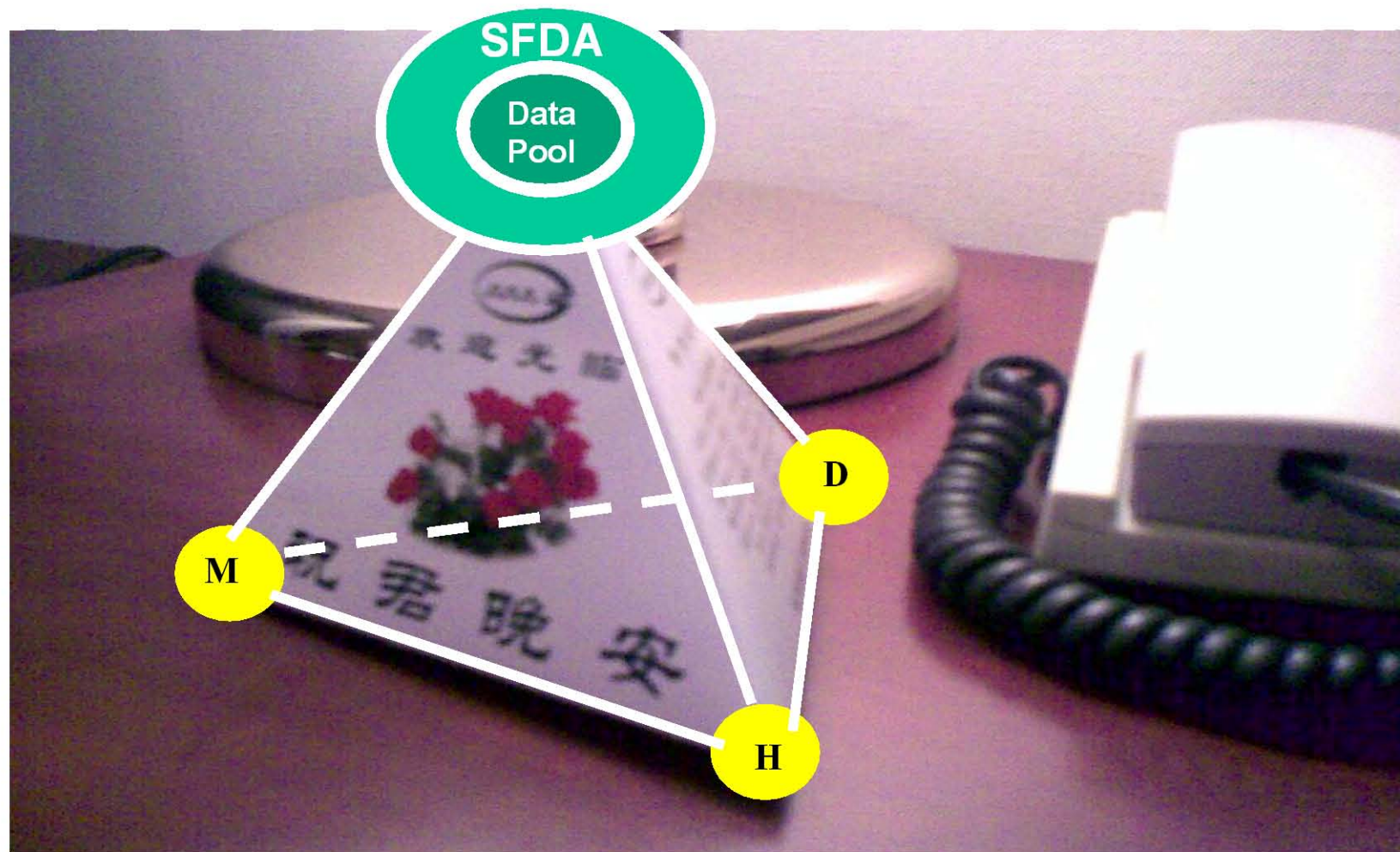
# Implantable Device Information Flow



# ***UDI* A Pilot Project Implementation in *FDA* Shanghai China on 2007**

- On the end of 2005, starting this project after an investigation, which focus on implantable high risk device.
- At the middle of 2006, establishing a coding standard scheme and solving special decode technology and attributes content of UDID.
- On Nov.11 2006, SH-FDA worked together with SH-Hygiene Bureau establish a document to promote the project implementing.
- At the end of 2007, more than 100 hospitals use this UDI tracing system in Shanghai city tracing back implantable device.
- Right now, there are more 1000 companies; 200,000 implantable devices; 530,000 device used information feedback from 120 hospital

# The Simplest Model for FDA to Tracing





# Implementation of a post-market traceability program for implantable medical devices adopting unique device identification

## 2009-2010 Healthcare Reference Book

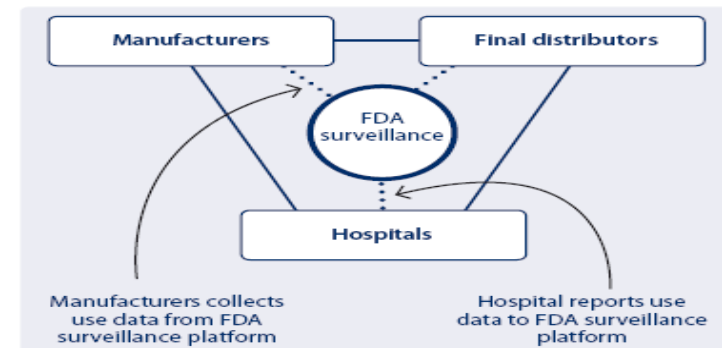
### ABSTRACT

This article discusses the distribution and traceability model of Implantable Medical Devices (IMD) for post-market surveillance purposes, and the IT and automatic identification technology that has been used in the supply chain to complete post-market tracking in Shanghai. To build up this system successfully, it was necessary to establish a Unique Device Identification (UDI) for IMD's, based on GS1 Standards, to define the minimum information in the tracking process, and to establish a central data pool to support automatic reading in the hospital management system. Meanwhile it is necessary to have a Shanghai FDA monitor platform to collect the traceability information from the end user. This article also contains a real case study that took place in Shanghai.



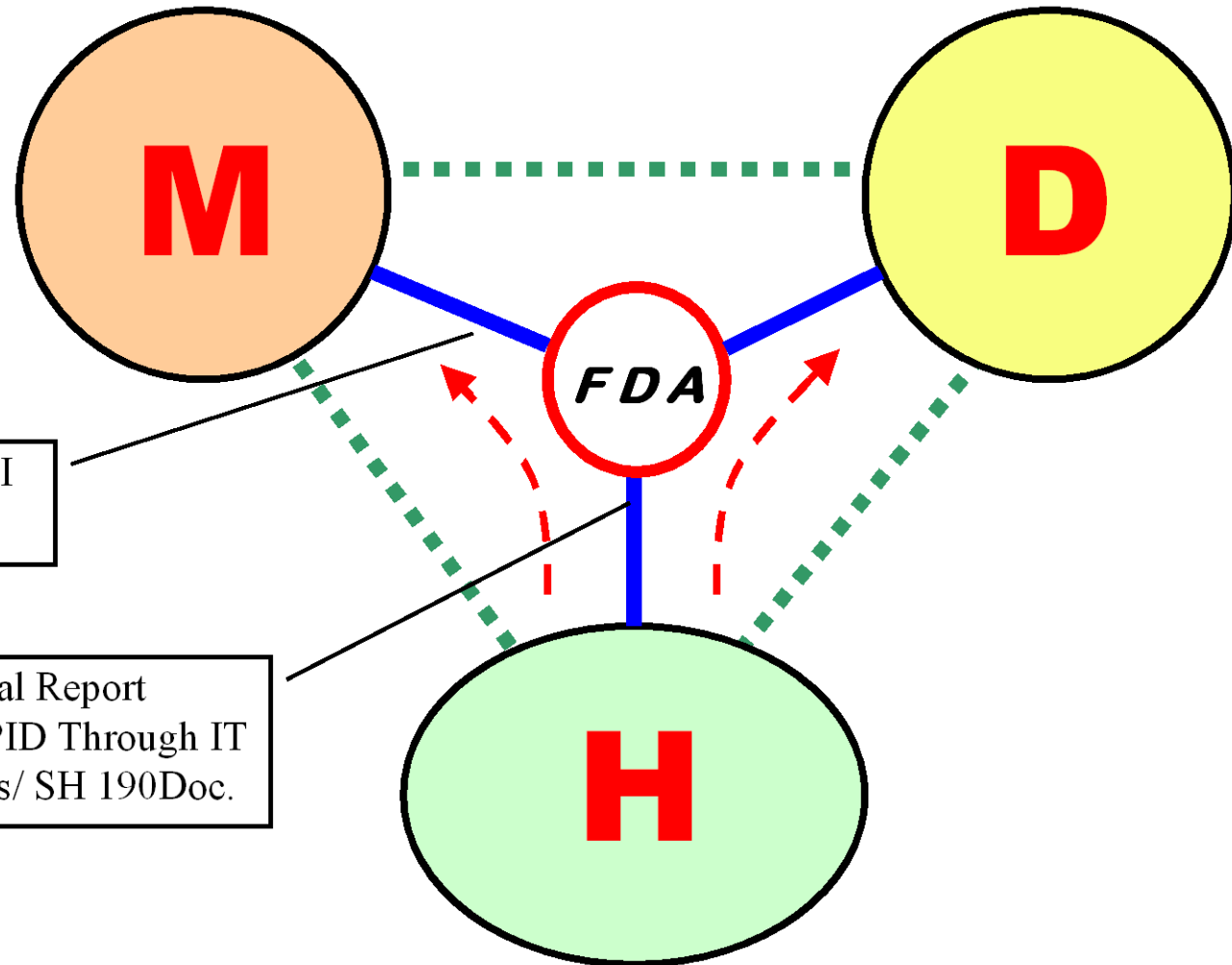
Article by **Liang Yan**

Figure 1: IMDs sales channel and device use data reporting channel



Maf. And Distributor collecting data from FDA Platform  
the result will show the system balance. "0" result is expectation by FDA.

$$H \text{ ( On FDA Platform )} - M - D = 0$$

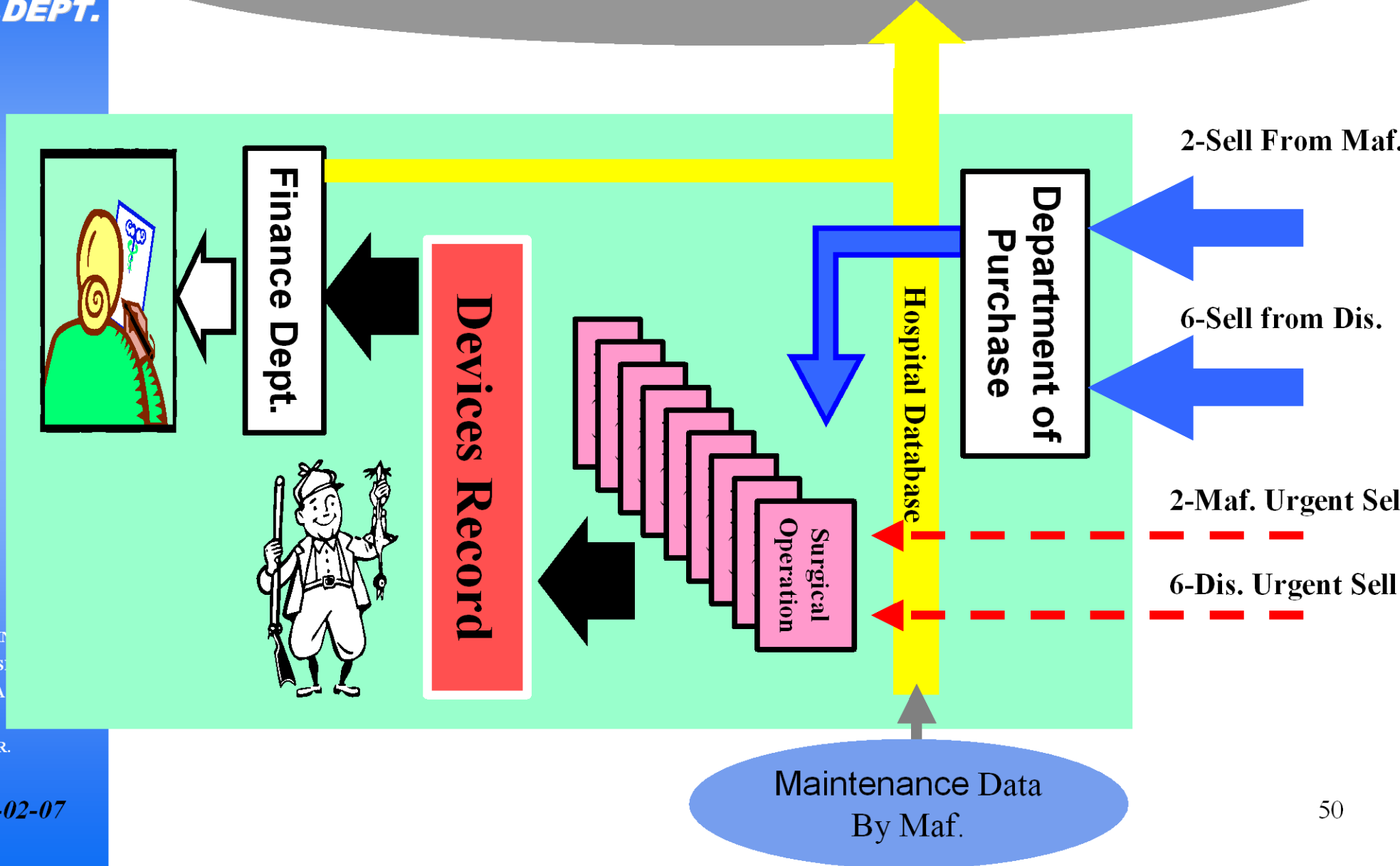


Maf. Up Load UDI  
Down Load PID

Hospital Report  
UDI Links PID Through IT  
22 Attributes/ SH 190Doc.

SI  
TR  
POST  
AE. VIGILANCE  
MONITOR AND  
INSPECTION  
IN  
ZHE JIANG &  
JIANG SU  
2007-11-08  
2007-11-22

# Data Platform of FDA



# System accepts only HIBC and GS1 standards, others will be rejected.



MDR.DEPT.

2006  
BAR CODE  
FOR ALL  
MANUFACTURERS  
SH-FDA-MDR.

2006-11-14

System accepts only HIBC and GS1 two standards otherwise will be rejected.



25

# Shanghai Chang Hai Hospital in 2006



2007  
ESTABLISHING  
MD. ADVERSE EVENT  
TRACING BACK SYSTEM  
BY UDLI  
SH-FDA-MDR.

2007-5-24



79

# 3 Data Sources Supporting A Device Form for Patient Keeping

SH-FDA  
MDR.DEPT.

## Used Device Form of Patient

Hospital  
Purchase  
Database

HIS

Lot / Batch /  
Series NO. In  
Secondary Code

上海市东方医院  
同济大学附属东方医院

植入性医疗器械使用明细费用清单

单据编号: 2006104235 第 1 页, 共 1 页

病人姓名	阮耀廷	住院号	555941	手术时间	2006-10-25 12:19:15
证件类型	身份证	证件号码	342422197301152050		

手术材料明细

Ref.	商品名称	规格型号	生产日期	有效期	Lot/SN	数量	进货价格	零售价格	生产厂家	生产国名称
7862-09	VerSys金属腕 袖型腕关节假体	7862-09	2006-10-24	2006-10-24	235644/36236 2	1	12,000.00	12,600.00	上海新陆医疗	Synthes GmbH
7850-11	VerSys膝假体 TK假体节假体	7850-11	2006-10-24	2006-10-24	/234454	1	7,000.00	7,350.00	上海新陆医疗	Synthes GmbH
204-070	钛骨螺钉 (SYNTHES)	3.5mm 皮质 骨螺钉, 不 锈钢	2006-10-24	2006-10-24	/234454	1	2,500.00	2,625.00	上海新陆医疗	Synthes GmbH
204-070	钛骨螺钉 (SYNTHES)	3.5mm 皮质 骨螺钉, 不 锈钢	2006-10-24	2006-10-24	/234454	1	500.00	525.00	上海新陆医疗	Synthes GmbH
204-070	钛骨螺钉 (SYNTHES)	3.5mm 皮质 骨螺钉, 不 锈钢	2006-10-24	2006-10-24	/234555	1	2,500.00	2,625.00	上海新陆医疗	Synthes GmbH
478-280	髓内钉系统 R. One 髓内 钉骨鞘内	R. One 髓内 钉骨鞘内	2006-10-24	2006-10-24	/513121	1	8,000.00	8,400.00	上海新陆医疗	Synthes GmbH
合计金额							32,500.00	34,125.00		

科主任签字: \_\_\_\_\_ 手术医师签字: \_\_\_\_\_ 科室: \_\_\_\_\_ 操作医师签名: \_\_\_\_\_

2007-11-22 浙江

155

# Basic information of one device feedback from Hospital by scan a package *Bar Code*

1. UDI code (Static & Dynamic \*)

2. Name of Manufacturer

3. Maker / contract maf.

4. Manufacture Site.

5. Name of Device

6. Device Specification

7. Device Expiration Date \*

8. Device Release Date

9. Lot/batch/serial number \*

10. Quantity

11. No. of Re. Certification

12. Issue Date of Certificationg

13. *Expiration Date of Certification*

14. Contact Person

15. Final Distributor

16. **GMDN Code**

# Minimum Patient Information links with UDI feedback from hospital

1. Patient ID / Patient Hospital ID
2. Patient Name
3. Case Name
4. Operation Theater
5. Date of Operation
6. Doctor Name



# How to reform the control of supply chain more fast

1. One is the product UDI code
2. Other is Nomenclature code
3. The HOSPITAL management
4. Right things Right way from bottom

全程  
编码  
关联

Shipping NO.

Pallet No.

Carton No.

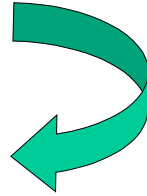
Package No.

Device UDI = HS code

Custom NO. = CQI NO.

Notice No. for gate clearance

海关会不差钱  
Task of Ecom



P.T.P

First trade can be happened at the port

The product can be directly to the patient.

P To L To B To C To P  
Possible or Impossible?

57

**Codman**  
Codman & Shurtz, Inc.  
30 Stryker Street  
Burlington, MA 01824  
UNITED STATES OF AMERICA  
PH: 351-251-0000  
FAX: 351-251-0007

COMMERCIAL INVOICE

Bill of Lading: H2C82091928  
INVOICE NUMBER: Export Order

Invoice No.: 110927487  
DC: 826632

Product Description: **90121930** 膝关节假体 (IP+主柄)  
UOM: 个  
Quantity: 3  
Unit Price: 1,174.99  
Extended Price: 3,524.97

INVOICE TOTAL: 3,524.99

中华人民共和国海关保税港区进境货物备案清单

进境备案清单号: 221801019069003 Page: 1

商品名称	商品编号	数量	单位	单价	总价	币种
膝关节假体 (IP+主柄)	90121930	3	个	1,174.99	3,524.97	美元
膝关节假体 (IP+副柄)	90121930	3	个	1,174.99	3,524.97	美元

Add UDI information  
in the form of  
customs

付汇证明联

中华人民共和国海关进口货物报关单

报关单号: 311390220

商品编号	商品名称	数量	单位	单价	总价	币种
8.9481902200	电脑臂1	2,500	套	181.3600	453,400.00	人民币
7.39231000	聚丙烯	2,300	件	137.6400	316,152.00	人民币
8.39113300	塑料管	370	条	638.1600	238,119.60	人民币
9.38290010	全髋假体	16,390	件	271.2268	4,446,645.18	人民币

外高桥保税区仓储货物出区(库)提货单

仓库号码: 0628

提货单号: 0207394

提货单位: 上海三瑞进出口有限公司

提货日期: 2010-06-02

提货数量: 3,000 个

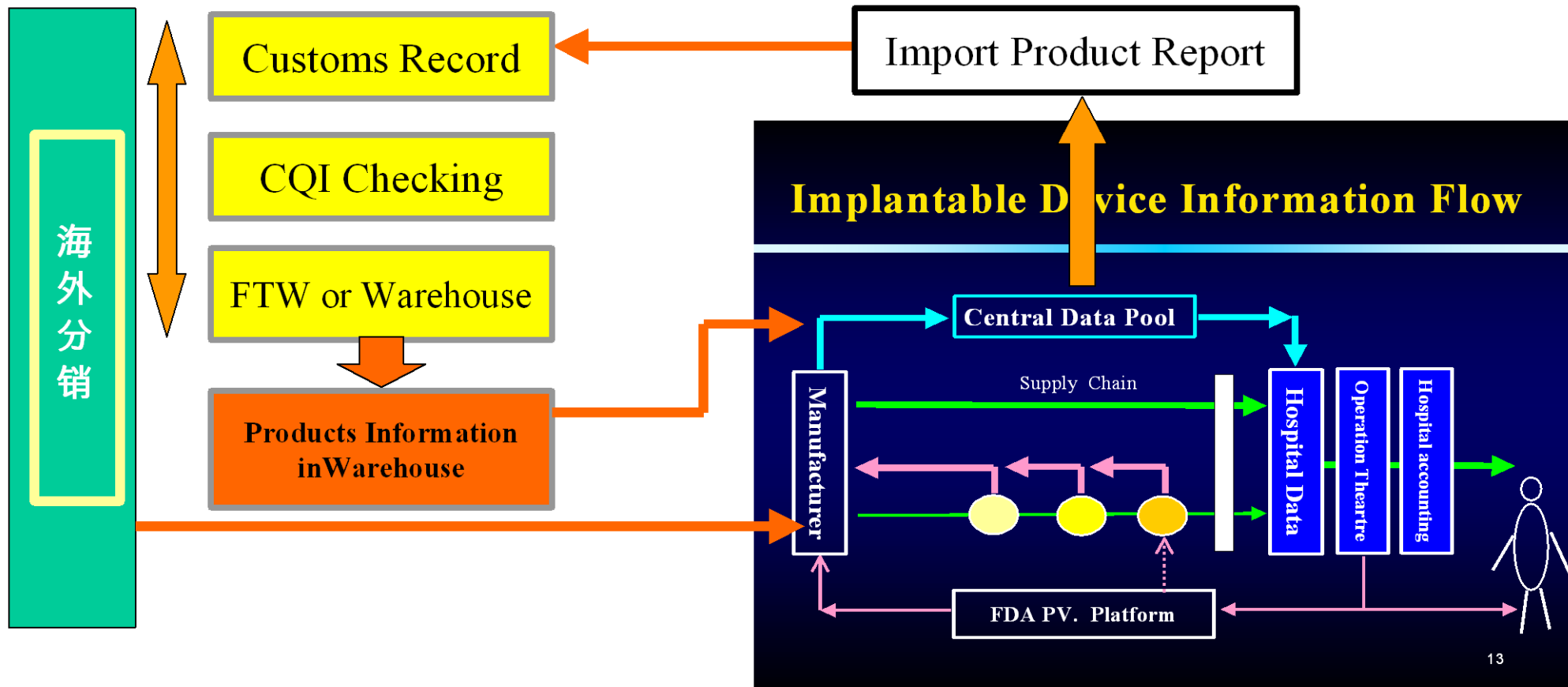
提货重量: 49,400.00 KG

提货金额: 8174.00 USD

提货人签名: 姜志孝

提货日期: 2010年6月2日

# The Flow of the Medical Device Information for Distribution and Supply Chain Control With Device UDI



*Our Target of UDI Is ?*

***It is the time for Chian  
Take a consideration of  
changing MD sales model***

**UDI suport the new sales model**



# 形成三港三区联动机制，加快国际贸易中心建设步伐

## Forming three-port linkage mechanism to accelerate the international trade center development



胡锦涛总书记视察上海外高桥保税区国际医疗器械展示交易中心



胡锦涛总书记视察上海外高桥保税区国际医疗器械展示交易中心

上海综合保税区积极探索，先行先试，加快转变经济发展方式。  
Shanghai Comprehensive Free Trade Zone actively explores, acts and attempts to accelerate the transformation of economic growth mode.

- 2009 年上海浦东新区与南汇区合并  
Shanghai combined Pudong New District with Nanhai District in 2009
- 2009 年 11 月 19 号上海成立综合保税区管理委员会  
Commission of Shanghai Comprehensive Free Trade Zone was established on November 11, 2009
- 2010 年初上海浦东国际机场第一块 3.59 平方公里保税区封关运作  
The first 3.59 square kilometers of Free Trade Zone was occupied and starting operation in Shanghai Pudong International Airport on early 2010
- 国际医疗航空货物运输从浦东机场与外高桥物流园区联动清关  
The international medical device through airline can be conducted customs clearance at Pudong Airport which links Waigaoqiao Logistics Park
- 洋山海运物资通过三区货物调拨系统快速与长三角交通设施对接  
Shipping goods from Yangshan Port can connect with traffic facilities in Yangtze River Delta through Three-district Goods Transfer System

要进一步创新体制机制，不断完善服务措施，把物流园区建设得更好，为促进上海经济方式转变，产业结构优化升级发挥更大作用。

We should further innovate institutional mechanism and continuously improve service measures in order to make the Logistics Park better and play a greater role in promoting the transformation of the mode of Shanghai economic development and upgrading the industrial structure.





**MDTA** is an association particularly serves for the company of foreign investment and export com. on medical device area

Established on Dec. 31th 2008 and 75 members

## 2008年12月31日成立医疗器械贸易行业协会

打造国际贸易和交流的平台 促进医疗器械行业全面发展



[www.mdta.org.cn](http://www.mdta.org.cn)

# Summary

1. Harmonize with GHTF UDI principle.
2. Only adopt International coding system as GS1 or HIBCC.
3. Only Manufacturer responds for initiate a UDI code and maintain UDI Unique on worldwide market. No other one have right to change the product UDI label in the market.
4. Minimum attributes when build a UDI database for tracing.
5. Most efficiency tracing system is that the keeping the record of device UDI links with PID (patient identification).
6. the SN or LOT was automatic recognized at last stage of supply chain (in Hospital), this is a critical control point when we discuss the issue of device traceability.
7. Device identifier of a UDI including package level information that will easy treat with quantity issue in supply chain.

# How to reform the control of supply chain more fast

*GS1 is*

**only powerful force to push advance**

1. One is the product UDI code
2. Other is Nomenclature code
3. The HOSPITAL management
4. Right things Right way from bottom



**Thanks**  
**for your attention**

Email:

[yanliang@smda.gov.cn](mailto:yanliang@smda.gov.cn)

[Yanliang@online.sh.cn](mailto:Yanliang@online.sh.cn)