Implementation of GHTF UDI Principle in Medical Device Tracing System

A Case of UDI Pilot Project in Shanghai China

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2010 11 10  GS1 Heathcare 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
Recall failure comes from existing recording measures. Using automatic product Code reading to instead personal writing. Promote the device traceability on higher correctness level.
# Current Device Identification

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

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

Source: US Department of Defense Study
What is the basic element of information whether discussing on information flow or physical 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
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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.
AGENDA

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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

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

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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
H BCC Code Structure

Manufacturer Code

Product Code

Expiration Date

Lot / SN
What is the basic elements if
We discuss the traceability

1. One is the procuct 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

GHTF

UDI and Nomenclature

R&D  Maf.  Dis.  Use  AE.

GHTF-\textit{SG} 1/5  \quad GHTF-\textit{SG} 3/4

\textbf{GS1 ONLY}
GS1 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)

GS1 System - Integrated system of standards

- GS1 BarCodes: Global standards for automatic identification
- GS1 eCom: Global standards for electronic business messaging
- GS1 GDSN: The environment for global data synchronisation
- GS1 EPCglobal: Global standards for RFID-based identification

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

ADR. Report

UDI Database infor.

Auto. Decode ID infor.

Hospital & Patient infor.

UDI

D. code
P. code
Oper. system

Recall

DID

PID
The Flow Path of UDI Dynamic information

\[ \text{PID} + \text{UDI} = \text{EHR} \]

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

Final distributors

```
产品UID (D UDI)
生产UID (P UDI)
```

```
Distributor - 01
Distributor - 02
Distributor - 03
```

```
Hospital - 1
医院 - 2
医院 - 3
医院 - 4
医院 - 5
医院 - 6
```

One LOT for 3 distributors in different location
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.

Manufacturer to trace a device

World Hospital / CA.
Health Care others

Manuf. Name

GMDN
UMDN

Nomenclature & code

UDI Coding

GS1/HIBC code
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
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Implantable Device Information Flow

Central Data Pool

Manufacturer → Supply Chain → Hospital Data → Operation Theatre → Hospital accounting → FDA PV. Platform → Manufacturer

13
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.
Maf. And Distributor collecting data from FDA Platform
the result will show the system balance. “0” result is expectation by FDA.

\[ H \text{ (On FDA Platform)} - M - D = 0 \]
System accepts only HIBC and GS1 standards, others will be rejected.
Shanghai Chang Hai Hospital in 2006
3 Data Sources Supporting A Device Form for Patient Keeping
### Basic Information of One Device

Feedback from Hospital by scan a package **Bar Code**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>UDI code (Static &amp; <strong>Dynamic</strong> *)</td>
</tr>
<tr>
<td>2.</td>
<td>Name of Manufacturer</td>
</tr>
<tr>
<td>4.</td>
<td>Manufacture Site</td>
</tr>
<tr>
<td>5.</td>
<td>Name of Device</td>
</tr>
<tr>
<td>6.</td>
<td>Device Specification</td>
</tr>
<tr>
<td>7.</td>
<td>Device Expiration Date (*)</td>
</tr>
<tr>
<td>8.</td>
<td>Device Release Date</td>
</tr>
<tr>
<td>9.</td>
<td>Lot/batch/serial number *</td>
</tr>
<tr>
<td>10.</td>
<td>Quantity</td>
</tr>
<tr>
<td>11.</td>
<td>No. of Re. Certification</td>
</tr>
<tr>
<td>12.</td>
<td>Issue Date of Certification</td>
</tr>
<tr>
<td>13.</td>
<td><strong>Expiration Date of Certification</strong></td>
</tr>
<tr>
<td>14.</td>
<td>Contact Person</td>
</tr>
<tr>
<td>15.</td>
<td>Final Distributor</td>
</tr>
<tr>
<td>16.</td>
<td><strong>GMDN Code</strong></td>
</tr>
</tbody>
</table>
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
Add UDI information in the form of customs

海关会不差钱
Task of Ecom

Shipping NO.
Pallet No.
Carton No.
Package No.
Device UDI = HS code
Custom NO. = CQI NO.
Notice No. for gate clearance

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?
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*
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 models.

2009年上海浦东新区与南汇区合并
Shanghai combined Pudong New District with Minhang District in 2009

2009年11 19日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 19, 2009

2010年初上海浦东国际机场第一块3.59平方公里保税区正式运营
The first 3.59 square kilometers of Free Trade Zone was occupied and started operation in Shanghai Pudong International Airport in 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通关
The international medical delivery through airline can be conducted customs clearance at Pudong Airport which links Waigaoqiao Logistics Park

洋山港货物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，把综合保税区建设得更好。为促进上海经济发展方式转变，产业结构优化升级发挥作用更大作用。
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

Half of worldwide top 50 MD companies join the CMDIT project promoted by MDTA in Shanghai

www.mdta.org.cn
1. Hamonize 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. Minimus 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:
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