GS1 Coding in The UDI of Medical Device
Enhancing the Tracebility of High Risk Medical Device

Pilot Project Implementation in Shanghai China

YAN, Liang
Legal /International Affairs FDA Shanghai
CHINA SFDA
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CONTENT

- Global challenge in post market of medical device.
- The regulatory requirements for MD. supply chain control
- GS1 standard used in medical device tracing system
- The pilot project implement in China
Big Challenge for MD Industry and Competent Authority (CA)

- Device label description and records not meets the safety requirements of supervision when in recall.
- Tracing device in AE. often failure even US/EU international big company in China market.
- Needs a scheme of Device **UDI** to promote tracebility for medical device in post market vigilance system.
UDI is Not Regulated

- GHTF requires in principle a systematic traceability of products as part of the manufacturers post market surveillance activities.
- Manufacturers can chose what they want or what the different national markets need.
- Hospitals, distributors as well as the traders are using their own barcode and classification system,
- The way of a systematic post market surveillance is not regulated
**UDI - Unique Device Identification**

**Consideration Unique on:**

- Unique requirement must be considered on global scope
- Using distributors or hospital own coding is not meet safety principle of Medical Devices Regulation.
- GS1 standard has been adopted in worldwide supply chain environment which meets Unique requirement.
Global challenge in post market of medical device.

The regulatory requirements for MD. supply chain control

GS1 standard used in medical device tracing system

The pilot project implement in China
Establish a Worldwide Vigilance System Base on “Medical Device UDI”

- 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

M. Name

GMDN
UMDN

Nomenclature & code

UDI Coding

GS1 standard
Establish Principals for System Base on Regulatory Technology Support the Regulatory Requirement (1) Basis of System

1. Adopt global uniform coding system to reduce barrier: GS1
2. Minimum data set in the bar code and database of device tracing system.
3. Separate two section in the tracing system,
   – 1) Responded and controled by manufacturer for the data not been used in sales chain and
   – 2) Hospital for the data which has been used with patients.
Establish Principals for System Base on Regulatory Technology Support the Regulatory Requirement

(2) Responsibility

1) Manufacturer take the fully responsibility for their own products released on the market.

2) Only manufacturer initiates the bar code on the label, distributor and hospital not been permitted to relabel or initiated a bar code.

3) Manufacturer should control the distributors which have been recognized to sale their product. Distributor should report the tracing information to manufacturer in sales chain on any time if it is need for.

4) Hospital should use the laser scanner to automatically read the Device UDI data to reduce the mistake in the record.

5) Hospital opens the device information to the patient under the rule necessary.
Establish Principals for System Base on Regulatory Technology Support the Regulatory Requirement

(3) Data Environment

1. Establish a public device **Data Pool** to support the database maintenance in hospital.

2. Establish a data **Reporting Platform** as a bridge link the hospital and manufacturer and CA for tracing device used on patient.

3. Every manufacturer **site** needs **Own Manufacturer ID code on the device label**.
Manufacturers must implement a tracking system for certain devices whose failure is likely to have serious health consequences for users. FDA issues letters to manufacturers who make and/or distribute devices subject to this requirement.

After receiving notification, a manufacturer must write a standard operating procedure detailing how its product can be tracked through distribution, including audit procedures, in the event that the device must be removed from distribution and/or use.

Final distributors must also furnish the manufacturer with patient identification data and device information (lot number, batch number, and/or serial number) to ensure effective tracking of the device if necessary.
Implantable Device Information Flow

Central Data Pool

Manufacturer

Supply Chain

Hospital Data

FDA PV. Platform

Operation Theatre

Hospital accounting
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Coding Standard

1. System adopts **GS1 EAN-UCC128 standard** for all imported products and domestic products.

2. **HIBC standard** only permits for oversea manufacturer.

3. Manufacturer who has **China business license** should use **GS1 standard**.

4. Two standards **covers nearly 80%** implantable device in China market.

5. To permit Individual HIBC user to use EAN UCC 128 code on second code (production code) in transition period.

6. System adopts **GS1 EAN 13 code** for not implantable device.
Information in the Bar Code

1. Two bar code combined printing on the product label. To be arranged as up and down position or in one line on the product label.

2. 5 basic information should be in the Bar Code.

3. Main code is product code for identify which product:
   Manufacturer + Product and Specification + Package size

1. Second code is production code. Include device’s time information, use it for trace product in Quality System of the manufacturer.
   Expiration date / Manufacture date + Production lot/Serial number
Different Possible Combination of Two Code on the product label

- Main and Secondary code are: HIBC;
- Main and Secondary code are: EAN-UCC128;
- **Main**: EAN13 + **Secondary**: EAN-UCC128;
- Main: HIBC + Secondary code EAN-UCC128;
System accepts only GS1 and HIBC standards, others will be rejected in read.

Scanner recognizing area

GS1
EAN-UCC 128
HIBC
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Project Implementation

- To the end of 2005, starting this project after investigation, which focus on implantable high risk device.
- At the middle of 2006, establishing a coding standard scheme and solving special code reading technology.
- On Nov. 11 2006, SH-FDA worked together with SH-Hygiene Bureau published documents to promote the project implementing.
- At the end of 2007, more than 100 hospitals in Shanghai city tracing back implantable device with the UDI.
Two Documents Put on Public For Using UDI System to Trace Implantable Device

上海食药监局和卫生局联合发文规定

关于印发《上海市食品药品监督管理局、上海市卫生局关于进一步加强本市植入性医疗器械管理的意见》的通知

上海市食品药品监督管理局

上海市卫生局文件

沪食药监[2007]751号

关于做好植入性医疗器械追溯管理系统实施工作的通知

上海市食品药品监督管理局

上海市卫生局文件

沪食药监人（2007）190号

2008-10-28

2007-5-24
Data Platform of FDA

Finance Dept. → Devices Record

Department of Purchase

Hospital Database

Surgical Operation

Maintenance Data By Maf.

Sell From Maf.

Sell from Distributor.

Maf. Urgent Sell

Dis. Urgent Sell

2007-02-07

SH-FDA-MDR.
First User: Chang Hai Hospital
2006 Shanghai China
14 Basic information of one device in database links with product Bar Code

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<td>3.</td>
<td>Manufacture Site.</td>
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<td>4.</td>
<td>Name of Device *</td>
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<td>6.</td>
<td>Device Expiration Date *</td>
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<td>7.</td>
<td>Device Release Date</td>
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<td>8.</td>
<td>Lot/batch/serial number *</td>
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<td>9.</td>
<td>Quantity *</td>
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<td>Issue Date of Certification</td>
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<td>Contact Person</td>
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<td>Final Distributor</td>
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3 Data Sources Supporting A Device Form for Patient Keeping

Used Device Form of Patient

- Hospital Purchase Database
- HIS
- Read Lot / Batch / Series NO. In Secondary Code
Structure of Hospital Information System
Maf. And Distributor collecting data from FDA Platform
FDA check the balance result of data on the supervision platform

H (On FDA Platform) \( M - D = 0 \)

- Manufacturer collects data and report
- Hospital report data
- FDA platform

Report of MD UDI Implementation in Shanghai, China, GS1 Meeting, Tokyo, Japan.

2008-10-28
Thank You

REGULATION SIMPLYEST OPEN