UDI
Unique Device Identification

9. Augsburger Forum für Medizinprodukterecht
12. September 2013, Augsburg
UDI
Agenda

GHTF/IMDRF Framework
EU Activities
FDA Activities
Implications for Manufacturers
GHTF/IMDRF Framework
UDI - Rational, purpose and scope

Rational
A common, worldwide system for identification of medical devices should eliminate differences between jurisdictions and offer significant benefits to manufacturers, users, patients and regulatory authorities

Purpose
Improve patient safety by:
- Facilitating traceability of devices
- Enhancing the identification of devices in case of adverse events
- Assisting in the recalls and other field safety correction
- Reducing medical errors

Scope
All products placed on the market that fall within the definition of a medical device that appears within the GHTF document:
‘Information Document Concerning the Definition of the Term MEDICAL DEVICE’
GHTF/IMDRF Framework
UDI - History and players

2007  US Congress mandates FDA to develop UDI system

2008  GHTF* recognizes global relevance

2008 – 2011  GHTF ad-hoc WG for guidance preparation to ensure global harmonization

2010  EU Commission established EU UDI ad-hoc WG to prepare UDI specific text for the MDD recast

2012 - 2017  GHTF transformed to IMDRF**
UDI consulting groups to address implementation issues

*  Global Harmonisation Task Force (www.ghtf.org)

**  International Medical Device Regulators Forum (www.imdrf.org)
Voluntary group of medical device regulators from Australia, Brazil, Canada, China (observer), European Union, Japan, Russia (observer) and the United States
GHTF/IMDRF Framework
Guidance documents

UDI Guidance Documents

- Non-binding guidance
- Provides a framework for Regulatory Authorities that intend to develop their own UDI system
- Framework can be used at a local, national or global level
GHTF/IMDRF Framework
UDI system overview

UDI system

**UDI**
- **DI** (static data)
- **PI** (dynamic data)

**UDI Carrier**
- **AIDC** (machine readable)
- **HRI** (human readable)

**UDID**
- Database with static data elements
- UDI is access key

DI = Device Identifier
PI = Production Identifiers
AIDC = Automatic Identification and Data Capture
HRI = Human Readable Interpretation

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GHTF/IMDRF Framework

UDI

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The UDI is a series of numeric or alphanumeric characters

The UDI contains two parts: Device Identifier (DI) and Production Identifier (PI)

The DI should be globally unique and based on ISO standards

The PI consists of lot or serial number and expiration date
  → As they appear on the label

The manufacturer assigns the UDI to a device following the relevant coding standard (e.g. GS1, HIBCC, ICCBBA)

A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDIs → Logistic units are exempted

At a minimum, a new UDI is required whenever there is a change that could lead to misidentification of the device or ambiguity in its traceability.

Note: The word “unique” does not imply serialization of every medical device
GHTF/IMDRF Framework
UDI Carrier

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UDI Carrier is the AICD and HRI representation of the UDI and contains DI + PI

The marking of the medical device with its UDI shall be an additional labeling requirement

No particular AIDC technology required
  → Data carrier should be based on ISO standards and international recognized AIDC standards (such as GS1 and HIBCC)

UDI should be human-readable and encoded in AIDC format
  → AIDC format shall be favored in case of significant space constraints

In case of RFID; human-readable and bar code shall also be provided
  → RFID has to comply with open, commercially acceptable, industry standards (such as EPC) and be vendor neutral

UDI Carrier should be readable during normal use and throughout intended life of the medical device.
The UDI carrier shall be on the label of the medical device, its package or on the medical device itself, and on all higher levels of packaging.

The UDI carrier for low risk devices packed and labeled individually does not need to be on the primary pack, but rather on a higher level.

In case of multiple bar codes on the same package the UDI carrier shall be ‘readily identifiable’.

Devices that require reprocessing or sterilization between patient use should be Direct Part Marked (DPM) in addition to the UDI on the label.

For implants the UDI must be identifiable prior to implantation.

For Standalone Medical Device Software the UDI should be assigned at the system level.
UDI system

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GHTF/IMDRF Framework
UDI Database - Principles

- No product commercial confidential information shall be included
- The data should be publicly available and free of charge
- The manufacturer is responsible for initial submission and updates
  - Data for new UDI’s must be available before product is placed on the market
  - Update within 30 days when a change is made to an data element
- The presence of a device in the UDID doesn’t mean that the device is authorized in all jurisdictions
- UDID shall use HL7 Structured Product Labeling (SPL) standard for data exchange
- The core elements are the minimum elements to identify a device through distribution and use
  - Regional or national UDID’s may contain additional elements/attributes
- The UDID should allow for the linking of all the packing levels of the product
General agreements on Regulatory Authorities side

- The UDI system shall be implemented stepwise
- Starting with highest risk class first, lowest risk class last
  → According GHTF risk-classes (A, B, C, D)
- Between the steps time to review
  → Analyze achieved results, experiences, etc.
  → Make system adjustments if necessary
- Introduction shall allow sufficient implementation time for manufacturers to maintain compliance with quality system requirements
UDI Agenda

GHTF/IMDRF Framework

EU Activities

FDA Activities

Implications for Manufacturers
Commission Recommendation on a common framework for a unique device identification system of medical devices in the Union

Goals

- UDI should contribute to patient safety by facilitating vigilance, market surveillance and transparency
- UDI should ensure effective traceability of medical devices in the EU

Prerequisite

- UDI must be harmonized on international level

Scope

- UDI applies to medical devices, active implantable medical devices and *in vitro* diagnostic medical devices
EU Activities
Risk based approach

UDI implementation should follow a risk based approach.

- The UDI should vary according to the risk class of devices
- The UDI system should be implemented gradually, starting from higher risk class devices

<table>
<thead>
<tr>
<th>Risk class</th>
<th>Production Identifier (minimum)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Expiration and/or manufacturing date</td>
</tr>
<tr>
<td>Class IIa</td>
<td>Batch number</td>
</tr>
<tr>
<td>Class IIb</td>
<td>Batch number</td>
</tr>
<tr>
<td>Class III</td>
<td>Batch number or serial number</td>
</tr>
</tbody>
</table>

Different approaches:

**FDA:** Class I Devices do not need to include Production Identifiers

**GHTF:** The UDI Carrier for low risk devices does not need to be on its package but rather on a higher level of packaging
Obligations for manufactures

- Manufacturers should appropriately allocate a UDI (static and dynamic parts) to the medical devices they manufacture.
- They should provide the required data elements to be included in the UDI database.
- They should modify the labelling of their products in order to print the UDI code on the label or directly on the products (Direct part mark).
- They should keep electronic record of both device identifier (static information) and production identifier (dynamic information).
- They should keep electronic record of the economic operator, health institution or professional users to whom they have sold each specific product.
The UDI database will be part of the future EUDAMED database
Static information will be centralised at European level
Dynamic information will not be part of the UDI database
The use of the Extensible Markup Language (XML) as a common format for data exchange is promoted

From the Proposal for a EU Regulation on Medical Devices
Information should be accessible to the public
Changes of data elements have to be updated within one week
Accuracy of data has to be confirmed every 2 years

Data elements
Data elements mostly identical compared to GHTF proposal
EU Activities
Timeline (presumably)

Q4 2012
EC MD Regulation Proposal

2014
EU MD Regulation

2014/2015
Delegated Acts

Implementetation Time
(after Delegated Acts):
Class III 1 year
Class II 3 years
Class I 5 years

1.5 – 2 years Revision
Delegated Acts
Implementation

Q2 2013
EC UDI Recommandation

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GHTF/IMDRF Framework

EU Activities

FDA Activities

Implications for Manufacturers
Unique UDI applied to all levels of packaging, down to the lowest level (patient use/unit of use)
- Default location is the label
- Human readable and AIDC format
- No specific technology (technology neutral)
- Direct Part Marking (DPM) for
  - An implantable device (>30 days)
  - Intended to be used more than once
  - Intended to be sterilized before each use
  - Stand-alone software
- Some additional elements for the UDI Database
  - e.g. FDA premarket submission number, FDA listing number
If label includes a date (expiration, manufacture):

- Presented as Month Day, Year (JAN 1, 2012)
- All dates must include a day (JAN 2012 not allowed)
- The month shown as a three letter abbreviation in capital letters
  → e.g., JAN, FEB, MAR
- Day is an number from 1-31
- Year is a 4 digit number
- Effective 1 year after final rule publication

* ISO 8601 - *Data elements and interchange formats – Information interchange – Representation of dates and times*
A list of product codes for devices that FDA considers to be implantable, life-saving, and life-sustaining [...] is available in docket FDA–2011–N–0090 (Ref. 12).
UDI
Agenda

- GHTF/IMDRF Framework
- EU Activities
- FDA Activities
- Implications for Manufacturers

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Implications for manufacturers
UDI – General considerations

- Get membership with an issuing agency (e.g. GS1, HIBCC, ICCBBA)
- Assignment of identification numbers (e.g. GS1 GTIN, HIBC-LIC, ISBT product code) to all products
  - Which products are concerned (risk class)?
  - Which packaging levels are concerned?
  - How to manage identification numbers (e.g. storage in ERP)?
- Define data carrier and content
  - 1D or 2D Code (depending on space/packaging level)
  - Identification number, expiry date, batch number or serial number
- Change labels accordingly, if necessary
  - Space for AIDC and HRI?
  - Approval process?
- Evaluate print and scan systems
  - Upgrading/retrofitting may be necessary
- Provide data for the UDI data base
Implications for manufacturers
UDI – Print- and scan systems

- Is the used technology suitable for AIDC?
  - Printing technology (resolution, print quality)
  - Ink (validated ink only)
  - Packaging material (absorptive, translucent, preprinted on back side)
  - Line speed (adjustments necessary?)

- Quality of the inline print must be checked during production
  - Installation of suitable cameras/scanners
  - Insufficient prints have to be discharged

- Data transfer to printer and scanner (expiry date, batch number)
  - Manuel input, MES, ERP

- Retrofitting of packaging line (HW/SW), if necessary
  - Investment, installation, qualification, validation
Implications for manufacturers

UDI – UDI data base

- Which are the required data elements?
  → Additional country specific requirements?

- Are all data elements available in electronic form?

- Are all data elements available in the right format (e.g. cm vs. inch)?

- Set up an internal data base for UDID, if necessary
  → Data comes from different sources (e.g. ERP, isolated DB’s, paper files)

- Establish a system to ensure data quality
  → Change Control process if data changes
  → Define responsibilities

- Data format must be converted to HL7
Implications for manufacturers
UDI – Implementation

- UDI implementation is extremely complex
- Cross functional project teams are needed
  → Regulatory, production, engineering, IT, QM, labeling, controlling
- Many production lines will be affected at the same time
- Stepwise implementation (from high to low risk) is essential
- Training of staff is very important due to new process steps
- Negative impact on production speed and cost should be avoided

UDI is not rocket science but start now to cover all aspects in time
UDI will bring great benefits for:

- Patient safety
- Improved traceability, vigilance & market surveillance
- Integration of information on MD into medical records

But it is essential that:

- A pragmatic (risk-based, standard-based) approach is adopted
- Regional authorities co-operate to ensure a truly global and harmonized UDI approach
- Healthcare providers are fully resourced to respond
- All stakeholders (manufacturers, wholesalers, healthcare providers) start preparing for UDI now
Thank you very much for your attention!

Questions are welcome!

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