The upcoming EU MDR UDI requirements

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The global need for UDI -

UDI = Unique Device Identification

A globally harmonized approach on UDI will help in:

- Traceability of medical devices (MD)
- Identification of MD through distribution and use
- Identification of MD in adverse events
- Reduction of medical error
- General index of documenting and capture of data on medical devices

Large diversity of medical devices
Global Landscape – IMDRF guidance
IMDRF
International Medical Device Regulators Forum

Identified Stakeholders

FDA USA
TGA Australia
HC Canada
MHLW Japan
HSA Singapore

27 MS + EEA Europe
ANVISA Brazil
Taiwan

CFDA China
DOH South Africa
CDSCO India

SFDA Saudi Arabia
KFDA South Korea

UDI Guidance

- Unique Device Identification (UDI) of Medical Devices
- IMDRF UDI Working Group
- Date: 9 December 2013

- Avoids country specific requirements
- Development of UDI using globally accepted standards
- Application of the UDI on the label
- Submission of appropriate information to a UDID
Global Timeframes

Japan – Agency: GS1, HBC - Implementation: DI, PI to unit of Use Level
Spain – Agency: GS1 - Implementation: DI, PI to unit of Use Level
Turkey – Agency: GS1, HBC - Implementation: DI, PI to unit of Use Level
India – Agency: GS1, HBC - Implementation: DI, PI to unit of Use Level
USA – Agency: GS1, HBC, ISBT - Implementation: DI, PI
Argentina – Agency: GS1 - Implementation: DI, PI and Global Location Numbers, Track and Trace

Source: GHX Consulting, 2014
Implications of UDI systems

Brief Introduction

A UDI system implies both:

- **Labelling requirements**
  - Additional marking of the globally unique UDIs on the product label

- **Data submission requirements**
  - Submission of non-confidential information to a centralized UDI database (UDID) - Eudamed

- **Information Storage**
  - Keep track of UDI information through the supply chain
Purpose of EU UDI

Main goals:
- Improve incident reporting
- Facilitate efficient recalls and other field safety corrective actions (FSCA)
- Facilitate efficient post-market actions by national competent authorities
- Enabling queries in numerous data systems
- Reducing the likelihood of medical errors linked to misuse of the device

Secondary Goals
- Fight against counterfeiting
- Better distribution control
- Better stock management
- Improved communication between different stakeholders in the medical device industry
The UDI Format

• The UDI contains two parts:

  • **Device identifier**
    • Globally unique
    • Static information specific to the **manufacturer** and **device version**

  • **Production Identifier**
    • Specific to each product and can include: lot number, serial number, software version, expiration date, manufacturing date
    • Dynamic information identifying data related to the **unit of device production**

• A UDI is assigned to the device itself or its package
The UDI Carrier

= means to convey the UDI

- UDI should be represented in AIDC and HRI technology on the label of the device and/or higher levels of device packaging

- **AIDC** – Automatic Identification and Data Capture
  = A technology used to automatically capture data
  - e.g. bar codes, smart cards, biometrics, RFID
  - no particular AIDC method is required

- **HRI** – Human Readable Interpretation
  = legible interpretation of the data characters encoded in the UDI Carrier
The UDI Database

General Principles

• No confidential information should be made available
• The public should be able to access the data entered in the UDID
• Made available once the device is placed on the market
• Manufacturer is responsible for the initial submission

UDID Data Elements

• Contains mandatory and optional elements
• Some of the data elements include:
  • Manufacturer related information (name, address, contact address, etc.)
  • Product related information (size, storage conditions, single use, sterilized, critical warnings or contraindications etc.)
MDR Text on UDI

• Chapter III Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices

• Annex VI: Information to be submitted upon the registration of devices and economic operators in accordance with articles 29(4) and 31, core data elements to be provided to the UDI database together with the UDI-DI in accordance with articles 28 and 29, and the UDI system
MDR Text on UDI

• Additional requirements are described in various sections of the MDR as UDI traceability should be integrated in the entire lifecycle of the medical device

  e.g.
  • Article 29 – Summary of safety and performance
  • Article 55 – Certificate of free sale
  • Annex II – Technical Documentation
  • Annex IV – EU Declaration of Conformity
  • Annex XII – Certificate issued by a Notified Body
Unique Device Identification
USA vs. EU

Alexandra Tautan
USA vs. Europe

• Aim: Compatible UDI System on a global level (with Trade Partners)

• Similarities
  • Both want traceability on a global level for improved medical services

• Differences
  • Different regulatory frameworks are in place
General Requirements

FDA UDI Requirements
21 CFR 801.20 and 21 CFR 801.30

• UDI is required to appear on the label of all commercialized medical devices
• Information on the specific version or model needs to be submitted to FDA’s GUDID

EU UDI Requirements
Medical Device Regulation – Article 24, 24a, 24b, 25

• Production of a UDI that comprises the following
  • Device Identifier
  • Production Identifier
• Application of the UDI on the device label or package
• Storage of the UDI by the economic operators, the health institutions and the healthcare professionals
• Establishment of an electronic system on UDI (UDI database)
Major differences

- The European MDR introduces requirements on
  - Manufacturer, importer, distributor, economic operators, health institutions and even healthcare professionals
  - Storage of UDI requirements by economic operators
  - Additional core database elements
  - Usage of UDI in post-market surveillance reporting
  - Requirements for specific device types
  - Periodic accuracy check of the data by the economic operators
## Deadlines

- Risk based approach in both implementations

<table>
<thead>
<tr>
<th>FDA UDI requirement</th>
<th>Compliance Date</th>
<th>EU UDI Requirement</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class III</td>
<td>1 year after publication of the final rule 24&lt;sup&gt;th&lt;/sup&gt; of September, 2014</td>
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<td>1 year after application of the MDR</td>
</tr>
<tr>
<td>Implantable, life-supporting and life-sustaining devices (all classes)</td>
<td>2 years after publication of the final rule 24&lt;sup&gt;th&lt;/sup&gt; of September, 2015</td>
<td>Class Ila and Class Iib</td>
<td>3 years after application of the MDR</td>
</tr>
<tr>
<td>Class II</td>
<td>3 years after publication of the final rule 24&lt;sup&gt;th&lt;/sup&gt; of September, 2016</td>
<td>Class I devices</td>
<td>5 years after application of the MDR</td>
</tr>
<tr>
<td>Class I</td>
<td>5 years after publication of the final rule 24&lt;sup&gt;th&lt;/sup&gt; of September 2018</td>
<td>Reusable devices (bearing UDI carrier)</td>
<td>2 years after the data applicable for its device class</td>
</tr>
</tbody>
</table>
UDI Responsibilities
Responsibility of UDI

EU
- The manufacturer or its authorized representative is the only one responsible for assigning a UDI to the medical device and ensuring compliance to labeling and database submission requirements
- Clear obligations for manufacturers, importers, distributors and other stakeholders in the supply chain are defined

FDA
- Labeler is responsible for the UDI compliance
- Responsibility is not explicitly defined in UDI regulations
- Agreement between the parts to fulfill the UDI requirements for labeling and data submission
- Stakeholders in the supply chain are not mentioned
**Obligations of the Manufacturer**

**EU**
- Manufacturers shall comply with the obligations related to the UDI system referred to in Article 24 and with the registration obligations referred to in Article 24a, 24b and 25a
- Their quality management system shall address:
  - Control of UDI code assignment to all relevant devices ensuring consistency of information provided according to Article 24a and 24b
- The manufacturer shall assign the UDI to a device following the relevant coding standards
- Manufacturers who repackage and/or relabel devices, with their own label shall retain record of the Original Equipment Manufacturer’s (OEM) UDI

**FDA**
- No explicit requirements for the manufacturer
- The labeler of the device is responsible
Obligations of Distributors

EU
- Are required to verify that, where applicable, a Unique Device Identifier has been assigned by the manufacturer

FDA
- No explicit requirements for distributors in the UDI ruling
- 21 CFR 821.30 – Tracking requirements for distributors:
  Distributor shall provide the manufacturer (labeler) with tracking information
  - name and address
  - UDI information
  - Date received
  - Date delivered
  - Physician delivered to and/or using the device
  - Person the device was received from
  - date of incidents, product returned, recalled
Obligations of Importers

EU

- Are obliged to verify that, where applicable, a Unique Device Identifier has been assigned by the manufacturer in accordance with Article 24

• FDA

- No requirements
UDI Labeling
Labelling Requirements

• The content of the UDI will be the same in Europe as in the US
  • EU is more specific on the labeling requirements
  • FDA gives more general guidance
• Reusable devices should be directly marked with UDI information in both frameworks
• The UDI carrier should contain both Human Readable Text (HRI) and Automatic Identification and Data Capture Technology
• Specific data format in the USA: yyyy-mm-dd
The UDI shall contain two parts:

- **UDI-DI**
  - a device identifier specific to the manufacturer
  - unique at all levels of device packaging

- **UDI-PI** – a production identifier that identifies the produced device’s unit and if applicable the packaged device
  - if a lot number, serial number, software identification or expiration date appears on the label, it shall be part of the UDI;
  - if also a manufacturing date is on the label, it does not need to be part of the PI;
  - if only a manufacturing date is present – it should be part of the PI

Higher levels of packaging shall have their own UDI

Shipping containers shall be exempt

- Is a contained where the traceability is controlled by a process specified to logistics systems

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**FDA**

- **DI** – mandatory, fixed portion that identifies the labeler and the specific version or model of a device. It is issued by an FDA Accredited Issuing Agency (according to ISO standards 15459-2, 15459-4, 15459-6)

- **PI** – conditional, variable portion that identifies one or more of the following when included on the label of a specific device
  - Lot or batch number
  - Serial number
  - Expiration date
  - Manufacturing date
  - Distinct identification code for a human cell, tissue or cellular and tissue-based product regulated as a device

Higher levels of packaging should also bear a UDI

Shipping containers are exempt

- A container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another
The UDI carrier (AIDC and HRI) shall be placed on the label or on the device itself and on all higher levels of packaging (excludes shipping containers).

In case of significant space constraints on the unit of use package, the UDI carrier may be placed on the next higher package level.

For single use devices of class I and class IIa, the UDI carrier shall not be required to appear on the package but it shall appear on a higher level of packaging.

For devices exclusively intended for retail Point of Sale the PI in AIDC shall not be required to appear on the package.

UDI carrier shall be readily identifiable from other AIDC technology.

If space constraints, only AIDC shall be required.

If the device is intended to be used outside healthcare facilities, the HRI shall be present.

RFID must be accompanied by linear or 2D barcode.

Reusable devices – shall bear a UDI on themselves in a permanent fashion.

Exceptions: direct marking interferes with the safety or performance of the device, it is not technologically feasible to mark it.

UDI carrier shall be readable for the entire life of the device.

A finished device made up of multiple parts that must be assembled before use may bear the UDI Carrier only on one part.
UDI Database
Several other functionalities besides UDI

- Users: member states, notified bodies, economic operators, sponsors
- Manufacturer is obliged to make sure all information is correctly transferred in the UDI database for the medical device and its packaging
- After two weeks after placing the device on the market, importers are obliged to verify that the manufacturer or authorized representative has uploaded the data into Eudamed
- The accuracy of the data will be confirmed one year after registration and then every two years

Developed for UDI purposes only

- Users: labeler and FDA
- The labeler is responsible for the initial submission, afterwards only FDA staff can modify the information
**UDI Database Elements**

**EU**
- 22 Core data elements
- Number of fields not yet specified as this part of the Eudamed database is not yet developed
- Differences from the USA implementation – additional data requirements
  - Single Registration Number
  - If applicable, name and address of authorized representative
  - Medical Device Nomenclature Code (not confirmed that this is GMDN)
  - Labelled with specific substances (carcinogenic, mutagenic etc. according to annex I, section 7.4.5)
  - URL for additional information
  - If applicable, critical warnings and contraindications
  - Status of the device on the market (choice box, no longer placed on the market, recalled, FSCA initiated)

**FDA**
- 64 fields: optional, required, conditionally required
- Specific information requirements not applicable to the EU:
  - DUNS number required
  - Issuing agency
  - FDA specific information
  - Device Status
    - Human cell, tissue or cellular or tissue-based product
    - Kit
    - Combination product
DI Issuing Agencies
System for Assignment of UDI

EU

- Entity is an organization with legal personality
- Conforms to relevant international standards
- Entity undertake
  - To operate the assignment of UDI for at least 10 years after its designation
  - Make available information on its system to the Commission and to the Member States
  - Remain in compliance
  - UDI carriers should be universally readable
- Until the commission has designated assigning entities, the following are considered:
  - GS1
  - HIBCC
  - ICCBA

FDA

- Issuing Agency = organization accredited by FDA to operate a system for the issuance of UDIs.
  - Labeler assigns a UDI to a device -> participate in a system administered by an accredited issuing agency
  - Three FDA accredited issuing agencies are available
    - GS1 – the most popular – DI = GTIN
    - HIBCC
    - ICCBBA
Specific Device Requirements
Configurable Devices

EU

• Configurable device = device consisting of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices themselves

  • UDI shall be assigned to the entirety of the device – Configurable device UDI

  • The configurable device shall be allocated to groups of configurations = collection of possible configuration

  • A Configurable device UDI-PI shall be assigned to each individual Configuration

  • Carrier will be placed on the assembly least likely to be changed during the lifetime of the device

  • Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI

FDA

- No explicit requirements
**Medical Device Software**

**EU**

- UDI assigned to the system level of the software
- A new UDI-DI is required when the following change:
  - Performance and effectiveness
  - Safety or the intended use of the Software
  - Interpretation of data
- A new UDI-PI only is required when:
  - Minor software revisions (e.g. bug fixes, security patches or operating efficiency)
- Only software commercially available on their own will require a UDI
- Software identification shall be considered the UDI-PI
- UDI placement
  - When delivered on a physical medium – each package level shall bear AIDC and HRI
  - UDI shall be provided on a readily available screen
  - Software lacking a user interface – will provide the UDI through an API
  - Only HRI required on electronic displays

**FDA**

- Stand-alone software – must provide a UDI through either or both of the following:
  - Software start-up – readable plain-text statement
  - Menu command (e.g. “About”,..) – readable plain-text statement
- Stand-alone software distributed in package form:
  - Device label and device package – bear UDI in plain-text and AIDC formats
- Stand-alone software distributed in both packaged and not packaged form can have the same DI
- Stand-alone software – not packaged – bears version number and production identifier
- No special provisions for software incorporated in a medical device
Systems and Procedure Packs / Convenience Kits

**EU**

**Systems and Procedure Packs**
- Identifiable with a UDI (DI+PI)
- Device contents or system or procedure packs shall bear a UDI Carrier on their packaging or on the device itself
- UDI carrier shall be affixed to the outside of the packaging

**FDA**

**Convenience**
- UDI required on the Kit’s label
- Individual devices inside the kit do not require a UDI
- If a device in a kit is sold separately (maybe as a replacement) then it would require a UDI on the base package level
Storage Requirements
### Data Storage Requirements

<table>
<thead>
<tr>
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<th>FDA</th>
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</table>
| Economic operators store and keep by digital means the UDI of supplied devices that:  
  - Are class III implantable devices  
  - Specific devices determined by the Commission  
| - No explicit requirements in UDI ruling |
| Health Institutions shall store and keep by electronic means the UDI of devices they have supplied or have been supplied to them that:  
  - Are class III implantable devices  
  - Other device types, storage is encouraged  
|  |
| Health care professionals are encouraged and may be required to store the UDI of devices they have been supplied with |  |
Post Market Surveillance
Post Market Surveillance

EU

- Reporting of serious incidents using UDI
- Field Safety corrective actions using UDI
  - Shall allow the correct identification of the device or devices involved, including the UDI, and of the manufacturer, including the SRN, that has undertaken the field safety corrective action

FDA

- No explicit requirements in UDI ruling
Technical Documentation
Technical Documentation

EU

• Basic UDI identifier shall appear on the Declaration of Conformity

• Keep up-to-date a list of all applied UDI as part of the technical documentation

• Summary of Safety and Clinical performance for class III devices (from Eudamed) includes the basic UDI-DI

• Device Description – includes the Basic UDI device identifier

FDA

• Keep DHF up to date with respect to DI information
Conclusions
Major differences

- The European MDR introduces requirements on
  - Manufacturer, importer, distributor, economic operators, health institutions and even healthcare professionals
  - Storage of UDI requirements by economic operators
  - Additional core database elements
  - Usage of UDI in post-market surveillance reporting
  - Requirements for specific device types
  - Periodic accuracy check of the data by the economic operators
UDI through the supply chain
Stakeholder Identification

• The identification of the medical devices through the different parts of the supply chain requires several elements and procedures to be put in place. A key element for communication would be the Basic UDI-DI. The Basic UDI-DI is used as input for several processes of distribution and documentation that concerns medical devices.

• Moreover, competent authorities should also be able to track medical devices based on UDI information.

• Patients should also be able to use the Basic UDI-DI to check relevant information in EUDAMED database.
UDI System Characteristics

• For facilitating identification and traceability, the UDI system should allow the stakeholders to:

  • **Use the same language**
    • High variety of medical devices available on the market & many manufacturers competing on the same target group -> unified language for tracking and identification in the medical device industry
      • Common terminology: definition of Annex VI, Part C
      • Imposed Nomenclature system: GMDN?

  • **Use the same ‘display’**
    • Such that *patients* can identify tracking information:
      • UDI placed on the label and package of the device
      • Specific labeling requirements for different types of devices: location, content and method of capturing UDI information
UDI System Characteristics

- **Have the same way of working**
  - Some of the documentation that needs to be updated with UDI information includes:
    - Labeling
    - Declaration of Conformity
    - Technical File Content – Device Description
    - Post-market surveillance reports
    - Vigilance reporting
    - Field Safety Corrective Actions
    - Free Sale Certificate
  - Including UDI information in the above documents implies changing the QMS procedures to incorporate the UDI requirements
  - Data submission to EUDAMED must be ensured
  - Requirement for storage of UDI information by electronic means by the economic operators, health institutions and healthcare professionals in case of high risk devices.
  - The traceability of medical devices between distributors/importers and manufacturers/authorized representatives should be ensured
  - All economic operators should be able to identify to the competent authorities, all economic operators, health institutions or healthcare professional to which they have directly supplied a medical device
UDI System Characteristics

**Provide Transparency**
- Basic information on the safety and performance of the medical device should be made available to the general public
- *EUDAMED provides this functionality, among others*

**Avoid Duplication of UDIs**
- Each medical device is traceable to a unique number.
- Commission will designate one or several entities as UDI issuing agency
- Currently considered: GS1, HIBCC, ICCBBA
Thank you for your attention

More guidance at www.qservegroup.com
Or ask at gert.bos@qservegroup.com