International Medical Device Regulator Forum (IMDRF)

Global UDI Harmonization

April 24, 2018
9:00-9:45 am

Terrie L. Reed MS, FDA CDRH
Establish a UDI System

- Develop a standardized system to create the UDI
- Place UDI on label and (sometimes) the device
- Create and maintain the UDI Database
- Adoption and Implementation
What is a System?

System*: Set of integrated, interacting components with a common goal or purpose

System life Cycle: the course a system follows - recognition of the need for the system, through system development and installation, system growth, maturity, decline and obsolescence, eventual replacement or refurbishing

Rationale of a UDI System

- Creates a single, globally harmonized system for positive identification of medical devices (IMDRF)
- Based on standards, core data elements and standard methods of data exchange
- Relies on individual jurisdictions to build UDI reference databases (UDIDs) capable of linking globally through the device identifier of UDI
- Requires engagement by **ALL** stakeholders across the device ecosystem to achieve its objectives
GHTF/IMDRF & UDI System

2007/2008
- FDAAA Mandate
- GHTF UDI Workgroup

2011/2012
- FDASIA update
- GHTF to IMDRF (2011)

2013
- US FDA UDI Regulation
- IMDRF UDI Final Guidance

2017
- EU MDR published
- IMDRF UDI Application Guide NWI

2018
- GUDID >1.6 million records
- IMDRF UDI Application Guide Draft

April 24-25, 2018
Renaissance Baltimore Harborplace Hotel
Baltimore, Maryland
Global Harmonization Task Force (GHTF)
UDI Guidance (IMDRF/WG UDI/N7Final:2013)

• Framework for those regulatory authorities that intend to develop their UDI Systems that achieves a globally harmonized approach to the UDI
• Established fundamental concepts of a globally harmonized UDI System
• Outlined benefits for manufacturers, supply chain, patient safety, and post market surveillance
• Defined foundational Unique Device Identification Database (UDID) data elements
• Provided key principles for development of UDIDs
• Initial insights for rules in applying UDI to specific device types
IMDRF Application Guide Work Item

• Proposed by GMTA
• Approved by IMDRF Management Committee
  • Purpose: To promote a globally harmonized approach to the application of a UDI system in support of the IMDRF UDI Guidance Document (IMDRF/WG UDI/N7Final:2013)
  • Continue efforts towards global convergence on UDI, while providing a learning and training opportunity for those IMDRF jurisdictions that have not yet commenced work on UDI implementation
# IMDRF Application Guide Workgroup

## Participants

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<th>Australia</th>
<th>Brazil</th>
<th>Canada</th>
<th>China</th>
<th>EU</th>
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<td>Japan</td>
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- **UDI Regulatory Work**
- **WG Regulatory Member**
- **Manufacturer Rep**
- **Observer**
IMDRF Application Guide Workgroup

Operating principles:

• Commitment to UDI as a global standard
• Build upon and enhance the IMDRF/WG UDI/N7Final:2013 guidance
• Recognize the shared responsibility of UDI system success across device ecosystem entities
• Learn from and include best practices gained from UDI implementation experience
IMDRF UDI Application Guide Topics

- Fundamental elements of a harmonized UDI system
- Roles and responsibilities for establishing and maintaining a UDI
- Representation of UDI – format and structure
- Considerations related to placement of UDI on all packaging levels, on package labelling and on the device itself
- Capture of UDI in forms and integration in databases
- General principles of a good UDI-Database design
- General consideration to facilitate effective transition to UDI application
- Best practices/lessons learned and example use cases
- Data elements comparisons across jurisdictions
Expected IMDRF UDI Application Guide Timeline

• First F2F meeting took place in Brussels on Feby 12-15, 2018
• Expected deliverables:
  • Endorsement of draft for public consultation by the IMDRF Management Committee at the June or September 2018 teleconference
  • Public Comment period
  • Endorsement of the final draft by the IMDRF Management Committee either at the December 2018 teleconference or March 2018 F2F meeting
UDI alignment with other IMDRF Documents

- Principles of International System of Registries Linked to Other Data Sources and Tools (IMDRF/REGISTRY WG/N33 FINAL:2016)
- Methodological Principles in the Use of International Medical Device Registry Data (IMDRF/Registry WG/N42FINAL:2017)
- Tools for assessing the Usability of Registries in support of Regulatory Decision Making (IMDRF/Registry WG/N46 FINAL:2018)
- Data Exchange Guidelines - Common Data Elements for Medical Device Identification (IMDRF RPS WG/N45FINAL:2017)
Status of Jurisdiction Activities on UDI

Brazil – activities to raise awareness, conduct surveys and draft regulations

China – Draft UDI Regulation published for comment March 2018

South Korea – roll out of UDI barcode labelling obligations starting in 2019 for Class IV devices and ending in 2022 for Class I devices

India - Medical Device Rule, UDI composed by DI and PI must be applicable to all licensed device from Jan. 1st, 2022

Saudi Arabia – UDI initiative for identification and traceability; creating Saudi UDI database

Taiwan – voluntary UDI guidance issued and implemented in Oct. 2015; Set up UDI database as a platform of information exchange in 2017. Rollout around 2018-2020

Turkey – UTS Product Track & Trace System rolled out in June 2017

UK – Scan4Safety demonstration projects
Shared Responsibility

Go beyond compliance with UDI regulation

Reduce gap between what UDI users need and what manufacturers/third parties and regulatory authorities produce.

- Improve the global scannability of UDI at point of care
- Improve the value of each UDID as a public good by reducing access barriers and linking to other UDID’s using the UDI-DI
- Improve device identification data submitted to support local and global regulatory decisions made using real world evidence
Learning UDI System

To improve patient safety

UDIDs

Manufacturer (Labeler)

Electronic Health Records

Device Recalls

Incident Reports

Adverse Event Reporting

Registries

Payment Systems

Item Masters

UDIs

To improve patient safety

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