IMDRF UDI Application Guide Overview

GS1 Global Healthcare Conference

Bangkok, Thailand

October 27, 2018

JACKIE RAE ELKIN - MEDTRONIC GLOBAL REGULATORY AFFAIRS

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INDUSTRY INTERACTION WITH IMDRF

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IMDRF International Medical Device Regulators Forum

IMDRF is a voluntary group of **medical device regulators from around the world who have come together to** build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) and aims **to accelerate international medical device regulatory harmonization and convergence**.

INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM (IMDRF) UDI WORK GROUP

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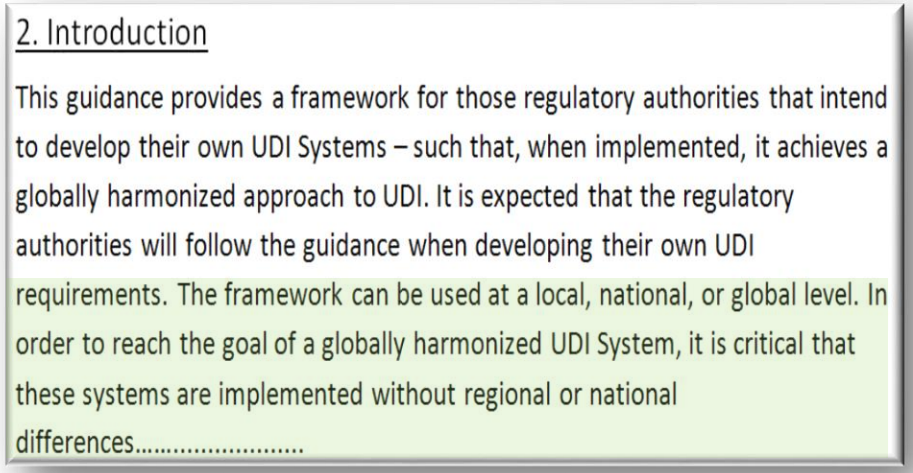


2. Introduction

This guidance provides a framework for those regulatory authorities that intend to develop their own UDI Systems – such that, when implemented, it achieves a globally harmonized approach to UDI. It is expected that the regulatory authorities will follow the guidance when developing their own UDI requirements. The framework can be used at a local, national, or global level. In order to reach the goal of a globally harmonized UDI System, it is critical that these systems are implemented without regional or national differences.....

UDI WG Established under Global Harmonization Task Force (GHTF) October, 2008.

IMDRF Guidance
UDI for Medical Devices
Final Version,
December 9, 2013
(IMDRF/WG UDI/N7Final:2013)

http://www.imdrf.org/documents/documents.asp

Global Medical Technology Alliance

Innovating for a Healthier World

GMTA is the Global Medical Technology Alliance. **Its members are national or regional medical technology associations**, which represent innovative **companies that currently develop and manufacture 85 percent of the world's medical devices**, diagnostics and equipment. It **provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs**. Medical technologies save, support, and improve lives every day around the world.

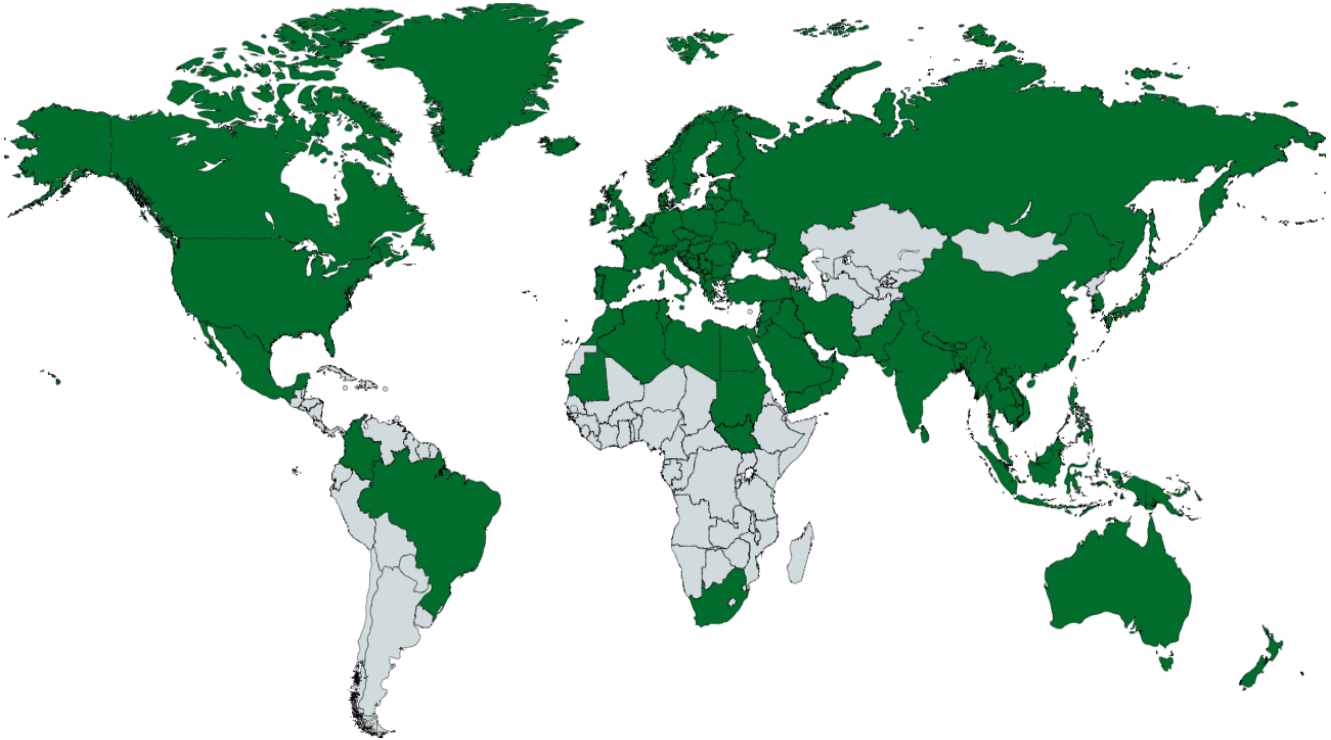
Global Medical Technology Alliance
Innovating for a Healthier World

- Origins date to **1990s as informal network**

- **Formally established in 2010 with Secretariat and website in Geneva**; legally constituted in Switzerland as an “association” in 2013; WHO recognized NGO in 2015

- Membership open to **Medical Technology Associations (not companies)**:
  - Willing to accept GMTA governance rules
  - With functioning code of ethical business practices

25 MEMBER ASSOCIATIONS AROUND THE WORLD



GMTA ASSOCIATION MEMBERSHIP

Advanced Medical Technology Association - AdvaMed
Asia-Pacific Medical Technology Association -APACMed
Assoc. Research Based Medical Technology Mfg. in Turkey – ARTED
Brazilian Association of Imported Medical Technology – Abimed
Bundesverband Medizintechnologie – BvMED
Câmara Brazileira de Diagnóstico Laboratorial – CBDL
Canada's Medical Technology Companies – MEDEC
Chinese Medical Devices Industry Association – CAMDI
Medical Technology Association of Europe – Medtech Europe
Association of British HealthTech Industries - ABHI
International Medical Device Manufacturers Association - IMEDA
Irish Medical Devices Association – IMDA

Irish Medical and Surgical Trade Association - IMSTA
IVD Australia Limited – IVD Australia
The Japan Federation of Medical Devices Associations - JFMDA
Korea Medical Device Industry Association -KMDIA
Medical Imaging & Technology Alliance – MITA
Medical Technology Industry of Denmark - MEDICOINDUSTRIEN
Medical Technology Association of Australia - MTAA
Middle East & N. Africa Medical Technology Association - Mecomed
Medical Technology Association of New Zealand – MTANZ
Mexican Association of Innovative Medical Devices - AMID
South African Medical Device Industry Association - SAMED
ASEDIM

“UDI APPLICATION GUIDE”

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IMI ON

Focus is on Implementation Information Does Not Change 2013 Guidance

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New Work Item Proposal (NWIP)
For Management Committee consideration

Proposed Title of the Project	**IMDRF Harmonized Unique Device Identification (UDI) Application Guide**
Initiator	Global Medical Technology Alliance (GMTA)
Purpose and Rationale (including a reference to one or more of the goals or objectives of the IMDRF)	**Purpose** To promote a globally harmonized approach to the application of a UDI system in support of the IMDRF UDI Guidance Document (IMDRF/WG/N7Final:2013)

- New Work Item Proposal (NWIP) for Harmonized UDI Application Guide **presented to IMDRF Management Committee (MC) - March 2017**
- IMDRF MC instructed **GMTA to prepare first draft of IMDRF UDI Application Guide.** Draft submitted to IMDRF - July 7, 2017
- IMDRF MC **Approved** NWIP (w/ revisions), **"Harmonized Unique Device Identifier Application Guide." -** September 2017

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UDI WORK GROUP MEMBERSHIP

Chaired by the EU Commission – Salvatore Scalzo

IMDRF UDI Application Guide Workgroup Members				
Australia	**Brazil**	Canada	**China**	**EU**
Japan	Russian Federation	Singapore	**South Korea**	**US**
GMTA	DITTA	WHO		

- UDI Regulatory Activity
- No Current Regulatory Activity
- Manufacturer
- Observer

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PURPOSE AND SCOPE

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)**

- **Extension of original IMDRF UDI Guidance**
- Provide details and specifications **necessary to enable a harmonized approach to UDI**
- **Builds on work** carried out at national levels
- **Not redefining content or requirements** of original IMDRF UDI Guidance of 2013

DOCUMENTS PRODUCED BY WG

The WG Produced 3 Draft Documents:

- A Main **UDI Application Guide**
- An document **mapping the use/specifications of UDI data elements in different jurisdictions** (based on voluntary contributions submitted by jurisdictions that have started to implement a UDI system)
- An information document related to the **use of UDI in electronic health sources**

In June 2018, the IMDRF Management Committee Endorsed all Three Documents for a 90-day Public Consultation.

The WG Received > 500 Comments

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KEY SECTIONS OF DRAFT UDI APPLICATION GUIDE (1)

- Fundamental Elements of a Harmonized UDI System
- Develop a Standardized System of Unique Device Identifiers (UDIs)
- Guiding Principles for UDI System Design and Operation
- Establishing Responsibility for Creating and Maintaining a UDI System

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KEY SECTIONS OF DRAFT UDI APPLICATION GUIDE (2)

- Content and Structure of a UDI
- Representation of UDI in Human Readable Interpretation and Auto Identification Data Capture (AIDC) Formats on the Package Label and in Some Cases, on the Device Itself
- The Unique Device Identification Database (UDID)
- General Considerations to Facilitate an Effective transition to UDI Application
- Special Device Types

UDI IN 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)

IMDRF UDI WORK GROUP SCHEDULE

- **Kick-off Work Group: December 2017**
- **UDI Workshop**: February 2018 (Brussels)
- Submission of draft guide to Management Committee **- Approval for public consultation: July 2018**
- Consultation period 90 days – **Comments Due: October 12, 2018**
- F2F Work Group Comments Review Session: **October 15 – 19, 2018**
- **Final submission to Management Committee: Jan – February 2019**
- **Will Seek Management Committee Approval – March 2019**

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THE WORLD'S HEALTHCARE
CHALLENGES ALONE.
LET'S TAKE HEALTHCARE FURTHER, TOGETHER.

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THANK YOU FOR YOUR ATTENTION!

Jackie Rae Elkin

Global Process Owner - Standard Product Identification | Corporate Regulatory Operations

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710 Medtronic Parkway, LS330 | Minneapolis, MN, 55432 | USA

Office: 1.763.505.2575 | Mobile: 1.612.801.6615 | Fax: 1.763.505.8205

jackie.elkin@medtronic.com

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