Johnson & Johnson MEDICAL DEVICES COMPANIES

IMDRF Update

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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."

www.imdrf.com

IMDRF Structure

Management Committee:

- Australia
- Brazil
- Canada
- China
- EU
- Japan
- Russian Federation
- Singapore
- USA
- South Korea

Official Observers:

- World Health Organization (WHO)
- Asia Pacific Economic Cooperation Regulatory Harmonization Steering Committee (APEC RHSC)

Invited Observers:

- TBD

Affiliate Organizations:

- Asian Harmonization Working Party (AHWP)
- Pan American Health Organization (PAHO)

Industry:

- Global Medical Technology Alliance (GMTA)
- Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Ass'n (DITTA)

2018 Management Committee Chair: China

Current IMDRF Working Groups

Working Group	Management Committee Lead
Adverse Event Terminology and Coding	Japan
Good Regulatory Review Practices	US
Regulated Products Submissions (RPS)	Canada
Unique Device Identification (UDI) Application Guide	EU
Personalized Medical Devices	Australia
Clinical Evidence	China
Standards - Improving the quality of international medical device standards for regulatory use	US

NEW Items Spring 2018

Summary of Working Group Activities in 2018

Working Group	Activity
Adverse Event Terminology and Coding	Continuing to work on IMDRF adverse event terminology (Annexes E & F)
Good Regulatory Review Practices	**Document Approved**: *Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making* (March 2018) **Draft in Process**: *Labeling Principles for Medical Devices and IVD Medical Devices* (to be published shortly for comment) **Consultation**: *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices* (Closed April 18th, 2018)
Regulated Products Submissions (RPS)	**Document Approved**: *In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)* (March 2018) **Document Approved**: *Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)* (March 2018)
Unique Device Identification (UDI) Application Guide	**Draft in Process**: Application Guide Document (draft to be published shortly for comment)
Personalized Medical Devices	**Consultation Activity**: *Definitions for Personalized Medical Devices* (Closed May 24th, 2018)
Clinical Evidence	Working Group Formed
Standards - Improving the quality of international medical device standards for regulatory use	**Consultation Activity**: *Optimizing Standards for Regulatory Use* (Closed May 24th, 2018)

Working Group: Clinical Evidence

NEW Work Group Approved Spring 2018

Key Focus Area

Develop document that

- Defines Decision-Making Principles for whether a Medical Device Clinical Trial is should be Carried Out, and
- Provides guidelines for the Acceptance of Overseas Medical Device Clinical Trial Data

Activities & Next Steps

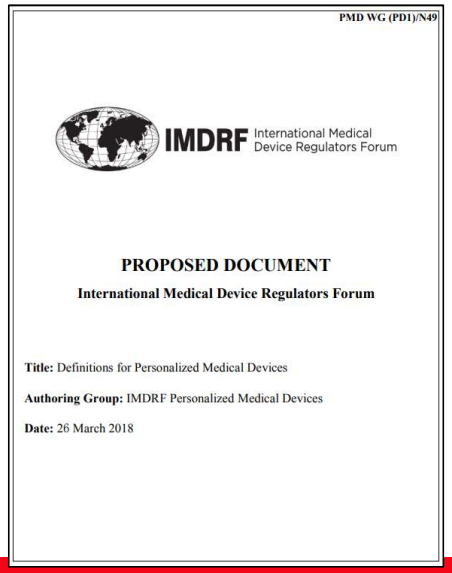
- Working group formed & kick off meeting scheduled
- Targeting March 2019 for draft document presentation to Mgmt Committee

Working Group: Personalized Devices

NEW Work Group Approved Spring 2018

Key Focus Area

– Develop guidance that establishes definitions and regulatory pathways for Regulatory Authorities to consider in the regulation of medical devices that are intended for individual patients


PMD WG (PD1)/N49

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PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Definitions for Personalized Medical Devices

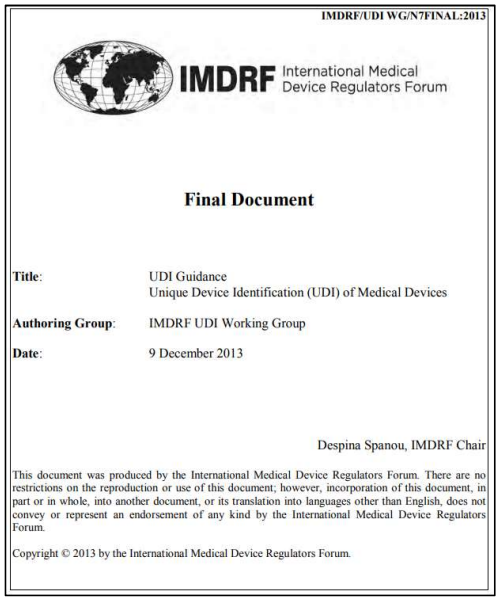
Authoring Group: IMDRF Personalized Medical Devices

Date: 26 March 2018

Activities & Next Steps

- Developed Draft Document "Definitions for personalized (patient-specific, Customized and Custom-made) Medical Devices" (consultation closed May 2018)
- Subsequent document intended to describe regulatory pathways for personalized devices

Working Group: Unique Device Identification (UDI) Application Guide



IMDRF/UDI WG/N7FINAL:2013

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Final Document

Title: UDI Guidance
Unique Device Identification (UDI) of Medical Devices

Authoring Group: IMDRF UDI Working Group

Date: 9 December 2013

Despina Spanou, IMDRF Chair

Key Focus Area

- Build on the principles outlined in the IMDRF UDI Guidance (published in 2013) to provide more granular details on UDI implementation
- Partnership between Mgmt Committee Members and industry UDI experts

Activity/Next Steps

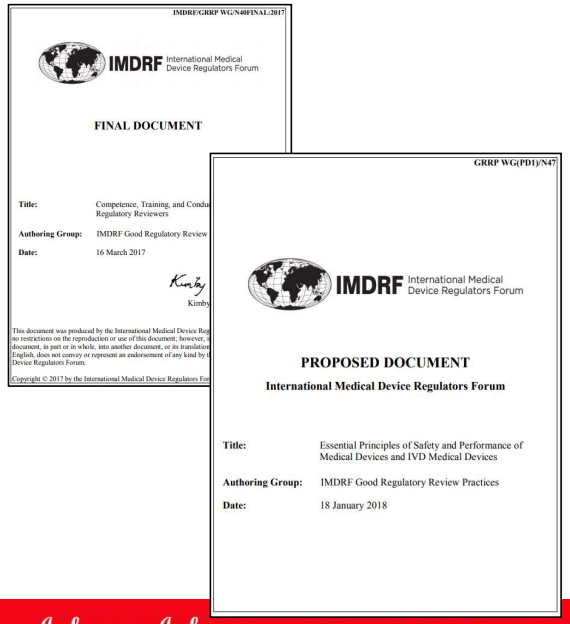
- Developing Technical Document as an Application Guide for UDI – provide guidance (definition, instruction, context, etc.) needed for a globally harmonized approach to the application of a UDI system.

Working Group: Good Regulatory Review Practices

Key Focus Area

– Develop guidance that establishes good regulatory review practices for Regulatory Authorities

➢Intent is promote global harmonization in the premarket review process


IMDRF/GRRP WG/N40FINAL:2017

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Competence, Training, and Conduc Regulatory Reviewers

Authoring Group: IMDRF Good Regulatory Review

Date: 16 March 2017

Kimby

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GRRP WG(PD1)/N47

IMDRF International Medical Device Regulators Forum

PROPOSED DOCUMENT

International Medical Device Regulators Forum

Title: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

Authoring Group: IMDRF Good Regulatory Review Practices

Date: 18 January 2018

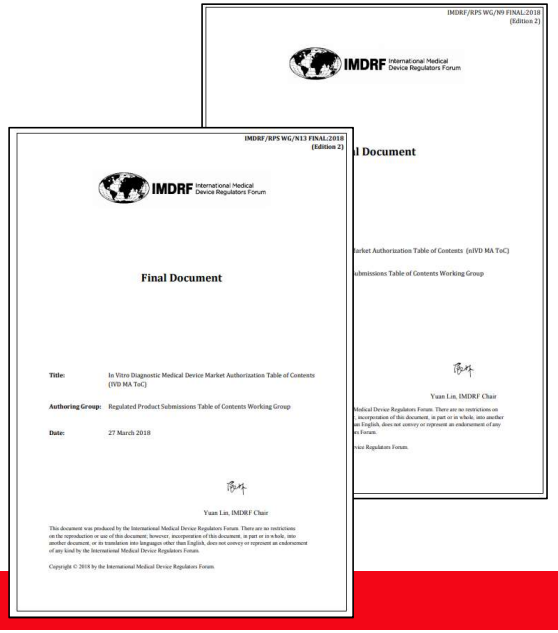
Activity/Next Steps

- Developed Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices
- Developing Principles of Labeling for Medical Devices and IVs

Working Group: Regulated Products Submissions (RPS)

Key Focus Areas

- Ultimate goal is a standard that supports the electronic transmission of regulatory submissions
- First step is defining a common 'Table of Contents' (ToC) for medical device submissions

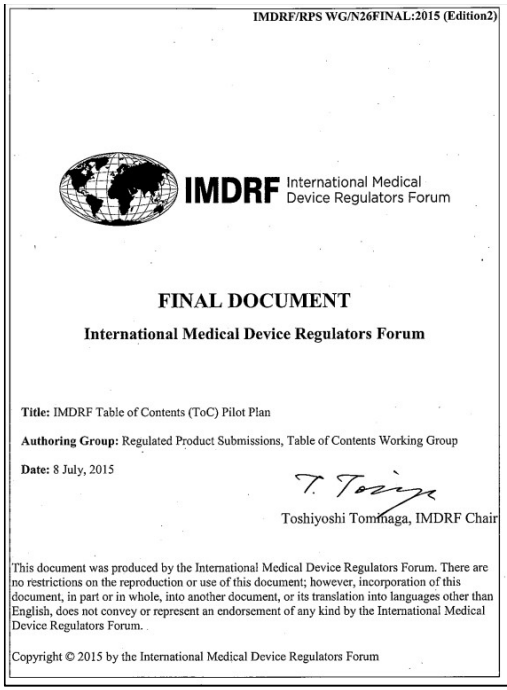


Activity/Next Steps

- Final ToC Documents published in March 2018
  - Implementation of ToC as a voluntary option is expected within the foreseeable future for multiple jurisdictions
- RPS testing continues

Table of Contents (ToC) Pilot

- Initiated October 2015, closed December 2017
- Applications received and reviewed by region:
  - Australia: 1
  - Brazil: 7
  - Canada: 2
  - China: 4
  - EU: 1
  - USA: 2
- Health Canada Regional Pilot received a Total of 56 applications (18 Class IV, 38 Class III)
- Overall Pilot demonstrated successful use of the ToCs, with Reviewers liking the ToC format and issues encountered to date considered minor.



IMDRF/RPS WG/N26FINAL:2015 (Edition2)

IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: IMDRF Table of Contents (ToC) Pilot Plan

Authoring Group: Regulated Product Submissions, Table of Contents Working Group

Date: 8 July, 2015

T. Tozin

Toshiyoshi Tominaga, IMDRF Chair

Table of Contents (ToCs) Approved March 2018

Following the Pilot the IVD and Non-IVDs ToCs were updated including:

- **minor revisions to regional content**
- **2 new sections – Cybersecurity and Interoperability**

Excerpt from Non-IVD ToC Document

HIERARCHY PRESENTATION

The following is a hierarchical presentation of the submission structure. More detailed guidance regarding where elements belong is provided following this table.

CHAPTER 1 – REGIONAL ADMINISTRATIVE	
CH1.01	Cover Letter
CH1.02	Submission Table of Contents
CH1.03	List of Terms/Acronyms
CH1.04	Application Form/Administrative Information
CH1.05	Listing of Device(s)
CH1.06	Quality Management System, Full Quality System or Other Regulatory Certificates
CH1.07	Free Sale Certificate/ Certificate of Marketing authorization
CH1.08	User Fees
CH1.09	Pre-Submission Correspondence and Previous Regulator Interactions
CH1.10	Acceptance for Review Checklist
CH1.11	Statements/Certifications/Declarations of Conformity
CH1.11.1	Performance and Voluntary Standard
CH1.11.2	Environmental Assessment
CH1.11.3	Clinical Trial Certifications
CH1.11.4	Indications for Use Statement with Rx and/or OTC designation Enclosure
CH1.11.5	Truthful and Accurate Statement
CH1.11.6	USFDA Class III Summary and Certification
CH1.11.7	Declaration of Conformity
CH1.12	Letters of Reference for Master Files
CH1.13	Letter of Authorization
CH1.14	Other Regional Administrative Information
CHAPTER 2 – SUBMISSION CONTEXT	
CH2.1	Chapter Table of Contents
CH2.2	General Summary of Submission
CH2.3	Summary and Certifications for Premarket Submissions
CH2.4	Device Description
CH2.4.1	Comprehensive Device Description and Principle of Operation
CH2.4.2	Description of Device Packaging
CH2.4.3	History of Development
CH2.4.4	Reference and Comparison to Similar and/or Previous Generations of the Device
CH2.4.5	Substantial Equivalence Discussion
CH2.5	Indications for Use and/or Intended Use and Contraindications
CH2.5.1	Intended Use; Intended Purpose; Intended User; Indications for Use
CH2.5.2	Intended Environment/Setting for use
CH2.5.3	Pediatric Use
CH2.5.4	Contraindications For Use
CH2.6	Global Market History
CH2.6.1	Global Market History
CH2.6.2	Global Incident Reports and Recalls
CH2.6.3	Sales, Incident and Recall Rates
CH2.6.4	Evaluation/Inspection Reports
CH2.7	Other Submission Context Information
CHAPTER 3 – NON-CLINICAL EVIDENCE	

Table of Contents Adoption – Momentum is Building

March 2018 WG Update

"Without an commitment from IMDRF MC members on approach, further use of the ToC may be limited"

" Industry will not invest if jurisdictions do not offer options to use ToC for medical device submissions in each of their regions"

June 2018 Mgmt Committee Call

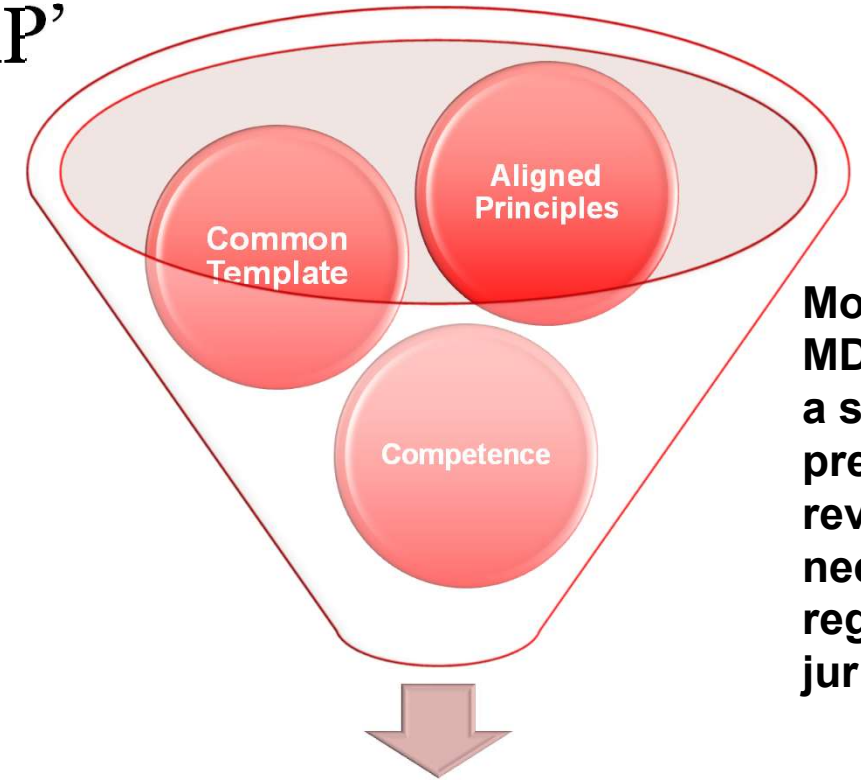
- *Half of the Mgmt Committee members indicated that they have plans to implement the ToC as a voluntary option within the foreseeable future*

What's Next?

- *Health Canada to recommend ToC as preferred option (but not mandated)*
- *China plans to adopt ToC for electronic (PDF) submission format*
- *US discussing plans as voluntary option for PMAs*

Multiple Working Group Efforts with a Common Future Goal – 'MDSRP'

- WG: Good Regulatory Review Practices
- WG: Regulated Products Submissions (RPS)
- WG: Clinical Evidence



Modelled after MDSAP, MDSRP is a single regulatory premarket review to satisfy the needs of multiple regulatory jurisdictions

Medical **D**evice **S**ingle **R**eview **P**rogram

Fall 2018 IMDRF Meeting – Beijing, China

Fall 2018 IMDRF Meeting Schedule

MONDAY SEPT. 17TH	TUESDAY SEPT. 18TH	WEDNESDAY SEPT. 19TH	THURSDAY SEPT. 20TH
Pre-IMDRF Workshop: UDI	Open Stakeholder Day	Management Committee Meeting Day 1	Management Committee Meeting Day 2

2019 Host Country - Russia


Questions