

# The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

Tuesday 23rd March 2021 | 20:00 KST



Ministry of Food and Drug Safety



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# PROGRAM

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Korea Standard Time	Program
20:00 ~ 20:05	Welcome Introduction : <b>Ganglip Kim</b> , MFDS
20:05 ~ 20:40	<b>Session 1 : Regulatory Updates by IMDRF Regulatory Authorities Members</b> <ul style="list-style-type: none"><li>– Australia : <b>Tracey Duffy</b>, TGA</li><li>– Brazil : <b>Leandro Rodrigues Pereira</b>, ANVISA</li><li>– Canada : <b>David Boudreau</b>, Health Canada</li><li>– China : <b>Yuan Peng</b>, NMPA</li><li>– EU : <b>Erik Hansson</b>, European Commission</li><li>– Japan : <b>Tetsuya Kusakabe</b>, PMDA</li><li>– Russia : <b>Astapenko Elena</b>, Ministry of Health of Russia</li><li>– Singapore : <b>Rama Sethuraman</b>, HSA</li><li>– South Korea : <b>Jeong Lim Lee</b>, MFDS</li><li>– USA : <b>Jeff Shuren</b>, US FDA</li><li>– UK : <b>Graeme Tunbridge</b>, MHRA</li></ul>



Korea Standard Time	Program
20:40 ~ 21:10	<p><b>Session 2 : Progress Overview of IMDRF Work Items</b></p> <ul style="list-style-type: none"> <li>– RPS : <b>Nancy Shadeed</b>, Health Canada</li> <li>– GRRP : <b>Lakshmidevi Balakrishnan</b>, HSA</li> <li>– AE : <b>Hiroshi Ishikawa</b>, PMDA</li> <li>– PMD : <b>Tracey Duffy</b>, TGA</li> <li>– MDCE : <b>Yinghui Liu</b>, CMDE</li> <li>– CYBER : <b>Marc Lamoureux</b>, Health Canada</li> <li>– IVD : <b>Tatyana Buryakina</b>, RZN</li> <li>– AIMD : <b>Se-il Park</b>, MFDS</li> </ul>
21:10 ~ 21:40	<p><b>Session 3: Stakeholders Session</b></p> <ul style="list-style-type: none"> <li>– WHO : <b>Irena Prat</b></li> <li>– APEC : <b>Cheng-Ning Wu</b></li> <li>– AHWP/GHWP : <b>Ali Al-Dalaan</b></li> <li>– PAHO : <b>Alexandre Lemgruber</b></li> <li>– DITTA : <b>Masaaki Ohtsuka</b></li> <li>– GMTA : <b>Emmett Devereux</b></li> <li>– KMDIA : <b>Myung Jung Kim</b></li> <li>– KMDICA : <b>Byung-Chul Ahn</b></li> <li>– ASTM : <b>Craig Updyke</b></li> </ul>



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# Session 1



## Regulatory Updates by IMDRF Regulatory Authorities Members

Australia

Brazil

Canada

China

EU

Japan

Russia

Singapore

South Korea

USA

UK





The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# Australia

⋮

Tracey Duffy, TGA



## Regulatory Update from Australia



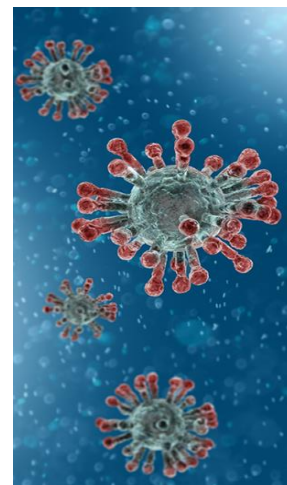
**Tracey Duffy**  
Medical Devices and Product Quality Division  
Therapeutic Goods Administration - Department of Health

March 2021



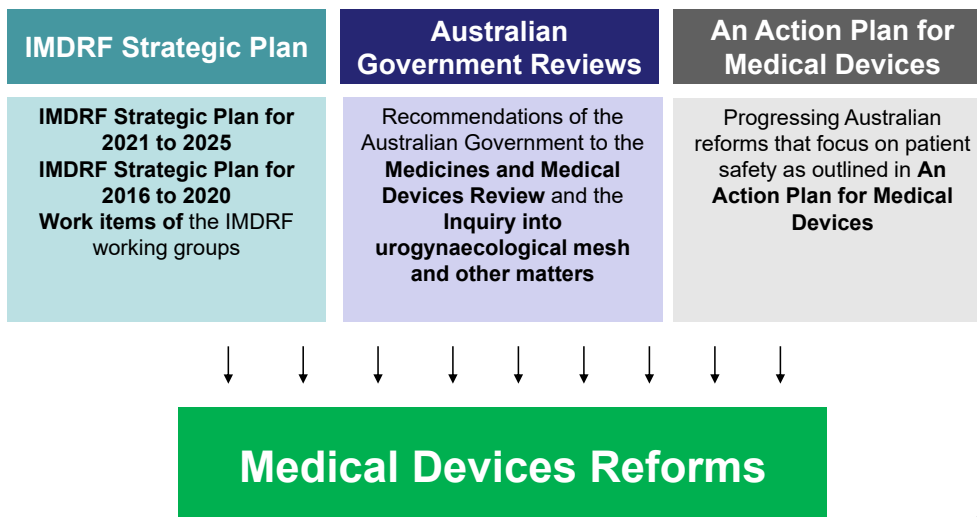
## Overview

- ❖ **IMDRF Strategic Plan**
- ❖ **Progress with Medical Device Reforms**
  - **Australian Government Reviews**
  - **An Action Plan For Medical Devices**
- ❖ **COVID-19 update**
- ❖ **TGA's new accommodation**





## Australia is implementing three medical device reform streams



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## IMDRF Strategic Plan 2016 - 2020

**“Support innovation and timely access to safe and effective medical devices”**

*Primary objective of IMDRF Strategic Plan 2016-2020*

### Focus areas:

- Aligning regulatory requirements and practice
- Broadening access to medical devices of public health importance across jurisdictions

## Australia's progress

### Fully implemented

- ✓ Medical Device Single Audit Program
- ✓ Medical device cybersecurity
- ✓ National Competent Authorities Reports Exchange Program
- ✓ Edition 4.1 of adverse event terminology

### Partially implemented or still in progress

- Common principles on registries
- Development of Regulatory Product Submissions
- Good Review Practices for pre-market reviews
- Improving medical device standards (via Standards Australia)
- Improving quantity and quality of clinical data
- Software as a Medical Device
- Personalised medical devices
- Rules for unique device identifiers

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## IMDRF Strategic Plan 2021 - 2025

Australia will support the IMDRF to continue to build on its achievements from the 2020 Strategic Plan, with an emphasis on the two key objectives below:

1. Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance
2. Strengthening post-market surveillance for medical devices and implement regulatory life cycle processes

### Priorities

Australia will contribute to the delivery of the Strategic Plan key priorities:

- Pre-market - *Develop a risk calibrated regulatory approach for innovations and promote harmonized pre-market review requirements for medical devices*
- Post-market - *Leverage post-market monitoring and surveillance to ensure accessibility to safe and effective innovations for patients*
- Relationships with Stakeholders

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## How we contribute and support the IMDRF

- ✓ Participation in [IMDRF Management Committee](#) and [Working Groups](#)
- ✓ Reference to IMDRF final documents in our [consultations](#) on Australian medical device reforms where appropriate
- ✓ Changes to TGA [processes to harmonise](#) and implement IMDRF documents
- ✓ Information [exchange](#) with IMDRF members on various topics including COVID
- ✓ Continued [engagement](#) with WHO, ISO, IEC, APEC, AHWP, PAHO
- ✓ Continued hosting of [IMDRF website](#)

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## IMDRF website update

Australia has proposed modernising the IMDRF website to reflect that the Forum is a strong, well-organised, contemporary group of Medical Device Regulators.

Management Committee considerations:

- Changes to structure and layout
- Review font type and logo
- Homepage navigation
- Multiple ways to find documents
- More information about Working Groups
- Language translation function



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## Australia's Medicines and Medical Devices Review

### Implemented

Priority review pathway for medical devices (averaging 70 days)  
Use of comparable overseas regulator approvals (341 used as of 5 February 2021) from USA, Canada and Japan  
Benchmarking TGA timeframes with other regulators (published)  
Review of Class 1 medical devices  
Improvements to post market surveillance and adverse event reporting processes

### Under way

Establishment of Australian Conformity Assessment Bodies  
Guidance to support the reclassification of certain devices (non IVD)

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## Government Inquiry into urogynaecological mesh – progress

- Upclassification to Class III for mesh devices, deadline for urogynaecological mesh products was 1 December 2020
- Patient Implant Cards and Patient Information Leaflets required for surgical mesh and implantable devices after 1 December 2018
- Pelvic Floor Procedure Registry commenced January 2021
- Consultations on UDI and enhancements to adverse event reporting closed on 2 December 2020. Analysis of responses is underway. Consultation on mandatory reporting of adverse events by healthcare facilities commenced.

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## An Action Plan for Medical Devices



The safety of Australian patients comes first

### An Action Plan for Medical Devices

Improving Australia's medical device regulatory framework



**STRATEGY 1 : IMPROVE HOW NEW  
DEVICES GET ON THE MARKET**

**STRATEGY 2: STRENGTHEN  
MONITORING AND FOLLOW-UP OF  
DEVICES ALREADY IN USE**

**STRATEGY 3: PROVIDE MORE  
INFORMATION TO PATIENTS ABOUT THE  
DEVICES THEY USE**

Our strategies take into consideration harmonisation with IMDRF, balanced with patient safety considerations and identified issues particular to the Australian healthcare and regulatory systems

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## Action Plan: Strategy 1 Achievements

### Strategy 1: Improve how new devices get on the market

- Legislation changes in August 2020 to a number of definitions including 'medical device', 'accessory to a medical device', 'reusable surgical instrument', 'use' and 'user', 'system and procedure pack'
- Validation of Class 1 medical devices to increase integrity and confidence of performance
- Regulation changes for products without a medical intended purpose (focussing on cosmetic lasers and IPL equipment), software-based medical devices and personalised medical devices
- Exemptions and exclusions for some low risk software-based medical devices and apps
- Pilot of 'low risk' medical devices self-assessment tool to verify classification levels

**Open consultations - Central Circulatory System Medical Devices and Medical Devices containing nanomaterials**

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## Action Plan: Strategy 2 Achievements

### Strategy 2: Strengthen monitoring and follow-up of devices already in use

- Funding of \$7.7 million (over four years) to implement the Australian Unique Device Identification database (AusUDID) by 2024
- Consultation on changes to adverse event reporting for medical devices currently underway
  - Removal of some existing exemptions on adverse event reporting requirements
  - How UDI can assist tracking and tracing devices through the healthcare system
  - Onsite auditing of adverse event reporting processes
  - Feasibility of mandatory reporting of adverse events by hospitals
- A new Post Market Review Compliance IT system implemented – an efficient, secure way to provide evidence and reports

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## Action Plan: Strategy 3 Achievements

### Strategy 3: Provide more information to patients about the devices they use

- Consumer Working Group established – 10 consumer representative organisations including Choice and the Consumer Health Forum to help with consumer-friendly information
- *'Five questions to ask your health professional before you get a medical implant'* published from work of the Consumer Working Group
- From 1 December 2020, all new implantable devices require a patient implant card (PIC) and patient information leaflet (PIL) to demonstrate compliance with essential principles
- Existing implantable devices will require a PIC and PIL from December 2021
- Updated guidance for PIC and PIL released shortly

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## Action Plan: Stakeholder Engagement

- 27 consultation papers published on the TGA website on proposed changes to medical device regulation
  - Proposed changes consider EU MDR, IMDRF documents and any Australia-only regulatory requirements
  - Submissions to consultations published on TGA website
  - Meetings and workshops held with stakeholders to clarify details and understand their views about the impacts of the proposed changes
- Guidance material has been published
  - Used a collaborative approach with medical device stakeholders to draft guidance
  - Developing fact sheets and Q&As to support complex changes
  - Delivering webinars and other education methods with stakeholder groups

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## Challenges

- Implementation of regulatory changes ahead of other jurisdictions
- Development of guidance material in the absence of IMDRF guidance
- Regulatory changes that are specific to Australia
- Differences between various regulatory frameworks and what is appropriate for Australia to reduce regulatory burden on manufacturers and suppliers
- Balancing workloads and burdens on industry dealing with change globally



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## COVID-19 - Update

### Unprecedented times.....

Australian Government agreed to **delay implementation** start dates for some reforms:

- Medical device software and personalised medical devices (25 February 2021)
- Reclassification of certain devices and changes to system and procedure packs (25 November 2021)
- Amendments to essential principles – 2 years after EU MDR commencement

### Time limited exemptions:

- Medical device personal protective equipment (PPE) (ceased 31 January 2021)
- COVID-19 tests for the purpose of donor screening (ceases on 30 June 2021)
- Domestically manufactured ventilators (ceased 31 January 2021)

Processes to validate COVID test kits to ensure their continued performance with the **emerging genetic variants of SARS-CoV-2**

Face mask review continues including TGA **laboratory testing** to validate claims

Significant dialogue and interactions with **other regulators**



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## COVID-19 - Update

### Unprecedented times.....

- Medical Devices information line **call volumes** increased by over 200%
- **Compliance referrals** increased by 150 %
- Many enquiries were from new suppliers/manufacturers who had not marketed medical devices before
- **Procurement by government** of face masks, other PPE and COVID tests in a competitive global environment
- Greatly enhanced **focus on cleaning and use of disinfectants** with antiviral activity
- **Remote “virtual” and hybrid** audits and inspections
- Expedited and **prioritised** COVID related assessments



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## TGA's new accommodation



The Therapeutic Goods Administration Laboratories building in Canberra was officially opened on 24 May 1993.



Construction of two purpose-built buildings is underway. Plan to move into the new premises in mid-2022

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**IMDRF** International Medical  
Device Regulators Forum







# Brazil



**Leandro Rodrigues Pereira,  
ANVISA**



**IMDRF** International Medical  
Device Regulators Forum

## IMDRF Stakeholders Forum

# Regulatory and Policy Update ANVISA

March 2021

**Leandro Rodrigues Pereira**  
General Manager – Medical Devices Office  
Brazilian Health Regulatory Agency



## Construction of the Regulatory Agenda for 2021/2023



ANVISA  
Regulatory Agenda

-  **Draft Regulatory Agenda proposal**  
→ 106 project proposals identified
-  **Public Consultation**  
→ Directed Consultation, including the medical device sector, held between November and January 2021
-  **Publication of the Regulatory Agenda 2021 – 2023**  
→ Forecast: April 2021

 **ANVISA**  
Agência Nacional de Vigilância Sanitária





## New Medical Device Cybersecurity Guide



ANVISA published [Guide No. 38/2020](#) (link in Portuguese), *Principles and Practices of Cybersecurity in Medical Devices*, which is based on the [IMDRF/CYBER WG/N60](#) guidance issued by the International Medical Device Regulators Forum (IMDRF).

The 45-page document includes a comprehensive treatment of general cybersecurity principles as well as guidance on documentation for regulatory submissions. Discussion of major points is divided into sections on pre- and post-market considerations.

Guide No. 38/2020 went into force upon publication in late September/20, and ANVISA is soliciting public comments on it until March 23, 2021.



## UDI Working Group

Anvisa published Ordinance 631/20 which created a working group to establish guidelines for implementation of a UDI system in Brazil. It is expected to be aligned to the UDI Guidance Document (IMDRF/WG UDI/N7Final:2013)

**Participants:**

Anvisa  
Medical Device Manufacturers and Importers  
Hospitals  
Issuing Bodies

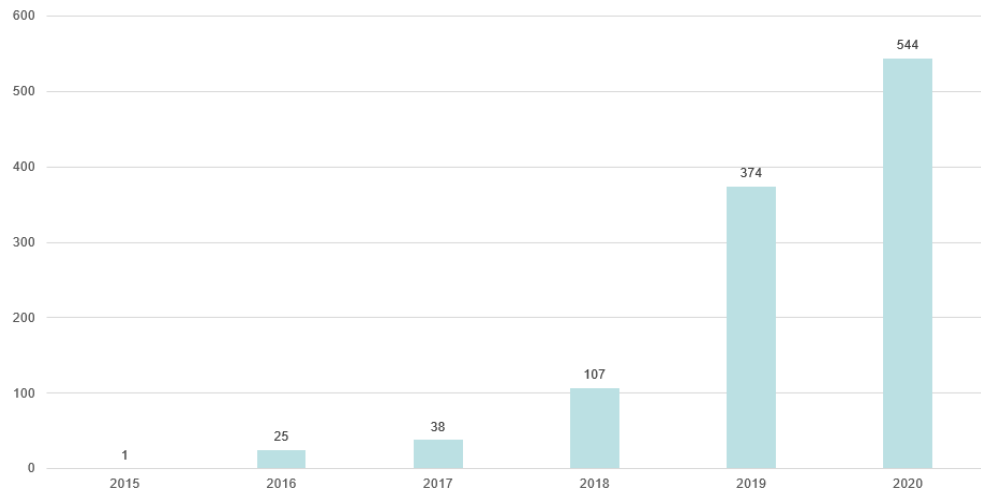
**Scope:**

Responsibilities for establishing and maintaining a UDI  
General UDI rules  
UDI-Database design





ANVISA's GMP Certificate using MDSAP Reports per year



THANK YOU

Leandro Rodrigues Pereira  
General Manager  
Medical Devices Office

Agência Nacional de Vigilância Sanitária - Anvisa  
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# Canada



**David Boudreau,  
Health Canada**



**IMDRF** International Medical  
Device Regulators Forum

## **Regulatory and Policy Updates**

**Medical Devices Directorate  
Health Canada**

**David Boudreau  
Director General**



**IMDRF** International Medical  
Device Regulators Forum

## **Overview**

- COVID-19
- New Post-Market Surveillance Regulations
- Regulatory Initiatives
- Guidances



## COVID-19

- The *Interim Order Respecting the Sale and Importation of Medical Devices Used in Relation to COVID-19* expires on March 18, 2021
- HC has consulted stakeholders on a second Interim Order that will extend the emergency provisions and transitional regulations

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## COVID-19

- The *Interim Order Respecting the Clinical Trials For Medical Devices and Drugs Relating to COVID-19* expires on May 23, 2021
- HC is working on a second Interim Order to extend the emergency provisions

4



## **COVID-19**

- As of February 17, Health Canada has issued Interim Order authorizations for 55 testing devices and over 600 non-testing devices
- Guidance on respirator safety and performance requirements updated to include information on new certification programme from Canadian Standards Association

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## **COVID-19**

- Webpages, such as those on test kits, updated to include information on variants
- Public advisory on UV lights and wands to warn against unsubstantiated COVID-19 claims

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## New Post-Market Surveillance Regulations

- Published December 23, 2020
- Allows HC to order licence holders to
  - Conduct an assessment
  - Compile information, conduct tests or studies or monitor experience
  - Notify HC when risk mitigation actions are taken outside Canada relevant to devices marketed in Canada
  - Conduct analysis
  - Prepare summary reports for Class II devices every two years and for Class III & IV devices every year, and notify HC of any changes to benefits and/or risks

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## New Post-Market Surveillance Regulations

- Guidance documents have been published:
  - [Amendments to the \*Food and Drugs Act\*: Guide to New Authorities, including power to require assessment and power to require tests, studies, etc.](#)
  - [Foreign risk notification for medical devices](#)
  - [Incident reporting for medical devices](#)
  - [Summary reports and issue-related analyses of safety and effectiveness for medical devices](#)

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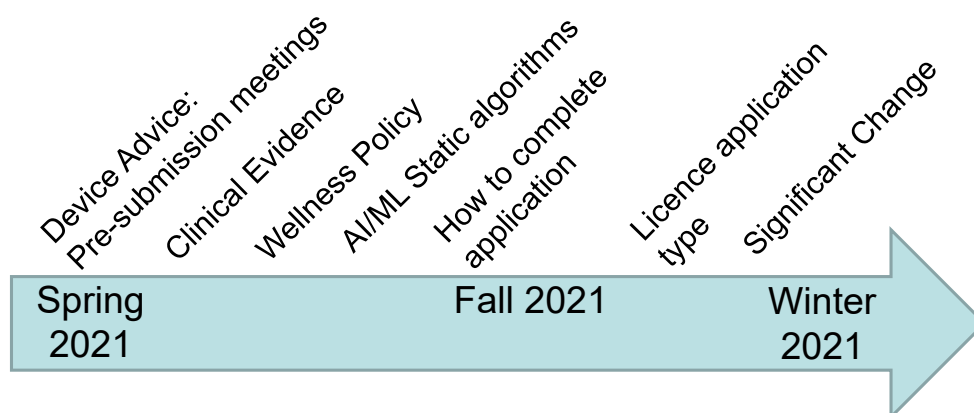
## Regulatory Initiatives

- Clinical Trial modernization
  - Will provide a risk-based, flexible framework for drugs, biologics, vaccines, natural health products, and medical devices
- Advanced Therapeutic Products framework
  - Intended for novel, complex products that challenge existing regulatory frameworks
  - Pilot candidate expected by 2022

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## Planned Guidance Documents for Consultation



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## Questions/comments

Thank you!





# China



Yuan Peng, NMPA



## Update on China regulatory

**Yuan Peng**  
**NMPA**



### **Regulations on medical device supervision and administration**

✓ On December 21, 2020, the State Council Executive Meeting approved the revised version of the regulations on medical device supervision and administration, which was signed by the premier on February 9. Now it is waiting for the official publish.

✓ To cooperate with the implementation of the regulations, NMPA has made a plan to revise some corresponding provisions and Normative documents of the Regulations.



The Provisions.....

- The provisions for the medical device registration
- The provisions for the IVD registration
- The provisions for the supervision and administration of medical device production

.....

The Normative documents.....

Requirements for medical device registration application materials and format of the approval certificate

Standard operation procedure for review and approval

.....

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1. According to the reformation requirements of the state, encourage industry innovation and development

For example:

Optimize the approval procedure and simplify the approval materials

2. Fully implement medical device MAH system, Strengthen the responsibilities and obligations of MAH

The MAH responsible for the safety and effectiveness of medical devices in the life cycle of development, production, sale and use according to the regulation.

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### 3.improve the supervision efficiency

Establish professional inspector system, use UDI system to realize the traceability of products, and so on.



- **Covid-19 Epidemic prevention and control**
- Up to now, NMPA had approved 56 COVID-19 IVD kits for 38 manufacturer, including 26 nucleic acid IVD kits, 27 antibody IVD kits and 3 antigen IVD kits.
- NMPA will continue to strengthen the cooperation with WHO and other regulators, provide information on time.



- **Optimize the licensing matters related to the production of imported medical devices in domestic enterprises**

In order to further implement the Opinions on the Reform of Review and Approval System for Drugs and Medical Devices issued by the State Council and the Opinions on Deepening the Reform of Review and Approval System to Encourage Innovation of Drugs and Medical Devices issued jointly by the General Office of the CPC Central Committee and the General Office of the State Council



- under the premise that the main raw materials and production process do not change, and the quality management system is consistent, the NMPA and provincial Regulatory Authority will recognize part of the original declaration data for the registration of domestic products, which will be beneficial to the development of China's medical device industry In order to save resources, improve the efficiency of review and approval, promote the rapid development of China's medical device industry, and better meet the needs of the people.



- **Technical guidelines for clinical evaluation of medical devices using real world data**

The main contents include real world data and evidence, advantages and limitations of real world research, common real world data sources, quality evaluation, common types of real world research design and statistical analysis methods, and real world evidence can be considered for clinical evaluation of medical devices.

NMPA has approved two products that use real world data as the part of clinical evidence.

This year, NMPA plan to hold Real world data research conference in Hainan, to discuss the hot topic further with experts from all over the world

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- **Guidance for On-Site Inspections of SaMD GMP Appendix**
- To strengthen the supervision and inspection over medical device manufacturers' implementation of the Good Manufacturing Practice for Medical Devices and its appendix for SaMD, and guide the regulatory authority to better carry out on-site inspections, NMPA issued on June 4, 2020 the Guidance for On-Site Inspections of SaMD GMP Appendix
- The main contents include requirements for organization and personnel, premises and facilities, equipments, document management, design and development, quality control, etc.

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- **Connection with the world wide regulation or standard**
- As a member of IMDRF, China actively promotes the implementation of the IMDRF guidelines in China. Up to now, among the 31 IMDRF guidelines, the 14 guidelines had been fully implemented in china, and 14 guidelines had been partly implemented in china.
- NMPA will continue to strengthen cooperation with IMDRF and contribute to the work of IMDRF, and now, NMPA will propose some new work items need to harmonize, according to the strategic 2020-2025, hope to submit the application in future.

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## Thank you

1. The Regulation on medical device supervision and administration had been approved, waiting for the official publish.
2. Serve for Covid-19 Epidemic prevention and control
3. Optimize the licensing matters related to the production of imported medical devices in domestic enterprises
4. Promote the real world evidence operation
5. Guidance for On-Site Inspections of SaMD GMP Appendix

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# EU



**Erik Hansson,  
European Commission**



# Update on EU regulatory developments

**Erik Hansson**  
**European Commission**  
**IMDRF – 19**

Health



## The EU single market for medical devices



1. EU



2. EFTA/EEA:  
Norway, Liechtenstein, Iceland



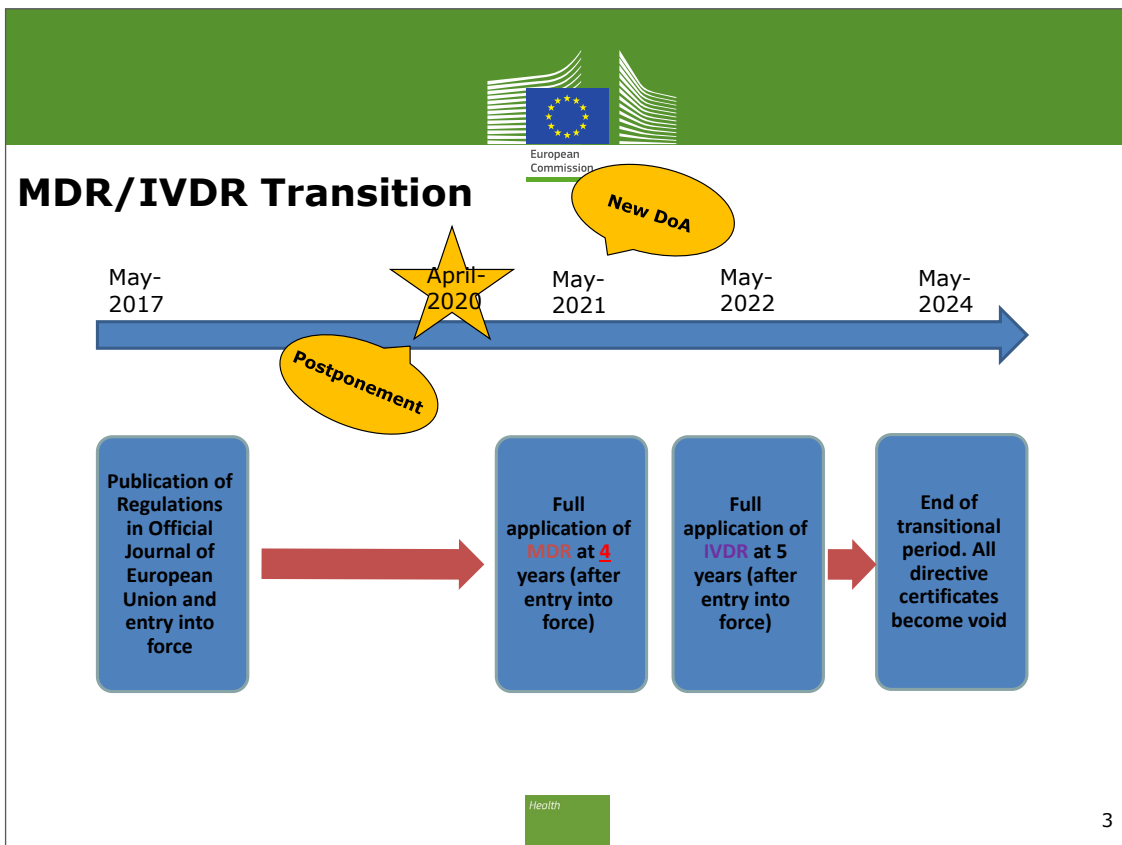
3. Turkey



4. Switzerland

Health

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### COM implementation priorities (1)

- Notified Bodies**
  - ✓ 60 (46+14) applications received up to date. Full scope of MDR and IVR covered
  - ✓ 23 (19+4) notified bodies designated under new Regulations
- Governance**
  - ✓ Setting up of MDCG (November 2017)
  - ✓ MDCG technical subgroups (13) operational as from 1<sup>st</sup> Mar 2019
  - ✓ Work on 70+ guidance documents ongoing or finalised
- Scientific structures**
  - ✓ Expert panels designated (2019)
  - ✓ Publication of designated experts to expert panels (Q1 2021)
  - ✓ Expert laboratories and reference labs (timelines under revision)
- Design and establishment of the new EUDAMED - Staged approach**
  - ✓ Core actor registration module of database made available Q4 2020
  - ✓ UDI module in Q2 2021
- Establishment of UDI system**
  - ✓ 10 guidelines published, designation of issuing entities finalised in Jun 2019, release of Q/A in Aug 2019

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## COM implementation priorities (2)

- **European Medical Device Nomenclature official publication** (Q1-Q2 2021)
- **Mandate for revision of standards** (Q1 2021)
- **Communication campaign**
  - ✓ Dedicated website, factsheets in all EU languages and some major non-EU languages
  - ✓ Specific factsheets for competent authorities in non-EU/EEA countries
- **Common specifications on devices without medical purpose** (Q2-Q3 2021)
- **Common specifications on reprocessing of single-use devices** (Q3 2020)

### Planning of activities:

- **Publication of Commission's rolling plan on DG SANTE website**

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## COM implementation priorities (3) - Key guidance published since March 2020

### March 2020

- ✓ Update of guidance on implant card
- ✓ Transitional provisions of article 120 (3) and (4) for class I medical device
- ✓ Significant changes regarding transitional provisions in Art.120
- ✓ Clinical evaluation/ Performance evaluation of medical device software

### April 2020

- ✓ Update of guidance on Article 54(2)b
- ✓ PMCF templates
- ✓ Sufficient clinical evidence for legacy devices
- ✓ Clinical evaluation – Equivalence

### May 2020

- ✓ Safety reporting in clinical investigations

### June 2020

- ✓ Consultations of authorities on devices with ancillary substances and TSE susceptible tissues
- ✓ Update of guidance on UDI for systems and procedure packs

### July 2020

- ✓ Clinical evaluation assessment report template

### August 2020

- ✓ MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
- ✓ Guidance for notified bodies on the use of MDSAP audit reports under MDR and IVDR

### November 2020

- ✓ Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

### December 2020

- ✓ MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers
- ✓ Questions and Answers related to MDCG 2020-4: "Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions"

### January 2021

- ✓ Guidance on Management of legacy devices in EUDAMED.

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## **Covid-19 (1) - Shortages**

- Ramping up of production
- Many European Standards made freely available
- Combatting export restrictions
- Derogations
- Joint procurement Agreement
- Clearing House

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## **Covid-19 (2) – main MDR and MDD regulatory measures**

- Regulation (EU) 2020/561 adopted on 23 April 2020 amending MDR, as regards the dates of application of certain of its provisions
- Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies
- Commission notice the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment

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## **Covid-19 (3) - related guidance documents issued (selection)**

- Guidance on placing medical devices and PPE **on the EU market**
- Guidance on Medical devices, Active implantable medical devices and in vitro diagnostic medical devices **in the COVID-19 context**
- Guidance to increase production of **PPE, hand gel, 3D printing**
- Guidance on regulatory requirements for **ventilators**
- Guidelines on COVID-19 IVD **tests** and their performance
- Working document on **performance of COVID-19 test methods**
- Database of publ. available **performance data COVID-19 IVD**
- Commission guidelines on **Union-wide derogations**
- Guidance on temporary measures on **notified body audits** during COVID-19 quarantine orders and travel restrictions + renewal designations.

Health

# **Thank you for your attention !**

Erik Hansson  
European Commission  
Medical Devices and Health Technology Assessment Unit

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# Japan



**Tetsuya Kusakabe, PMDA**

# Regulatory Updates on Medical Devices in Japan

- Amendment of Pharmaceuticals and Medical Devices Act (PMD Act) -

Tetsuya Kusakabe

Pharmaceuticals and Medical Devices Agency (PMDA), Japan



IMDRF Stakeholders Forum, March 23, 2021

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## Overview of Amendment of Pharmaceuticals and Medical Devices Act (PMD Act)

- Enacted in November, 2019  
Implemented in September, 2020
- Following provisions are introduced :
  1. SAKIGAKE designation system
  2. Priority review for specific uses, e.g. pediatric use
  3. Conditional early approval system
  4. Post-Approval Change Management Protocol (PACMP) for Medical Devices

IMDRF Stakeholders Forum, March 23, 2021

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# 1. SAKIGAKE Designation System

## 【Ordinal Review】



## 【Review under SAKIGAKE Designation System】



NOTE: SAKIGAKE was originally introduced as a pilot program based on the administrative notification in 2015.

IMDRF Stakeholders Forum, March 23, 2021

Administrative notification No.0831-6, August 31, 2020

3



## Criteria and Advantage of SAKIGAKE Designation

### ➤ Criteria

- innovativeness
- severity of disease
- prominent effectiveness or/and safety
- willingness and framework to first development in Japan

### ➤ Advantage

- Prioritized Consultation: waiting time; 2 months → 1 month
- Pre-application Consultation: de facto review before application
- Prioritized review: targeting total review time; 12 months → 6 months
- Review Partner: assignment of PMDA manager as concierge

IMDRF Stakeholders Forum, March 23, 2021

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## Approved Products under SAKIGAKE Designation

### ➤ Products designated as SAKIGAKE

- Medical devices: 12
- In Vitro Diagnostics (IVDs): 2

### ➤ Approved Products under SAKIGAKE system

Category	Product name	Company	Indication	Date of designation	Approval date
Medical Device	TITANBRIDGE	Nobelpharma Co. Ltd.	Adductor spasmodic dysphnia	Feb. 10, 2016	Dec. 15, 2017
Medical Device	Boron neutron capture therapy(BNCT) system	Sumitomo Heavy Industries, Ltd.	Head and neck cancer	Feb. 28, 2017	Mar. 11, 2020
IVD	OncoGuide NCC Oncopanel System	Sysmex Corporation	Solid tumors	Feb. 28, 2017	Dec. 25, 2018

NOTE: These were approved as a pilot program based on the administrative notification in 2015.

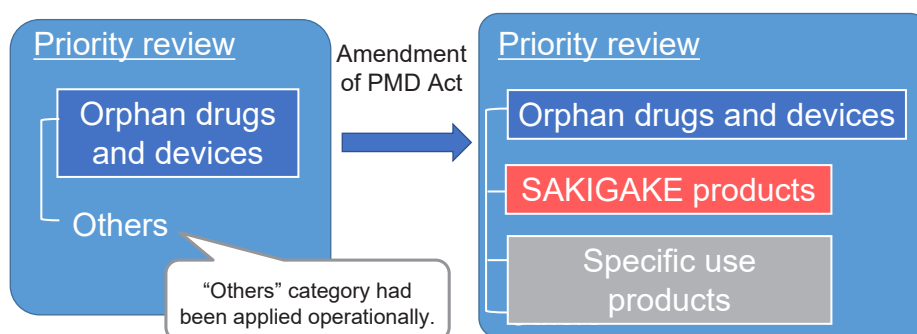
5



## 2. Priority Review for Specific Uses

- Designation of “Specific use product” for highly unmet medical needs (e.g. pediatric use).
- Priority review and other supportive measures are applied to designated products for specific use.

Administrative notification No.0831-5, August 31, 2020



6



## Criteria for Specific Use Products Designation

### ➤ Criteria

- use for diagnosis, treatment or prevention of illness for children
- highly unmet medical needs
- excellent effectiveness and safety

### ➤ Advantage

- Prioritized Review: **targeting review time; 12 months → 9 months**
- Tax benefits and grants of subsidy for product development

IMDRF Stakeholders Forum, March 23, 2021

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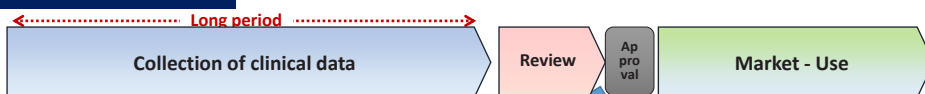


## 3. Conditional Early Approval System

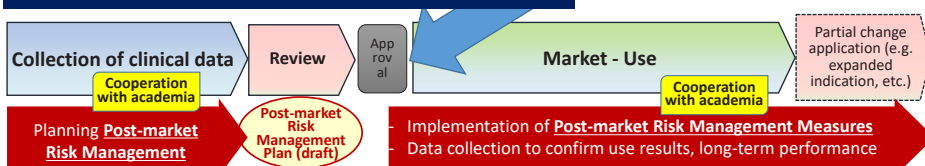
Accelerate approval of MDs of high medical needs by balancing the pre- and post-market requirements, based on the lifecycle management of the MDs.

Administrative notification No.0831-2, August 31, 2020

### ■ Ordinary review



### ■ Conditional Early Approval for Innovative MDs



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## 4. Post-Approval Change Management Protocol (PACMP)

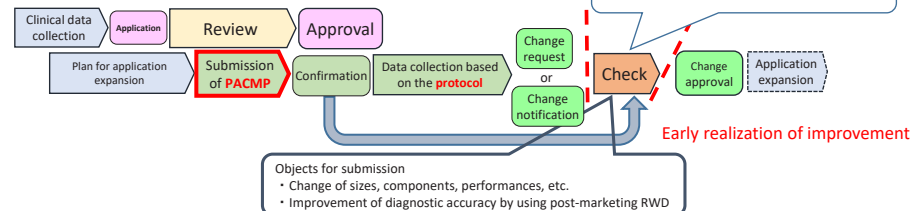
PACMP is introduced for medical devices to enable continuous improvements through product lifecycle.

Administrative notification No.0831-14, August 31, 2020

### Regular Approval Process



### Approval Process using PACMP

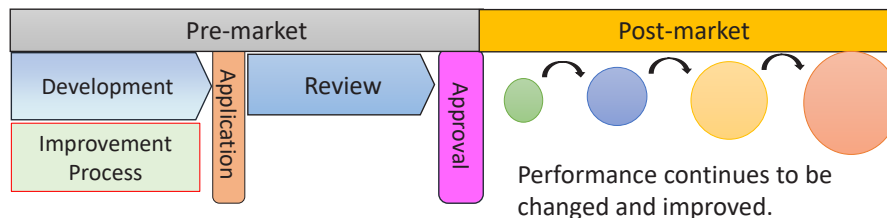


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## PACMP for AI medical devices

Approval review process which enables continuous improvement of performance of SaMD using AI

- Changes of performance must be in one-direction (improvement) and be managed by MAH.
- MAH may develop a process which ensures such performance changes as “Improvement Process”, and submit in the approval review process.



IMDRF Stakeholders Forum, March 23, 2021

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**Thank you for your attention!**







# Russia



**Astapenko Elena,  
Ministry of Health of Russia**



**IMDRF** International Medical  
Device Regulators Forum

## **NEW ASPECTS IN MEDICAL DEVICES REGULATION IN RUSSIAN FEDERATION**



**IMDRF** International Medical  
Device Regulators Forum

### **The Scheme of State Registration of Medical Devices (because of COVID-19) in the Russian Federation**

Russian Government order **No. 1416 dated 27.12.2012** "Adoption of rules for state registration of medical devices"  
(as revised in the Russian Government order **No. 299 Dated 18.03.2020**)

Russian Government order **No. 430 dated 03.04.2020** "About features of the circulation of medical devices, including state registration of a series (batch) of a medical device"

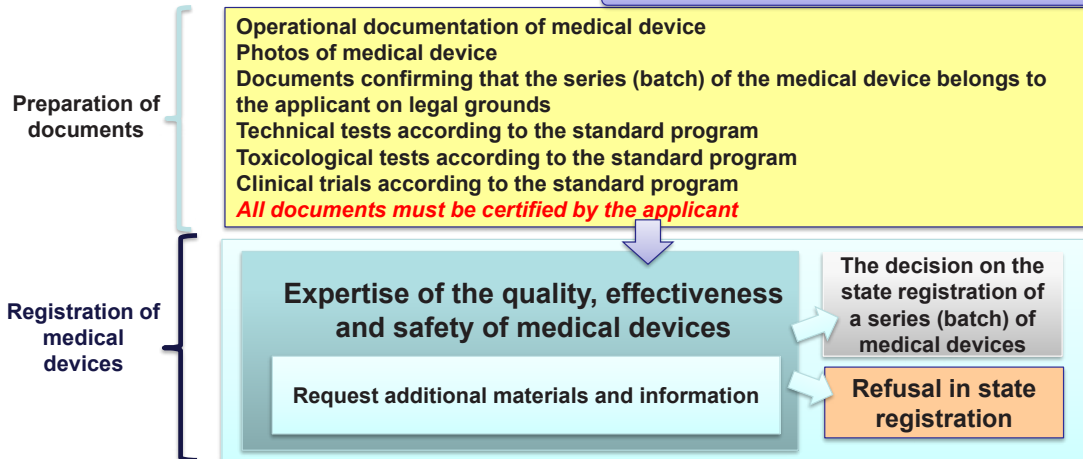
**Single-use medical devices registered in the country of origin are not subject to registration in Russian Federation**



# IMDRF International Medical Device Regulators Forum

Russian Government order **No. 1826 dated 13.11.2020** "About features of the circulation of medical devices, including state registration of a series (batch) of a medical device"

**Came into force on 23 November 2020**



**Validity of the registration certificate – 01.01.2022**

3



# IMDRF International Medical Device Regulators Forum

Russian Government order **No. 1906 dated 24.11.2020** "On amendments to the Rules of State Registration of Medical devices"

**Entered into force on 05.12.2020**

- An accelerated procedure for bringing new software as medical device to the market, including software with the use of artificial intelligence technologies, has been introduced by introducing a one-stage procedure for their state registration



**The order of the Ministry of Health of the Russian Federation  
No. 661n dated 30.06.2020 “On approval of the Procedure for  
the Import of medical devices into the territory of the Russian  
Federation for the purpose of state registration ”**

**Entered into force on  
01.01.2021**

- The procedure for importing medical devices into the territory of the Russian Federation for the purpose of state registration, including for the purpose of making changes to the documents contained in the registration dossier for a medical device, has been established.
- It is determined that a permit for the import of medical devices is not required for software that is a medical device.
- A permit for the import of a medical device is issued in electronic form.



**The order of the Ministry of Health of the Russian Federation  
No. 1236n dated 20.11.2020 “On amendments to the  
requirements for the content of the technical and operational  
documentation of the manufacturer (manufacturer) of a  
medical device, approved by Order of the Ministry of Health of  
the Russian Federation No. 11n dated 19.01.2017”**

**Entered into force on  
01.01.2021**

- The requirements for the technical and operational documentation of the manufacturer (manufacturer) for software that is a medical device, including software with the use of artificial intelligence technologies, are established. These requirements are harmonized with the provisions of the acts of the Eurasian Economic Union and the IMDRF acts



# IMDRF International Medical Device Regulators Forum

The order of the Ministry of Health of the Russian Federation **No. 980n dated 15.09.2020** "On approval of the Procedure for monitoring of medical device safety"

The order of the Ministry of Health of the Russian Federation **No. 1113n dated 19.10.2020** "On the approval of the Procedure for reporting by the subjects of circulation of medical devices on all cases of detection of side effects not specified in the instructions for use or operating instructions of the medical device, on adverse reactions during its use, on the features of interaction of medical devices with each other, on the facts and circumstances that pose a threat to the life and health of citizens and medical workers during the use and operation of the medical device"



Entered into force on  
01.01.2021

- The Orders establish the procedure for monitoring of medical device safety harmonized with the IMDRF principles.



# IMDRF International Medical Device Regulators Forum

Russian Government order **No. 1440 dated 15.09.2020** "On approval of the Rules for the Destruction of Seized Counterfeit Medical Devices, Substandard Medical Devices and Counterfeit Medical Devices"



Entered into force on  
01.01.2021

- The procedure for the destruction of seized counterfeit, substandard and counterfeit medical devices is defined
- The procedure for the owner's actions to destroy the seized medical devices is regulated



**IMDRF** International Medical  
Device Regulators Forum

### **Circulation of Medical Devices in Eurasian Economic Union**

**4** medical devices are registered in accordance with the rules for registration of medical devices of the EEU

Amendments have been prepared to the Agreement of EEU, under which the validity of national registration certificates is extended, from January 1, 2022, the primary registration of medical devices is carried out only under the legislation of the Eurasian Economic Union

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**IMDRF** International Medical  
Device Regulators Forum

**Thank you for your attention!**







# Singapore



Rama Sethuraman, HSA



## Regulatory Updates Health Sciences Authority Singapore

March 2021

**Rama Sethuraman**  
Director, Medical Devices Branch,  
Health Sciences Authority, Singapore



### UDI - Phased Implementation Plan

- HSA will be implementing UDI for medical devices (MDs) supplied in Singapore in phases starting from 2022 and the proposed approach is:
  - **Aligned to internationally harmonised principles** outlined in the UDI guidance published by IMDRF
  - **Leveraging the existing UDI barcodes** that manufacturers have applied on their MDs for US and/or EU markets
    - No Singapore specific UDI will be required for MDs with existing US or EU UDI
  - **Risk calibrated**, Only medium to high risk MDs will require UDI label; For low risk MDs (Class A), UDI will not be mandatory.
    - May be implemented on a voluntary basis e.g. UDI labelled in country of origin
  - **Phased approach**, In phase 1 (2022) only three types of high risk implantable MDs will be required to be labelled with UDI
    - Coronary stents, orthopaedic joint replacement implants & IOLs
    - The 3 subsequent phases of implementation will start 2 years after each phase for Class D, Class C and then Class B respectively





## UDI - Phased Implementation Plan

- The UDI information will be captured and published on the Singapore Medical Device Register (SMDR), our current online database for registered medical devices which is available to the public.
  - SMDR already captures most of the essential data such as intended use, model information, manufacturer information etc. for registered MDs
  - SMDR is fit-for-purpose to serve as the database for UDI related information – No new database is required
  - Minimum necessary additional UDI related data fields will be incorporated into our current SMDR database
- A webinar was held on 19 Oct 2020 to engage stakeholders early regarding this initiative and presentation can be accessed online at:  
[https://www.hsa.gov.sg/docs/default-source/announcements/regulatory-updates/udi-implementation-for-singapore\\_19oct20.pdf?sfvrsn=ce7c866c\\_0](https://www.hsa.gov.sg/docs/default-source/announcements/regulatory-updates/udi-implementation-for-singapore_19oct20.pdf?sfvrsn=ce7c866c_0)



## Guidance Documents – Updates

- An interim guideline “Change Notification applications arising from the EU MDR/IVDR related changes to registered medical devices” has been finalised and published in October 2020
  - A significant percentage of the registered medical devices distributed in Singapore are from Europe. With the MDR and IVDR implementation, many of these registered medical devices are impacted by the new or updated requirements
  - Changes to the registered medical devices here could include simple labelling updates to more complex changes
  - The document provides clarity on different changes that would require/not require the submission of a CN application, as well as the changes that could be bundled in a single submission
  - The document can be accessed online at:  
[https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-\(oct--pub\).pdf?sfvrsn=9ccfdc77\\_0](https://www.hsa.gov.sg/docs/default-source/hprg-mdb/change-notifications-arising-from-the-eu-mdrivdr-related-changes-(oct--pub).pdf?sfvrsn=9ccfdc77_0)





## Guidance Documents – Updates

- **Regulatory Guidelines for 3D Printed Medical Devices**
  - Currently published for consultation until 28 February 2021.
- This document presents HSA's current thinking and policy on regulating 3D printed medical devices
  - Approach to differentiate custom-made and mass manufactured medical devices that are 3D printed
  - Regulatory controls applicable to these categories of 3D printed medical devices
  - Key design, manufacturing and validation considerations applicable for all 3D printed medical devices in demonstrating compliance with essential safety and performance requirements
- This document can be accessed online at:  
<https://www.hsa.gov.sg/announcements/regulatory-updates/consultation-on-regulatory-guidelines-for-3d-printed-medical-devices>



Thank you!









The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# South Korea

⋮

**Jeong Lim Lee, MFDS**



**IMDRF** International Medical  
Device Regulators Forum

# **Regulatory Updates on Medical Devices in South Korea**

**Ministry of Food and Drug Safety**  
**March 2021**



**IMDRF** International Medical  
Device Regulators Forum

## **Table of Contents**

- 01** Major Achievements in 2020
- 02** Regulatory Initiatives in 2021
- 03** Guidances

# 01

## Major achievements in 2020



## IMDRF International Medical Device Regulators Forum

### New Division

- Establishment of Innovative and Diagnostic Medical Device Policy Division under the Medical Device Safety Bureau
  - in charge of the policy on innovative medical devices, IVD devices, etc.

### Nomenclature

- Revision to medical devices nomenclature for SaMD
  - 90 SaMD items in 11 clinical areas newly added

### COVID-19

- Official approval for 18 IVDs in response to COVID-19
- Approval for 269 IVDs intended for export in response to COVID-19

### Innovative Medical Devices

- 8 innovative medical devices designated
  - MLMD (Machine Learning enabled Medical Device) : 6
  - BNCT (Boron Neutron Capture Therapy) : 1
  - Augmented Reality : 1
- 1 research institute for innovative medical devices and 1 training center for experts designated

※ Data as of March 4, 2021

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# 02

## Regulatory Initiatives in 2021



**IMDRF** International Medical  
Device Regulators Forum

### Regulatory Initiatives in 2021

#### Vision

To create environment where people feel reassured  
of the use of medical devices in the post COVID-19 era

#### Goal

- > Reinforcement of responsibility with the development of patient-focused safety management system
- > Introduction of preemptive measure for balanced growth of innovative technologies and regulations

Development of Regulatory  
Competency

Strengthening  
Post Market Regulation  
of Medical Devices

Strengthening  
International Cooperation



## **The Enforcement of the Act on IVDs (since May 1, 2020)**

### **- Development of Regulatory Competency for IVDs -**

#### **Supporting in Technology for the Quality Improvement of IVDs**

- Designating IVDs manufacturers and cooperating with external experts to evaluate the adequacy of the quality management
- Providing technical support by giving information about the review and approval process, QMS, clinical performance test in a number of jurisdictions
  - Providing information for manufacturers with the database development
  - Information on regulatory requirements in consideration of the development stage of IVDs

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## **The Enforcement of the Act on Nurturing the Medical Devices Industry and Supporting Innovative Medical Devices (since May 1, 2020)**

### **- Development of Regulatory Competency for Innovative Medical Devices -**

#### **Supporting Innovative Medical Devices and SaMD**

- Streamlining the process and simplifying submissions when applying for the approval of innovative medical devices
- Fine tuning of regulatory framework for the approval of clinical trials protocol with the aim of promoting the clinical trial of SaMD
- Development of guidance on clinical trial protocol for Digital Therapeutics to expedite approval process
- Development of guidance on QMS for SaMD manufacturers
- Leveraging expertise for the quality management of SaMD

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## Strengthening Post Market Regulations of Medical Devices

- Reinforcing compensation system for patients who are damaged by implantable medical devices
- Mandating regular submission of Usage Record of Medical Devices subject to the traceability system
- Achieving international harmonization of terms and codes regarding Cause Investigation for Adverse Events
- Mandating Reporting of Supply Suspension of medical devices that have huge impact on public health

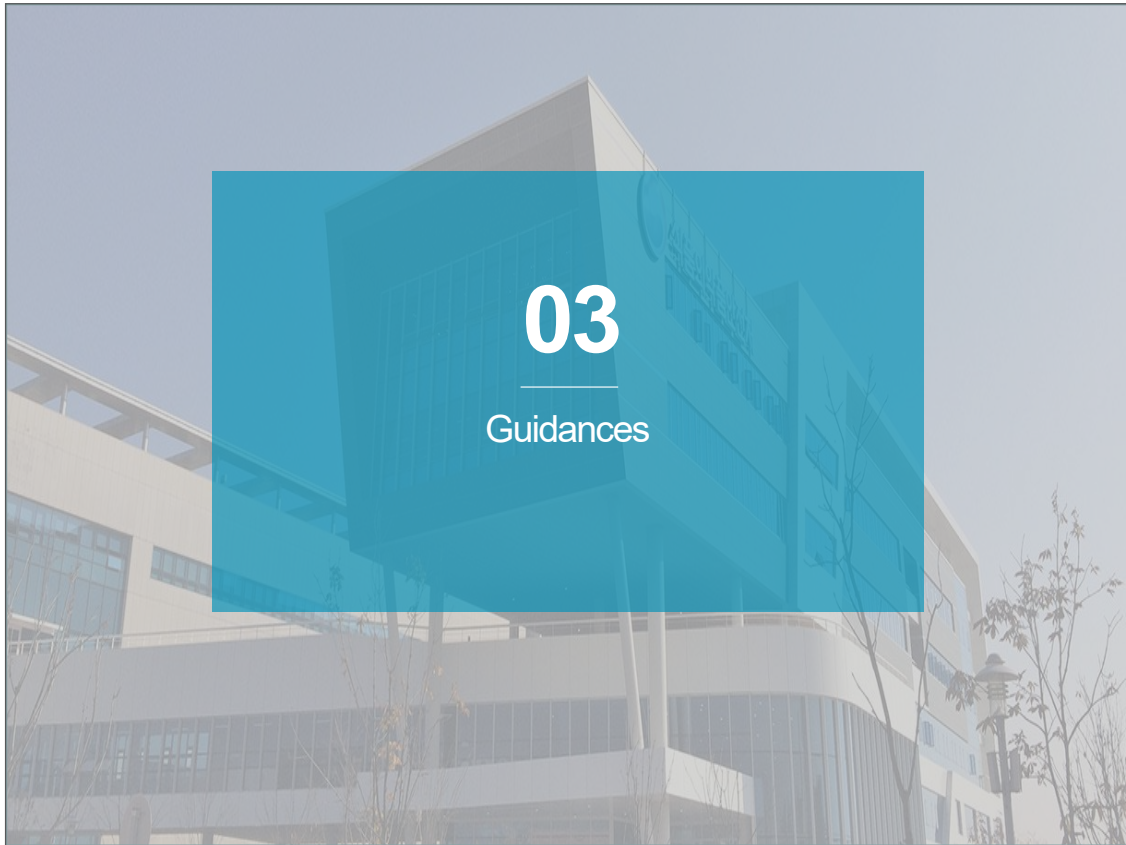
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## Strengthening International Cooperation

- Contribution to the harmonized regulatory approach to innovative medical devices as a member of IMDRF
- Establishment of the mid and long term strategies for the international standardization of IVDs, MLMD (Machine Learning enabled Medical Device) and Digital Therapeutics
- Development of a draft of the Infectious Disease Prevention Model (Test-Trace-Treat) and sharing with the international community

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IMDRF

International Medical  
Device Regulators Forum

**Newly Developed Guidances for Industry**

<b>COVID-19</b>	<ul style="list-style-type: none"> <li>Guidance on the Review &amp; Approval of IVDs for COVID19(3<sup>rd</sup> Edition)</li> <li>Guidance on the Review &amp; Approval of Medical Respirator</li> </ul>
<b>MLMD</b>	<ul style="list-style-type: none"> <li>Guidance on the Evaluation of Safety/Performance and Clinical Protocol for Software of Image Detection and Diagnosis Support for Brain, Colon Cancer, Prostate Cancer</li> <li>Guidance on the Procedure and Criteria of Certification for Innovative Software Manufacturer</li> </ul>
<b>3D Printing</b>	<ul style="list-style-type: none"> <li>Guidance on the Review &amp; Approval of Co-Cr Artificial Joint Manufactured using 3D Printing</li> <li>Guidance on the Review &amp; Approval of Denture base Resin Manufactured using 3D Printing</li> <li>Guidance on the Review &amp; Approval of Aesthetic Crown Manufactured using 3D Printing</li> </ul>
<b>English Version</b>	<ul style="list-style-type: none"> <li>Guidance on the Review &amp; Approval of IVDs for COVID-19</li> <li>Guidance on the Review &amp; Approval of AI and Big data based Medical Devices</li> <li>Guidance on the Review &amp; Approval of Digital Therapeutics</li> <li>Guidance on the Review &amp; Approval for Cybersecurity of Medical Devices</li> </ul>

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## Ongoing Projects

### IVD

Development of Guidance on the Evaluation of Clinical Performance of AI based Digital Pathologic IVDs

### DTx

Development of Guidance on the Evaluation of Safety/Performance and Clinical Protocol for Digital Therapeutics

### Review Practice

Revision of Evaluation Method of Medical Device Substantial Equivalence for Premarket Approval

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Thank you

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# USA



**Jeff Shuren, US FDA**



**IMDRF** International Medical  
Device Regulators Forum

## US FDA Update

IMDRF Open Stakeholder Session  
March 2021



**IMDRF** International Medical  
Device Regulators Forum

## COVID-19 Overview



**27**  
GUIDANCE  
DOCUMENT  
S



\*Data as of February 12, 2021

2



## Medical Device User Fee Amendments (MDUFA)

- Program where industry pays user fees which the agency uses to increase review capacity to meet performance goals on review timelines and implement targeted process improvements.
- Helps assure patients have access to safe, effective, high-quality devices in a timely fashion and there is a clear, predictable path to market for new innovations.
- The user fees authorized by MDUFA are crucial to enabling CDRH to continue to modernize our regulatory programs.
- The program is reauthorized every five years based on new negotiated agreements and new legislation:
  - MDUFA I: FY 2003-2007
  - MDUFA II: FY 2008-2012
  - MDUFA III: FY 2013-2017
  - MDUFA IV: FY 2018-2022



## MDUFA V Reauthorization

- The authorization for the current program (MDUFA IV) expires in September 2022 and will need to be reauthorized (MDUFA V).
  - MDUFA V: FY 2023-2027
- Initial public meeting was held on October 27, 2020 involving various stakeholders to present their views on reauthorization.
- Periodic stakeholder consultation meetings will be held during which public stakeholders — including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts — can discuss their views on the MDUFA V reauthorization and provide suggestions for improving the program.
  - First scheduled for March 10, 2021
- Meetings will also be held with industry representatives to develop recommendations for MDUFA V.



## Device Safety Guidances: Breast Implant Guidance Documents

- *Breast Implants – Certain Labeling Recommendations to Improve Patient Communication*
  - Contains recommendations concerning the content and format for certain labeling information for saline and silicone gel-filled breast implants to help ensure that a patient receives and understands the benefits and risks of these devices.
  - <https://www.fda.gov/media/131885/download>
- *Saline, Silicone Gel, and Alternative Breast Implants*
  - Identifies the device description, non-clinical, clinical, and labeling information that should be included in a premarket approval application (PMA) for a saline, silicone gel, or alternative filler breast implant.
  - <https://www.fda.gov/media/71081/download>

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## Device Safety Guidances: Laparoscopic Power Morcellators

### *Product Labeling for Laparoscopic Power Morcellators (LPMs)*

- Contains recommendations concerning the content and format for certain labeling information for laparoscopic power morcellators in order to enhance the physician-patient discussion of the benefits and risks of use of LPMs that uniquely pertain to individual patients. Specifically:
  - Labeling should provide greater specificity regarding the risk of use as it relates to age, information regarding the risk of spreading malignant and benign uterine tissue, and information regarding the use of LPM containment systems.

Contains Nonbinding Recommendations

#### Product Labeling for Laparoscopic Power Morcellators

#### Guidance for Industry and Food and Drug Administration Staff

Document issued on December 30, 2020.

The draft of this document was issued on February 26, 2020.

This guidance supersedes "Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators," issued on November 25, 2014.

For questions about this document, contact OHTD: Office of Gastro-Intestinal, Obstetric, Gynecological, and Urology Devices (OHTD) Division of Reproductive, Gynecology, and Urology Devices for gynecologic indications at (301) 796-7030 or OHTA: Office of Surgical and Infection Control Devices (OHTA) Division of General Surgery Devices for general surgical indications at (301) 796-6970.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health

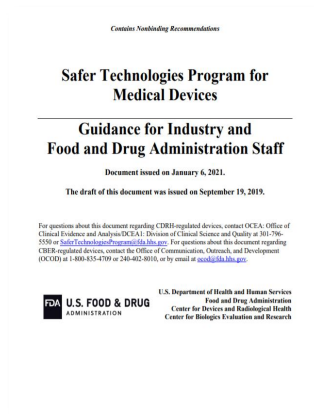
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-labeling-laparoscopic-power-morcellators>

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## Safer Technologies Program (STeP) for Medical Devices

- ✓ Final guidance published on January 6, 2021.
- ✓ Voluntary program for certain types of medical devices that are reasonably expected to significantly improve the safety of currently available medical treatments and diagnostics through innovative technological features.
- ✓ Focuses on increasing timeliness of patient access to these medical devices.
- ✓ Key features:
  - ✓ Expedites device development and review
  - ✓ Provides opportunities for interaction to efficiently support device development
  - ✓ Provides increased opportunity for senior management involvement



<https://www.fda.gov/medical-devices/how-study-and-market-your-device/safer-technologies-program-step-7-medical-devices>



## Safety and Performance Based Pathway

- Program where devices must meet FDA-identified performance criteria to demonstrate it is as safe and effective as predicate device.
- Device specific guidances issued:
  - [Spinal Plating Systems](#)
  - [Orthopedic Non-Spinal Metallic Bone Screws and Washers](#)
  - [Magnetic Resonance Receive-Only Coils](#)
  - [Cutaneous Electrodes for Recording Purposes](#)
  - [Conventional Foley Catheters](#)
- Benefits:
  - Promotes the use of modern predicate devices, and adoption of up-to-date benchmarks and standards for performance.
  - Promotes the use and development of international consensus standards rather than reliance on comparison to predicate devices.
  - Facilitates greater harmonization of pre-market requirements with other regulatory jurisdictions.

<https://www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway>

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## AI/ML Medical Device Software Action Plan



1. Update the proposed AI/ML framework, including through guidance
2. Strengthen FDA's role in harmonizing GMLP through standards development & other initiatives
3. Foster a patient-centered approach, starting with a workshop on transparency to users
4. Support development of regulatory science methods related to algorithm bias and robustness
5. Advance real-world performance pilots in coordination with stakeholders and other programs



## AI/ML Medical Device Software Action Plan: Tailored Regulatory Framework for AI/ML Based SaMD

- A strength of AI/ML systems is their ability to learn from real world data and improve performance over time
- Predetermined Change Control Plan includes:
  - **SaMD Pre-Specifications (SPS):** describes "what" aspects the manufacturer intends to change through learning,
  - **Algorithm Change Protocol (ACP):** explains "how" the algorithm will learn and change while remaining safe and effective
- Goal is to issue a Draft Guidance on the Predetermined Change Control Plan in 2021

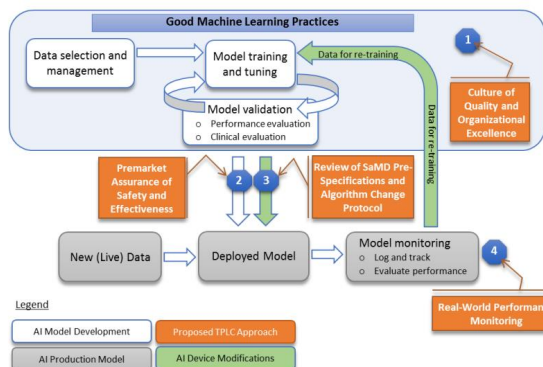
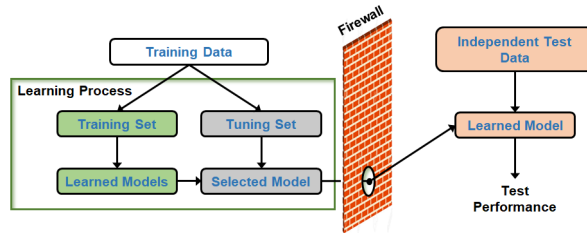


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow



## AI/ML Medical Device Software Action Plan: Good Machine Learning Practice (GMLP)

- Accepted practices in ML/AI algorithm design, development, training, and testing that facilitate the quality development and assessment of ML/AI-based algorithms
- Based on concepts from quality systems, software reliability, machine learning, and data analysis
- Ongoing work through standards development, collaborative communities, and other collaborations



## AI/ML Medical Device Software Action Plan: Patient-Centered Approach Incorporating Transparency to Users

AI/ML-based devices have unique considerations that necessitate a proactive patient-centered approach:

- that takes into account issues including usability, equity, trust, and accountability
- promotes transparency to all users and to patients more broadly

Patient Engagement Advisory Committee (PEAC) Meeting held Oct 2020

Next Step: Workshop on  
Transparency planned for 2021





## AI/ML Medical Device Software Action Plan: Regulatory Science Methods Related to Algorithm Bias & Robustness

- Need for improved methodologies for the evaluation and improvement of machine learning algorithms
- Includes methods for the identification and elimination of bias, and on the robustness and resilience of these algorithms to withstand changing clinical inputs and conditions
- Regulatory science research efforts to develop these methods to evaluate AI/ML-based medical software
- Ongoing research being conducting in collaboration with Centers for Excellence in Regulatory Science and Innovation (CERSIs)

Opinion  
**A.I. Could Worsen Health Disparities**  
In a health system riddled with inequity, we risk making dangerous biases automated and invisible.  
By Dhruv Khullar  
Dr. Khullar is an assistant professor of health care policy and research.  
Jan. 31, 2019

HEALTH TECH STAT+  
**AI could help rid health care of biases. It also might make them worse**  
By STAT STAFF / SEPTEMBER 16, 2020

### Racial Bias Found in a Major Health Care Risk Algorithm

Black patients lose out on critical care when systems equate health needs with costs

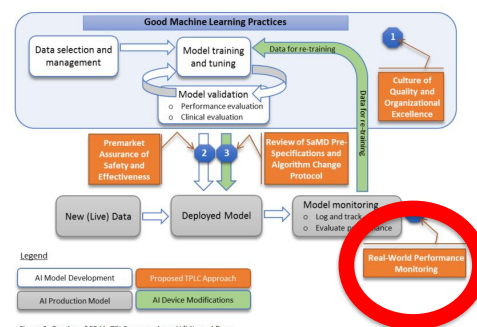


## AI/ML Medical Device Software Action Plan: Real-World Performance (RWP)

- Collection and monitoring of real-world data will support a total product lifecycle (TPLC) approach to the oversight of AI/ML-based SaMD and can allow manufacturers to:
  - Improve their understanding of how their products are being used
  - Identify opportunities for improvements, and
  - Respond proactively to safety or usability concerns

### Actions:

- Support the piloting of real-world performance monitoring by working with stakeholders on a voluntary basis
- Coordination with other ongoing FDA programs focused on the use of real-world data
- Develop a framework for seamless gathering, validation, and evaluation of relevant real-world performance metrics
- Continued stakeholder and public engagement





**Thank you**





**UK**



**Graeme Tunbridge, MHRA**



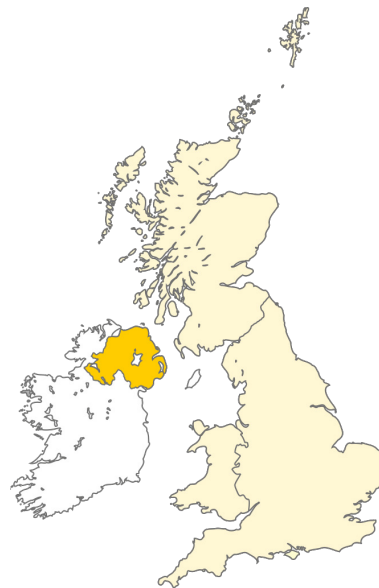
Medicines & Healthcare products  
Regulatory Agency

## Overview of UK Medical Device Regulation



### Standstill Position

- The transition period between the UK and the EU ended on 1 January 2021
- 2.5 year 'standstill period'
- Different regulation in Great Britain (England, Wales, Scotland) and Northern Ireland due to the Northern Ireland Protocol
- Northern Ireland will have access to the EU Single Market and it will continue to align with EU rules for medical devices



## Standstill Position

### Great Britain



- EU MDR/IVDR not implemented
- Recognition of the CE marking until 30 June 2023
- UKCA marking required after 30 June 2023
- Approved Bodies can now conduct assessments for the UKCA mark

### Northern Ireland

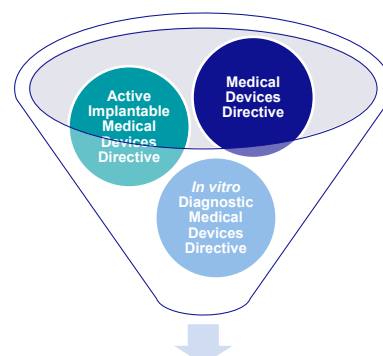


- EU MDR/IVDR implemented with EU timeline
- Devices must be CE or CE UKNI marked
- CE UKNI applied where UK Notified Body used for conformity assessment

3

## UK Legislation

- Medical devices are regulated in the UK under the **UK Medical Devices Regulations 2002** (UK MDR 2002)
- The UK MDR 2002 is based on existing EU legislation which has been transposed into UK law
- **The Medicines and Medical Devices Act (2021):**
  - allows us to update the UK MDR 2002
  - consolidates enforcement provisions
  - provides for a device information system
  - allows for enhanced data sharing



UK Medical Devices Regulations 2002  
(as amended)



Medicines  
and Medical  
Devices Bill  
2019-21

4

# Future Regulation of Medical Devices in Great Britain

Attractive world-class regulatory system which prioritises patient safety

Early 2021	Late 2021-Early 2023	July 2023
<ul style="list-style-type: none"><li>• MMD Act in force</li><li>• Informal consultation with stakeholders</li></ul>	<ul style="list-style-type: none"><li>• Formal public consultation</li><li>• Agree position and finalise secondary legislation</li></ul>	<ul style="list-style-type: none"><li>• Stop recognition of CE marking in GB</li><li>• New medical device regulatory framework in force</li></ul>

We will take into consideration international standards and global harmonisation in the development of our future system







# Session 2



## Progress Overview of IMDRF Work Items

RPS  
GRRP  
AE  
PMD  
MDCE  
CYBER  
IVD  
AIMD





# RPS

⋮

**Nancy Shadeed,  
Health Canada**



## IMDRF Regulated Products Submission (RPS) WG Update

Nancy Shadeed  
Health Canada



### Updates

- Current Status of Electronic Submission
- Electronic submission environments using the IMDRF Table of Contents



## **RPS (Electronic Submission Standard)**

- Stakeholders continue to voice concerns with the current interim solution of folder structure and pdf.
- Absence of harmonized dynamic template intended for the collection of harmonized content in IMDRF/RPS WG/N9 and IMDRF RPS WG/N13, as well as regionally specific content.
- Some jurisdictions are starting to develop their own templates for electronic submissions, moving away from harmonization

3



## **Update of Work on Electronic Submissions**

- The US Food and Drug Administration (FDA) has developed a medical device submission assembly tool (eSTAR).
- The FDA is intending to make eSTAR fully harmonized with the TOC structure.
- FDA and Health Canada have recently worked on the eSTAR tool to include the TOC structure for Health Canada's Class III and IV applications.

4



## **New Work Item Extension (NWIE) Proposal**

- Experiences to date have identified several recommendations to make the documents “fit for purpose” – using the FDA and HC feasibility work already developed; and
- Achieve the desired end goal- electronic preparation of regulatory submissions for product licensing applications between industry and regulatory authorities.

5



## **NWIE Proposal**

- Specifically, the following enhancements have been identified:
  - Creation of dynamic templates for IMDRF/RPS WG/N9 and IMDRF/RPS WG/N13;
  - Creation of specific electronic content for each regulatory authority, as well as harmonized content for all regulatory authorities; and
  - Minor updates to contents of IMDRF/RPS WG/N9 and IMDRF/RPS WG/N13.

6



## NWIE Proposal

- Opportunities for harmonization
  - Allowing industry to file electronic applications with multiple regulatory authorities using the same method
  - Instead of separate vocabularies and implementation guides for each regulatory authority, one harmonized approach reduces regulatory burden while increasing predictability, transparency, and regulatory cooperation.

7



## NWIE Proposal

- Opportunities for harmonization
  - Creation of a “fit for purpose,” harmonized, electronic approach to regulatory submissions also serves to operationalize higher level IMDRF documents (e.g., IMDRF/GRRP WG/N47: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices).

8



## Next Steps

- Discussion of NWIE at IMDRF MC meeting
- If approved, timeline is expected to take 12-18 months

9



## Questions/comments

Thank you!

10







# GRRP



**Lakshmid devi Balakrishnan, HSA**



**IMDRF** International Medical  
Device Regulators Forum

## **IMDRF GOOD REGULATORY REVIEW PRACTICES (GRRP) WORKING GROUP UPDATE**

Working Group Chairs:

Lakshmid devi Balakrishnan  
HSA – Singapore

Melissa Torres  
US Food and Drug Administration



**IMDRF** International Medical  
Device Regulators Forum

## **IMDRF GRRP Working Group Goals**

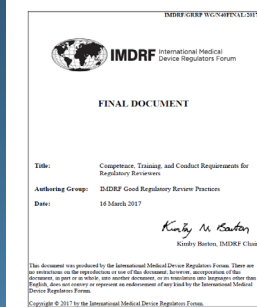
- Develop documents focused on harmonizing pre-market review requirements globally. Documents focus on:
  - Technical requirements for conducting pre-market reviews
  - Competency requirements for pre-market reviewers
  - Requirements for organizations performing pre-market reviews
- Work products align with the IMDRF strategic priority to promote harmonized pre-market review requirements for medical devices.



2

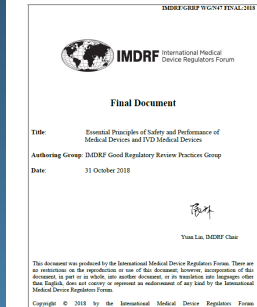


# IMDRF International Medical Device Regulators Forum



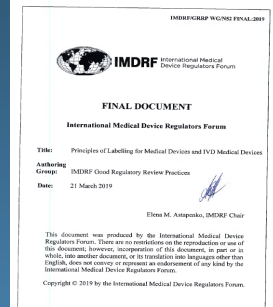
IMDRF GRRP WG/  
N40 FINAL:2017

*Competence, Training,  
and Conduct  
Requirements for  
Regulatory Reviewers*



IMDRF GRRP WG/  
N47 FINAL: 2018

*Essential Principles of  
Safety and  
Performance*



IMDRF GRRP WG/  
N52 FINAL: 2019

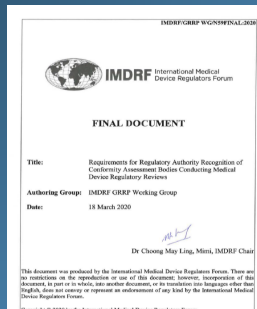
*Principles of Labelling*

**Pre-market Review Processes**

3



# IMDRF International Medical Device Regulators Forum



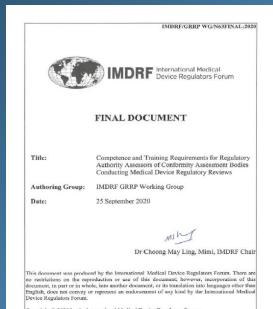
IMDRF GRRP WG/  
N59 FINAL:2020

*Requirements for  
Regulatory Authority  
Recognition of CABs*



IMDRF GRRP WG/  
N61 FINAL:2020

*Assessment Methods  
for Recognition of  
CABs*



IMDRF GRRP WG/  
N63 FINAL:2020

*Competence and  
Training  
Requirements for  
Assessors of CABs*

**Recognition of Conformity Assessment Bodies (CABs)**

4



## CURRENT WORK ITEM

IMDRF GRRP WG/N66 PD1: *Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews*

- Outlines the assessment process and outcomes, including the method to “grade and manage” nonconformities resulting from a recognizing Regulatory Authority’s assessment of a Conformity Assessment Body (CAB).
- Documents the decision process for recognizing a CAB or cessation of recognition.
- Models the Medical Device Single Audit Program (MDSAP) document IMDRF/MDSAP WG/N11 FINAL:2014.
- Public consultation through April 19, 2021:

<http://www.imdrf.org/consultations/cons-adpr-cab-cmdrr.asp>

5



## NEW WORK ITEM EXTENSION

The GRRP WG has developed a NWIE to further harmonize pre-market review processes:

- Submitted for the March 2021MC meeting for review.
- Focused on the development of a reporting model for medical device regulatory reviews conducted by CABs.
  - Involves the creation of templates and work instructions to guide CABs in consistently evaluating marketing submissions and documenting their certification recommendations in marketing review reports.
- Provides the opportunity for convergence across RAs with respect to how medical devices are evaluated.

6



## BENEFITS OF GRRP WG DOCUMENTS

- Promotes consistency, predictability and transparency in the regulatory pre-market review programs through agreed upon sets of criteria and processes.
- Provides confidence that pre-market regulatory reviews conducted by CABs are rigorous enough to meet the requirements of Regulatory Authorities.
- Provides opportunities for convergence of pre-market review requirements.
- Benefits all regulators, even those just starting to develop a regulatory medical device premarket review system.

7



## NEXT STEPS

- NWIE has been submitted to the IMDRF MC for consideration during the March 2021 IMDRF MC.
  - If approved, begin working on NWIE through teleconferences.
- Address comments received from the public consultation for IMDRF GRRP WG/N66 PD1: *Assessment and Decision Process for the Recognition of a Conformity Assessment Body Conducting Medical Device Regulatory Reviews* and finalize document for consideration for the September 2021 IMDRF MC meeting.

8



**IMDRF** International Medical  
Device Regulators Forum

**THANK YOU**









# AE

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**Hiroshi Ishikawa, PMDA**



**IMDRF** International Medical  
Device Regulators Forum

# Adverse Event Terminology and Coding Working Group

IMDRF Open Stakeholders Forum Webinar  
March 2021

Presented by  
H. Ishikawa, Working Group Chair  
Pharmaceuticals and Medical Devices Agency (PMDA)



**IMDRF** International Medical  
Device Regulators Forum

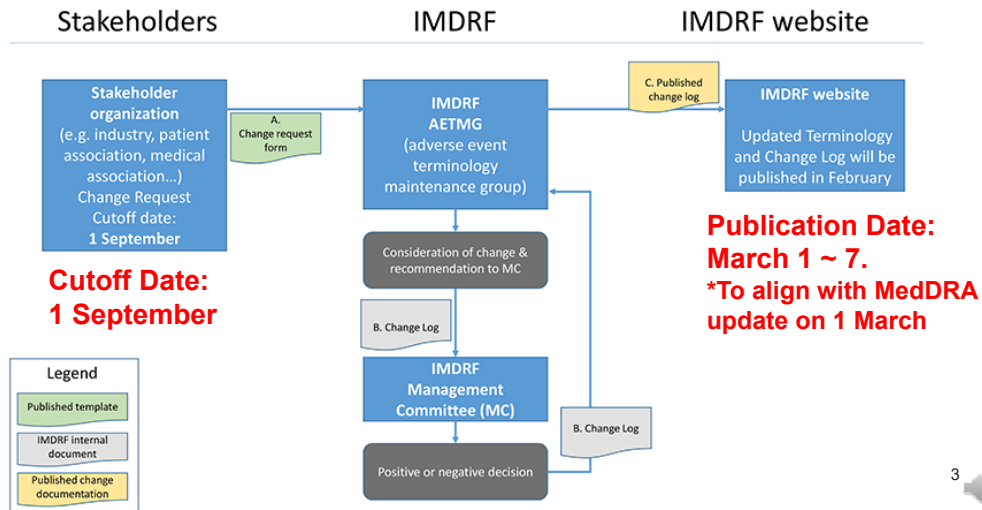
## 1. OVERVIEW OF ANNUAL MAINTENANCE PROCESS





## Maintenance Process

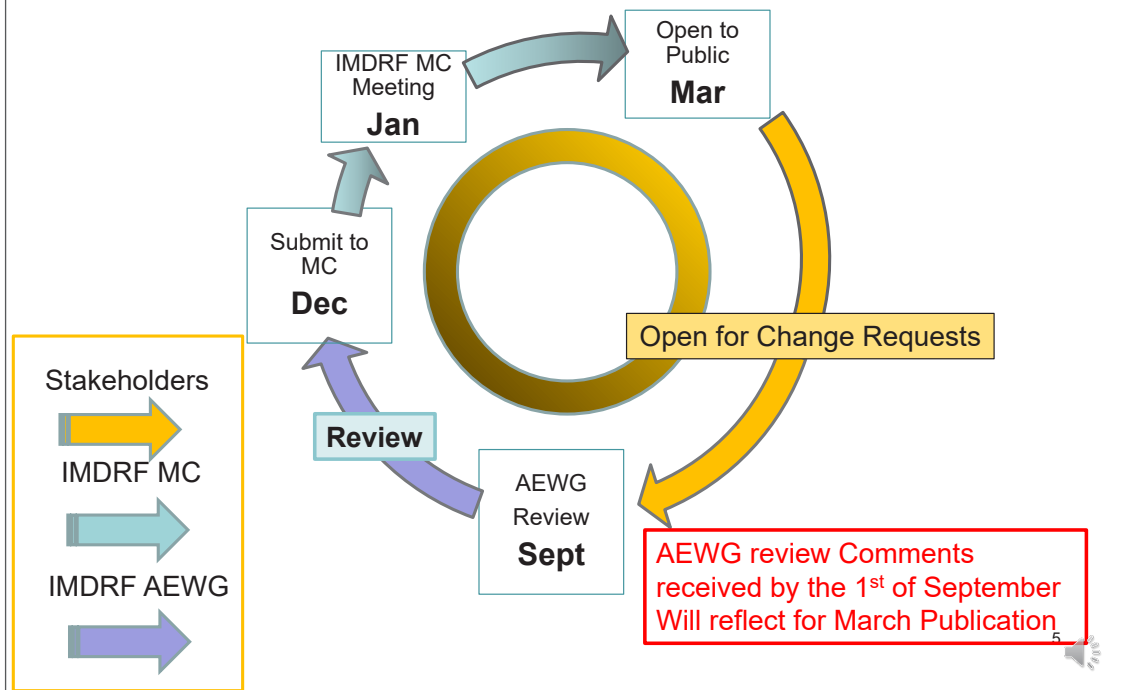
- The maintenance process and Change Request form are available on the [IMDRF AE Terminology Maintenance webpage](#).



## 2 HOW TO SUBMIT CHANGE REQUESTS



# IMDRF International Medical Device Regulators Forum



# IMDRF International Medical Device Regulators Forum

## How to Fill in the Change Request Form

	Item	Description
1	Date submitted (DD/MM/YYYY)	DD/MM/YYYY
2	Requester information	Submitter
3	Terminology (Annex A, B, C, D, E, F, G)	Organization name
4	Version of Annex	Please indicate which Annex
5	Code	The version number is indicated in cell A3 of the excel files. In general, comments should be submitted to the published version ( <a href="#">available here</a> ). If you are submitting a comment to a previous version, please check the newest version to make sure it has not already been addressed.
6	Term	IMDRF
7	Location in the hierarchy	Level 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000



## Outcomes of Change Requests are published in a Change Log

Documentation of IMDRF decision on webpage

- IMDRF AE WG will review the request and make a recommendation
- After IMDRF MC approval, the results of the change requests will be published as a Change Log.
- The revised Terminology Annexes will be designated with an updated version number and published in March.
- **Note that all information provided in the Change Request Form will be published as part of the Change Log.**

### Change Log

Requester Information		Change Proposal Information										IMDRF Decision		
Date submitted (DD/MM/YYYY)	Submitter (organization name)	Terminology (Annex A, B, C, D, E, F, G)	Version of Annex	Code	Term	Location in the hierarchy	Definition	Category of change (e.g., new, revised, deleted)	Description of change (e.g., the change is intended to address the following issue)	Rationale for change (e.g., the change is intended to address the following issue)	Impact on other existing terms	Examples of use cases which would be affected by the proposed change	Outcome of change request (ACCEPTED or REJECTED)	Date Published (DD/MM/YYYY)

Outcome of change request	Results of Review (ACCEPTED or REJECTED)
Justification	An explanation of the outcome of the change request.
New code if applicable	If the request was to add a new term, the new code will be indicated
Date Published	This is the date of publication of the terminology based on the change request.



## Before Submitting a Change Request, Please review the most recent Change Log!

- The Change Log for IMDRF Terminology Edition 5.0 has been published on the IMDRF website.
- Please review past resolutions to ensure that your comment has not already been addressed.





9 



Figure 1: A multi-panel figure showing the analysis of a COVID-19 outbreak. The top left shows a zoomed-in view of the first 100 days of the outbreak, highlighting the initial rise and peak. The top right shows a zoomed-in view of the last 100 days, highlighting the decline and stabilization. The middle section displays a grid of 12 plots showing the time series of various variables, including the number of cases, deaths, and recoveries, along with the estimated parameters of the model. The bottom left shows a zoomed-in view of the first 100 days of the outbreak, highlighting the initial rise and peak. The bottom right shows a zoomed-in view of the last 100 days, highlighting the decline and stabilization. The bottom center shows a heatmap of the correlation matrix of the variables, indicating strong positive correlations between cases, deaths, and recoveries.



Thank you for your kind attention!



## Resources

### IMDRF Terminology

- [IMDRF AE WG Webpage](#) (Includes links to the terminology web browser)
- [IMDRF AE Terminology \(Current Version\)](#)
- [IMDRF AE Terminology \(Archived Versions\)](#)

### IMDRF Terminology Maintenance

- [IMDRF Terminology Maintenance Webpage](#)
- [Change Request Form](#)

### Related Documents

- [IMDRF AE Terminology Guideline Main Body \(N43 Document\)](#)
- [IMDRF Terminology Maintenance \(N44 Document\)](#)





# PMD



Tracey Duffy, TGA



## Personalized Medical Devices (PMD) Working Group March 2021 Update

Tracey Duffy  
Therapeutic Goods Administration - Australia



### Working group members

Jurisdiction	Representatives	Jurisdiction	Representatives
Argentina	Marcela Rizzo	Japan	Yoshifumi Nagai Kanao Sasaki Yoshimasa Yokoyama
Australia	Tracey Duffy (Chair) Rebecca Bateson Uphar Chamoli Madeleine Neill	Portugal	Mariana Isabel Vaz Afonso Pires Madureira
Brazil	Priscilla Consiglierio de Rezende Martins Maria Angela da Paz Marcia Cristina de Moraes Reis Ribeiro	Russia	Konstantin Ivanov
Canada	Andrea Katynski	Saudi Arabia	Abdullatif S. Al Watban
China	Yue Min Shuo Pan	Singapore	Shuling Peng
European Commission	Nada Alkhayat	South Korea	Jang-yong Choi Seon-mi Lee Sang-jin Park
Germany	Matthias Neumann	USA	Matthew A. Di Prima



## Benefits of additional guidance for PMD

- Addresses an emerging trend for increased use of personalized treatments in healthcare
- Enhances sharing and use of relevant information and scientific expertise among stakeholders
- Supports harmonization for safety, performance and manufacturing of these products
- Provides a basis for consistent and transparent requirements across multiple jurisdictions
- Aligns with IMDRF strategic priorities

3



## PMD working group publications

### Definitions for PMD (N49)

IMDRF/PMD WG/N49 FINAL:2018

**Published in October 2018**

- Custom-made medical device
- Patient-matched medical device\*
- Adaptable medical device

\* Designed and produced within a specified design envelope



**IMDRF** International Medical  
Device Regulators Forum

#### Final Document

Title: Definitions for Personalized Medical Devices

Authoring Group: IMDRF Personalized Medical Devices

Date: 18 October 2018

Yun Lin, IMDRF Chair

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum.

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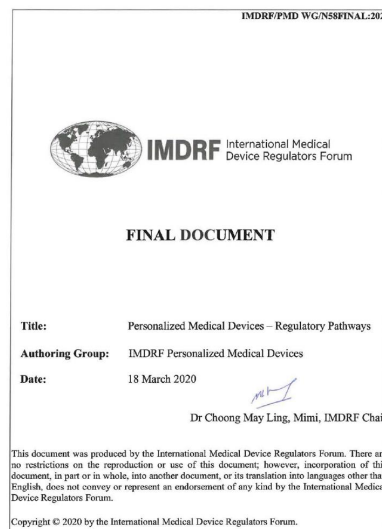


## PMD working group publications

### Regulatory Pathways for PMD (N58)

**Published in March 2020**

- Regulatory requirements for different categories of PMD
- Medical Device Production System
- Considerations for point-of-care manufacturing of PMD



5



## PMD working group publications

- [N49](#), [N58](#) introduced new definitions and concepts relating to the production of personalized medical devices
- PMD Working Group proposed developing a new technical document building on the previous publications
- Technical document to propose requirements for validation of production processes that are unique to PMD
- MC approved drafting of the new technical document (New Work Item Extension) on 25 September 2020

6



## New Work Item Extension (NWIE)

### PMD – Production Validation

#### Scope of work

Technical considerations for validation aspects of a specified design envelope	Technical considerations for validation aspects of a Medical Device Production System
<ul style="list-style-type: none"><li>• Intended use(s) and range of user needs</li></ul>	<ul style="list-style-type: none"><li>• Quality management system requirements</li></ul>
<ul style="list-style-type: none"><li>• Geometrical, material, performance, operational variants</li></ul>	<ul style="list-style-type: none"><li>• Risk management plans</li></ul>
<ul style="list-style-type: none"><li>• Worst-case scenario design validation testing</li></ul>	<ul style="list-style-type: none"><li>• Usability assessments</li></ul>
<ul style="list-style-type: none"><li>• Clinical evaluation, etc.</li></ul>	<ul style="list-style-type: none"><li>• Requirements for labelling and instructions for use, etc.</li></ul>

7



## PMD - Production Validation

- First meeting (held 15 December 2020) via teleconference
  - Discussed the scope of work
  - Identified a number of countries already have useful documents that can inform this NWIE
- Members have shared relevant documents to inform the Working Draft
- Working Draft to be discussed at the next Working Group meeting in March 2021

8



## Forward plan

### Key dates:

- Working Group currently developing the Working Draft
- Aiming to submit the final Working Draft to the MC in January 2022 for review<sup>\*</sup>
- Three months (March-May 2022) public consultation on the Proposed Document
- Potentially Final Document due to the MC for consideration before September 2022 meeting<sup>#</sup>

<sup>\*</sup> Following MC approval, the Working Draft will advance to the Proposed Document stage

<sup>#</sup> Following resolution of comments received during the public consultation, the Proposed Document will advance to become the Final Document

9



## Forward plan

### Key dates:

- Targeted circulation of Working Draft among Working Group members (October – November 2021)
- Final Working Draft forwarded to the MC (January 2022)
- Public consultation of the Proposed Document (March – May 2022)
- Submission of Final Document to MC (July – August 2022) for consideration at the September 2022 meeting

2021				2022								
Event	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Targeted circulation of Working Draft												
Final Working Draft to MC												
Public consultation of Proposed Document												
Final document for MC consideration												

10



Thank you





The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# MDCE

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Yinghui Liu, CMDE



## **Medical Device Clinical Evaluation (MDCE) Working Group**

### **---- Post-Market Clinical Follow-up Studies**

23<sup>th</sup> March 2021



#### **Work Item**

Update existing GHTF documents.

GHTF SG5 N4: *Post-Market Clinical Follow-up Studies*

And following issues need to be addressed (NWIE)

- a) Requirements for Clinical Evidence from new sources of Clinical Data (i.e. Real-World clinical experience) for Post-Market Clinical Follow-Up Studies.
- b) Basing a Post-Market Clinical Follow-Up Study on clinical experience such as registries or medical records or other sources of data.
- c) What clinical issues are appropriate to investigate prior to marketing and what may be investigated post-market.
- d) Updates to align guidance on Post-Market Clinical Follow-Up Study to changes in other documents.



## Working Group Members

### Australia:

Simon Singer  
Jeffrey Brownscombe

### Brazil :

Alessandro Ferreira do  
Nascimento  
*Leticia Barel Filler*

### Canada :

Amanda Jones  
Patrick Fandja

### China :

**Yinghui Liu (Chair)**  
Shan Ju  
Yawen Wang

### Europe :

Gwennaëlle Even  
Tom Melvin  
Paul Piscoi  
*Camilla Fleetcroft*  
*Jean-Claude Ghislain*

### Japan :

Taku Oohara  
Fumihito Takanashi  
Mami Ho  
Daisuke Fujisawa  
Nobuhiro Handa  
Haruka Yoshitake  
Yuki Kimura  
Yukari Namba  
Mika Togashi  
*Mari Shirotani*

### Russia :

Anna Dmitrieva  
*Valeeva Aisylu*  
*Kurtukov Yaroslav*

### Singapore :

Low Lai Peng

### South Korea :

Hee-jung Kim  
MOON, Sun-Young  
*Youngsook Choi*  
*Youngmin Han*

### the United States :

Minerva Hughes  
Nilsa Loyo-Berrios  
Adam Donat  
*Owen Faris*

### Soma Kalb

*William Sutton*

### PAHO :

Micaela Dominguez  
Jose Medico

### DITTA :

Leo Hovestadt  
Keiichiro Ozawa  
Greg Leblanc  
*Bradley Matsubara*  
*Susumu Uchiyama*

### GMTA :

Michael Pflieger  
Theodore Lystig  
*Robin Newman*



## Teleconferences

Develop working draft

2020

3.10 1<sup>st</sup> WG T-con  
3.24 2<sup>nd</sup> WG T-con  
4.07 3<sup>rd</sup> WG T-con  
4.21 4<sup>th</sup> WG T-con  
5.12 5<sup>th</sup> WG T-con  
5.26 6<sup>th</sup> WG T-con  
6.09 7<sup>th</sup> WG T-con  
6.10 8<sup>th</sup> WG T-con  
6.23 9<sup>th</sup> WG T-con  
7.07 10<sup>th</sup> WG T-con  
7.14 11<sup>th</sup> WG T-con

Public consultation

Received  
**176**  
comments

Develop final draft

2021

1.19 12<sup>th</sup> WG T-con  
1.26 13<sup>th</sup> WG T-con  
2.02 14<sup>th</sup> WG T-con  
2.09 15<sup>th</sup> WG T-con




## The Final draft

### Document Structure:

- 1.0 Introduction
- 2.0 Scope
- 3.0 References
- 4.0 Definitions
- 5.0 Circumstances where a PMCF study may be indicated
- 6.0 Elements of a PMCF study
- 7.0 The use of information from PMCF studies
- Appendix A
- Appendix B
- Appendix C

IMDRF MDCE WG/Nx FINAL 2021

 **IMDRF** International Medical  
Device Regulators Forum

**Final Document**

**Title:** Post-Market Clinical Follow-Up Studies

**Authoring Group:** Medical Device Clinical Evaluation Working Group

**Date:** 18 February, 2021

[Signature], IMDRF Chair

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## Key changes

- Update the definitions of terms.

***Post-market clinical follow-up study:*** A study carried out following marketing authorization intended to answer specific questions (uncertainties) relating to Safety, clinical performance and/or effectiveness of a device when used in accordance with its labelling.

- Update reference documents.



- Updated the circumstances where a PMCF study may be indicated, including:

- a) Unanswered questions of long-term Safety, clinical performance and/or effectiveness.*
- b) Novel technologies or new intended use.*
- c) Higher-risk device and use scenarios.*
- d) Uncertainties in generalizing clinical investigation results.*
- e) Devices approved with clinical data from comparable devices.*
- f) Emergence of new information relating to Safety, clinical performance and/or effectiveness.*
- g) Urgent market access in public health emergencies.*
- h) Rare anticipated adverse events.*
- i) Effectiveness of the mitigation for a known risk.*



- Revised the elements of a PMCF study, added the requirements and considerations about the objective, design and implementation of PMCF studies that based on clinical experience data. 3 new informative appendixes are introduced in the design of PMCF studies.

*Appendix A Examples of Clinical Experience Data Sources for PMCF Studies*

*Appendix B Considerations for Using Clinical Experience Data for PMCF Studies*

*Appendix C Potential Biases and Confounding in PMCF Studies and Controlling Methods*



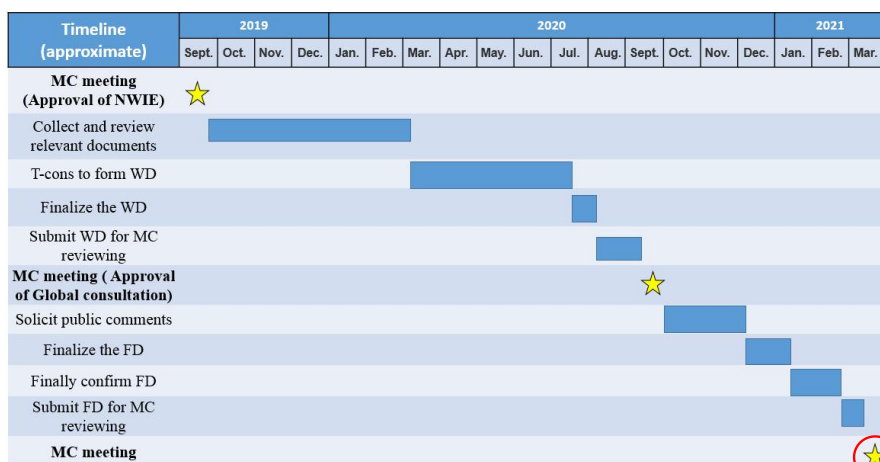
- Update the use of information from PMCF studies

*“The data and conclusions derived from the PMCF studies are part of the post-market surveillance program and used as input to the clinical evaluation and risk management process. This may result in the need to reassess whether the device continues to comply with the Essential Principles. Such assessment may result in corrective or preventive actions, for example:*

- *changes to the labelling/instructions for use,*
- *changes to manufacturing processes,*
- *changes to the device design,*
- *public health notifications, or*
- *product removal.*

*In addition, clinical data/evidence generated from PMCF studies can be used to:*

- *become the part of premarket clinical evidence, or supplementary data for next- generation or similar technologies when applying for marketing authorization,*
- *develop objective performance criteria and performance goals,*
- *form control/comparison groups.”*



★ MC approval WD = Working draft FD = Final Document.



***Thank you***





The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# CYBER



**Marc Lamoureux,  
Health Canada**



**IMDRF** International Medical  
Device Regulators Forum

# **IMDRF Stakeholders Forum March 2021**

## **Medical Device Cybersecurity Update**

**US FDA & Health Canada Co-Chairs**



**IMDRF** International Medical  
Device Regulators Forum

## **Presentation Outline**

- IMDRF/CYBER WG/N60 Final Guidance, published March 2020
  - Purpose and Scope
  - General Principles
  - Introduction of Legacy and Software Bill of Materials (SBOM)
- New Work Item Extension to expand on and advise on implementation of Legacy and SBOM concepts
- Progress and Planned Milestones

2



## Guidance Purpose & Scope

- Purpose:
  - To provide fundamental concepts and considerations on the general principles and best practices on medical device cybersecurity
- Scope:
  - Considers cybersecurity broadly in the context of medical devices that either contain or composed of software, and not just network connected devices
  - Excludes information security and directly state scope includes medical device safety and performance
  - Includes recommendations to all stakeholders, not just manufacturers

3



## General Principles

1. **Global Harmonization:** Stakeholders are encouraged to harmonize their cybersecurity approaches across the entire life cycle of the medical device.
2. **Total Product Life Cycle (TPLC):** Risks associated with cybersecurity threats and vulnerabilities should be considered throughout all phases in the life cycle of a medical device.

4



## General Principles cont'd

3. **Information Sharing:** Stakeholders are encouraged to engage in information sharing to increase transparency and collaboration to enable the safe and effective use of medical devices.
4. **Shared Responsibility:** All stakeholders must understand their responsibilities and work closely with other stakeholders to respond to potential cybersecurity risks and threats.

5



## Two Concepts introduced in N60

- **Legacy Medical Device:** medical devices that cannot be reasonably protected (via updates, and/or compensating controls) against current cybersecurity threats.
- **Software Bill of Materials (SBOM):** a list identifying each software component by its name, origin, version and build of any commercial, open source, or off-the-shelf software components which are included in the medical device.

6



## Legacy Conceptual Framework

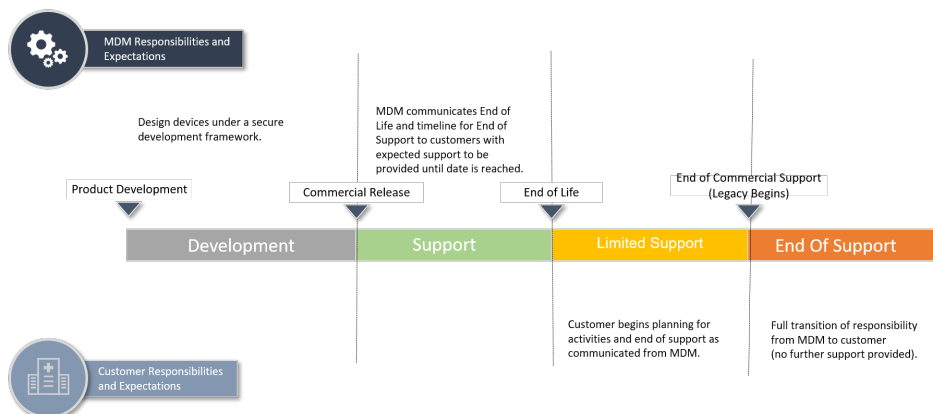
- N60 defined a conceptual framework to define the responsibilities between manufacturer and customer throughout the total product life cycle.
- N60 emphasizes that device age is not a sole determinant of legacy status.
- N60 provides some recommendations to both the manufacturer and the customer throughout the different stages of the total product life cycle.

7



## Legacy Device Conceptual Framework as a Function of TPLC

### Cybersecurity and the Total Product Life Cycle



\*Medical Device Manufacturer (MDM) follows regional guidance for medical device responsibilities, support levels may vary and as agreed upon with customers.

8



## Software Bill of Materials (SBOM)

- SBOMs can enable device operators to manage their assets and related risks.
- Device operators can use the SBOM to facilitate work with the device manufacturer in identifying software that may have vulnerabilities, update requirements, and performing appropriate security risk management.
- The SBOM can help inform purchasing decisions by providing prospective buyers with visibility into the components used in applications and determining potential security risk.
- Manufacturers should leverage industry best practices for the format, syntax and markup used for deployment of the SBOM.

9



## New Work Item Extension

How should stakeholders implement and operationalize:

- SBOM
- Legacy conceptual framework

10



## New Work Item Extension

**Goal:** To increase international alignment and improved safety and security by:

1. Addressing implementation of SBOM, as well as transparency in the use and support of third-party software;

- Topics may include: lessons learned regarding construction, granularity, distribution, use, and support of third-party software including SBOM.

2. Operationalizing the legacy device conceptual framework articulated in the N60 document in a related, but separate document.

- Topics may include: additional definitions, legacy device best practices, post-market vulnerability management, economic and regulatory incentives, etc.

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## Progress and Planned Milestones

- February 3, 2021: New Work Kickoff Meeting
- April 2021: Final Document Outline
- April-October 2021: WG Meetings every two weeks
- October/November: 4-day WG Meeting
- February 2022: Submission of draft to IMDRF MC
- April 2022: Public Consultation\*
- April-October 2022: WG Meetings
- October/November 2022: 4-day WG Meeting
- March 2023: Publish Final Document(s)\*

\* Pending IMDRF MC Approval

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## Thank you

- IMDRF Cybersecurity WG
- IMDRF Management Committee
- IMDRF Secretariat
- IMDRF Webmaster







# IVD



**Tatyana Buryakina, RZN**



# Principles of In Vitro Diagnostic (IVD) Medical Devices Classification

## Progress report

March 23  
2021

Tatyana Buryakina, PhD

IVD Working Group Chair

Rosdravnadzor

Moscow, Russia

1



## Working Group members

**Australia: TGA**

Antje Janssen  
Michelle McNiven

**Brazil: ANVISA**

Fabio Pereira Quintino

**Canada: Health Canada**

Monica Magidin

**China: NIFDC**

Ying Huang  
Le Cui

**European Union:**

Heiner Scheiblaue  
Gaelle Lebrun  
Nada Alkhayat

**Japan: MHLW**

Fumihito Takanashi  
Manabu Fukuzawa

**Japan: PMDA**

Hiromi Yamada  
Eri Orihara  
Mika Togashi  
Yasuyuki Sakurai

**Russia: Rosdravnadzor**

Tatyana Buryakina  
Vladimir Antonov  
Roman Bystrov

**Singapore: HSA**

Rama Sethuraman  
Danny Ong

**South Korea: MFDS**

Yong-kyoung Lee  
Hye-jin Hwang  
Hyo-jin Kim

**USA: FDA**

Dina Jerebitski

**WHO:**

Irena Prat  
Helena Ardura

**AHWP:**

Wen-Wei Tsai  
Yung-Chuan Lee  
Razan Asally  
Mariammah Krishnasamy

**PAHO:**

Mariela Aranda  
Noaris Marquez  
Marcia Rodriguez

**Industry (GMTA)**

Danelle Miller, J.D.  
Masaki Sakakibara  
Petra Kaars-Wiele

2



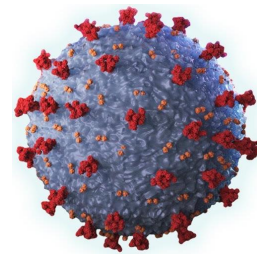
## Public consultations

63 comments from public consultation  
Over 200 comments and corrections by WG

Comments compiled to the table – each comment  
had it's discussion and resolution

Approved changes included in the text

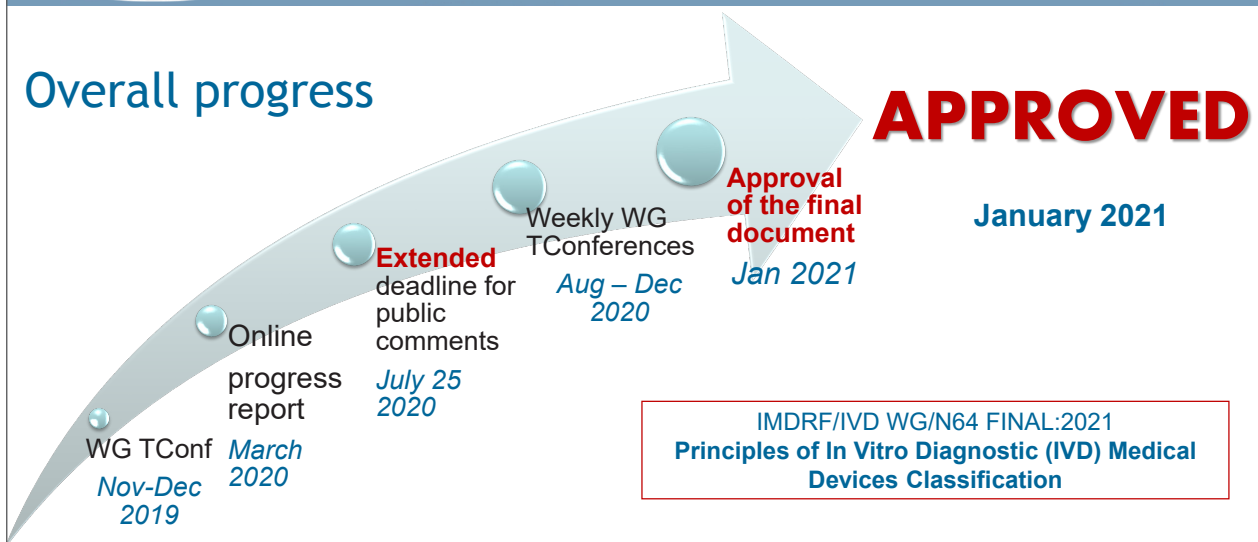
More than 20 WG members participated in weekly Teleconferences



3



## Overall progress



4



## Next steps

### IMDRF/GHTF documents Systematic Review

- ☐ Approved by MC – review and update
- ☐ Proposal formulation
- ☐ IVD WG discussions (e-mails exchange)
- ☐ Teleconferences (draft discussion)
- ☐ Final version of NWIP + discussion with MDCE
- ☐ Further Teleconferences upon NWIP approval



NWIP on GHTF documents review and update – to be formed

Collaboration with MDCE

5



## Future work

### New Work Item Proposal

#### Review and update of:

- ☐ GHTF/SG5/N6 (Clinical Evidence for IVD Medical Devices-Key Definitions and Concepts)
- ☐ GHTF/ SG5/N7 (Clinical Evidence for IVD Medical Devices-Scientific validity determination and Performance Evaluation)
- ☐ GHTF/SG5/N8 (Clinical Evidence for IVD Medical Devices-Clinical Performance studies for IVDs)



Collaboration with MDCE WG  
Proposal to be approved by MC

6



**IMDRF** International Medical  
Device Regulators Forum

**THANK YOU FOR YOUR ATTENTION!**







# AIMD



## Se-il Park, MFDS



**IMDRF** International Medical  
Device Regulators Forum

## **Artificial Intelligence Medical Device (AIMD) Working Group Update**

Medical Device Evaluation Department,  
Ministry of Food & Drug Safety, South Korea



**IMDRF** International Medical  
Device Regulators Forum

### **Purpose of AIMD WG**

- Achieve a harmonized approach to the management of Artificial Intelligence (AI) medical devices
- Establish a guidance to share the views of member jurisdictions on terminology



## AIMD WG Members

WG members from RA			WG members from RA				
Country	Name	Affiliation		Name	Affiliation		
Australia (3)	Dr David Hau	Therapeutic Goods Administration (TGA)	Russia (1)	Vladimir Kutichev	Roszdravnadzor		
	Mr David Wotton (ISO/IEC SC42)		Singapore (2)	Dr Yow Soh Zeom	Health Sciences Authority (HSA)		
	Mrs Olivia Reeves			Mr Lin Anle			
Brazil (3)	Mr Helio Bomfim de Macedo Filho	Agência Nacional de Vigilância Sanitária (ANVISA)	South Korea (7)	Dr Young-Kyu Kang	Ministry of Food & Drug Safety (MFDS)		
	Mr Francisco Iran Cartaxo Barbosa			Mr Seung-Ho Son			
	Mr Janglely Bahia Costa			Dr Se-Il Park			
Canada (2)	Daniel Yoon	Health Canada		Mr Hyun-Soo Kim			
	Janet Hendry			Mr Byeong-Nam Kim			
China (5)	Mr. Zhang Song	Center for Medical Device Evaluation (CMDE), NMPA		United States of America (2)		Mr Dong-Jun Kim	U.S. Food and Drug Administration (FDA)
	Mr. Liu Xiaoyin					Bakul Patel	
	Mr. Wang Zehua	Matthew Diamond					
	Mr. Wang Hao	WG members from organizations					
	Mr. Wang Chenxi	National Institute for Food and Drug Control (NIFDC), NMPA	World Health Organization (2)		Dr Philippe Boeuf		
European Union (4)	Steffen Buchholz	Federal Ministry of Health (BMG)		Anita Sands			
	Mariana Madureira	INFARMED	GMTA (4)	Pat Baird (ISO/IEC SC42)	Philips Healthcare		
	Rolf Oberlin	Danish Medicines Agency		Mr. Toshiaki Nakazato	Canon Medical Systems cooperation		
	Nada Alkhayat	European Commission		Patricia A. Krantz-Zuppan	Medtronic		
Japan (6)	Mr Yuhei Fukuta	Ministry of Health, Labour and Welfare (MHLW)	DITTA (4)	Mr. Hyun-Bae Park	VUNO		
	Ms Yoko Tateno			Koen Cobbaert	Philips Healthcare		
	Ms Kanako Sasaki	Pharmaceuticals and Medical Devices Agency (PMDA)		Naoki Morooka	Shimadzu Corporation		
	Mr Watanabe Yoshitomo			Camille Vidal	GE Healthcare		
	Mr Sato Yuchi			Annika Eberstein	COCIR		
	Mr Kuniki Imagawa			Total 45			

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## Main Contents of the Guidance

1. Title
2. Introduction (Background and purpose of the document)
3. Scope of ML enabled Medical devices, and Definitions of the Relevant Terms
4. Standardized Terminology

4



## Main Contents of the Guidance

### 1. Title

- Machine Learning enabled Medical devices
  - a subset of Artificial Intelligence:

### Key Terms and Definitions

5



## Main Contents of the Guidance

### 2. Introduction (Background and purpose of the document)

#### ‘1.0 Introduction’

- Background
  - Increase significance of AI based medical devices
  - Limitations with existing regulations on AI based medical devices
- Purpose
  - Establish relevant terms and definitions across the total product life cycle (TPLC) to promote consistency, support global harmonization efforts

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## Main Contents of the Guidance

### 3. Scope of ML enabled Medical devices, and Definitions of the Relevant Terms

#### **‘2.0 Scope’**

- All medical devices that enabled by ML techniques (MLMD) to achieve its intended medical purpose(s), including Software as a Medical Device (SaMD), Software in a Medical Device (SiMD), and In-Vitro Diagnostics (IVD).
- Focus on terms and definitions relevant to MLMD.  
(not define established definitions in the field of computer science; however, it highlights and clarifies conflicting terms and definitions as necessary.)

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## Main Contents of the Guidance

### 4. Standardized Terminology

- Discussions about selection of relevant terms and definitions on machine learning enabled medical devices, in progress
- ✓ Review the 25 relevant terms

**ex:** *Machine Learning(ML)*: Process using computational techniques to enable systems to learn from data or experience. (ISO.IEC CD 22989)

- Consider adding Concept and Description Sections

8



## Progress Status

- Host a monthly meeting
- Researched and analyzed regulations and guidance of member jurisdictions, Combined relevant terms and definitions on ML enabled medical devices from members (~ Sep '20)
- Established the scope of the guidance (~Oct '20)
- Discussed the terms regarding process (~Nov '20)
- Discussed the concepts of pre and post market (Dec '20)
- Discussed the title of the document (Jan '21)
- Established the title and introduction of the guidance and review the relevant 25 terms (Feb '21)

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## Work Plan

### ● Work Plan and Time

- 1) Draft Review (May, 2021)
- 2) Asking Public Comment (July, 2021 ~ October, 2021)
  - ✓ Draft Submission to IMDRF MC to ask public comment in May
- 3) Final document development (January, 2022)
- 4) Endorsement (March, 2022)

### ● Time schedule

	1Q '21	2Q '21	3Q '21	4Q '21	1Q '22
<b>Draft Development</b>	→	May '21			
<b>Draft Submission to MC</b>		May '21			
<b>Asking Public Comment</b>		←	Jul '21 ~ Oct '21	→	
<b>Meeting for Comment Review</b>				←	Nov '21~Jan '22→
<b>Submit Final Document</b>					Jan '22
<b>Endorsement</b>					Mar '22

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**Thank you**







# Session 3



## Stakeholders Session

WHO

APEC

AHWP/GHWP

PAHO

DITTA

GMTA

KMDIA

KMDICA

ASTM





The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# WHO



Irena Prat



**IMDRF** International Medical  
Device Regulators Forum

## Update from the World Health Organization

Irena Prat, Team Lead  
Department of Regulation and Prequalification  
World Health Organization



**IMDRF** International Medical  
Device Regulators Forum

### 1. WHO Emergency Use Listing Procedure for IVDs





## WHO EUL for IVDs

IVDs eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

WHO instructions and requirements for NAT and Ag detection RDTs and IVDs detecting antibodies to SARS-CoV-2 virus.

Manufacturers who are interested in an EUL contact [diagnostics@who.int](mailto:diagnostics@who.int) to arrange a pre-submission call

<https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open>



## 2. WHO Prequalification of IVDs





## PQDx: New abridged assessment procedure implementation in Q1 2021

Manufacturers leveraging abridged PQ assessments have provided comments on the previous procedure through their associations

- Avoiding site inspections where MDSAP reports are available
- Requesting abridged product dossier to assess data from technical files
- Consider other IMDRF jurisdictions with recognized assessments

New guidance developed based on comments received during consultation period

New procedure launched in Jan 2021

- Abridged dossier with focused sections: replaces reviews on-site
- Site inspections leveraging MDSAP reports
- No changes to performance evaluation
- Addition of HSA to the list of recognized reviews



## PQDx: implementation of ToC dossier format extended until 2022

A new, ToC-specific version of the WHO publication “PQDx\_018 Instructions for Compilation of a Product Dossier” is available at our website:

• [https://extranet.who.int/pqweb/sites/default/files/document/s/200324\\_draft\\_Instruction\\_for\\_compilation\\_of\\_a\\_product\\_dossier\\_pqdx\\_018\\_v4\\_toc\\_0.pdf](https://extranet.who.int/pqweb/sites/default/files/document/s/200324_draft_Instruction_for_compilation_of_a_product_dossier_pqdx_018_v4_toc_0.pdf)

These instructions are open for public comment over the transition period

Any comments may be directed to [diagnostics@who.int](mailto:diagnostics@who.int)

In light of the Covid-19 pandemic, the transition period is extended to end of 2021.





## PQDx: Update on inspections

### Inspections:

- Most onsite inspections postponed
- Desk assessments performed
- SOP for remote assessment developed

### Training and workshops:

- Prequalification / Collaborative Registration Procedure for African states
- Joint UNICEF – UNFPA – WHO Meeting with Manufacturers and Suppliers

### Future plans:

- Accelerate deployment of remote or hybrid assessments
- Initiate post-market surveillance inspection

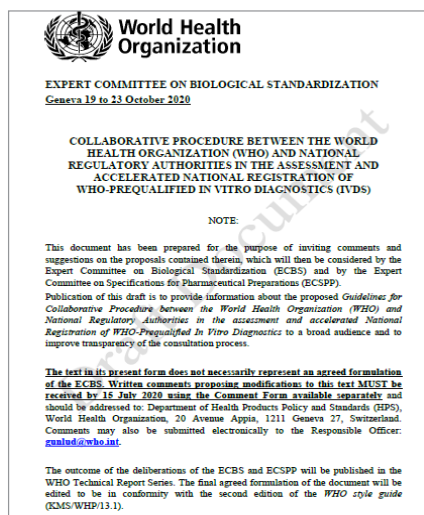


## 3. Regulatory strengthening





## Collaborative registration procedure



Guidance document was adopted by the 72<sup>nd</sup> ECBS

which took place in October 2020 and is available at

<https://www.who.int/publications/m/item/collaborative-procedure-between-the-who-and-nra-s-in-the-assessment-and-accelerated-national-registration-of-who-prequalified-ivd-s-annex4>

Roll out is planned from May 2021 after the guidance is published in the WHO Technical Report Series during the WHA.

Three CRP workshops on HIV self test were conducted in Uganda, Cameroon and Mozambique to facilitate registration of IVDs.



## Regional Initiatives for medical devices including IVDs regulation

WHO is supporting the Africa Medicines Regulatory Harmonization Initiative through the African Medical Devices Forum (AMDF) Technical committee to harmonize regulatory requirements and strengthen regulation of medical devices including in vitro diagnostics in Africa. Some of the activities supported by WHO include :

- Monthly update of the list of COVID-19 IVDs and other medical devices which have been listed by WHO PQ and other matured NRAs including IMDRF MS;
- Development of guidance documents based on IMDRF recommendations;
- Development of training materials for regulatory experts;
- Conduct webinars and meetings and
- Secretariat role in collaboration with AUDA-NEPAD.





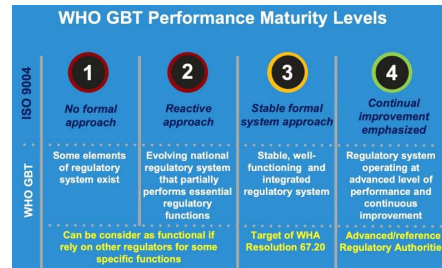
## WHO Global Benchmarking Tool Plus medical devices

**WG members:** WHO, Medical devices  
and IVDs regulators and laboratory  
experts and other MDs experts

**Discussion :** 1 September 2020 to 18  
January 2021.

**Status:** Final review and consultation  
within WHO and experts until end on  
March 2021.

Piloting of the WHO GBT plus medical  
devices tool is planned on Q2 of 2021



## 4. Safety of medical devices





## Safety of medical devices

Updated WHO guidance on post-market surveillance and market surveillance for medical devices including IVDs, launched Nov 2020

WHO guidance on use of Artificial Intelligence-based medical devices, use case for cervical cancer screening and diagnosis

Use of blockchain to enable better post-market surveillance of IVDs – won internal WHO innovation challenge, concept paper on-going



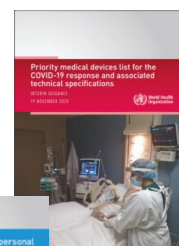
[https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab\\_1](https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1)



## WHO Medical devices, PPE and IVDs for COVID-19

- The list of Priority medical devices for COVID-19, includes technical specifications for 100 medical devices. (Nov 2020)
- The technical specifications for personal protective equipment for COVID-19 (Nov 2020)
- These specifications have allowed procurement of
  - \$1 billion of essential Covid19 supplies for 181 countries
  - 720 million units of PPE were supplied to 163 countries
- The 3<sup>rd</sup> edition of Essential in vitro diagnostic list,
  - Includes 200 tests including 2 COVID-19. (January 2021)

Ref: [https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab\\_1](https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1)  
[https://www.who.int/health-topics/medical-devices#tab=tab\\_1](https://www.who.int/health-topics/medical-devices#tab=tab_1)





## Nomenclature for Medical devices

- 23<sup>rd</sup> of January 2021, discussion on nomenclature took place in Executive Board of WHO.
  - 16 Members States (MS) gave a statement.
  - Requests: To have a MS information session to provide more information on the analysis.
- Next steps: A MS information session proposed to take place in April and September. Dates to be confirmed.

<https://www.who.int/teams/health-product-and-policy-standards/access-to-assistive-technology-medical-devices/medical-devices/nomenclature>  
[https://apps.who.int/gb/ebwha/pdf\\_files/EB148/B148\\_13-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_13-en.pdf)

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Thank you





The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# APEC



## Cheng-Ning Wu



**IMDRF** International Medical  
Device Regulators Forum

## Update on Medical Device PWA of RHSC



**Asia-Pacific  
Economic Cooperation**

### **APEC Co-Champion Economies:**

Japan – MHLW/PMDA

South Korea – MFDS

USA – FDA



**IMDRF** International Medical  
Device Regulators Forum

## **Priority Work Areas (PWAs)**

- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US and BIO)
- Advanced Therapy Products (Singapore and US)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity (US)
- **Medical Device** (Japan, Korea, US)

2



## Medical Device PWA

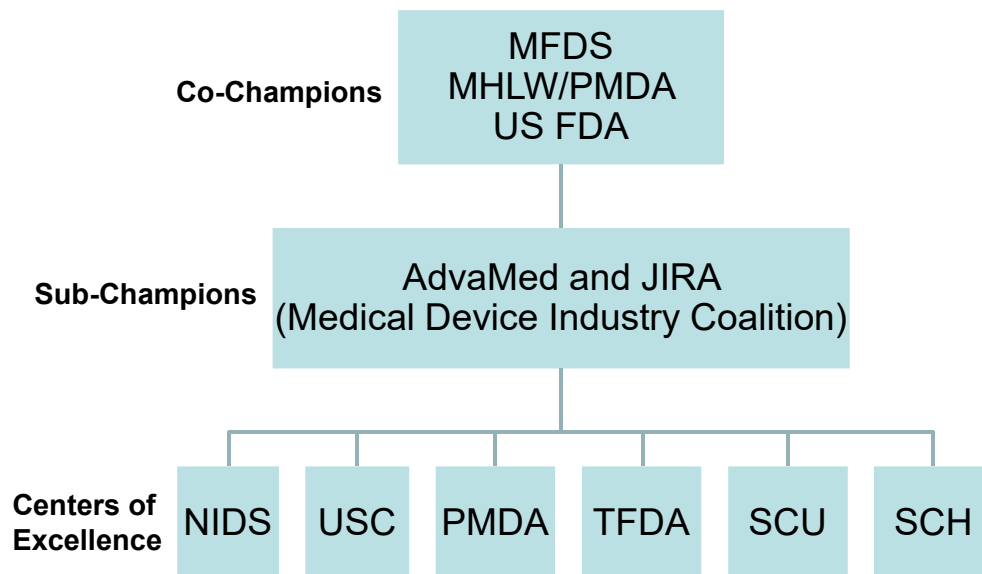
### Goals of PWA:

- Promote international harmonization initiatives (i.e., GHTF/IMDRF guidance documents)
- Build regulatory capacity and knowledge
- Support harmonized implementation efforts among APEC economies

3



## Medical Device PWA Structure



4



## **Medical Device PWA Roadmap**

- Promotes regulatory convergence for medical device regulatory systems
- Focuses on training and education efforts related to topics across the Total Product Life Cycle (TPLC) of medical devices:
  - Premarket
  - Postmarket
  - Quality Management System (QMS)

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## **PWA Core Curriculum**

- Annex to the PWA roadmap
- “Reference library” of harmonized guidance documents on TPLC topics
- Medical Device PWA includes specified GHTF/IMDRF documents
- Both medical devices and in vitro diagnostic (IVD) medical devices are inclusive
- Co-Champions continuously update Core Curriculum with intersessional approval

6



## Center of Excellence (1/2)

- The Vision
  - A sustainable platform for promoting regulatory convergence, capacity and cooperation in areas of medical products
  - Science and best practice focus
- The Approach
  - Partnership among training institutions/organizations, regulators and industry, to deliver and maintain educational programs
  - CoE Host Institutions collaborate with PWA Champions, PWA Steering Committee and CoE Coalition

7



## Center of Excellence (2/2)

- Follows principles in CoE Operating Model
- Ensures quality & consistent training programs via PWA roadmap, Core Curriculum, performance indicators & periodic assessments

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## CoE Activities in 2020

2020	DEC	APEC Centers of Excellence Established Soonchunhyang University (SCH), Korea
	NOV	APEC CoE Training (Virtual) National Institute of Medical Device Safety Information (NIDS), Korea
	NOV	APEC CoE Training (Virtual) Pharmaceuticals and Medical Devices Agency (PMDA), Japan
	OCT-NOV	APEC Pilot CoE Training (Virtual) Soonchunhyang University (SCH), Korea
	AUG-SEP	APEC CoE Training (Virtual) Taiwan Food and Drug Administration (TFDA), Chinese Taipei
	JUN	APEC Centers of Excellence Established Sichuan University (SCU), China Pharmaceuticals and Medical Devices Agency (PMDA), Japan Taiwan Food and Drug Administration (TFDA), Chinese Taipei APEC Pilot Center of Excellence established Soonchunhyang University (SCH), Korea Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School, Singapore

<https://www.apec.org/RHSC/RHSC-Priority-Work-Areas/Medical-Devices>

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## 2020 CoE Training Programs

CoE	Economy	Program	Format	Date
TFDA	Chinese Taipei	2020 APEC Medical Devices Regulatory Science Center of Excellence Workshop	Online	Aug. 29 - Sep. 11
SCH	Korea	2020 AHC-SCH Medical Device CoE Pilot Training	Online	Oct. 26 - Nov. 17
PMDA	Japan	PMDA-ATC Medical Devices Webinar 2020	Online	Nov. 16-20
NIDS	Korea	2020 NIDS-APEC Medical Device Vigilance CoE Training	Online	Nov. 18-24

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## 2021 CoE Training Programs

CoE	Economy	Planned Program	Format	Date
SCU	China	The trainings of UDI and Clinical Trial (TBC)	TBA	TBA
PMDA	Japan	PMDA-ATC Medical Devices Webinar 2021	TBA	TBA
NIDS	Korea	2021 NIDS APEC Medical Device Vigilance CoE Training	TBA	Oct.
TFDA	Chinese Taipei	2021 APEC Medical Devices Regulatory Science Center of Excellence Workshop	TBA	Q3
USC	United States	CoE Training by University of Southern California	Online	Apr.
SCH	Korea	2021 SCH APEC Medical Device CoE Training	Online	TBA
CoRE	Singapore			
NEU	United States	Pilot CoE Training by Northeastern University	TBA	2 <sup>nd</sup> half



## Next Steps

- Continue to conduct CoE training programs
- Revise PWA roadmap
  - Initiate the drafting
  - Hold Steering Committee teleconferences or meetings
- Update Core Curriculum as needed



**IMDRF** International Medical  
Device Regulators Forum



**Asia-Pacific  
Economic Cooperation**

Thank you







The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# AHWP/GHWP



**Ali Al-Dalaan**



**Global Harmonization Working Party**

Towards Medical Device Harmonization

## AHWP/GHWP Updates

Ali Al Dalaan, MBA-IT,PRA,QMS-LA  
Vice Executive President, Medical Devices Sector  
SFDA, Kingdom of Saudi Arabia

AHWP/GHWP Chair

Mar 2021

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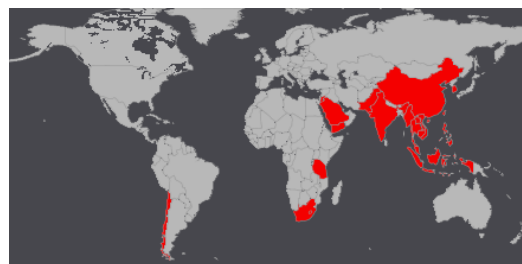


**Global Harmonization Working Party**

Towards Medical Device Harmonization

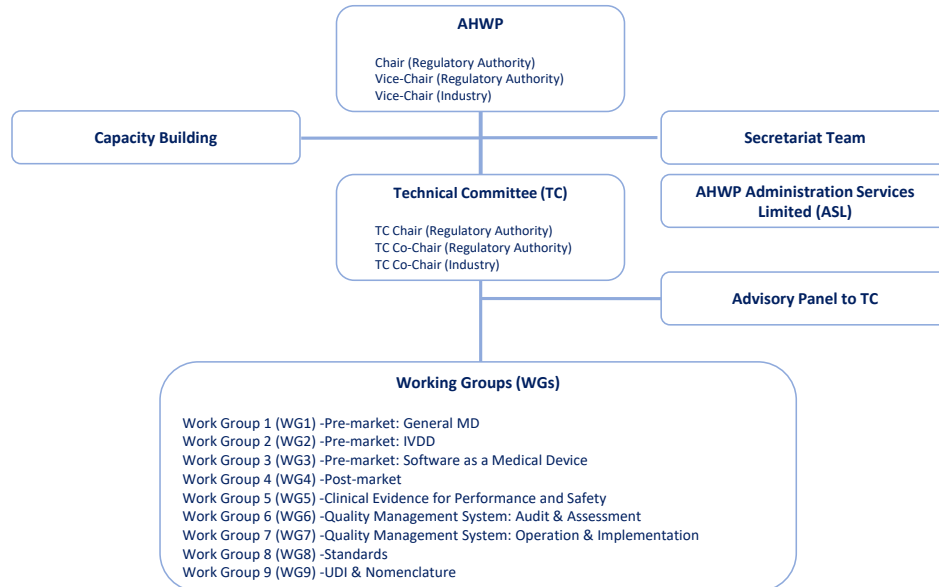
### AHWP/GHWP

- Established as a **non-profit** organization **formed in 1996-97**
- Its goals are to study and recommend ways to **harmonize medical device regulations** for establishing harmonized requirements, procedures and standards
- The Working Party is a **group of experts from the medical device regulatory authorities** and the medical device **industry**



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# AHWP/GHWP Organization Structure



**Global Harmonization Working Party**  
Towards Medical Device Harmonization

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**Global Harmonization Working Party**  
Towards Medical Device Harmonization

## Goal 1

To develop and recommend approaches for the convergence and harmonization of medical device regulations in Asia and other continents.

## Goal 2

To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements.



## Goal 3

To promote capacity building in member economies and to foster strategic membership expansion.

## Goal 4

To work in collaboration with related international organizations such as International Medical Device Regulators Forum (IMDRF), WHO, ISO, IEC.



## AHWP/GHWP Members from 31 Countries / Regions

Brunei Darussalam	Kazakhstan	Pakistan	Sultanate of Oman
Cambodia	Kingdom of Bahrain	People's Republic of China	Tanzania
Chile	Kingdom of Saudi Arabia	Philippines	Thailand
Chinese Taipei	Kyrgyz Republic	Republic of Kenya	United Arab Emirates
Hong Kong SAR, China	Laos PDR	Republic of Korea	Vietnam
India	Malaysia	Singapore	Yemen
Indonesia	Mongolia	South Africa	Zimbabwe
Jordan	Myanmar	State of Kuwait	



**Global Harmonization Working Party**  
Towards Medical Device Harmonization

(as of Feb 2021)

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**Global Harmonization Working Party**  
Towards Medical Device Harmonization

## AHWP/GHWP Office Bearers (Term 2018-2020)

[ Term of Office Bearers extended until next election in annual meeting, targeting Fall 2021 ]

AHWP Main Committee	
Chair	<b>Mr. Ali M. AL-DALAAN</b> Vice Executive President, Medical Device Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
Vice Chair (Regulatory Authority)	<b>Mr. GAO Guobiao</b> Party Secretary, Center for Medical Device Evaluation, National Medical Products Administration, People's Republic of China
Vice Chair (Industry)	<b>Ms. Quan TRAN</b> Head of Regulatory & Government Affairs and Quality Assurance Asia Pacific, Invisalign Singapore Pte Ltd., Singapore

AHWP Technical Committee	
<b>Acting Chair</b> (until next election)	<b>Ms. Salbiah YAAKOP</b> Acting Director, Policy, Codes and Standards Division, Medical Device Authority, Ministry of Health Malaysia
Co-Chair (Regulatory Authority)	<b>Dr. Jeong-Rim LEE</b> Director, Cardiovascular Devices Division, Ministry of Food and Drug Safety (MFDS), Republic of Korea
Co-Chair (Industry)	<b>Mr. Alfred KWEK</b> Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd., Lao PDR

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**Global Harmonization Working Party**  
Towards Medical Device Harmonization

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**Global Harmonization Working Party**  
Towards Medical Device Harmonization

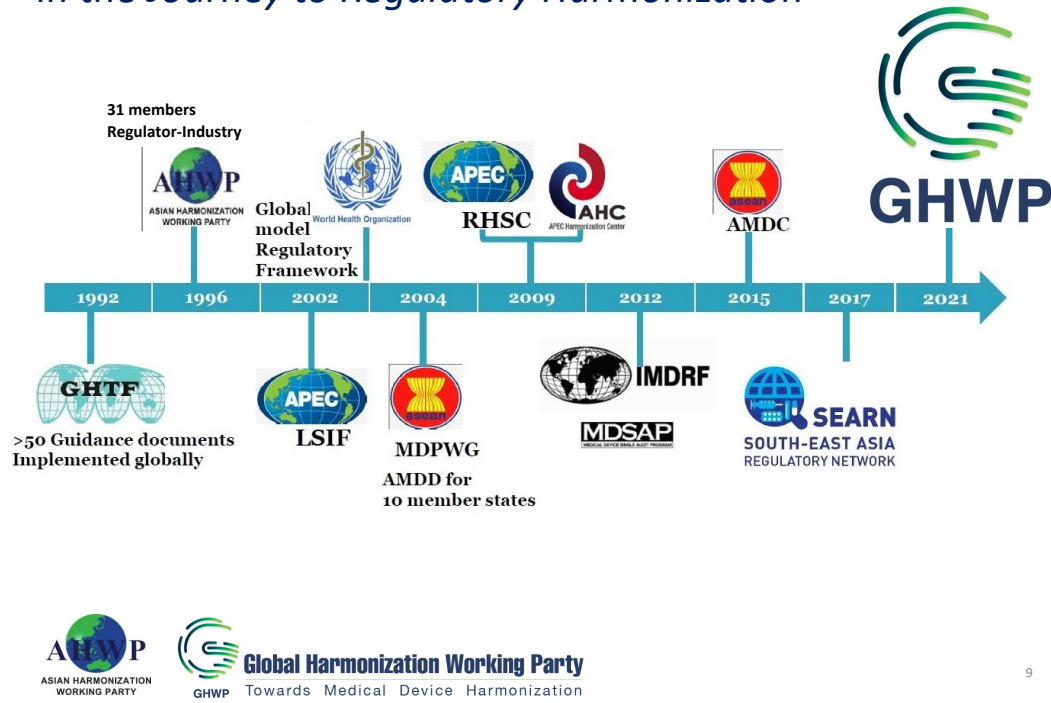
- Annual Meeting 2020 deferred, due to COVID-19 pandemic
- Upcoming AHWP/GHWP Annual Meeting in China  
(**targeting Nov/Dec 2021**, subject to further web-announcement)



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## AHWP Rebranding into GHWP

- in the Journey to Regulatory Harmonization



9

## New Name, Logo and Website



[ghwp.info](http://ghwp.info)



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## Rationales of the Change



- Better reflect the vision and representation of the Working Party with members from Asia, Africa, Middle East and South America
- Open up membership to medical device regulatory authorities and industries worldwide
- Extend efforts in medical device regulatory harmonization from the original focus in Asia into a global prospective



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## Meanings of the New Name

### **Global Harmonization Working Party (GHWP)**

- **“Global”:**

Global collaboration in medical devices regulation

- **“Harmonization Working Party”:**

Continuity of work and commitment on the convergence of medical device regulations



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## Meanings of the New Logo



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## Meanings of the New Logo



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## Timeline for the Change of Name into GHWP

- PRESS RELEASE "Pre-announcement on AHWP Change of Name to GHWP" issued and web-posted on 30<sup>th</sup> March 2020
- OPEN LETTER "AHWP transformation into GHWP with Unchanged Position on Regulatory Authorities-Industry-Partnership" issued and web-posted on 29<sup>th</sup> June 2020
- New name & logo to be formally announced and endorsed in the coming Annual Meeting (target Nov/Dec 2021, subject to further web-announcement)
- More information also available at [ahwp.info](http://ahwp.info) / [ghwp.info](http://ghwp.info)



**Global Harmonization Working Party**  
Towards Medical Device Harmonization

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## List of Emergency Use Authorization (EUA) of AHWP Member Country/Region



**Asian Harmonization Working Party**  
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CHAIRMAN'S MESSAGE | HISTORICAL DEVELOPMENT | MEETING CALENDAR | CONTACT | Search the AHWP website. Search

- + About AHWP
- + Members
- + Technical committee
- + News
- + Events Announcements
- + Events
- + Country Updates
- + Documents
- + SADS Online
- + Trade Related Issue
- + Web Resources
- + Secretariat
- + Archive

### LOG ON HERE

Username \*

Password \*

▼ CAPTCHA

This question is for testing whether or not you are a human visitor and to prevent

### List of Emergency Use Authorization (EUA) of AHWP Member Country/Region

Submitted by admin on Thu, 04/09/2020 - 05:45

Members	EUA Information
Chinese Taipei	List of COVID-19 related EUA on Manufacturing/Import of Medical Device <a href="http://www.fda.gov.tw/ENG/site.aspx?id=11194">http://www.fda.gov.tw/ENG/site.aspx?id=11194</a>
Kingdom of Saudi Arabia	List of SFDA Emergency Use Authorization (EUA) and Medical Devices Marketing Authorization for COVID-19 IVD Test Kits <a href="https://www.sfda.gov.sa/en/medicaldevices/AuthorizedDocuments/EADdevices.pdf">https://www.sfda.gov.sa/en/medicaldevices/AuthorizedDocuments/EADdevices.pdf</a> Saudi FDA Regulatory requirements for Emergency Use Authorization (EUA) for IVD and Personal Protective Equipment (PPE) during the outbreak of COVID-19 <a href="https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-Efforts-COVID19.pdf">https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-Efforts-COVID19.pdf</a> New Update <a href="https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-International-EffortsEN.pdf">https://www.sfda.gov.sa/en/medicaldevices/regulations/Documents/SFDA-International-EffortsEN.pdf</a>
People's Republic of China	1. NMPPA gives emergency approvals to COVID-19 test kits <a href="http://english.nmpa.gov.cn/2020-03/27/c_465663.htm?from=singlemessage&amp;isappinstalled=0">http://english.nmpa.gov.cn/2020-03/27/c_465663.htm?from=singlemessage&amp;isappinstalled=0</a> 2. Regulatory Requirements and Standards for Coronavirus Reagent Test Kits and Protective Equipment in China <a href="http://english.nmpa.gov.cn/2020-03/30/c_467202.htm">http://english.nmpa.gov.cn/2020-03/30/c_467202.htm</a>
Republic of Korea	List of COVID-19 Diagnostic Kits Authorized for Use under Emergency Use Authorizations <a href="https://www.mfds.go.kr/eng/brd/m_52/view.do?seq=74424&amp;srchFr=&amp;srchTo=&amp;srchWord=&amp;srchTp=&amp;itm_seq_1=0&amp;itm_seq_2=0&amp;multi_itm_seq=0&amp;company_cd=&amp;company_nm=&amp;page=1">https://www.mfds.go.kr/eng/brd/m_52/view.do?seq=74424&amp;srchFr=&amp;srchTo=&amp;srchWord=&amp;srchTp=&amp;itm_seq_1=0&amp;itm_seq_2=0&amp;multi_itm_seq=0&amp;company_cd=&amp;company_nm=&amp;page=1</a>
Singapore	Guidance on expedited approval of COVID-19 Diagnostic Tests - Provisional Authorisation HSA's Regulatory Position on Respiratory Devices: Supply for Management of COVID-19 patients Guidance on 3D Printing of Essential Medical Devices and Accessories for Use in COVID-19 Situation

[www.ahwp.info](http://www.ahwp.info)

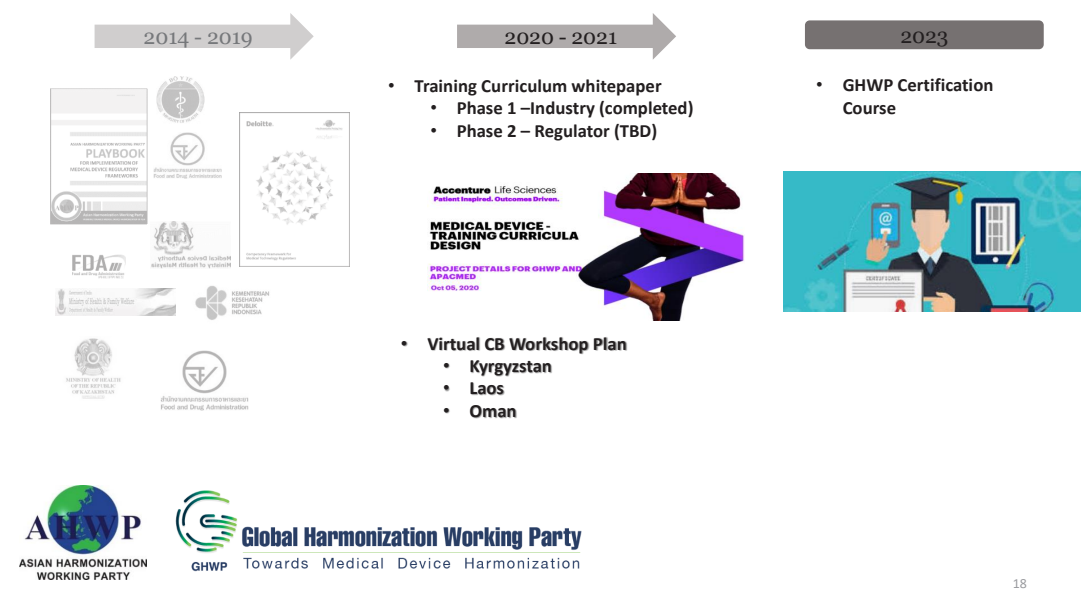
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## AHWP/GHWP Capacity Building Program 2015-2019



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## Forging on AHWP/GHWP Capacity Building Journey



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## Medical Device Regulatory Training Curriculum for Industry Professionals

- White Paper Curriculum on Industry by AHWP/GHWP and APACMed
- As part of the AHWP/GHWP Capacity Building program, the draft Curriculum White Paper for Industry has been posted for public commenting on the AHWP/GHWP website
- Webinar supported by Accenture AHWP/GHWP member representatives on 30<sup>th</sup> Nov 2020, with speakers from Accenture



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## Medical Device Regulatory Training Curriculum for Industry Professionals

### Overview & Scope

- Training curriculum is created to provide a roadmap to Medtech regulatory industry professionals across companies
- The most essential and relevant trainings and courses for MedTech Regulatory Industry Professionals have been outlined in the training curriculum

### Guidelines

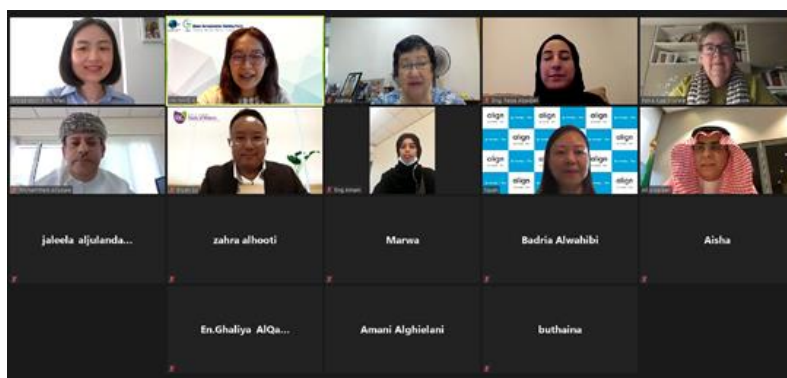
- Capability development leads should consider the curriculum as a roadmap and assess their current plan against the curriculum
- In case there is a module which is currently not present in their organization, they can leverage the indicative content for brief description to create trainings
- Post analysis, capability development leads should explain to their team resources the identified learning goals & its importance in a professional's career progression



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## Capacity Building - Oman Virtual Training on IVD

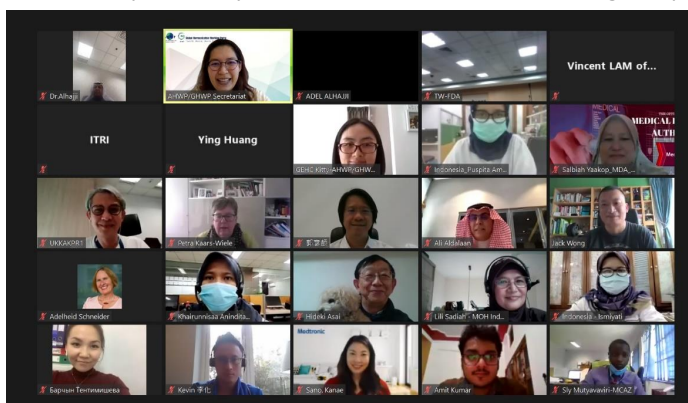
- 4-Days Capacity Building Training (30<sup>th</sup> Nov – 3<sup>rd</sup> Dec 2020)
- Speakers: Ms. Joanna Wee and Dr. Petra Kaars-Wiele
- To share insights and revisit key elements on IVD, EU regulation and certification, submission review, interim post-market consideration, stakeholders' roles and responsibility



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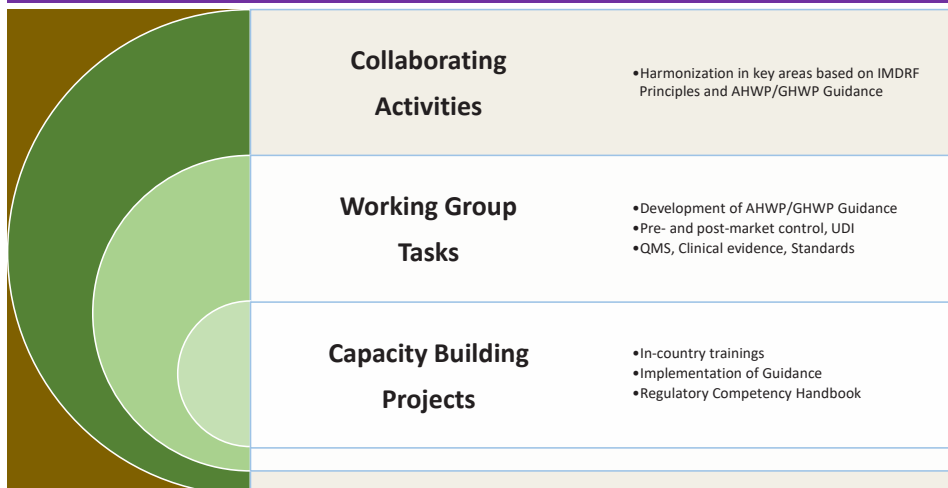
## Capacity Building - Awareness Training on Remote Auditing

- A virtual training held on 4<sup>th</sup> Feb 2021
- Conducted by Mr. Vincent Lam, WG 6 Co-Chair, Senior Lead Auditor and Product Specialist for TÜV SÜD Product Service
- An experience sharing on the skills for planning and conduction of remote audits, and the techniques for systematic audits execution during the pandemic



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## AHWP/GHWP TC Strategic Plan



## WG Plans for 2018 - 2021 (1)

WG	WORK PLAN	TIMELINE
Joint Work by WG 1, 2 & 3	New guidance on artificial intelligence Change management for medical device registration guideline E labeling/e IFU guideline	
WG1	Revised 2 Final Documents 'Handbook for Approval of Patient-matched Medical Devices Using 3D Printers' and 'Guidance for Minor Change Reporting' which have been posted on the AHWP/GHWP website	Q4, 2020
WG2	Guidance on Emergency Use Authorization of SARS-CoV-2 Nucleic Acid Tests Replacement reagent and instrument family policy Clinical Evidence for IVD Medical Devices-Clinical Performance Studies for In Vitro Diagnostic Medical Devices Contribution to IMDRF Document Titled Principles of In Vitro Diagnostic (IVD) Medical Devices Classification Continually work with IMDRF document updates on GHTF/SG5/N6:2012, GHTF/SG5/N7:2012 and GHTF/SG5/N8:2012	Q3, 2022 Q3, 2021 Q3, 2020 2018-2020 Ongoing
WG3	Contribution to WHO Technical Specification Documents White paper on pre market initial submission format for SaMD White paper on cybersecurity for SaMD Guidance document on Cyber Security for SaMD Guidance document for premarket submission format for SaMD (draft)	Ongoing Q2, 2021 Q2, 2021 Q4, 2021 Q4, 2021
WG4	Updating the Post-market Resource Centre Gap analysis on the implementation of AHWP guidance among AHWP members Participation in the development works of ISO TC210/ WG6 Report on post-market support in relation to COVID 19 Study on post-market trend in medical devices with AL and cybersecurity	Ongoing Q4, 2021 Ongoing Q4, 2021 Q4, 2021
WG5	Annual review SWOT analysis of WG5 framework Guidance document on general principles of clinical investigation audit & inspection for medical devices Training: WG5 & AHWP members Survey: country regulations/guidelines and implementation	Q4, 2018 Q4, 2018 Q4, 2018 Q4, 2019

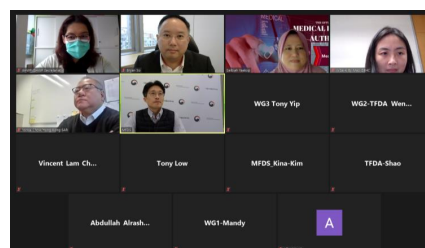
## WG Plans for 2018 - 2021 (2)

WG	WORK PLAN	TIMELINE
WG6	There are 3 guides on progress and endorsement expected during the Annual meeting 2021: 1) A guide to understanding best practices in audit life cycle management. 2) A guide to understanding presently available audit duration determination systems. 3) A guidance for NB auditing suppliers to medical device manufacturers. Co-Chair Vincent will conduct online training session on remote audit technique.	4 Feb, 2020
WG7	Comparison study of new ISO13485 vs QMS requirements in each country QMS consideration for manufacturers and importers for localization	Q2, 2020 Q4, 2020
WG8	Document on Code of practice for good engineering maintenance management of medical devices: endorsed, to be proposed to ISO /TC210 for development as ISO standard. <u>Current status:</u> New Proposal (NP 5137) on COP Good maintenance management of active medical devices has been approved and registered as new ISO project on 29 July 2020. A new WG, ISO/TC 210 WG 7 has been established on 17 Sept 2020 and Ms Salbiah Yaakop was appointed as Convenor. Member countries are encouraged to participate in the works of WG 7 through registration by their National Standards Body. Collecting a list of standards used for medical device regulatory purposes that are recognized by AHWP member countries -The secretariat is requested to put up the list of compiled standards in the AHWP/GHWP website for members' reference. - Member countries representatives are requested to maintain the list to ensure the lists are up to date. Continue working relationship with ISO TC210, etc - WG8/AHWP TC Chair will be participating in the next ISO/TC 210 meetings in May 2021 and Nov 2021.	Q3, 2023 Ongoing Ongoing
	Adoption of ISO 16142-2:2017 and ISO 16142-1:2016, to harmonize list of standards in demonstrating compliance with EPSP where member countries could recognize the same standards during IVD medical device evaluation by NB/CAB and regulators	Q1 2019, completed
	Proposal on development of guidance on regulatory control of medical gas - preparation of 1st draft by WG8 Chair, will be deliberated in the next WG8 meetings planned in April and June 2021.	Q4 2021
	Proposal on development of guidance on the guideline of process validation activity adaptation of International Society for Pharmaceutical Engineering (ISPE) document) for the propose of medical device validation. - preparation of 1st draft by WG8 Co-Chair - will be deliberated in WG8 meetings in June and Oct 2021.	Q4 2021
WG9	AHWP UDI report AHWP UDI rule White Paper, target endorsement at 2020 annual meeting	TBD Q4, 2020

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## TC-Work Groups Chairs/Co-Chairs Progress Meetings

- Virtual Meeting of TC WG Chairs and Co-Chairs
  - Meeting on 17<sup>th</sup> Dec 2020
  - Meeting on 3<sup>rd</sup> Feb 2021
- Chairs and Co-Chairs of WGs discussed on:
  - Overall objectives of TC and WGs
  - WGs representation on their respective focus of regulatory convergence
  - WGs work plans, new guidance documents and progress updates
  - WG membership updates



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## Key Events

- Annual Meeting
- TC Leaders Meeting
- TC Workgroup Meeting
- Secretariat Meeting
- Capacity Building Program



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## Recent Activities

- Capacity Building - Oman Virtual Training
- Capacity Building - Awareness Training on Remote Auditing
- Capacity Building - White Paper Webinar
- TC WG Chairs Meetings
- Secretariat Meetings

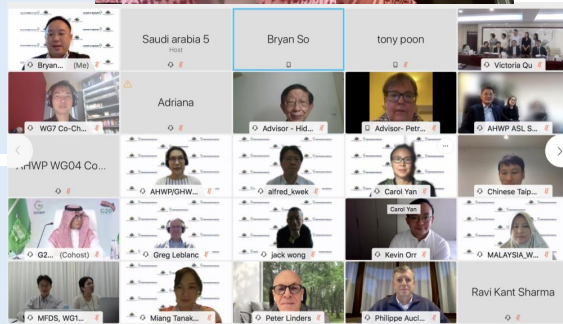


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## Meetings and Capacity Building go Online during COVID-19

### 2020

- TC Leaders Meeting 18<sup>th</sup> Mar
- TC Leaders Meeting 21<sup>st</sup> May
- Secretariat Meeting 26<sup>th</sup> Jun
- TC WGs Progress Meeting 9<sup>th</sup> Jul
- Secretariat Meeting 18<sup>th</sup> Aug
- TC Leaders Meeting 13<sup>th</sup> Oct
- Capacity Building 30<sup>th</sup> Nov - 3<sup>rd</sup> Dec
- Webinar on White Paper 30<sup>th</sup> Nov
- Secretariat Meeting 1<sup>st</sup> Dec
- TC WGs Progress Meeting 17<sup>th</sup> Dec



### 2021

- Secretariat Meeting 13<sup>th</sup> Jan
- TC WGs Progress Meeting 3<sup>rd</sup> Feb
- Capacity Building Training 4<sup>th</sup> Feb



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- Stay tuned for new activities and updates...



**Global Harmonization Working Party**  
Towards Medical Device Harmonization

[www.ahwp.info](http://www.ahwp.info) / [www.ghwp.info](http://www.ghwp.info)

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# Q&A

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The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# PAHO



**Alexandre Lemgruber**



## PAHO Update

Alexandre Lemgruber

IMDRF Meeting  
23 March 2021



## Regional Working Group on Medical Device Regulation

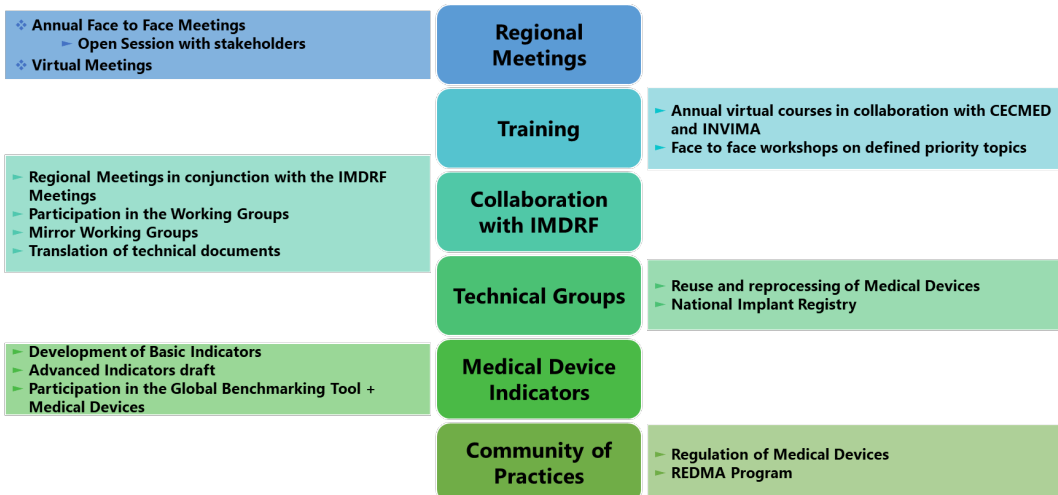
**24 countries** are currently members

Argentina	Belize	Bolivia	Brazil	Canada
Chile	Colombia	Costa Rica	Cuba	Dominican Republic
Ecuador	El Salvador	Guatemala	Guyana	Honduras
Jamaica	Mexico	Nicaragua	Panama	Paraguay
Peru	Trinidad & Tobago	Uruguay	Venezuela	





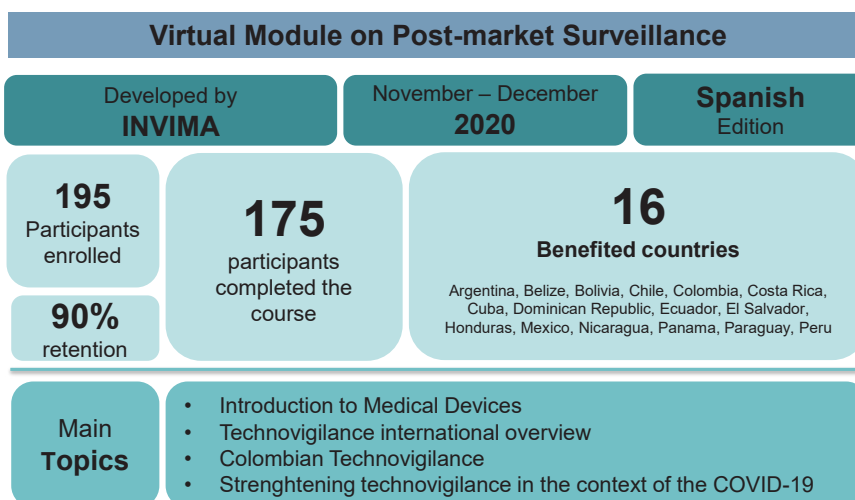
## Activities of the Regional Working Group



3



## Training activities



4



## Meeting of the Regional Working Group on Medical Devices Regulation

- Held on 13 October 2020
- 30 participants from 15 countries

### TOPICS

- Global Benchmarking Tool + Medical Devices
- Update on the collaboration with IMDRF
- Mirror Working Groups
- Program on exchange of reports on adverse events of Medical Devices - REDMA Program
- Regulation of Personal Protective Equipment

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## Meeting of the Program on exchange of reports on adverse events of Medical Devices - REDMA Program

- Held on 11 August 2020.
- Participation of 55 representatives of 17 Regulatory Authorities from: ARG, BOL, BRA, CHL, COL, CRI, CUB, DOR, ECU, GTM, MEX, NIC, PRY, SLV, URY, USA, VEN.

### TOPICS

- Results of the training activity on the REDMA Program
- Adverse events related to ventilators in the context of COVID-19
- Discussion of other COVID-19 related adverse events
- Discussion on adverse events' reports included on the REDMA Web System

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## Medical Devices Indicators

### WHO Global Benchmarking Tool + Medical Devices

#### WHO Working Group for the integration of indicators on Medical Devices and In Vitro Diagnostics into the GBT

PAHO participates in the activities of the Working Group coordinated by WHO, with the following NRA from the Region of the Americas:

- ANMAT, Argentina
- ANVISA, Brazil
- CECMED, Cuba
- COFEPRIS, Mexico
- FDA, USA
- Health Canada, Canada
- INVIMA, Colombia

PAHO advanced indicators tool was incorporated into the WHO GBT+ Medical Devices.

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## Work related to Medical Devices in response to COVID-19

- ▶ **Dissemination of information** with the *Regional Working Group* (Alerts, regulatory updates, publication of technical guidelines)
  - Weekly monitoring of COVID-19 related alerts and updates on post-market surveillance in the following agencies: AEMPS – Spain; ANMAT – Argentina; ANVISA – Brazil; CECMED – Cuba; COFEPRIS – Mexico; DIGEMID – Peru; FDA – USA; Health Canada – Canada; HSA – Singapore; INFARMED – Portugal; INVIMA – Colombia; TGA – Australia.
- ▶ Coordination of **webinars** and **virtual meetings** to share experiences and promote cooperation among countries of the Region
  - Meeting on *Regulation of Personal Protective Equipment*, 1 December 2020.
    - 43 participants from 13 countries.
    - Main topics: Challenges on PPE Regulation in the Americas, Panel on Experiences in the Regulation of PPE in the countries of the Americas with the participation of ANMAT – Argentina, CECMED – Cuba, Dirección Nacional de Medicamentos - El Salvador.

8



## Work related to Medical Devices in response to COVID-19

- ▶ **Quality assurance** of up to 150 Medical Devices, including Biomedical Equipment, In Vitro Diagnostics and Personal Protective Equipment procured through PAHO.
- ▶ **Technical support** to Member States in the evaluation of Medical Devices as part of local purchases or donations.
- ▶ **Training** sessions on quality assurance and operation of Biomedical Equipment procured through PAHO benefiting up to 350 participants.
  - ❑ 3 training sessions on quality assurance of Biomedical Equipment
  - ❑ 2 training sessions on the operation of oxygen concentrators

9



# Thank you!!

10







The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# DITTA

.....

**Masaaki Ohtsuka**



**DITTA** GLOBAL DIAGNOSTIC IMAGING,  
HEALTHCARE IT & RADIATION THERAPY  
TRADE ASSOCIATION



**IMDRF** International Medical  
Device Regulators Forum

## **DITTA Report** **IMDRF Open Stakeholder Forum**

*Wednesday 23 March 2021*

**Masaaki Ohtsuka, DITTA Chair**  
*Secretary General, JIRA*



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**Medtech**  
Canada



**IMEDA**

中国医疗器械行业协会  
China Association of Medical Device Industry

**ABIMED**

**Kmdica**  
Korea Medical Devices Industrial  
Group Association

**KMDIA**  
Korea Medical Devices Industry  
Association

**ITAC**  
International Technology  
Association of Canada



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## **DITTA GLOBAL PRESENCE**



2018: DITTA as a recognized non state actor in official relations with WHO  
2016: DITTA MoU with the World Bank  
2015: DITTA was granted a NGO status with WHO  
2014: DITTA has official liaison with AHPW



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## DITTA: 10 WORKING GROUPS

1. Regulated Product Submission (RPS) Working Group
2. Medical Device Single Audit Program (MDSAP) Working Group
3. Unique Device Identification (UDI) Working Group
4. Standardisation (STA) Working Group
5. Clinical Evaluation (CE) Working Group
6. Global Health (GH) Working Group
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group
10. Medical Software & AI (MSW & AI) Working Group



**IMDRF**



International Atomic Energy Agency



World Health Organization



WORLD BANK GROUP



BASEL CONVENTION



UNEP



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1. DITTA Feedback on IMDRF work items
2. Outcome of  
IMDRF/DITTA Virtual Workshop on COVID-19



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# 1. DITTA FEEDBACK ON IMDRF WORK ITEMS

1. Clinical Evaluation
2. Artificial Intelligence
3. Standards
4. Cybersecurity
5. Regulated Product Submission (RPS)
6. MDSAP
7. Good Regulatory Review Practice (GRRP)
8. UDI



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## KEY POINTS

### 1. Clinical Evaluation

- DITTA welcomes publication of the guidance document on Post-Market Clinical Follow-up (PMCF)

### 2. Artificial Intelligence

- DITTA supports draft guidance on terminology & definition for Machine Learning as first step, with further work necessary to achieve global convergence

### 3. Standards

- DITTA emphasizes that international standards are vital for global convergence
- DITTA urges IMDRF to operationalize its liaisons to ISO and IEC to ensure regulators' input into development of standards for regulatory use



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## KEY POINTS

### 4. Cybersecurity

- DITTA welcomes the approval of the New Work Item Extension Proposal in September 2020
- This will bring a useful aid to implement IMDRF/Cyber WG/N60 in the IMDRF jurisdictions

### 5. RPS

- DITTA supports further work on Table of Contents as essential building block towards Single Review Program



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## KEY POINTS

### 6. MDSAP

- DITTA continues to support the MDSAP program and encourages continuous improvement of the program based on experience and input from manufacturers, AOs, and regulators
- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits

### 7. Good Regulatory Review Practice (GRRP)

- DITTA supports to expand the current work of the work item on GRRP and moving towards a single regulatory premarket review process to satisfy in whole or in part the needs of multiple regulatory jurisdictions for selected medical devices

Note: Goal of GRRP: "The goal is to promote global harmonization in the premarket review processes."



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## KEY POINTS

### 8. UDI

- Support global harmonization of UDI requirements
- DITTA published a whitepaper on UDI, outlining needs for harmonization and providing solutions
- DITTA strongly recommends that document IMDRF/UDI WG/N53 FINAL:2019 "Use of UDI Data Elements across different IMDRF Jurisdictions" need to be updated



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## IMDRF / DITTA VIRTUAL WORKSHOP ON COVID-19 16 MAR. 2021

### WHAT TO LEARN FROM COVID-19?

#### Workshop Objectives:

- Learn how regulators have responded to the challenges posed by COVID-19, including the use of emergency authorizations or other measures
- Better understand how the medical device industry has contributed to the fight against COVID-19
- Learn how COVID-19 has impacted the supply of medical devices at global level & the difficulties industry faced
- Exchange views on the lessons learned from COVID-19 to improve regulatory frameworks for medical devices and make them resilient for future crises

**Attendance:** 480 registered participants  
(regulators, auditing organisations, healthcare providers, scientific societies and industries)

**Keynote Speakers:** South Korea MFDS, WHO

#### Speakers:

- IMDRF Jurisdictions: South Korea MFDS, US FDA, European Commission, Australia TGA, Japan MHLW
- Healthcare Providers: Severance Hospital of Yonsei University, Mayo Clinic
- Industries: DITTA, GMATA, KMDIA



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## IMDRF / DITTA VIRTUAL WORKSHOP ON COVID-19 16 MAR. 2021

### Conclusion:

We have learned from this pandemic,

1. Medical devices have been a critically important tool in the fight to diagnose and treat COVID-19
2. Regulators have been partners with industry to ensure medical devices are accessible and available to all parts of the world

Our hope is that in this moment of international collaboration and cooperation, that we keep the momentum going so we can be prepared for the next pandemic, and not repeat the same mistakes, but build on what worked and make those improvements more permanent.

Programme,  
[https://www.globalditta.org/fileadmin/Media\\_Centre/Media\\_Centre\\_2021/IMDRF\\_-\\_DITTA\\_Joint\\_Virtual\\_Workshop\\_What\\_to\\_learn\\_from\\_COVID-19\\_-\\_Program.pdf](https://www.globalditta.org/fileadmin/Media_Centre/Media_Centre_2021/IMDRF_-_DITTA_Joint_Virtual_Workshop_What_to_learn_from_COVID-19_-_Program.pdf)

Presentations,  
<https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop-what-to-learn-from-covid-19.html>



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# THANK YOU!

[www.globalditta.org](http://www.globalditta.org)

Follow us on  @DITTA\_online







# GMTA



**Emmett Devereux**



Global Medical  
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## Remote Audits

IMDRF Stakeholders Session  
March 23, 2021



Global Medical  
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## Outline

- Background
- Remote Audits
  - Basic Principles
  - Recommendations



## Background

- Regulators have adopted a number of agile, safe and pragmatic regulatory policies to help address the global public health emergency
- Given the safety concerns and travel restrictions, some regulators are doing remote audits
  - MDSAP accommodates for remote audits
  - European Commission recognizes the need
  - US FDA is conducting a pilot
  - ISO foresees remote audits as an acceptable auditing method
  - Already embraced in other sectors (e.g., pharma)

### References:

- International:
  - ISO 9001 Auditing Practices Group – Guidance on remote audits
  - ISO 19011:2018 Guidelines for Auditing Management Systems
  - [MDSAP Transmittal Number](#): AO 2020-10 [Superseding MDSAP Transmittal Number 2020-07]; Transmittal Date: 2020/12/31  
Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements
- Europe:
  - [MDCG 2020-4](#) *Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions*, April 2020
    - [MDCG 2020-17](#) Questions and Answers related to MDCG 2020-4, December 2020
  - [Commission Notice](#) on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (Text with EEA relevance) 2021/C 8/01; C/2021/119



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## Remote Audit

- Optimizing regulator, conformity assessment bodies and industry human and financial resources (e.g., cost, quality and delivery means) as well as other benefits, such as minimizing the environmental footprint, speed of use and a quick execution of required inspections.
- Remote Audits are currently being used by industry and will be expanded over the coming months to include supplier audits, ethics and compliance audits and intercompany audits.

5

### References:

- [MDSAP Transmittal Number](#): AO 2020-10 [Superseding MDSAP Transmittal Number 2020-07]; Transmittal Date: 2020/12/31

Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements

- [Commission Notice](#) on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (Text with EEA relevance) 2021/C 8/01; C/2021/119



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## Basic Principles

- Use available technology
- Replacement for physical inspection
- Same or similar scope as physical inspection
- Should be included as an overall part of audit plan that also includes recognition and reliance of existing audits (e.g., MDSAP)
- A lesson learned from the COVID-19 pandemic – Remote audits are beneficial during a public health emergency

6



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## Recommendations

- GMTA supports further development of concepts and principles for remote audits
- GMTA encourages regulators to consider the use of remote audits as a viable alternative to physical inspections (on-site audits) under specified circumstances

7



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# Early Lessons Learned During a Global Pandemic

IMDRF Stakeholders Session  
March 23, 2021



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## Presentation Outline

- Background
- Challenge
- Early Lessons Learned
- Recommendations



## Background

- Need for rapid review and approval mechanisms to meet specific needs during COVID-19 pandemic
- Access to COVID diagnostic tests, personal protective equipment, ventilators in high demand
- Required close collaboration with regulators, developers and healthcare providers

3



## Challenge

- Clinical and Regulatory
  - Access to virus samples
  - Accuracy of, and access to, comparator test
  - Changing and moving targets
  - Lack of clarity in regulation
  - Lack of harmonization in regulations to enable marketing authority at pace with urgent need to scale
- Scaling production in a short period of time
- Access to Real World Data

4



## Early Lessons Learned

- Leverage regulatory decisions from other regulators
- Regulatory agility during pandemic has been critical
  - Remote audits in place of on-site
  - Leverage regulatory reliance
  - Use of alternative sources for clinical evidence

5



## Recommendations

- Ensure that current IMDRF documents acknowledge the need to ensure rapid review and approval
- Utilize reliance mechanisms to promote rapid review and approval
- Consider the development of specific IMDRF guidance to promote the use of rapid review and approval mechanisms during a global pandemic
- Ensure adequate training and communication for regulators
- Regulatory agility should be leveraged beyond pandemic

6







The 19<sup>th</sup> IMDRF Stakeholder Virtual Forum

# KMDIA

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Myung Jung Kim



# 한국의료기기산업협회

Korea Medical Devices Industry Association

**Myung Jung Kim**, Vice Chairman  
KMDIA

Korea's leading and reliable association for competitive medical device companies

## Contents

01

Introduction

02

Organization

03

Major Responsibilities of KMDIA

04

Activities of the committee

# Vision

01 | Introduction

## Vision

**Korea's leading and reliable association  
for competitive medical device companies**

### Mission

**Development of  
MD Industry**

**Enhancement of  
Healthcare Technology**

**Growth of MD Market**

### Strategy

- 01 Establishing fundamental infrastructure for the growth of MD industry
- 02 Formulating regulatory framework for the MD industry
- 03 Forming a cooperative network within MD industry
- 04 Facilitating high-valued MD industry and supporting export of MD
- 05 Establishing a fair trade environment in supply of MD
- 06 Promoting global cooperation and regulatory harmonization

# History

01 | Introduction

**Advanced KMDIA with constant challenges and efforts**

**1999**

07.08

Establishment of Korea Medical Devices Association

**2001**

11.29

Changing the name to Korea medical Devices Industry Association

**2002**

03.14

Co-hosting KIMES

03.26

Commissioned as an organization of Statistic reports of Korean MD market

**2005**

07.18

Designated as GMP education center

**2007**

01.01

Designated as Pre-review organization for MD advertisements

**2011**

10.11

Joined GMTA

**2015**

02.05

Designated as an execution organization for international medical devices exhibitions

**2017**

12.28

Joined APACMED

**2019**

04.24

Built 'IMDRF Supporting Team' in KMDIA

**2020**

01.14

Joined DITTA

11.17

Hosted 'Korea IMDRF Working Groups' General Meeting



# Domestic & International Partners

01 | Introduction

## International (MOU Signing)

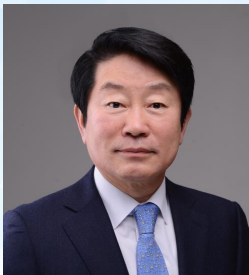


## Domestic (MOU Signing)



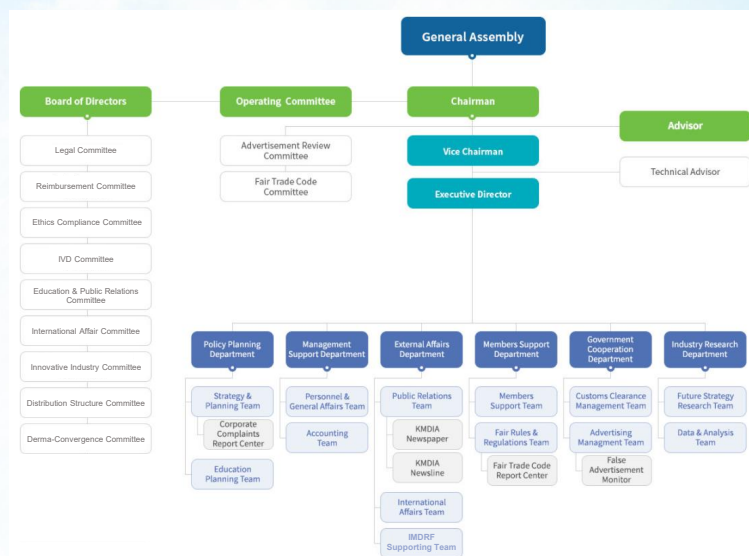
# Organization

02 | Organization



Korea Medical Device Industry Association  
Chairman **CHEOL WOOK YOO**

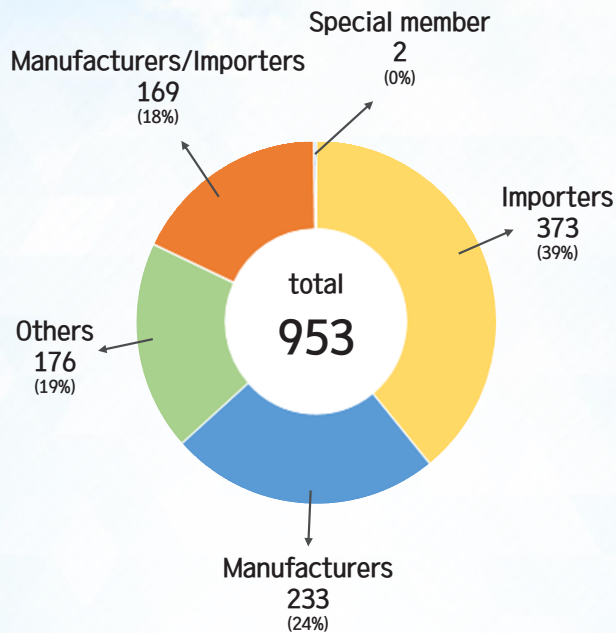
“We will keep our best to develop medical devices industry for growth in MD market to become the world's top seven MD powers by 2021”



## Current State of KMDIA

02 | Organization

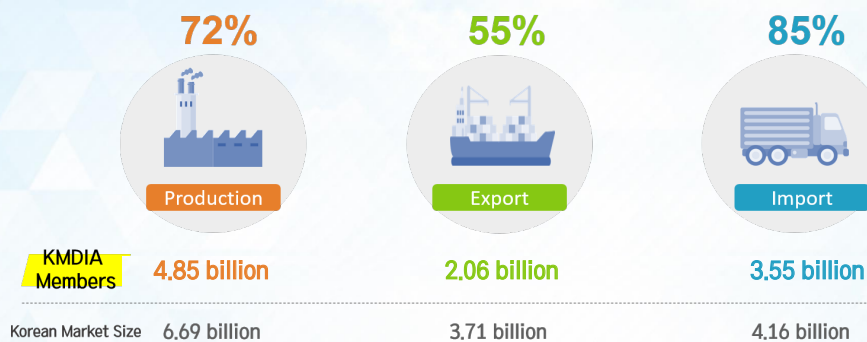
### Membership Status



## Current State of KMDIA

02 | Organization

### Market Share of Member Companies in The Korean Market (2019, USD)



### Korea's Top 5 Export and Import Item (2019)

#### Top 5 Export Items

1. Ultrasound Imaging System
2. Implant Fixture(endosseous)
3. Biomaterial Graft/Prosthesis
4. Soft Contact Lens(daily-wear)
5. IVD Reagents for Self-testing II

#### Top 5 Import Items

1. Soft Contact Lens(daily-wear)
2. CT System
3. MRI System
4. Coronary Artery Stent
5. Multifocal Intraocular Lens

## Major Responsibilities of KMDIA

03 | Major Responsibilities



## Major Responsibilities of KMDIA

03 | Major Responsibilities

### 01 Membership Support



02 Regulations & Reimbursement Policy Support

03 PR, Media support

04 Industry policy support

05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review

06 Ethics, Public service support

07 General Affairs, Budget, Human Resources

1

#### Supporting MD Industry and solving of a pending issue of members

- Cooperating with the government and related organizations
- Researching the current issues and proposing alternatives and regulations

2

#### Training programs for MD human resources

- Fostering professional MD manpower through practical education programs
  - Complimentary education by CHAMP (Government support business)
- \* CHAMP : Consortium for Human Resources Development Ability Magnified Program

3

#### Networking with Overseas MD Associations

- Interacting with foreign organizations such as GMTA, APACMED...etc.
- Supporting for international regulatory harmonization and global expansion

# Major Responsibilities of KMDIA

03 | Major Responsibilities

## 01 Membership Support



- 02 Regulations & Reimbursement Policy Support
- 03 PR, Media support
- 04 Industry policy support
- 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
- 06 Ethics, Public service support
- 07 General Affairs, Budget, Human Resources

4

### IMDRF Supporting team

- \* IMDRF : International Medical Devices Regulators Forum
- Cooperation with MFDS
  - To assist MFDS with its IMDRF roles and responsibilities
- IMDRF Working Groups Assistance
  - To operate and manage Korea IMDRF Working Groups
- External Relations
  - To conduct external relations with IMDRF member countries and their related organizations



# Major Responsibilities of KMDIA

03 | Major Responsibilities

## 02 Regulations & Reimbursement Policy Support



- 01 Membership support
- 03 PR, Media support
- 04 Industry policy support
- 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
- 06 Ethics, Public service support
- 07 General Affairs, Budget, Human Resources

1

### Proposing improved regulations for membership

- Supporting consultative groups to improve regulatory system
- Finding corporations' complaints and proposing improvements to the government

2

### Gathering industries' opinions about legislative/ Administrative guidelines

- Suggesting revised proposals by reflecting field opinions

3

### Gathering and distributing major MD-related issues and industrial support information

- Holding policy forum, workshop and panel discussion with government officials
- Delivering opinions and proposing alternatives through CEO meeting

# Major Responsibilities of KMDIA

03 | Major Responsibilities

## 03 PR, Media support



- 01 Membership support
- 02 Regulations & Reimbursement Policy Support
- 04 Industry policy support
- 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
- 06 Ethics, Public service support
- 07 General Affairs, Budget, Human Resources

1

### Introducing the activities of KMDIA and member companies

- Issuing press releases and on-offline newspapers

2

### Communicating industry's perspectives on major healthcare issues to the news media and general public

- Initiative activities (ex. Press conference)

3

### Publishing KMDIA newspaper and Newslne(online)

- Free distribution of 5,200 copies monthly
- Newsletter and mobile newspaper service

의료기기협회보

"대금결제기한 규정 및 공급내역보고 전가 금지" 서정숙 의원 특수 관계 거래 제한 법 개정안 발의



# Major Responsibilities of KMDIA

03 | Major Responsibilities

## 04 Industry Policy Research



- 01 Membership support
- 02 Regulations & Reimbursement Policy Support
- 03 PR, Media support
- 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
- 06 Ethics, Public service support
- 07 General Affairs, Budget, Human Resources

1

### Strengthening competitiveness of MD industry

- Data analysis on statistic reports of Korean MD market
- Publication of an yearbook of MD industry's statistics

2

### Proposing new policies throughout research and networking

- Performing research project for the development of MD industry
- Supporting for interconnected networks between domestic and global companies

3

### Supporting R&D of the Cutting-edge MD

- Operating the 4th Industrial Revolution Medical Devices Special Committee
- Holding Medical Devices Industry Awards
- Protecting the Intellectual Property Rights

## Major Responsibilities of KMDIA

03 | Major Responsibilities

05

**Customs clearance,  
Statistic report of  
Korean MD market,  
Advertisement  
pre-review**



- 01 Membership support
- 02 Regulations & Reimbursement Policy Support
- 03 PR, Media support
- 04 Industry policy support
- 06 Ethics, Public service support
- 07 General Affairs, Budget, Human Resources

1

### Issuing Standard Customs Clearance Reports

- Reviewing and issuing standard customs clearance reports to protect danger caused by importing MD

2

### Issuing Requirement Exemption Import Certification

- Issuing requirement exemption import certification to medical devices exempted from submitting standard customs clearance reports

3

### Statistic report of Korean MD market

- Gathering the statistic data on production, exports, imports and repairs of Korean MD market

4

### Medical Devices Advertisement pre-review

- Preventing customers' damages caused by false and exaggerated advertisements and providing the information for appropriate use

## Major Responsibilities of KMDIA

03 | Major Responsibilities

06

**Ethics, Public  
Service Support**



- 01 Membership support
- 02 Regulations & Reimbursement Policy Support
- 03 PR, Media support
- 04 Industry policy support
- 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
- 07 General Affairs, Budget, Human Resources

1

### Improving distribution environment of MD

- Enacting and conducting the 'Fair Trade Code' of medical device

2

### Strengthening MD management ethics

- Providing an institutional framework for the fair distribution environment
- Providing 'Fair Pay Med' system

3

### Promoting social contribution activities with membership

- Free health examination service for the vulnerable

4

### Conducting a campaign for safe use of MD

- Distributing the safety usage of life-friendly medical devices

# Major Responsibilities of KMDIA

03 | Major Responsibilities

## 07 General affairs, Budget, HRM



- 01 Membership support
- 02 Regulations & Reimbursement Policy Support
- 03 PR, Media support
- 04 Industry policy support
- 05 Customs clearance, Statistic report of Korean MD market, Advertisement pre-review
- 06 Ethics, Public service support

### 1 Support and management of the overall operation

- General affairs, Accounting, Computerizing and Human Resources management

### 2 Support of the board of directors and general meeting

- Holding the board of directors and general meeting
- Follow-up on decisions

### 3 Enactment and amendment of the articles of association

- Enactment and revision of internal guidances

# Activities of the Committee

04 | Activities of the committee

## 01 Legal Committee

- Improving regulatory system of MD
- Proposing improved regulations for membership
- Promotion of MD industry environment



## 02 Reimbursement Committee

- Proposal of improved reimbursement regulations
- Development of health policy for industry
- Research and analysis of reimbursement policy



## 03 Ethics Compliance Committee

- Improving fair distribution environment
- Disputing over conflicts within industry
- Discussion over Fair Trade Code and specific standards



## 04 IVD Committee

- Proposal of improved IVD regulations
- Research and analysis of reimbursement policy for IVD
- Improvement of new health technology assessment



## Activities of the Committee

04 | Activities of the committee

### 05 Education & Public Relations Committee

- ▶ Introduction of new laws and regulations of MD
- ▶ Improvement of MD environment
- ▶ Introduction of the activities of KMDIA & member companies
- ▶ Fostering human resource through training programs
- ▶ Development and review for new education programs
- ▶ Consulting on improved educational programs



### 06 International Affair Committee

- ▶ Research & Analysis for overseas MD market
- ▶ MOU signing with international organizations
- ▶ Information sharing on global MD market
- ▶ Networking with Foreign embassy



### 07 Innovative Industry Committee

- ▶ Business support of venture and start-up
- ▶ Cooperation with competitive corporations for global market
- ▶ Commercialization of MD connected to technical R&D business
- ▶ DB building about domestic MD technologies



## Activities of the Committee

04 | Activities of the committee

### 08 Distribution Structure Committee

- ▶ Distributing GMP obtained medical devices
- ▶ Improving medical devices distribution structure
- ▶ Ensuring fair distribution system



### 09 Derma-Convergence Committee

- ▶ Proposing policy and improving regulations of medical aesthetic device
- ▶ Building data base on medical aesthetic device industry
- ▶ Cooperation with related agencies and academic



## Location



1, 3F Hanjin Bldg., 6, Teheran-ro 103-gil,  
Gangnam-gu, Seoul, South Korea, 06173



# Thank you

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# KMDICA



**Byung-Chul Ahn**

# Introduction on KMDICA

*Supporting manufacturer  
for Regulatory Response*

**Byung-Chul Ahn / Managing Director**  
Korea Medical Devices Industrial Cooperative Association  
[abc@medinet.or.kr](mailto:abc@medinet.or.kr)



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### 1. Business Overview

### 2. Work scope of KMDICA

#### 2-1. Policy Development

#### 2-2. Capacity Building

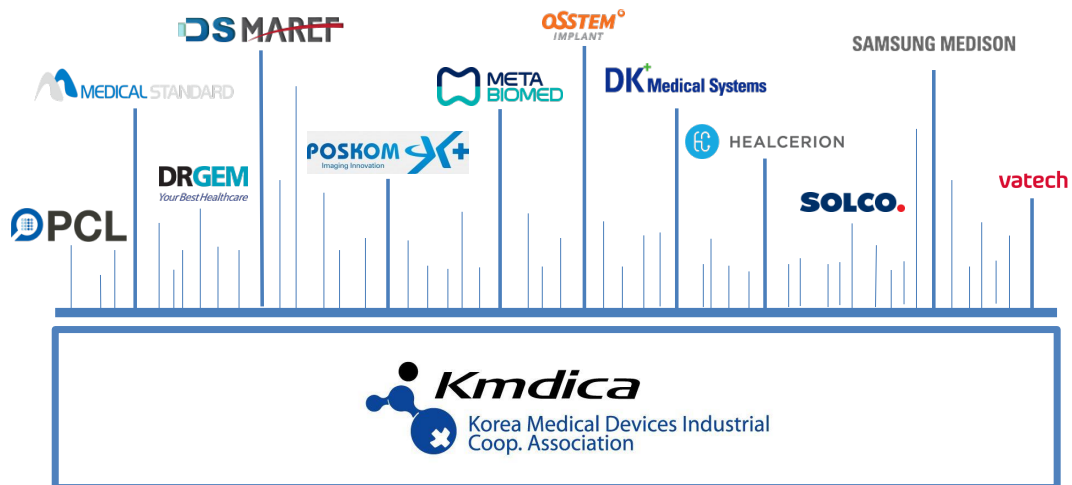
#### 2-3. Export Support & Local Center Business

#### 2-4. Expanding Domestic Market

## 1. Business Overview

### THE PLATFORM OF MEDICAL DEVICE MANUFACTURERS

[ With about 650 member companies ]



\* Membership qualification : Manufacturer of medical instruments and devices approved by Ministry of Food & Drug Safety of ROK

## 1. Business Overview

### Business Domain of KMDICA



## 2. Work scope of KMDICA

### 2-1. Policy Development

#### Cooperation with MFDS(Ministry of Food and Drug Safety) Korea

- Strengthening the network between MFDS and Medical Device Industries, such as operating 'Government-Industry consultative body'
- Participate in establishment & revision of regulation such as 'Medical Device Item Renewal System'
- Inform guidance on Regulation Establishment to industries.
- Collect opinions of Industries on regulatory enactment



## 2. Work scope of KMDICA

### 2-2. Capacity Building

#### Regulatory Response Support for Industries

- Coaching service  
(Guidance to establish regulatory response strategy)
  - Establish regulation approval strategies for each medical device development process
  - Establish roadmap for medical device certification
  - Provide manufacturer-customized training
- Training & Education Service
  - Provide latest regulatory response information and training to improve regulatory response capabilities for medical device manufacturers



## 2. Work scope of KMDICA

### 2-2. Capacity Building

#### Regulatory Response Support for Industries

- Others
  - Support surveillance test for Prototype
  - Guidance for design review
  - Support for preparing clinical evaluation report



## 2. Introduction on Detail task of KMDICA

### 2-3. Export Support & Local Center Business

- Export Support
  - : Leading Korean Pavilion for each major international exhibition and support overseas market entry
    - Arab Health (UAE), Western Vet Conference (USA), Hospitalar (Brazil), Medical Fair Asia (Singapore), CMEF(China), Hospital Expo (Indonesia), MEDICA (Germany)



## 2. Work scope of KMDICA

### 2-3. Export Support & Local Center Business

- Operate Local business Center in Asia-pacific region : Indonesia, Vietnam, China
  - Product Registration & License Holding support
  - Localization Assistance
  - Maintenance & Repair Service
  - PR Service
  - Show Room Service, etc.



## 2. Work scope of KMDICA

### 2-4. Expanding Domestic Market

- Holding domestic exhibition (*KIMES 2021 Mar 18-21 COEX*) : Vitalize domestic market
  - Securing new marketplaces and new business models for manufacturers
  - Support for promoting outstanding medical device manufacturers





# Thank You







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# ASTM



Craig Updyke



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## Presentation to IMDRF Stakeholders Forum

March 2021

### Topics



- 1  
About ASTM International
- 2  
ASTM Committees F04 and F23
- 3  
ASTM Collaboration Platform to  
Advance Personal Protective  
Equipment (PPE) Safety, Quality and  
Innovation
- 4  
ASTM Supports Global Convergence
- 5  
Conclusion/Q&A



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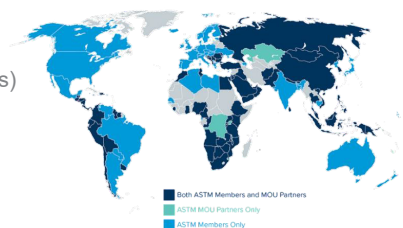
## About ASTM

## About ASTM International



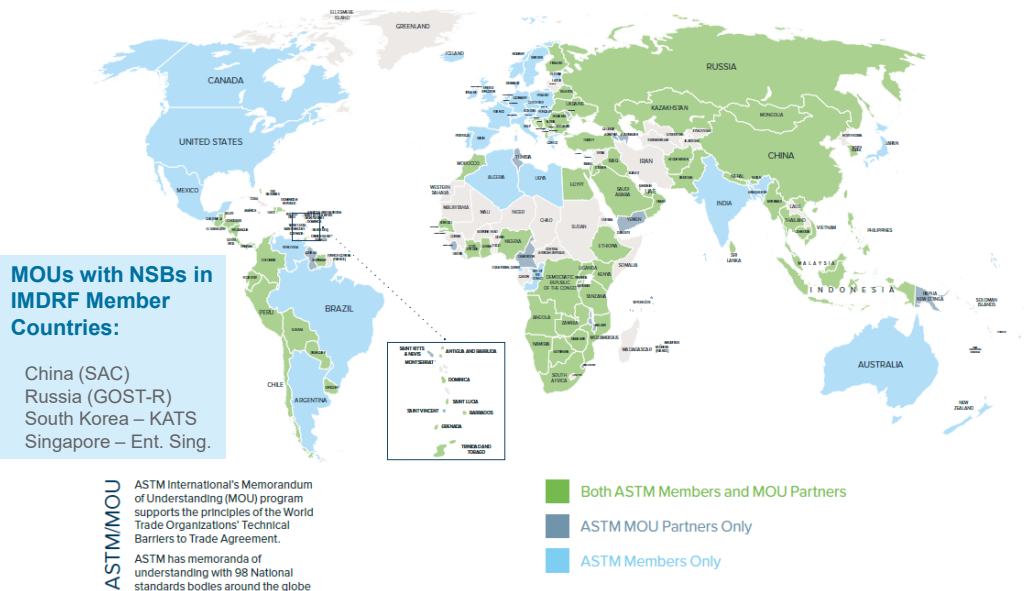
### A Proven and Practical System

- Established in 1898
- 150 Committees & 12,700+ Standards (Covering 90 industry sectors)
  - Recent: Additive Manufacturing, Exo and Exoskeleton Technology, etc.
  - Older: Medical Devices, Pharmaceuticals, Plastics, etc.
- 34,000+ members
  - 8,000+ International Members from 135 countries
  - 8,400+ ASTM standards used in 83 countries
- Headquartered in PA/USA, Offices in Washington DC, Europe (Brussels/London/Stockholm), Middle East (Dubai), China (Beijing), Canada (Ottawa), South America (Lima, Peru)
- Accreditation:
  - American National Standards Institute (ANSI)
  - Standard Council of Canada (SCC)
- ASTM standards are globally recognized for quality and relevance
  - Development and delivery of information made uncomplicated
  - A common-sense approach: industry driven
  - Consensus based
  - Market relevant globally



**150**  
main committees  
plus 2,030+  
subcommittees

## ASTM Global Membership



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## COVID-19 Response



- Key ASTM PPE standards available for the public to both view and download at no-cost.
  - 100,000+ visits to our site, 50,000+ views of our PPE standards by individuals in 100+ countries
- Additive Manufacturing Center of Excellence published a COVID-19 Response Guide, providing guidance on additive manufacturing for product designers and manufacturers
- WHO Technical Specifications for PPE and infection prevention control supplies (Aug. 2020) reference ASTM standards for medical gloves, masks, and gowns; hand sanitizers; and bio-hazard bags
- Developed New Standard for barrier face coverings (F3502)
- Launched Global Collaboration to Advance Personal Protective Equipment (PPE) Safety, Quality, and Innovation

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25 February 2021

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## ASTM Committees F04 and F23



### Committee F04 on Medical Devices

#### Scope

- Development of standardized nomenclature and definitions of terms, test methods, recommended practices, guides, specifications and performance standards for medical and surgical materials and devices
- Encourage research in this field and sponsor symposia, workshops and publications to facilitate the development of such standards
- Promote liaison with other ASTM Committees and other organizations with mutual interests

#### Subcommittees Include

- |                                      |                  |
|--------------------------------------|------------------|
| – Orthopaedic Devices                | – Cell Signaling |
| – Medical/Surgical Devices           | – Neurosurgical  |
| – Tissue Engineered Medical Products | – Urological     |
| – Cardiovascular                     | – Etc.           |

## Committee F04 on Medical Devices



### Examples of Noteworthy Members (among 1,100+)

- Government Agencies
  - Brazil INMETRO
  - Canada NRC
  - China NMPA
  - Japan AIST
  - U.K. MHRA
  - U.S. FDA and NIST
- Private Sector
  - 3M, Abbott, Boston Scientific
  - Johnson & Johnson
  - Medtronic, Pfizer
  - Stryker, WL Gore

### Sample of Current Activities/Work Items of Interest

- WK8279, New Standard Terminology Relating to Vascular Stents
- WK70330, Standard Guide for Chronic Particulate Characterization and Coating Integrity Testing of Coated Vascular Stents
- WK65452, Guide for Determining the Bioactivity for Bioactive Glass and Bioactive Glass-Ceramic Implantable Materials
- WK68696, Intra-operative Impaction Durability of Intervertebral Body Fusion Devices
- WK61103, New Guide for Corrosion Fatigue Evaluation of Absorbable Metals

## Committee F23 on Personal Protective Clothing and Equipment



### Scope

- Development of standard specifications, test methods, practices, guides, terminology, and classifications for protective clothing and related personal protective equipment (PPE) designed and constructed to protect the user from potential occupational hazards
- Where applicable, development of the requirements for conformity assessment of protective clothing and related personal protective equipment
- Coordination of its efforts with other ASTM Committees and outside organizations having mutual interests

### Noteworthy Members (among 500+)

- Canada NRC, China NIMTT, Trinidad & Tobago, U.S. CDC, U.S. EPA, U.S. FDA
- 3M, BV, Covestro, CSA Group, Honeywell, Instituto Biomechanica Valencia (Spain), Korea Apparel Testing & Research Inst., SGS, Solvay, UL, Walt Disney World

### New Standard

- F3502-21, *Standard Specification for Barrier Face Coverings*

# ASTM F3502-21



## Scope of the Standard

- Purposes
  - Source control (protect the public)
  - Offer protective capability (protect the wearer)
- Performance Requirements
  - Protection
  - Comfort
  - Re-Use
- Test Methods
  - Leverage existing text methods to evaluate performance to accommodate expected range of products
- Conformity Assessment



### Barrier Face Coverings

"3.1.3 barrier face covering, *n*—a product worn on the face specifically covering at least the wearer's nose and mouth with the primary purpose of providing source control and to provide a degree of particulate filtration to reduce the amount of inhaled particulate matter."

## Areas Not Addressed

- Specification does not set regulatory requirements or cover all safety issues

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ASTM Collaboration Platform to  
Advance Personal Protective  
Equipment (PPE) Safety, Quality and  
Innovation

## Challenges Identified



### PPE Quality and Availability

- Lack of Standardization, Qualification and Certification
- Re-Use of Single-Use Units
- Non-Traditional Manufacturing
- New Environments and Uses

### Standards Development

- Lack of Data
- *Coordination of Stakeholders*
- *Dissemination of Standards*
- *Timeframe and Anticipating Future Needs*

## Standards Needs



### Protective Clothing and Face Shields

- Guidance on manufacturing of isolation gowns
- Design guidance for face shields
- Basic requirements and definitions for face shields for healthcare use and material selection guidance (cleanability, disinfection)

### Respirators and Face Masks

- Particle filtration efficiency testing
- Optical particle counter detector limits and alternative detector methods

### Reprocessing and Re-Use of PPE

### Conformity Assessment

- Testing to identify counterfeit materials, kits and devices

## Standards Needs



### Conformity Assessment

- Testing to identify counterfeit materials, kits and devices

### Modeling and Additive Manufacturing

- Guidance document for computational modeling of aerosol leakage through AM face masks
- Modeling and simulation standards to test PPE designs prior to printing
- Computational and physical test methods

### Other

- Modifications to standard for infrared thermometers
- Field test methods to verify PPE function during PPE shortages
- Testing methods/guidance for decontamination of PPE

## Global Collaboration Platform



To address the numerous challenges facing PPE and accelerate standards development, the community needs a **global collaboration platform** that unifies PPE standardization efforts by leveraging the collective capabilities of the PPE industry



### Goal

To establish a common, shared workspace, enabled by and offering digital tools to facilitate collaborative activities and interorganizational communication

# Benefits of Global Collaboration



Efficient Standardization and Creation of Non-Standards Publications

Coordinated R&D Leading to Standards

Broader Participation and Information Sharing

Regulator Involvement

Expanded Networks

ASTM Leadership to Facilitate and Maximize Collaboration



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## Promoting Global Convergence

## APEC Project Proposal



- During the pandemic, PPE and nasopharyngeal (NP) swabs are in short supply.
  - Additively manufactured PPE and NP swabs can assist in addressing the bottlenecks.
- PPE and NP swabs may require regulatory review and approval.
  - Consensus standards can assist in providing data for additively manufactured PPE and NP
- APEC economy stakeholders (regulators, manufacturers, researchers, academia) invited to identify gaps
  - Identified needs shared with international SDOs to expedite development of required standards
  - Draft framework, citing developed standards, formulated to assist regulators
- Project CN submitted and approved in second cycle 2020
  - Awaiting final approval
- Project targeted to run from Q1 2021 through Q2 2022
- Outcomes
  - Prioritized list of international voluntary consensus standards to deliver data required for additively manufactured product approval
  - Framework of standards for use in regulatory citations
  - Regulatory acceptance of additively manufactured PPE and NP swabs to eliminate supply bottlenecks
  - Support for regulatory convergence

## ASTM Supports Global Convergence



- ASTM has entered into technical cooperation agreements with other international standards bodies like ISO and IEC.
- ASTM maintains Memorandums of Understanding to support technical cooperation with over 100 regional and national standards bodies – including CEN, Singapore Enterprise, Standards Institute of Israel, and others in the Middle East, Latin America, APEC/ASEAN, and Eurasia.
- Signatory of UNECE Declaration on Gender Responsive Standards (2019)
- Supporting UNECE initiative on Standards for the SDGs
- Member of the OECD Partnership of International Organizations (with ISO, WIPO, WTO, etc.)
- We advocate globally for policies where regulators have the flexibility to choose standards based on important attributes such as technical quality, relevance, and suitability to task.

## ASTM at Its Core



- Open and Transparent in deliberations, global in scope and reach
- Direct and balanced participation for all
- Keep science in and politics out
- Promote choosing standards based on merit
  - Ultimate measures of worth are technical quality and market relevance
  - Respect the choices of the market and needs of stakeholders

*The most innovative companies in the world demand flexibility and choice in standards so that they can offer exciting new products and services that meet emerging demands of the marketplace.*

*By enabling prosperity, innovation, and safety, ASTM helps our world work better!*



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## Thank you! Questions?

[www.astm.org](http://www.astm.org)



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Ministry of Food and Drug Safety