



## IMDRF Stakeholders Forum

*Webinar session via Zoom*

Wednesday, 23 September 2020, 6:00pm – 8.00pm Singapore Time\*

*\*Refer to corresponding time at the end of the programme*

### PROGRAMME

#### 1800 – 1810 OPENING ADDRESS

**Dr Choong May Ling, Mimi**, CEO, Health Sciences Authority (HSA), Singapore

#### 1810 – 1850 SEGMENT 1: REGULATORY UPDATES BY IMDRF MANAGEMENT COMMITTEE

*Panel Discussion to address Q&As*

Moderators: **Ms Liew Lailing** and **Dr Lakshmidevi Balakrishnan**, Regulatory Consultants, Medical Devices Branch, Medical Devices Cluster, Health Products Regulation Group, HSA

- a. **Australia**  
**Tracey Duffy**, First Assistant Secretary, Therapeutic Goods Administration (TGA), Department of Health
- b. **Brazil**  
**Leandro Rodrigues Pereira**, General Manager, Office of Medical Devices, Brazilian Health Regulatory Agency (ANVISA)
- c. **Canada**  
**David Boudreau**, Acting Director General, Medical Devices Directorate, Health Canada
- d. **China**  
**Yuan Peng**, Director of Division I, Department of Medical Device Registration, National Medical Products Administration (NMPA)
- e. **European Union**  
**Erik Hansson**, Deputy Head of Unit, Directorate General for Health and Food Safety (SANTE), Medical Devices and Health Technology Assessment, European Commission
- f. **Japan**  
**Kanako Sasaki**, Deputy Director, Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW)
- g. **Russia**  
**Astapenko Elena**, Head of Division of Organization of State Control and Registration of Medical Devices, Roszdravnadzor
- h. **Singapore**  
**Wong Woei Jiuang**, Assistant Group Director, Medical Devices Cluster, Health Products Regulation Group, HSA
- i. **South Korea**  
**Kim Yoo-mi**, Director, Medical Device Policy Division, Medical Device Safety Bureau, Ministry of Food and Drug Safety (MFDS)
- j. **United States**  
**Jeffrey Shuren**, Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA)

#### 1850 – 1920 SEGMENT 2: PROGRESS OF IMDRF WORK ITEMS

*Panel Discussion to address Q&As*

Moderator: **Ms Liew Lailing**, Regulatory Consultant, Medical Devices Branch, Medical Devices Cluster, Health Products Regulation Group, HSA

- a. **Regulated Product Submission (Canada)**  
Nancy Shadeed, Manager, International Programs, Medical Devices Directorate, Health Canada
- b. **Good Regulatory Review Practice (USA/Singapore)**  
Dr Lakshmidevi Balakrishnan, Regulatory Consultant, Medical Devices Branch, Medical Devices Cluster, Health Products Regulation Group, HSA
- c. **Medical Device Adverse Event Terminology (Japan)**  
Dr Tetsuya Kusakabe, International Coordination Officer, Pharmaceuticals and Medical Devices Agency (PMDA)
- d. **Personalized Medical Devices (Australia)**  
Tracey Duffy, First Assistant Secretary, Therapeutic Goods Administration (TGA), Department of Health
- e. **Medical Device Clinical Evaluation (China)**  
Ju Shan, Medical Device Clinical Evaluation I, Center for Medical Device Evaluation (CMDE), NMPA
- f. **Medical Device Cybersecurity Guide (USA/Canada)**  
Suzanne B. Schwartz, Deputy Director, Office of Strategic Partnerships & Technology Innovation (OST), Center for Devices & Radiological Health, U.S. FDA
- g. **Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (Russia)**  
Dr Tatyana Buryakina, Expert, Department of Medical Devices Premarket Submission Review, Roszdravnadzor
- h. **Artificial Intelligence Medical Devices (South Korea)**  
Kang Young-kyu, Director, Digital Health Device TF, High-Tech Medical Device Division, Medical Device Evaluation Department, National Institute of Food and Drug Safety Evaluation (NIFDS), MFDS

## 1920 – 2000 SEGMENT 3: STAKEHOLDERS SESSIONS

*Panel Discussion to address Q&As*

Moderators: Ms Liew Lailing and Dr Lakshmidevi Balakrishnan, Regulatory Consultants, Medical Devices Branch, Medical Devices Cluster, Health Products Regulation Group, HSA

- a. **WHO (Official Observer)**  
Irena Prat, Team Lead, In vitro diagnostics assessment, Prequalification Unit, World Health Organisation (WHO)
- b. **APEC LSIF RHSC (Regional Harmonisation Initiative)**  
Wu Cheng-Ning, Section Chief, Taiwan Food and Drug Administration
- c. **AHWP (Regional Harmonisation Initiative)**  
Ali M. Al-Dalaan, Chair of Asian Harmonisation Working Party (AHWP) and Vice Executive President, Medical Device Sector, Saudi Food and Drug Authority (SFDA)
- d. **PAHO (Regional Harmonisation Initiative)**  
Alexandre Lemgruber, Regional Advisor, Health Technologies, Pan American Health Organisation (PAHO)
- e. **DITTA (Industry)**  
Nicole Denjoy, DITTA Chair, Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DTTA)
- f. **GMTA (Industry)**  
Janet Trunzo, Senior Advisor to the President, Senior Executive Vice President, Technology & Regulatory Affairs, Advanced Medical Technology Association (AdvaMed)
- g. **Singapore Manufacturing Federation, Medical Technology Industry Group (SMF MTIG) (Industry)**  
James Chan, SMF MTIG Regulatory Services Chairman
- h. **Asia Pacific Medical Technology Association (APACMed) (Industry)**  
Harjit Gill, Chief Executive Officer, APACMed

## **Notes**

Registration link and presentation materials will be uploaded on [this website](#).

Participants are invited to access these materials in advance and submit questions for the speakers using the [Questions Submission Form](#) by **Wednesday, 9 September 2020**.

Please note that all questions will be moderated. Due to limited duration of the webinar, only questions which are submitted via the online form before the closing date will be prioritised for consideration.

## **Corresponding Time**

<b>Australia</b>	Wednesday, 23 September 2020, 8:00 PM AEST
<b>Brazil</b>	Wednesday, 23 September 2020, 7:00 AM BRT
<b>Canada</b>	Wednesday, 23 September 2020, 6:00 AM EST
<b>China</b>	Wednesday, 23 September 2020, 6:00 PM CST
<b>Belgium, France &amp; Germany</b>	Wednesday, 23 September 2020, 12:00 NOON CET
<b>Ireland</b>	Wednesday, 23 September 2020, 11:00 AM GMT
<b>Japan</b>	Wednesday, 23 September 2020, 7:00 PM JST
<b>Russia</b>	Wednesday, 23 September 2020, 1:00 PM MSK
<b>Singapore</b>	Wednesday, 23 September 2020, 6:00 PM SGT
<b>South Korea</b>	Wednesday, 23 September 2020, 7:00 PM KST
<b>Switzerland</b>	Wednesday, 23 September 2020, 12:00 NOON CET
<b>USA</b>	Wednesday, 23 September 2020, 6:00 AM EST