Asia Pacific Medical Device Regulatory Summit 2018

Date: 9:00-17:00 11 October 2018 (Thursday)

Venue: Suntec International Convention & Exhibition Centre, Singapore, Level 3, Room 331

09:00-09:15 Opening remarks

- *Mr. Fredrik Nyberg, CEO, APACMed*
- *Ms. Wong Woei Jiuang, Acting Assistant Group Director, Health Products Regulation Group, Medical Devices Cluster, Health Sciences Authority, Singapore; The current Chair of ASEAN Medical Device Committee.*

Section One: Challenges in New Regulation Implementation

09:15-10:30 Presentation (15 minutes each) + Panel Discussion (30 minutes including Q&A)

- **Medical Device Regulatory reform update**
  - *Ms. Korrapat Trisarnsri, Director, Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health, Thailand*
- **Europe's IVDR/MDR implementation**
  - *Mr. Serge Bernasconi, Chief Executive Officer, MedTech Europe*
- **Implementation of Medical Device Rules 2017**
  - *Dr. Milind Antani, Nishith Desai Associates, India*

Moderator:

- *Prof. John Lim, Executive Director, Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School*

Panelists:

- *Ms. Korrapat Trisarnsri, Director, Medical Devices Control Division, Food and Drug Administration, Ministry of Public Health, Thailand*
- *Mr. Serge Bernasconi, Chief Executive Officer, MedTech Europe*
- *Mr. Preecha Bhandtivej, President of THAIMED*
- *Dr. Milind Antani, Nishith Desai Associates, India*

10:30-11:00 Photo Session & Coffee Break

Section Two: Regulatory Convergence and Regional/Local Solutions

11:00-12:15 Presentation (15 minutes each) + Panel Discussion (30 minutes including Q&A)

- **Medical device regulatory collaboration, convergence, and harmonization**
  - *Mr. Lupi Trilaksono, Deputy Director, C and D class Medical Device Evaluation, Directorate of Medical Devices and Household Health Product, Ministry of Health, Indonesia*
- **MedTech RA roundtable in China**

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- *Ms. Katherine Wang, Partner, Ropes & Gray*

➢ **MDSAP implementation**

- *Mr. Dominik Reterski, Vice President Quality and Regulatory Affairs Asia Pacific at Medtronic/APACMed RA Committee Chair*

Moderator:

- *Mr. Dominik Reterski, Vice President Quality and Regulatory Affairs Asia Pacific at Medtronic/ Chair of APACMed RA Committee*

Panelists:

- *Mr. Lupi Trilaksono, Deputy Director, C and D class Medical Device Evaluation, Directorate of Medical Devices and Household Health Product, Ministry of Health, Indonesia*
- *Ms. Katherine Wang, Partner, Ropes & Gray*
- *Ms. Miang (Chadaporn) Tanakasemsu, Head of Regulatory Affairs, Asia, Alcon/Vice Chair of APACMed RA Committee*
- *Dr. Michael H. Scholla, Global Director Regulatory & Standards, DuPont Medical & Pharmaceutical Packaging*

12:15-13:30 Lunch Break

Section Three: Sustainable Talent Pipeline for Regulatory Professionals

13:30-14:45 Presentation (15 minutes each) + Panel Discussion (30 minutes including Q&A)

➢ **Regulatory strategy and capacity building plans for the region**

- *Dr.Yoshimasa Yokoyama, Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA)*

➢ **Medical Device Regulatory Authority Competency Program**

- *Ms. Sasikala Devi Thangavelu, MDA, Malaysia*

➢ **Talent Challenge of Innovation: Fostering Agility in Regulatory & Clinical Research Professionals**

- *Dr. Robin W. Newman, WW Vice President, Clinical & Medical Strategic Operations, Johnson & Johnson Medical Devices*

Moderator:

- *Prof. Silke Vogel, Deputy Director, Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School*

Panelists:

- *Dr.Yoshimasa Yokoyama, Office of International Cooperation, Pharmaceuticals and Medical Devices Agency (PMDA)*
- *Ms. Sasikala Devi Thangavelu, MDA, Malaysia*
- *Dr. Robin W. Newman, WW Vice President, Clinical & Medical Strategic Operations, Johnson & Johnson Medical Devices*
- *Prof. Jack Wong, Vice-Chair of APACMed RA Committee*

14:45-15:15 Coffee Break

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Section Four: Regulatory Challenges Posed by Disruptive Innovation

15:15-16:30 Presentation (15 minutes each) + Panel Discussion (30 minutes including Q&A)

- **Regulations on innovative products (AI, Software, big data, 3D printing)**
  - *Dr. Sangjin Park, Assistant Director, Cardiovascular Division, Ministry of Food and Drug Safety, Republic of Korea*
- **Regulatory challenges posed by disruptive innovation**
  - *Mr. George Faithfull, Chair of Regulatory Affairs Committee, MTAA /Vice President Government & Regulatory Affairs at Stryker, South Pacific*
- **Software as Medical Devices**
  - *Mr. Philip Desjardins, Vice President, Global Regulatory Policy and Intelligence, Johnson & Johnson*

Moderator:

- *Dr. Mark B. McClellan, Former FDA Commissioner and Professor of Business, Medicine & Policy, Duke Margolis Centre for Public Health*

Panelists:

- *Dr. Sangjin Park, Assistant Director, Cardiovascular Division, Ministry of Food and Drug Safety, Republic of Korea*
- *Mr. George Faithfull, Chair of Regulatory Affairs Committee, MTAA /Vice President Government & Regulatory Affairs at Stryker, South Pacific*
- *Mr. Jesús Rueda Rodríguez, Director International Affairs, MedTech Europe*
- *Mr. Philip Desjardins, Vice President, Global Regulatory Policy and Intelligence, Johnson & Johnson*

16:30-16:45 Updates of APACMed regulatory affairs activities

- *Mr. Jason Guo, International Regulatory Affairs Director, Asia Pacific, Abbott/Vice Chair of APACMed RA Committee*

16:45-17:00 Closing remarks

- *Mr. Dominik Reterski, Vice President Quality and Regulatory Affairs Asia Pacific at Medtronic/APACMed RA Committee Chair*

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