Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP & RAPS JOINT CONFERENCE

2–3 December 2013 • Kuala Lumpur, Malaysia

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Saleh Al Tayyar, PhD, *Chair, AHWP, Vice Executive President for Medical Devices, SFDA, Kingdom of Saudi Arabia*
Sherry Keramidas, PhD, *Executive Director, Regulatory Affairs Professionals Society*
Ali Al Dalaan, *Vice Chair, AHWP TC, Executive Director, Executive Administration, Radiation Protection and Safety, Medical Devices Sector, SFDA*
Philippe Auclair, PharmD, PhD, FRAPS, *Senior Director, Regulatory Strategy & Advocacy, Abbott Quality & Regulatory EMEA, Abbott Laboratories Inc.*
Joanna Koh, *Chair, AHWP TC, Director, Operations & Policy, Group Director's Office, Director, Compliance Branch, HSA*
Alfred Kwek, *Director, Regulatory Affairs, ASEAN, GE Healthcare*
Quan Tran, *Vice President, QARA, GE Healthcare*
Rainer Voelksen, *Scientific Collaborator, Therapeutic Products Law Section, Directorate Public Health*

Invited Faculty

Adriana Velazquez Berumen, *Coordinator, Diagnostic Imaging and Medical Devices, WHO*
William Duffell, PhD, *Global Advocacy, Medtronic*
Michael Gropp, *Chair, RAPS Global Advisory Council*
Fredrik Härén, *Author, Entrepreneur, and Founder of Interesting.org*
Manabu Hayashi, *Principal Reviewer, Medical Device Safety Division, PMDA*
Brad Hossack, *VP of Regulatory Affairs International, LATAM & Asia Pacific, Stryker*
David Klokowski, *Product Surveillance Manager, GE Healthcare*
Hideyuki Kondo, *Deputy Director, Office of Medical Device Evaluation, MHLW, Japan*
Kyungja Lee, *Regulatory Affairs Manager, Corporate Affairs, Medtronic Korea*
Geraldine Lissalde-Bonnet, *Public Policy Manager, GS1 Healthcare*
Scott Sardeson, RAC, *International Regulatory Affairs and Quality Compliance Leader, Health Care Business, 3M*
Wing Gang Seet, *Manager, Regulatory Affairs Asia Pacific, HOYA Surgical Optics*
Janet Trunzo, *Senior Executive Vice President, Technology and Regulatory Affairs, AdvaMed*
Nobuo Uemura, *Director, Office of Medical Device III & International Coordination Officer for Medical Devices, PMDA*

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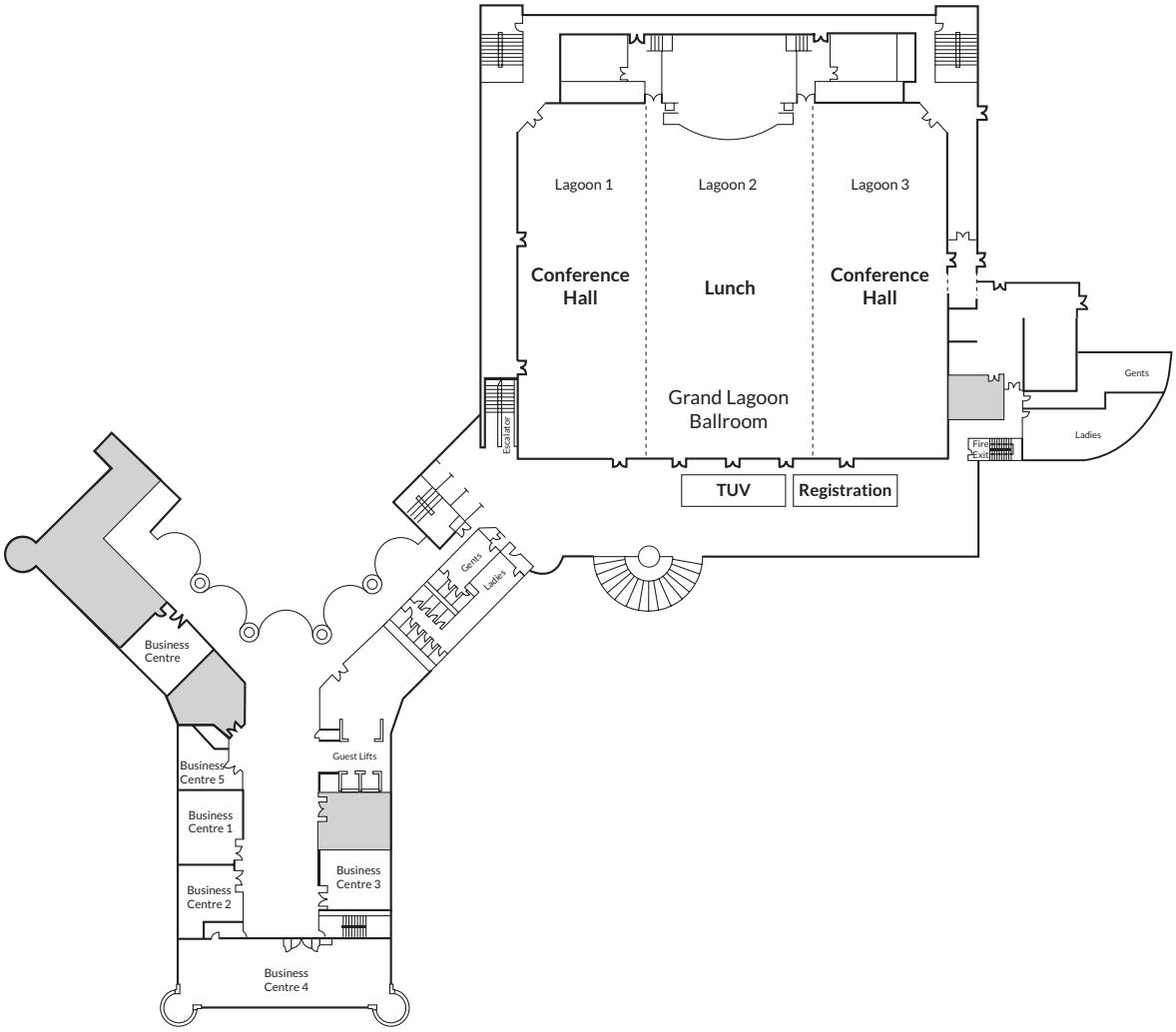
Sunway Resort Hotel & Spa - Level 15



Monday, 2 December 2013

11:00 am–12:00 pm	Registration	
12:00–1:00 pm	Lunch	
1:00–3:00 pm	**Opening Session** **Welcome and Formal Opening of Conference** ***Saleh Al Tayyar, PhD,*** *Chair, AHWP, Vice Executive President for Medical Devices, SFDA, Kingdom of Saudi Arabia* ***Sherry Keramidas, PhD,*** *Executive Director, Regulatory Affairs Professionals Society* **Innovation and the Global Regulatory Landscape** *Fredrik Härén, Author, Entrepreneur and Founder of Interesting.org* **Device Innovation and Regulatory Controls. Is a new paradigm needed?** ***Philippe Auclair, PharmD, PhD FRAPS****, Senior Director, Regulatory Strategy & Advocacy, Abbott Quality & Regulatory EMEA, Abbott Laboratories Inc.*	
3:00–3:30 pm	Break and Exhibits	
3:30–5:00 pm	**Building a Regulatory Framework – The ASEAN Experience** ***Session Leaders:*** ***Joanna Koh,*** *Chair, AHWP TC, Director, Operations & Policy, Group Director's Office, Director, Compliance Branch, HSA* ***Alfred Kwek,*** *Director, Regulatory Affairs, ASEAN, GE Healthcare* **Harmonisation of Medical Device Regulatory Framework in ASEAN** ***Wing Gang Seet,*** *Manager, Regulatory Affairs Asia Pacific, HOYA Surgical Optics* **Building a Regulatory Framework—A Perspective on the US and EU Regulatory Systems** ***Janet Trunzo****, Senior Executive Vice President, Technology and Regulatory Affairs, AdvaMed*	**Medical Device Single Audit Program (MDSAP)** ***Session Leaders:*** ***Saleh Al Tayyar, PhD,*** *Chair, AHWP, Vice Executive President for Medical Devices,* SFDA ***Ali Al Dalaan,*** *Vice Chair, AHWP TC, Executive Director, Executive Administration, Radiation Protection and Safety, Medical Devices Sector, SFDA* **Update of MDSAP Activities** ***Hideyuki Kondo,*** *Deputy Director, Office of Medical Device Evaluation, MHLW, Japan* **IMDRF's Single Audit Program, an Industry Perspective on the 2014 Rollout** ***William Duffell, PhD,*** *Global Advocacy, Medtronic*
3:45–4:00 pm	Break	

Tuesday, 3 December 2013

8:00–9:00 am	Registration	
9:00–10:00 am	**Morning Plenary: Regulatory Convergence – What is Next?** ***Michael Gropp,*** *Chair, RAPS Global Advisory Council*	
10:00–10:30 am	Break & Exhibits	
10:30 am–12:00 pm	**Building a Regulatory Framework – Essential Elements of Compliance/ Surveillance** ***Session Leader:*** ***Rainer Voelksen,*** *Scientific Collaborator, Therapeutic Products Law Section, Directorate Public Health* **Verification of Submission File Content** ***Brad Hossack,*** *VP of Regulatory Affairs International, LATAM & Asia Pacific, Stryker* **Regulatory Framework in Japan** ***Nobuo Uemura****, Director, Office of Medical Device III & International Coordination Officer for Medical Devices, PMDA*	**UDI - Purpose, Implementation and Challenges** ***Session Leaders:*** ***Quan Tran,*** *Vice President, QARA, GE Healthcare* ***Joanna Koh,*** *Chair, AHWP TC, Director, Operations & Policy, Group Director's Office, Director, Compliance Branch, HSA* **The What and Why - the UDI System** ***Joanna Koh,*** *Chair, AHWP TC, Director, Operations & Policy, Group Director's Office, Director, Compliance Branch, HSA* **The What and the How - The UDID** ***Geraldine Lissalde-Bonnet,*** *Public Policy Manager, GS1 Healthcare* **The Who - Implementation and Challenges** ***Kyungja Lee,*** *Regulatory Affairs Manager, Corporate Affairs, Medtronic Korea*
12:00–1:00 pm	Lunch	
1:00–3:00 pm	**Market and Postmarket Surveillance: Changing Global Perspective** ***Session Leaders:*** ***Saleh Al Tayyar, PhD,*** *Chair, AHWP, Vice Executive President for Medical Devices, SFDA* ***Quan Tran,*** *Vice President, QARA, GE Healthcare* **Postmarket Regulatory System of Medical Devices in Japan** ***Manabu Hayashi,*** *Principal Reviewer, Medical Device Safety Division, PMDA* **Comprehensive Complaint Systems** ***David Klokowski,*** *Product Surveillance Manager, GE Healthcare* **Postmarket Management – Challenges and Practical Approaches from an Industry Perspective** ***Scott Sardeson, RAC,*** *International Regulatory Affairs and Quality Compliance Leader, Health Care Business, 3M*	
3:00–3:30 pm	Break & Exhibits	
3:30–5:30 pm	**Closing Plenary: Implementation and Regulatory Capacity** ***Session Leader:*** ***Saleh Al Tayyar, PhD,*** *Chair, AHWP, Vice Executive President for Medical Devices, SFDA* ***Speakers:*** ***Adriana Velazquez Berumen,*** *Coordinator, Diagnostic Imaging and Medical Devices, WHO* ***Sherry Keramidas, PhD,*** *Executive Director, Regulatory Affairs Professionals Society* ***Rainer Voelksen****, Scientific Collaborator, Therapeutic Products Law Section, Directorate Public Health*	

Conference Information

Registration Counter

The registration counter is located at Level 15 (outside Lagoon 3), Sunway Hotel, Resort & Spa

Open Hours of the Registration Counter

2 December 2013, 7:00 am–4:00 pm
3 December 2013, 7:00 am–5:00 pm

Trade Exhibition

Trade Exhibition is located at Level 15 (Foyer), Sunway Hotel, Resort & Spa and opening hours are as follows:
2 December 2013, 11:00 am–5:00 pm
3 December 2013, 8:00 am–3:30 pm

Official Language

The official language of the conference is English.

Name Badges

Registered delegates are to wear their name badges at all times during the conference for identification and security purposes. Admission to all conference sessions and official functions is based on name badges.

Cellular Phone

As a courtesy to all delegates and speakers, cellular phones, pagers and others electronic devices must be operated in silent/vibrated mode throughout the conference sessions. No telephone conversations are permitted in the session rooms.

No Camera/Recording

Cameras or recording equipment are *not allowed* in the session room during the conference proceeding.

Lunch

Lunch will be served at Lagoon 2, Level 15, Sunway Hotel, Resort & Spa.

Coffee Break

Morning/ Afternoon coffee break will be served at the Trade Exhibition area located at Foyer, Level Level 15, Sunway Hotel, Resort & Spa.

Liability

The Organising Committee will not assume any responsibility for accidents, losses or damages, as well as delays or modifications of the conference programme.