AHWP & RAPS JOINT CONFERENCE

2–3 December 2013 • Selangor, Malaysia

AGENDA

MONDAY, 2 DECEMBER	
11:00 am–12:00 pm	Registration Check In
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, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* ***Sherry Keramidas, PhD,*** *Executive Director, Regulatory Affairs Professionals Society* **Global Regulatory Landscape** *Speaker TBD* **Medical Devices: Innovation in Regulatory Approaches** ***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****, Director, Medical Device Branch, Compliance Branch, Health Sciences Authority, Singapore* ***Alfred Kwek,*** *Director, Regulatory Affairs, ASEAN, GE Healthcare*
	Medical Device Single Audit Program (MDSAP) ***Session Leader:*** ***Saleh Al Tayyar, PhD,*** *Chair, AHWP, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* ***Speakers:*** ***Laurent Selles,*** Deputy Head of the Cosmetics and Medical Devices Unit European Commission ***Kim Trautman****, Associate Director International Affairs, Office of the Center Director, CDRH, FDA(Invited)*
TUESDAY, 3 DECEMBER 2013	
8:00–9:00 am	Registration & Breakfast
9:00–10:00 am	**Morning Plenary – Regulatory Convergence** ***Michael Gropp*** ***Mike Ward,*** *Co-chair, APEC Regulatory Harmonization Steering Committee at Health Canada*
10:00–10:30 am	Break & Exhibits
10:30 am–12:00 pm	**Building a Regulatory Framework – Essential Elements of Compliance/Surveillance** ***Rainer Voelksen,*** *Scientific Collaborator, Therapeutic Products Law Section, Directorate Public Health, Switzerland*
	Unique Device Identification (UDI) ***Speaker:*** ***Laurent Selles,*** Deputy Head of the Cosmetics and Medical Devices Unit European Commission
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, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* ***Quan Tran,*** *Vice President, QARA, GE Healthcare*
3:00–3:30 pm	Break & Exhibits
3:30–5:30 pm	**CLOSING PLENARY: IMPLEMENTATION AND REGULATORY CAPACITY** ***Session Leaders*** ***Saleh Al Tayyar, PhD,*** *Chair, AHWP, Director General, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia* ***Speakers:*** ***Sherry Keramidas, PhD,*** *Executive Director, Regulatory Affairs Professionals Society* ***Rainer Voelksen****, Scientific Collaborator, Therapeutic Products Law Section, Directorate Public Health*

Program subject to change.