

  
 **2014 AHC-AHWP**

**AHC-AHWP JOINT WORKSHOP,  
THE 18<sup>TH</sup> AHWP TC MEETING & THE 19<sup>TH</sup> AHWP ANNUAL MEETING**

**NOV. 18-21, 2014 | VISTA HALL, SHERATON GRANDE WALKERHILL**



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

[www.2014ahwp.com](http://www.2014ahwp.com)

# Highlights of Day-1 Programme

18 Nov 2014

- **Day 1 AHC-AHWP Joint Workshop**

- Session 1: Regulatory Status of Premarket Submission and Approval Requirements in AHWP and APEC Region**

- China
    - Korea
    - Japan
    - USA
    - Europe
    - AHWP members

- Session 2: Experiences of Industry on Premarket Submission and Approval Requirements**

- Analyzing approval process of substantial equivalence devices based on previously approved devices across Korea, USA, Japan, EU, AHWP members
    - Specific topic on Clinical Data Requirements
    - Performance Testing for IVDs in Europe, USA and China

- Special Topic: Commercialization in Korea (Pricing, Distributorship and Compliance)**

# Highlights of Day-2 Programme

19 Nov 2014

- **Day 2 AHC- AHWP Joint Workshop (cont.)**

## **KEY NOTE ADDRESS**

The Global Regulatory Profession: Opportunity Amid Challenges

## **Regulatory Intelligence**

## **Session 3: Special Topics on Medical Devices**

- **Post-market and market Surveillance**
- **Software as Medical Device**
- **Medical Device Refurbishment**

# Highlights of Day-3 Programme

20 Nov 2014

- **The 18<sup>th</sup> AHWP TC Meeting**
  - **Report and Overview of AHWP TC of the past term:**
    - i) Key Milestones
    - ii) SWOT analysis – new streamline proposal of the TC structure
  - **Speech by TC Advisors Representative**
  - **Intro to the Playbook**
    - Drive for acceptance
    - Next steps – guidance to its application
  - **AHWPTC Playbook**
    - Scope and content
  - **WG & STG Updates**

**Gala Dinner**

# Highlights of Day-4 Programme

21 Nov 2014

- **The 19<sup>th</sup> AHWP Meeting**
  - **IMDRF Status Updates**
  - **APEC Status Updates**
  - **AHWP Status Updates**
    - Implementation of Asian Harmonization Working Party Strategic Framework Towards 2020 - "The Foreseeable Harmonization Horizon"
  - **Country Regulatory Updates**
    - AHWP member economies
  - **Report Highlights - by AHWPTC**
  - **Secretariat Updates**
  - **Resolutions for Endorsement:**
    - AHWP Member Economy New Applicant
    - Working Group guidance documents
  - **Election of AHWP, AHWPTC and WG New Leadership (2015-2017)**