

The 20th AHWP Annual Meeting Program

(Version: 5.0)

Date : 2 – 6 Nov 2015
Venue : Dusit Thani Hotel, Bangkok, Thailand

Day 1: AHWP Playbook Workshop

2 Nov 2015	
08:30 – 09:00	Registration
09:00 – 09:10	Welcome Address by TC Chair
09:10 – 09:25	Opening Address of Capacity Building Project & Proposed Training Programs
09:25 – 09:55	The Industry's Viewpoint on Healthcare Regulations and its Impact on Business
09:55 – 10:30	What Role Should Industry Play in the Development & Implementation of Legislative Controls
10:30 – 11:00	TEA BREAK
11:00 – 11:40	Introduction & Objective of the Playbook Scope and Proposed Training Program
11:40 – 12:30	Development of Legislative Controls
12:30 – 13:30	LUNCH
13:30 – 14:30	Implementation Steps – Phased In Approach Consider Possible Scenarios – (i) Back log syndrome (ii) Controls by other agencies eg customs (iii) Loss of availability of current products
14:30 – 15:20	Manpower – What is needed to plan for manpower resources? What funding is required?
15:20 – 16:00	TEA BREAK
16:00 – 17:10	Panel – Hidden Challenges in Capacity Building Projects

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Day 2: AHWP Playbook and Other Workshops

3 Nov 2015		
09:00 – 09:10	Opening & Recap	
09:10 – 09:50	Post Market Considerations to Put in Place – WHY the POST before the PRE	
09:50 – 10:30	Premarket – the WHY of Essential Principles & Prudent Review Policies	
10:30 – 11:00	TEA BREAK	
11:00 – 12:30	Panel – Legislation & A Business Case – A Symbiotic Relationship What role can Industry play in development of legislation What and How should the roles be balanced	
12:30 – 13:30	LUNCH	
13:30 – 15:30	AHWP Workshop - Opening Address - Post-market Surveillance	
15:30pm – 17:00pm	Clinical Evaluation (for general MD & IVD)/Good Clinical Practice	WG Training on Quality System Audit
17:00pm – 18:30pm	- Panel Discussion - US Aid Program	

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Day 3: AHWP Workshop (Continue)

4 Nov 2015		
09:00 – 11:00	IMDRF Work Item for Single Audit Program - MDSAP IMDRF Work Item for Regulated Product Submission– New Table of Contents (ToC) Document	
11:00 – 12:00	Regulatory Updates from Other Non-member Economy <ul style="list-style-type: none"> - Brazil - Japan - Russia - US 	
12:00 – 12:30	Patient Registries	
12:30 – 13:30	LUNCH	
13:30 – 14:30	Keynote Speech	
14:30 – 18:30	Topics by DITTA (Medical Software Validation, Standards)	Capacity Building Meeting

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Day 4: 19th AHWP Technical Committee (TC) Meeting

5 Nov 2015	
08:00 – 09:45	AHWP TC & WG Leaders Meeting with TC Advisors (Close Meeting)
10:00 – 10:10	Welcome Speech
10:10 – 11:10	<ul style="list-style-type: none"> - Opening of Meeting/Adoption of Agenda - Roll Call - Highlight of TC
11:10 – 12:00	Work Group Updates <ul style="list-style-type: none"> ▪ WG1 – Pre-market: General MD ▪ WG2 – Pre-market: IVDD
12:00 – 13:00	LUNCH
13:00 – 16:30	Work Group Updates (Continued) <ul style="list-style-type: none"> ▪ WG3 – Pre-market: Software as a Medical Device ▪ WG4 – Post-Market ▪ WG5 – Clinical Performance & Safety ▪ WG6 – QMS: Audit & Assessment ▪ WG7 – QMS: Operation & Implementation ▪ WG8 – Standards ▪ STG (U&N) –UDI & Nomenclature
16:30 – 17:00	Highlight of AHWP Playbook Topics
17:00 – 17:10	Closing Remarks
18:00	Gala Dinner

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Day 5: 20th AHWP Annual Meeting

6 Nov 2015	
09:00 – 09:30	Opening Ceremony <ul style="list-style-type: none"> - Welcome Address - Opening Speech - Group Photo
09:30 – 13:00	Updates By: <ul style="list-style-type: none"> ▪ AHWP ▪ AHWP TC ▪ IMDRF ▪ APEC ▪ WHO ▪ ASEAN ▪ PAHO ▪ PAHWP ▪ Liaison Updates - DITTA, GS1
13:00 – 14:00	LUNCH
14:00 – 16:30	Regulatory Updates from Member Economy <ul style="list-style-type: none"> ▪ Thailand ▪ China ▪ India ▪ Korea ▪ Pakistan ▪ South Africa
16:30 – 17:30	Resolutions <ul style="list-style-type: none"> ▪ WG Documents towards endorsement
17:30 – 17:40	- Closing Remarks
18:00 – 18:30	The 4 th AHWP ASL Annual General Meeting (AGM)