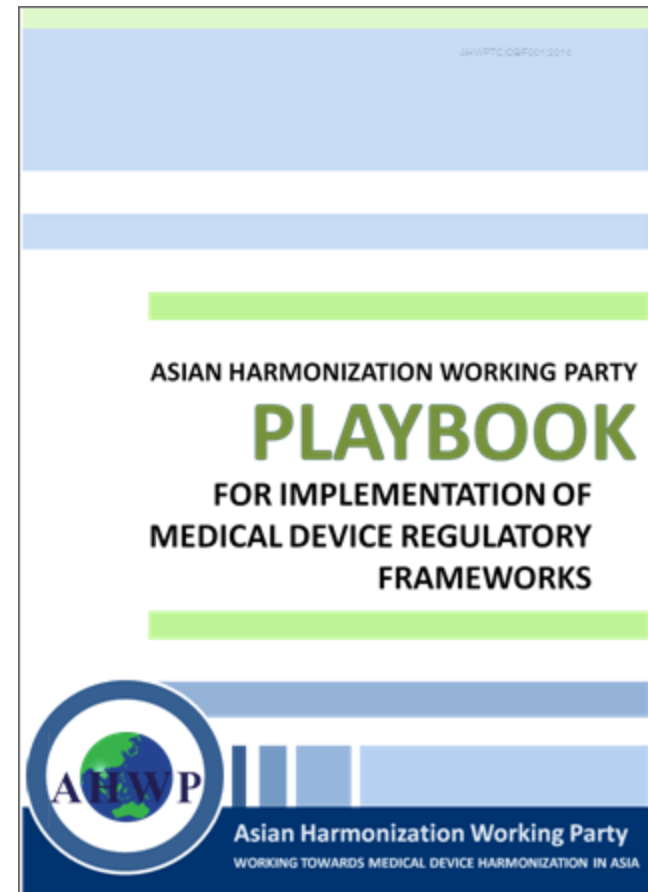


# Introduction to the Playbook

## Presentation content:

- Conception
- “Why?” – need & purpose
- Drive for acceptance
- Next steps – guidance to its application



# Conception of Playbook

- AHWP - Numerous technical documents published / adopted; focus on different aspects of regulation
- Need **guidance** on how different aspects come together in a cohesive regulatory **framework**

Defining a structure to frame the role of key regulatory  
'building blocks':

- Pre-market: General MD, IVD, Software
- Clinical performance & safety
- Standards
- Post-market
- QMS: Audit & Assessment
- QMS: Operation & Implementation

# Conception of Playbook

- Initiative of the Asia Harmonization Working Party
- Under recommendation of AHWP TC Advisors
- Building on a foundation of existing global guidelines from international organizations e.g.:
  - IMDRF/GHTF
  - WHO
  - APEC RHSC
  - AHC
  - IEC/ISO

# “Why?” – Need & Purpose

AHWP saw the need for:

- **Guidance** to member economies in developing and implementing their medical device regulatory framework
- **Encouragement** to adopt best practices from existing harmonized regulatory frameworks (GHTF model framework)

Consideration for:

- Practicality of guidelines – hence drawing from experiences of countries that have implemented regulations



# Standing on the Shoulders of Giants

## Referencing Guidelines published by international organizations

### AHWP TC Technical Guidelines

- Pre-market
- Post-Market
- Clinical Performance & Safety
- QMS
- Standards



APEC  
&  
OECD

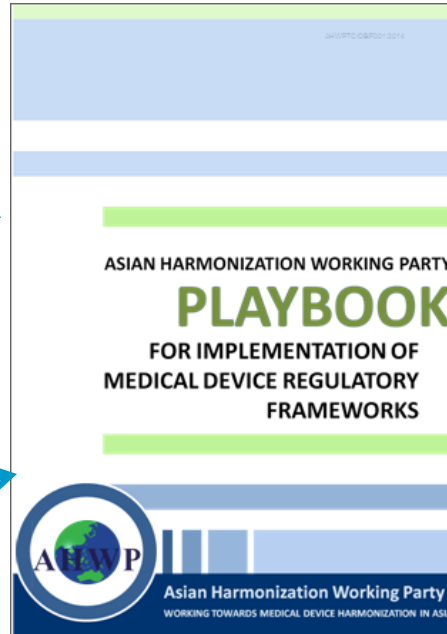


The APEC-OECD Co-operative Initiative on Regulatory Reform

### World Trade Organization



Agreement on Technical Barriers to Trade



ISO  
&  
IEC



Using and referencing ISO and IEC standards for technical regulations

### GHTF (IMDRF) Documents



**IMDRF** International Medical Device Regulators Forum

- “The GHTF Regulatory Model”
- Documents by 5 Study Groups

### World Health Organization



**World Health Organization**

Medical Device Regulations: Global overview and guiding principles

# Timeline of Playbook Development


<http://www.ahwp.info>

CALL FOR COMMENTS on the PROPOSED document "Playbook for Implementation of a Medical Device Regulatory Framework"  
Updated: Tue, 08/05/2014 - 19:02

The proposed document "Playbook for Implementation of a Medical Device Regulatory Framework" is prepared by the AHWP Technical Committee. If you have any comments, please send them to ([secretariat@ahwp.info](mailto:secretariat@ahwp.info)) and copy to AHWPTC Chair, Ms. Joanna KOH ([jko@ahwp.info](mailto:jko@ahwp.info)), AHWPTC Co-chair (Regulatory Authority), Mr. Ali M. AL-DALAAAN ([alid@ahwp.info](mailto:alid@ahwp.info)), AHWPTC Co-chair (Industry), Ms. Chadaporn TANAKASEMSUB ([chadaporn@alicon.com](mailto:chadaporn@alicon.com)) and Ms. Ming Hao TAN ([tanninghao@gmail.com](mailto:tanninghao@gmail.com)) on or before 15 July 2014 for your attention.  
C\_P01\_2014.pdf  
Comments Template\_verMay2014.docx

Endorsement of **Playbook Work Item** at AHWP main meeting (KL, Malaysia)

On AHWP website for public comments

  
**2014 AHWP**  
Endorsement at AHWP main meeting  
Nov 2014

2013

2014

26 Feb

5 Dec 23 May

15 Jul

1 Aug 8 Aug – 18 Sept 1 Nov

**Concept of Playbook**

proposed at 3<sup>rd</sup> AHWP TC leader's meeting (Bangkok)

**Draft v.1** of Playbook circulated within AHWP

AHWP TC Advisors comments & input

**Draft v.2** circulated within AHWP

Finalization of Playbook

# Drive for Acceptance

Next step for Playbook: 3-Prong Approach



# 3-Prong Approach

## Guidance Documents Development

- There is a need to go a level below high-level document and have a 2<sup>nd</sup> level interpretation document – e.g. examples on how to interpret the high-level document
- Examples that can be provided to supplement interpretation, will facilitate adoption into regulatory framework, training and continuity of interpretation



# 3-Prong Approach

## Training & Capacity Building

- Competency & clarity in interpreting the guidelines (Capacity Building)
- assisting member economies through regulatory guidance, training, coordination and promotion of international best practices

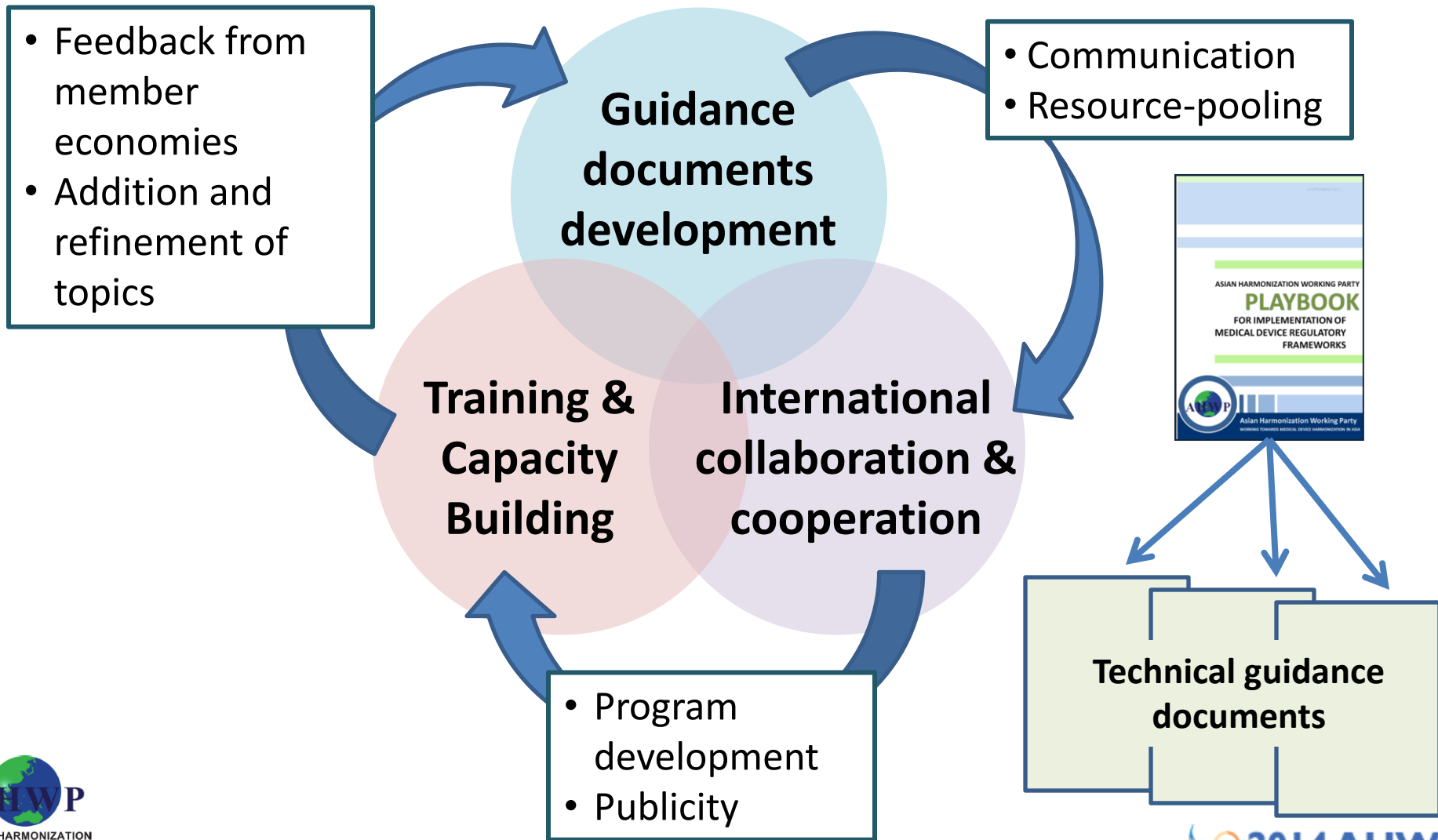
# 3-Prong Approach

## International collaboration & cooperation

- It is hoped for possible collaboration between AHWP & other international organizations
- Encourage resource-sharing, cooperation, harmonization/convergence
- Efforts to reach out to AHWP member economies & beyond
- Possible collaborators...and more...



# Next steps – Guidance to Playbook Application



# Thank You



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

NOV. 18-21, 2014

VISTA HALL, SHERATON GRANDE WALKERHILL, SEOUL, KOREA