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.:
  o IMDRF/GHTF
  o WHO
  o APEC RHSC
  o AHC
  o 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

**World Trade Organization**
Agreement on Technical Barriers to Trade

**GHTF (IMDRF) Documents**
- “The GHTF Regulatory Model”
- Documents by 5 Study Groups

**World Health Organization**
Medical Device Regulations: Global overview and guiding principles

**APEC & OECD**
The APEC-OECD Co-operative Initiative on Regulatory Reform

**ISO & IEC**
Using and referencing ISO and IEC standards for technical regulations
Timeline of Playbook Development

- **Endorsement of Playbook Work Item at AHWP main meeting (KL, Malaysia)**
- **On AHWP website for public comments**
- **Finalization of Playbook**

**2013**

- **26 Feb**
  - Concept of Playbook proposed at 3rd AHWP TC leader’s meeting (Bangkok)

**2014**

- **5 Dec 23 May**
  - Draft v.1 of Playbook circulated within AHWP

- **15 Jul**
  - AHWP TC Advisors comments & input

- **1 Aug – 18 Sept**
  - Draft v.2 circulated within AHWP

- **1 Nov**
  - Endorsement at AHWP main meeting Nov 2014
Drive for Acceptance

Next step for Playbook: 3-Prong Approach

- Guidance documents development
- Training & Capacity Building
- International collaboration & cooperation
3-Prong Approach

Guidance Documents Development

• There is a need to go a level below high-level document and have a 2\textsuperscript{nd} 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

- Feedback from member economies
- Addition and refinement of topics

Guidance documents development

Training & Capacity Building

International collaboration & cooperation

- Communication
- Resource-pooling

- Program development
- Publicity

Technical guidance documents
Thank You