

AHWP PLAYBOOK

the report

2015/16

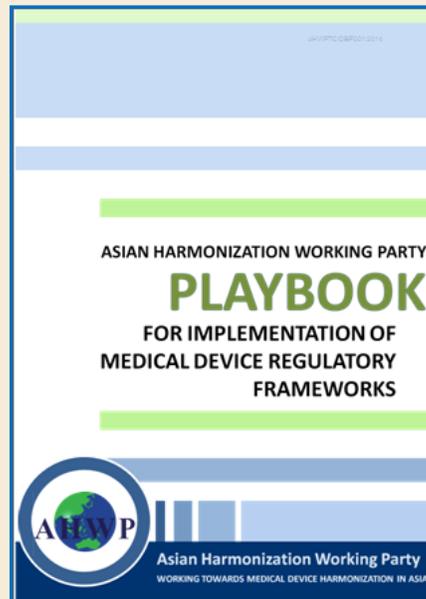


21st AHWP ANNUAL MEETING
Cebu – Philippines
20.11.16-25.11.16

Joanna Koh
Lead – Playbook Training Program

On the Road to Harmonisation...

AHWPTC Initiative: MD Playbook



Working towards...

- Predictable & harmonised regulatory environment across Asia
- Unified standards for product registration, establishment licencing, distribution and post-market

***Task:
Accomplishing
the
Objective***

Objective

- Develop a set of guidelines for MEs for a harmonised medical device (MD) regulatory framework in their implementation of controls
- Building on the experiences from other MEs who have
 - ❑ *implemented controls &*
 - ❑ *faced the challenges*

In view of the need for:

- Guidance on implementation of basic MD framework elements i.e achieving **HARMONISED Platforms.**



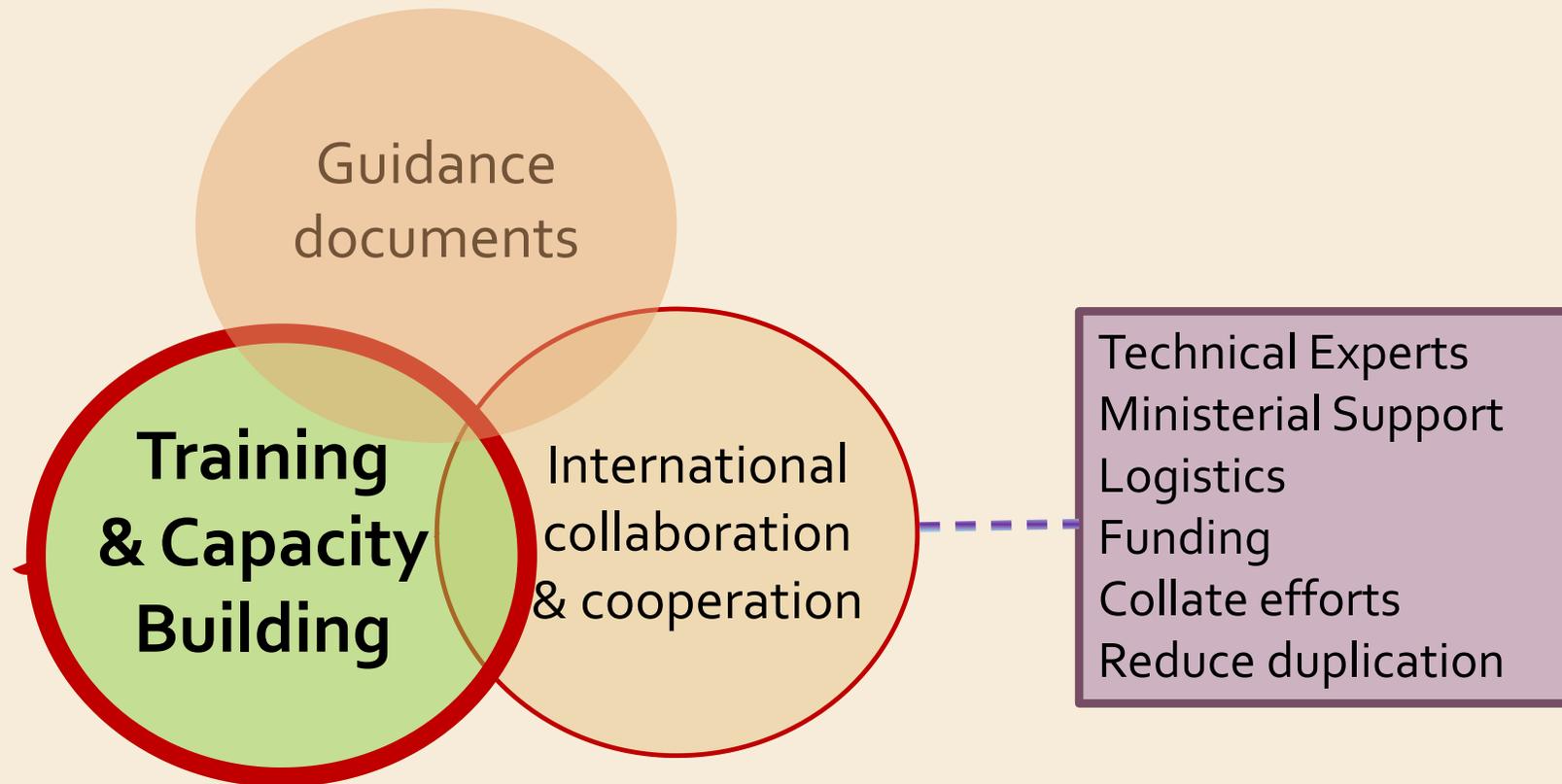
***PRIORITY AREAS OF
HARMONISATION / CONVERGENCE
covered in the Playbook***

- ❖ Quality Management Systems (QMS)
- ❖ Post Market Surveillance
- ❖ Technical Documentation
- ❖ Declaration of Conformity
- ❖ Registration of manufacturers, distributors
- ❖ Registration of medical devices



Recognizing important supports on the journey

3-Prong Approach

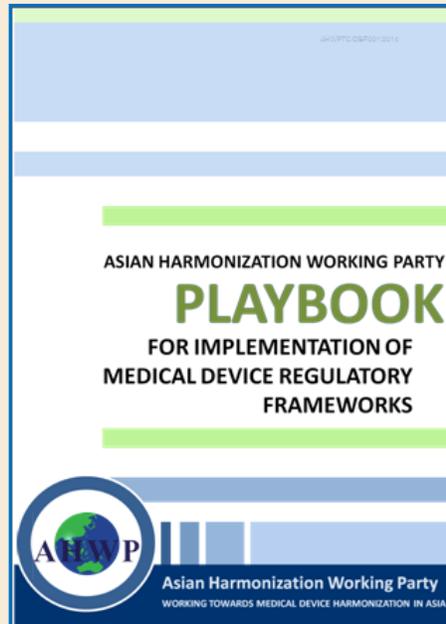


1st of the 3- Prong approach

Training & Capacity Building

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

Table of Contents



- Chapter 1: Objective of this Playbook
- Chapter 2: Introduction to Regulatory Controls
 - i) Basic Regulatory Controls
 - ii) More Advanced Controls
- Chapter 3: Legislation and Policy Framework
- Chapter 4: Phased Implementation Considerations
- Chapter 5: Manpower Considerations
- Chapter 6: Registration Databases
- Chapter 7: Essential Principles of Safety and Performance and Recognition of Standards

Topics covered in Annual meetings 2015/2016

Systematic Coverage of AHWP Playbook Chapter Topics

- **AHWP Playbook- Overview**
- **Team's task to accomplish**
- **Training Programs – proposed/approved**
- Why regulations ?
- Implementation Steps :-
Phased-In Approach
- Development of Legislative Controls
- Steps to Legislation Development
- Implementation of Controls
- Manpower
- Post Market
- Market access time lines
- Manpower Considerations
- Prudent Policies to overcome challenges

- **INDUSTRY's Interest:**
Background to an Industry partner's perspective
- **In an Emerging Economy, how can the 'CAB' play a balanced role and support prudent regulations for medical devices**
- **Legislation & A Business Case**

Medical Device Capacity Building
Sharing of Experiences:
Indonesia Experience
Capacity Building for Implementation of Medical Device Regulatory System (Malaysia)
Implementation of a GHTF Regulatory Framework (Lessons Learned)

PB Training Program

21/22nd Nov 16

PRE MARKET:

- ❖ Highlights of Essential Principles of MD– What’s essential for Emerging Countries
- ❖ Fact or Myth?
“CSDT by any other name will be as complicating”
What should be in That Product Dossier”

POSTMARKET:

- ❖ Cybersecurity
- ❖ GMDN : A Useful Aid for Post market Reviews
- ❖ Post Market Reports & Reviews
What to report (Industry) /
What is reviewed (Regulator)
- ❖ Product Liability

OTHERS:

- ❖ Technology needs for Regulatory Controls
- ❖ EU MDR & IMDRF recommendations effects on AHWP Capacity Building efforts

Typical PROGRAM In-Country in-depth Sessions



- **Covering: Chap 1 , 2 and 7**
- **Identifying Medical Devices – Definitions**
- **Risk Management considerations**
- **Grouping**
- **Risk – its titration, and applying to the CSDT Dossier**
- **Differences in Clinical Evaluation, Evidence, investigation ,**
- **Coverage & Overview of IVDDs**

Include :

- ❖ **Pre assessment of participants**
 - ❖ **Case studies**
 - ❖ **ASSESSMENTS**
-

Coverage of Considerations & accomplishments

2015/16

AHWP Annual Mtg PB Training sessions

3rd Qtr 15



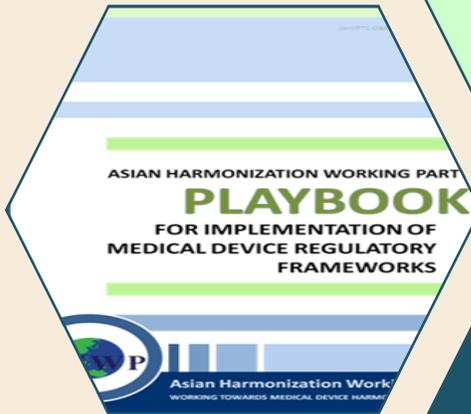
2017 plans

Identifying 2 other MEs & EXPANSION of TRAINING TOPICS

2nd Qtr 15

Identify ME with upcoming legislations

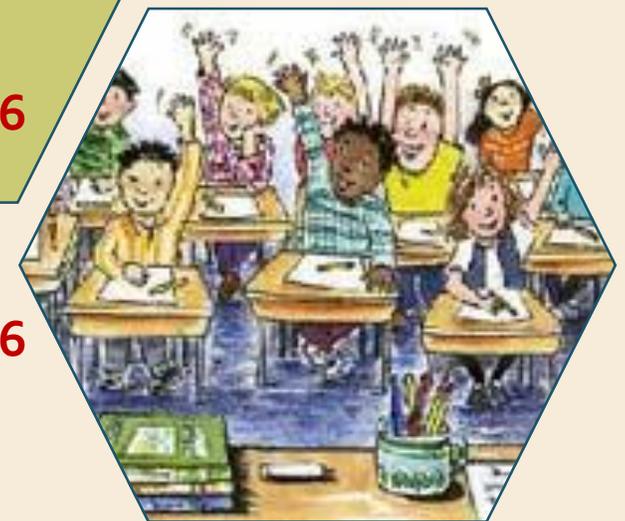
Nov 2014



Indonesia: 27-30 July 16
Vietnam 23-26 Aug 16

2 Countries responded :-
Vietnam
Indonesia

2nd/3rd Qtr 16



4th Qtr 15



Additional Goals Achieved

- Engagement of Industry Associations
- Meeting with other Government Ministries and Academicians
- Publicising the benefits of the AHWP participation



Thank
You

