Ministry of Health & Family Welfare
Government of India

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

1927-2017 FICCI @90

HIGHLIGHTS

AHWP PLAYBOOK TRAINING PROGRAM

IN-COUNTRY WORK SHOPS 2016/2017

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New Delhi -December 2017

AHWP

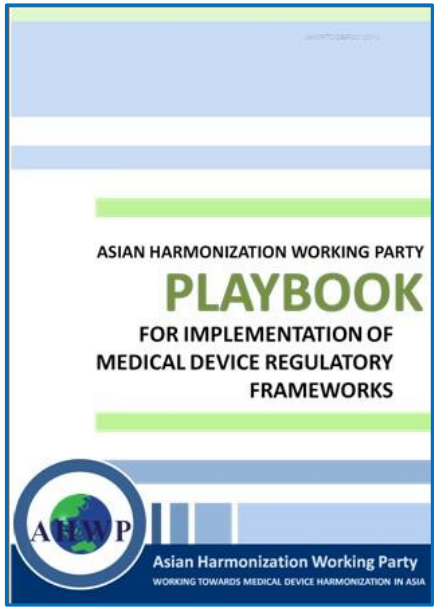
Its goals are to study and recommend ways to harmonize medical device regulations in the Asian and other regions

and to work in coordination with other international organisations of similar objectives

On the Road to Harmonisation…

AHWPTC Initiative: MD Playbook

Extracts from –
The 2016 Cebu PB Report:



Working towards…

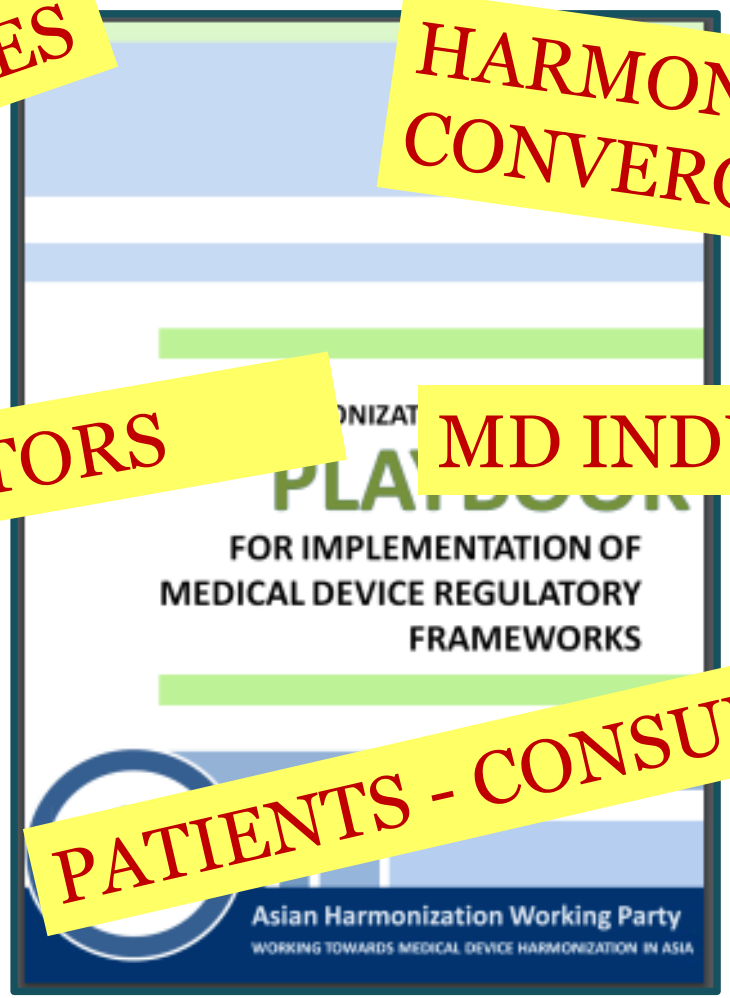
- **Predictable & harmonised regulatory environment across Asia**
- **Unified standards for product registration, establishment licencing, distribution and post-market**

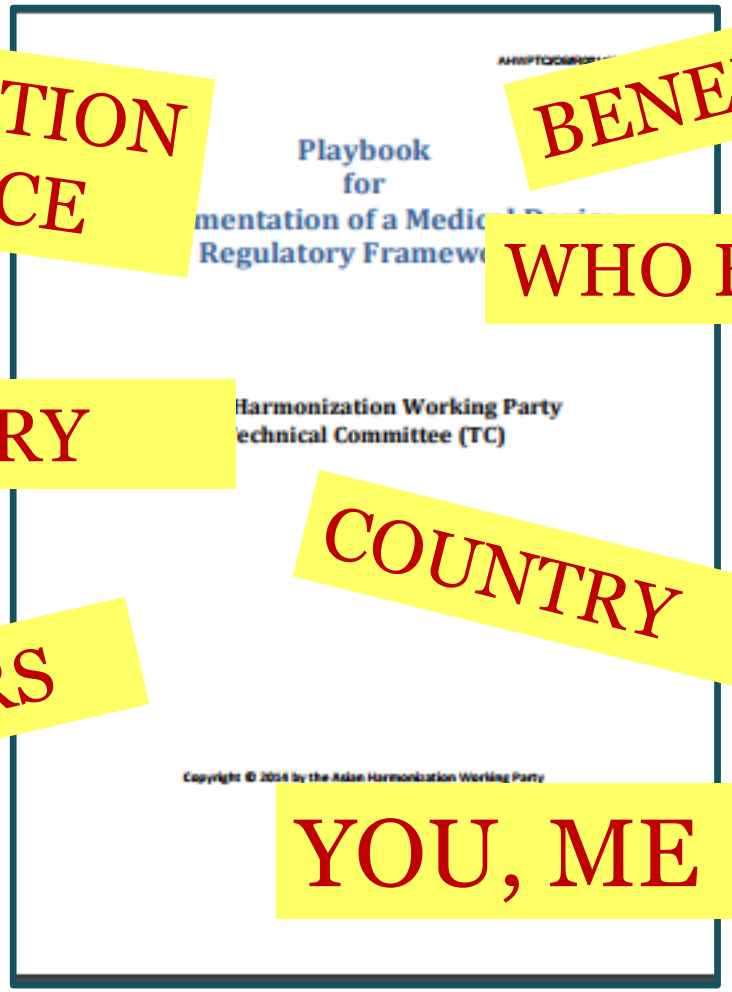
AHWP PLAYBOOK

OBJECTIVES

HARMONISATION
CONVERGENCE

BENEFITS





WHO BENEFITS ?

REGULATORS

MD INDUSTRY

COUNTRY

PATIENTS - CONSUMERS

YOU, ME !

Revisiting the Objectives of the AHWP Playbook

Objective

- Develop a set of guidelines for MEs for a harmonised medical device (MD) regulatory framework & implementation steps
- 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 frame work elements i.e **achieving HARMONISED Platforms.**

❖Initial Phase of the PB Training Program:

Target: Cover areas in –

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

The Journey Began in Thailand 2015.....

TRAININGS IN 3 AHWP ANNUAL MEETINGS & 4 MEMBER COUNTRIES

1st In-Country Capacity Training

- Local Host: Indonesia MOH
- Venue: Bandung, Indonesia
- Date: 18-29 July 2016
- Participants: Indonesia Regulators, ~50 attendees

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:** Backgr ound 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 Lear ned)

& in AHWP Annual meeting 2017 (India).....

Recap
PB Incountry Training Program 2016

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) / Wh
  at is reviewed (Regulator)
- Product Liability

OTHERS:

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

AHWP
ASIAN HARMONIZATION WORKING PARTY

PB Training Program 2017 – Malaysia
Focus on Software & Information Technology

PLENARY SESSION – New & developing technologies – What are the Regulatory pathways considerations?

SOFTWARE & INFORMATION TECHNOLOGY –

- Role & Impact on Medical devices
- Can it be fully regulated?
- Current Regulatory Aspects for
- (i) Medical Device Software and Software Validation
- (ii) Digital Health: Regulations applied to mobile health app, wearable devices,
- (iii) telehealth and telemedicine

SECURING THE IT ENVIRONMENT

- Cybersecurity
- Post Market Considerations and case studies

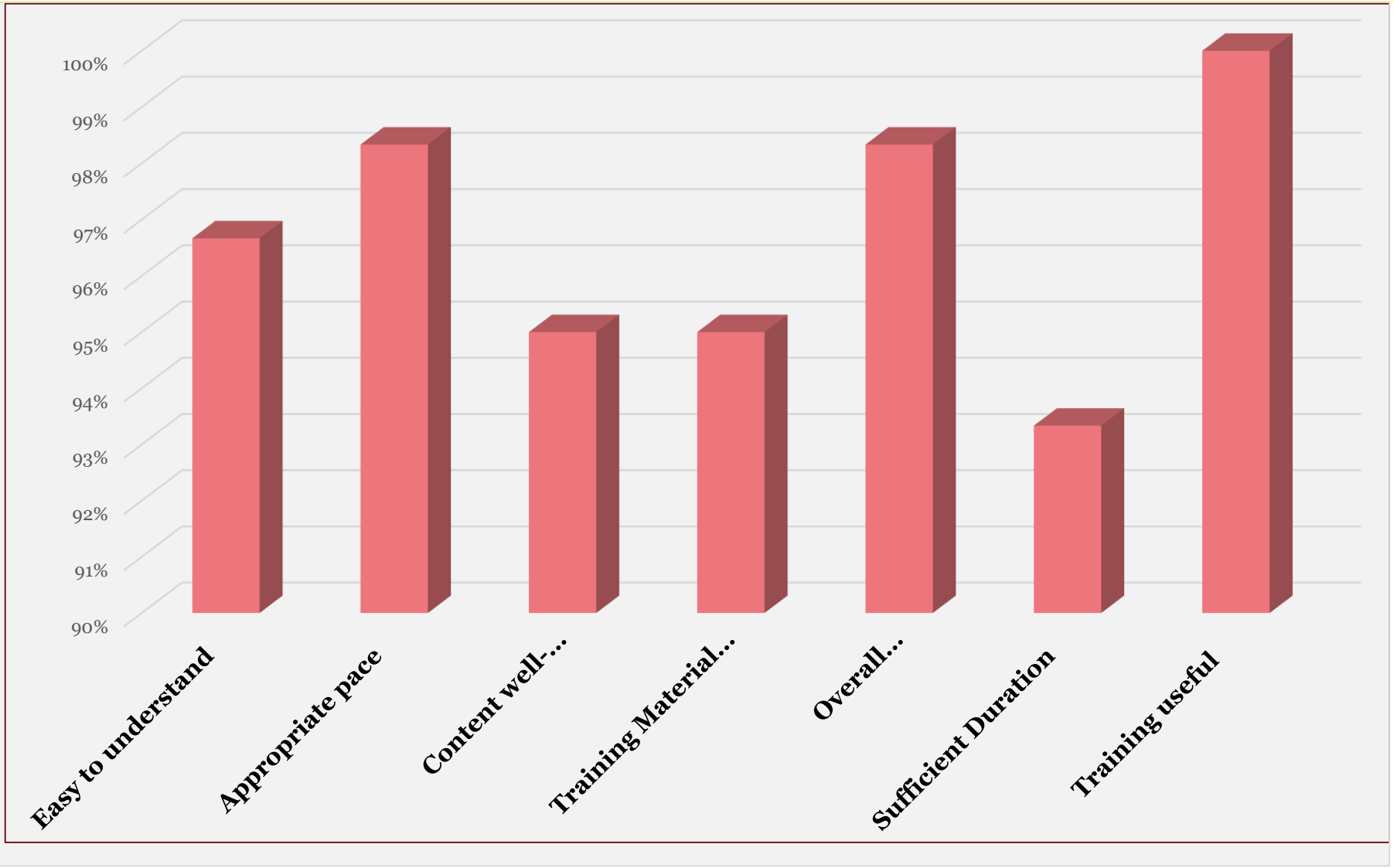
Incountry Training workshop - Republic of Kazakhstan

Workshop topics in Kazakhstan Oct 2017

- Introduction to Global MD Regulatory Framework
- Definition of a Medical Device – Harmonised Definition
- Risk Classification
- Grouping
- Essential Principle of Safety and Performance
- CSDT – Dossier format Filing
- QMS Audit of manufacturing sites
- Good Distribution Practice for medical devices
- Regulatory scope for Class A Low risk medical devices
- Q&A Session


Feedback

Overall RESPONSE to Incountry Training 2016/17 : Regulatory Control, Essential Principles, CSDT



Learning Points

Gathered through observations and feedback.

While a set of regulations can always be read,

- The ‘ Why’ of regulatory Principles and Objectives need to be better frequently addressed
- Clarity in what are the requirements is essential. Even in similar controls, different nuances in interpretations of regulatory clauses often cause confusion.
- Trainers should have a good knowledge of the concepts of regulations
- Good understanding of Risk Management is inherent – as ultimately justification for a risk based decision is essential

Quote: “Don’t build roadblocks out of assumptions.”
– Lorii Myers,

Special thanks

- PB leaders and trainers
  - Mr Ali Dalaan – TC Chair
  - Dr. Jeong-Rim Lee – TC Co-chair
  - Ms Tran Quan – Capacity Building Program Lead
  - Ms Kitty Mao – Secretary
  - Mr Alfred Kuek - Team Member
  - Ms Tan Ming Hao – Team Member
  - Mrs Joanna Koh – Lead Trainer

& The Journey Continues