the
AHWP Playbook
An Overview
www.ahwp.info
Asian Harmonization Working Party (AHWP) was established as a non-profit organization in 1996.

A group of experts comprising Medical Device Regulatory Authorities (“Regulatory Authorities”[RA]) and medical device industry & government agencies other than Medical Device Regulatory Authorities (“Industry”).

- 30 member economies as of March, 2017
- 4 new countries joined AHWP as member economies
Implementing Regulations – Concept of the AHWP ‘Playbook’

Possible ‘companion’ handbook to the WHO Model Regulatory Framework

A guidance on phased implementation

It gives a structure to for a cohesive, harmonized regulatory framework – i.e. ‘building blocks’:

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

Downloadable at www.ahwp.info
Elements of the Playbook

Recognition of Standards

Reasons for each building block to be provided in each chapter (e.g. licence, product registration)

- Registry / Database
- Manpower considerations
- Phased implementation considerations
- Legislation & policy framework considerations
- Basic regulatory controls

Introduction & Rationale for Harmonization
Implementation steps
for the Framework of Medical Device Controls

Regulatory model outlined in the AHWP Playbook is built on the foundation of the GHTF guidance documents and works towards the harmonisation of requirements.

Advanced Regulatory Controls
- Classification & conformity assessment of MDs
- Oversight of QMS audits of dealers
- Clinical investigation & clinical performance study controls

Basic Regulatory Controls
- Quality management systems (QMS)
- Post-market surveillance and vigilance
- Definitions & qualification of ‘medical device’ (MD)
- Registration / licensing of MDs & dealers

Implementing a Regulatory Framework
AHWP Playbook Elements
Providing the Tools for Planning a Framework

Chapters 3 & 6

Chapter 3 & 6

Phased Implementation – Voluntary Phase

Phased Implementation
Planning

Manpower & Resource Determination

Development of Legislation & Policy

Training of Stakeholders & Staff

Phased Implementation of Mandatory Controls

Full Implementation

Continued enhancement

Chapters 2 & 4

Chapter 5

Chapters 3 & 5

Chapters 3, 6 & 7

Chapter 4
Upcoming 22nd AHWP Annual Meeting in Delhi, India

Dec 4th-8th, 2017

All are cordially invited to 22nd AHWP annual meeting!

Thank you