



Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP Playbook - Implementation of a Medical Device Regulatory Framework

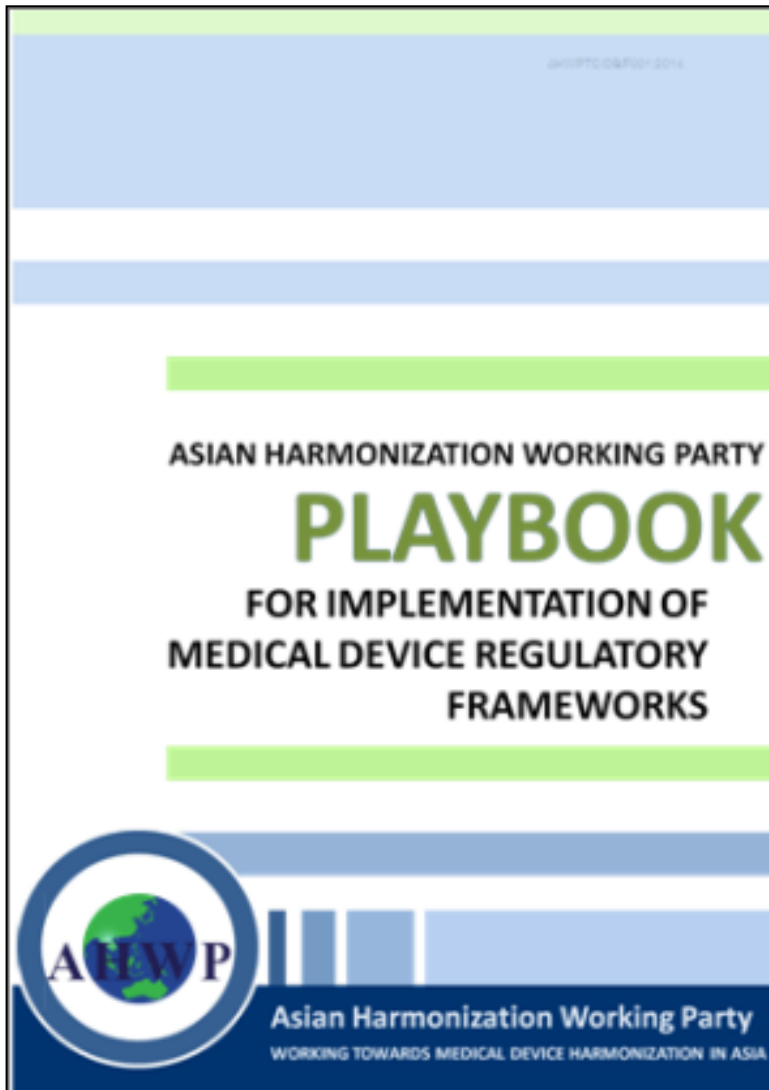
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ADS
CONSULTING



BUILDING BRILLIANCE TOGETHER



**What have to be considered
when setting up regulations?**

**A guide to countries with no
framework or existing framework
(2014)**

What is the content of the GHWP Playbook?

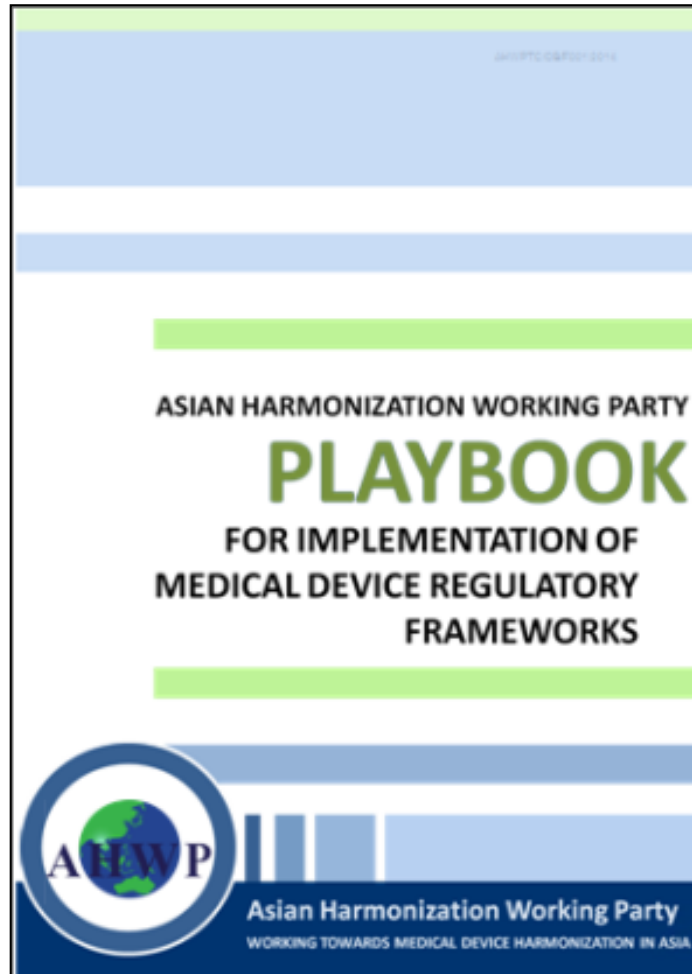


Chapter 1	Chapter 2	Chapter 3	Chapter 4
<ul style="list-style-type: none">• Objective	<ul style="list-style-type: none">• Regulatory Controls basic and advanced	<ul style="list-style-type: none">• Legislation and Policy Framework	<ul style="list-style-type: none">• Phased Implementation
Chapter 5	Chapter 6	Chapter 7	Conclusion
<ul style="list-style-type: none">• Manpower	<ul style="list-style-type: none">• Database	<ul style="list-style-type: none">• Essential Principles of Safety and Performance and Recognition of Standards	

Chapter 1- Objective

The playbook intends to provide **considerations and guidance** for member economies looking to develop their country's medical device regulation framework. This playbook also aims

- to guide member economies in leveraging existing country resources
- to improve their regulatory framework and
- strategically work towards internationally harmonized regulatory approach.



Guide to

Identify best practices and adapt them

Identify key considerations and potential limitations

Ensure resources and priorities are aligned to elements of the regulatory framework

Accelerate implementation of the regulatory framework, quickly and effectively

Most effectively use limited regulatory resources

Provide a policy framework in support of domestic and international trade

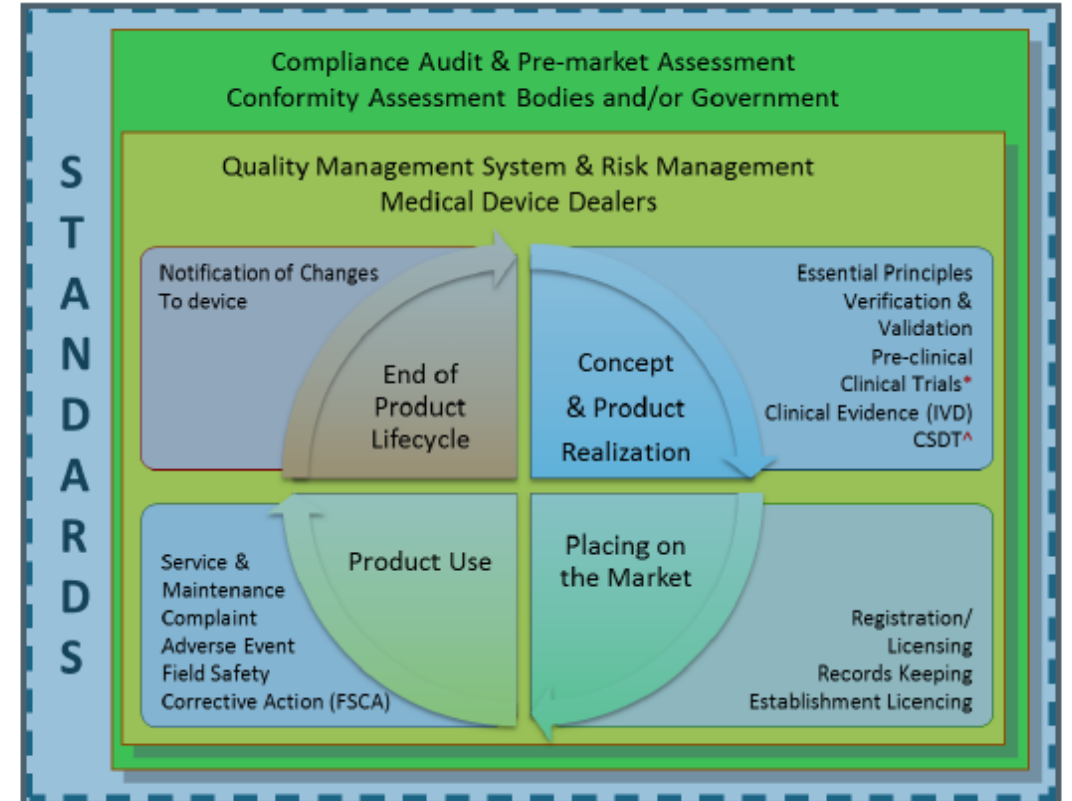
Chapter 2- Regulatory Controls

GHWP playbook recommends that regulatory authorities consider a framework that provides **comprehensive oversight of the medical device (including IVD medical device) lifecycle activities.**

While the full model might be implemented over time there are a few key elements (**Basic Regulatory Controls**) that member economies might want to start with:

- registration or licensing
- pre-market controls -definitions and qualification of 'medical device'
- QMS and risk management process
- post-market vigilance and surveillance.

More advanced controls may be considered later in the implementation process, such as the classification and conformity assessment of medical devices.



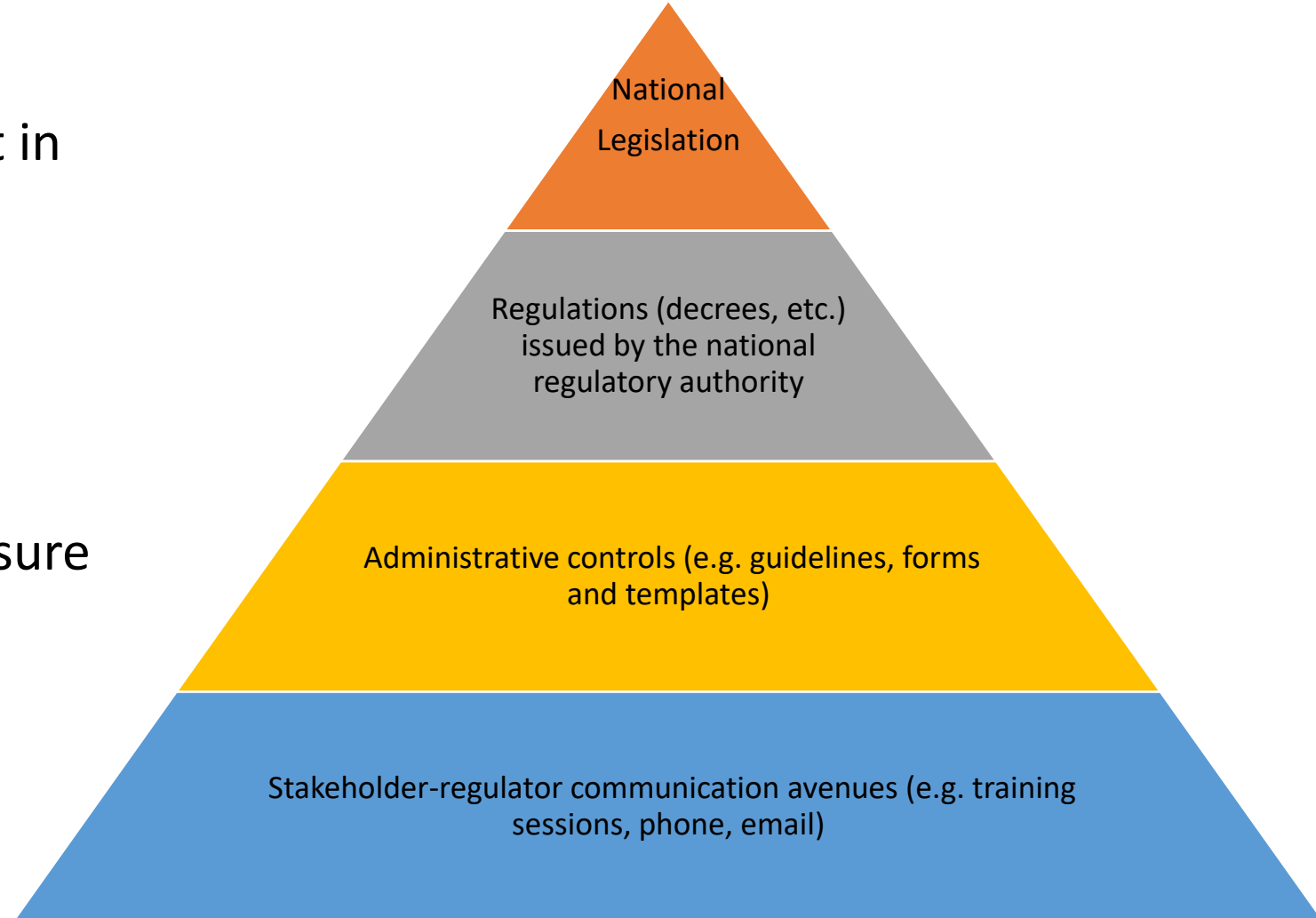
* Medical device only

^Common Submission Dossier Template – developed by the AHWP for pre-market submissions [1, 2]

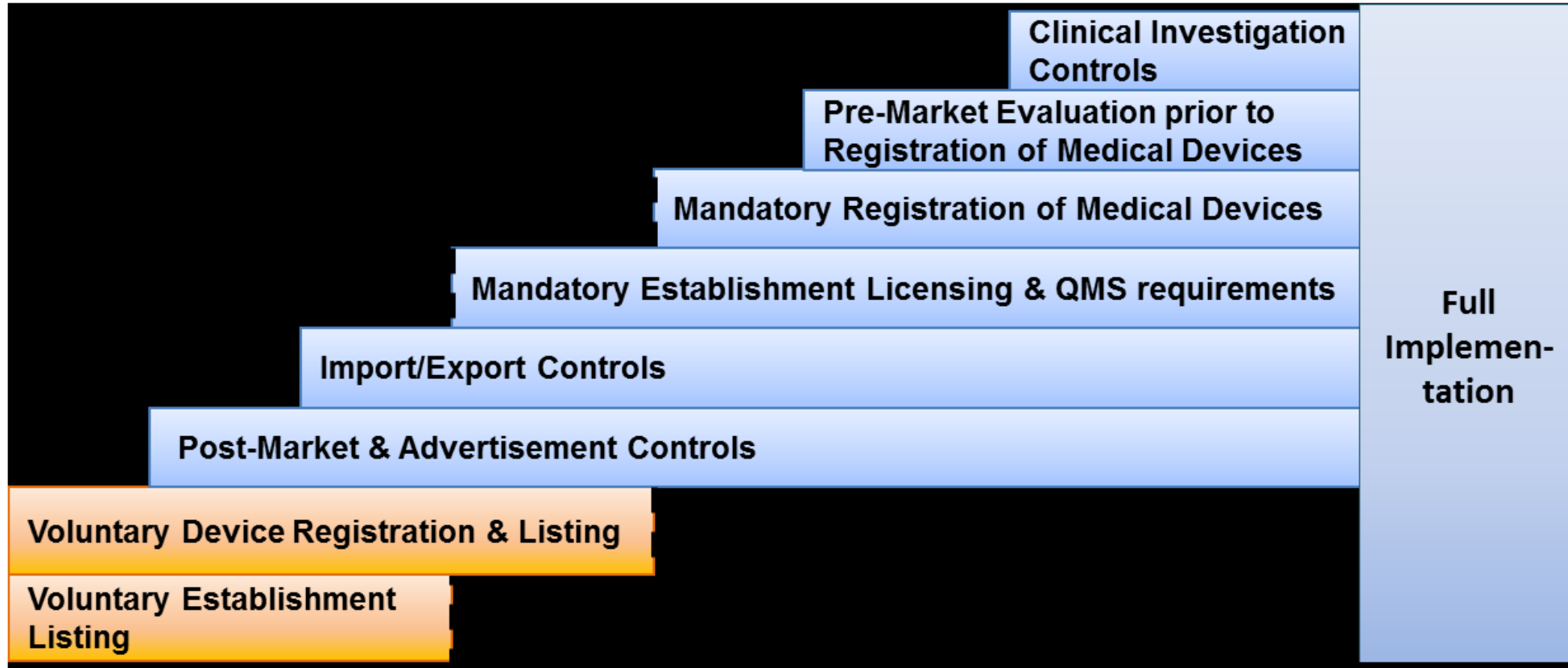
Chapter 3- Legislation and Policy Framework

Member economies will need to put in place legislation and policies that address the various activities in the medical device lifecycle.

A general hierarchy of regulatory controls should be considered to ensure effective implementation.



Chapter 4- Phased Implementation of the regulatory framework



Chapter 5- Manpower

Successful implementation of a regulatory system depends on human capacity and administrative systems.

Headcount as well as expertise, motivation of the staff hired are important and need to be considered for overall operational effectiveness of the regulatory body.

Identify regulatory authority (or CAB) activities and allocate manpower



Chapter 5- Manpower Allocation

Example

Mechanism	RA Activity	Manpower
Stakeholder Communication & Relations	Communication with stakeholders on regulatory controls, provide advice & obtain feedback	Admin Manager and Staff
Product Qualification & Classification	Advise on qualification & classification of specific products	Technical specialists
Import/Export Monitoring & Control	Liaising with Customs officials, Compliance checks of imports	Customs officer
Standards, Recognition	Review of standards & maintain recognized standards list	Technical specialists
QMS Audit	Assess and qualify QMS	Auditors
Licensing/Registration	Review of device applications	Technical specialists, Team Leads
Product Registration	Screening and/or conformity assessment	Experts
PMS	Review of AE or FSCA reports	Review officers, Team Leads
Clinical	Assessment of Clinical Evidence	Technical specialists
Finance	Billing, collection & refund of fees	Accountants
IT Support	Update and maintain IT infrastructure	SW & IT engineers

Chapter 6- Database

- Listing and registration systems to capture information on the devices imported or manufactured
- Information on device dealers within the member economy
- PMS and Vigilance information such as locally-implemented medical device recalls and other field safety corrective actions



Chapter 7- Essential Principles of Safety and Performance and Recognition of Standards

1. Adoption of the essential principles of safety and performance as developed by the GHTF/IMDRF
2. Use of international standards.
3. Establish a mechanism for recognizing international standards to provide manufacturers with a method of demonstrating conformity with the Essential Principles









Conclusion



1. The playbook is a **‘stepping stone’** for implementation of regulations, **use existing guidelines** for more details in setting up regulations
2. Ensure an appropriate balance between pre-market and post-market elements
3. Consider the implementation of more advanced pre-market controls only when you have a base of registration medical device and sufficient resources
4. **Simplify / standardize the regulatory framework premarket submissions or approval to market**
5. As regulatory frameworks globally continue to evolve, maintain balance in monitoring devices for safety, quality and performance against the need to facilitate market access for new medical technologies

Implementation of a new regulatory framework or reform regulations takes time!



-  EU – MDR/ IVDR
•8-10 years
-  Singapore – AMDD
•10 years
-  Indonesia – AMDD
•5 years
-  Australia – new reform
•5 years
-  Malaysia– AMDD
•6 years
-  Vietnam – AMDD
•7 – 10 years

Opportunities to Accelerate



Practice and develop regulatory agility concepts

- Fit-for-purpose regulatory framework that is **risk-calibrated** according to public health hazards
- Leverage **regulatory reliance** and **convergence models**

GHWP can support member economies in implementing new or updating regulations



- Provide a Network platform and connect Member economies
- Sharing best practices of implementation of a regulatory framework
- Provide harmonized guidances
- Provide training of established regulatory controls
- Provide best practise on regulatory reliance and convergence models to accelerate the journey
- Support the development process of regulatory controls



1. Establishment and implementation of a new regulatory framework **takes time** (up to 10 years) to ensure a reasonable transition timeline
2. Implement **regulation in phases** based on local landscape and capacity
3. Practice and develop **regulatory agility concepts – risk based**
4. Explore the different models **regulatory reliance and convergence** models to accelerate the journey
5. **Accept approvals and clinical data** from other countries
6. Using **grouping concepts** saves time for evaluator and submitter
7. **Public private partnership** is key to ensure success



Reference

GHWP Playbook 2014