Pre-Market Harmonization:

Developing a common pre-market submission dossier for the Asian markets

Wong Yew Sin
Director, Centre for Medical Device Regulation
Health Sciences Authority
SINGAPORE

2nd AHWP Technical Committee Meeting, Bangkok, 12 Dec 2002

Common harmonized approaches to:

- *Quality System and Audit*
- *Pre-market Submission Requirements and STED (Summary technical documentation for demonstrating conformity to essential principles of safety and performance of medical devices).*

- *Consensus at 9th AHWP Meeting in May 2002, Singapore, in regional collaboration*

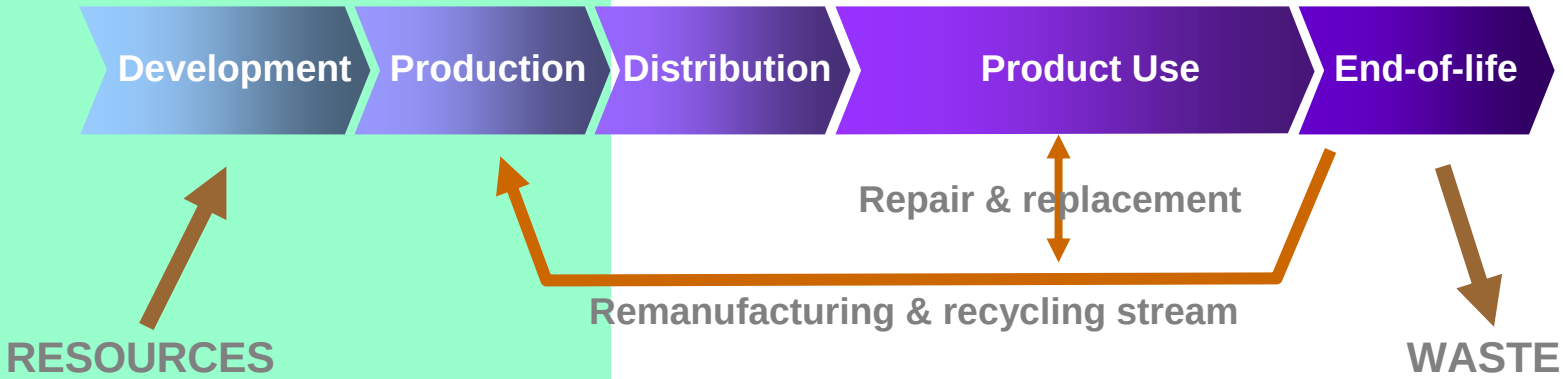
Manufacturer's obligations:

- Ensuring that the medical device meets the essential principles and the conformity assessment procedures
- Keeping objective evidence to establish that the medical device meets these requirements

Regulatory programs are driven by:

- Providing an assurance of device quality, safety and efficacy
- Ensuring that the public has timely access to beneficial medical devices

The life cycle of a manufactured product



Pre-market harmonization

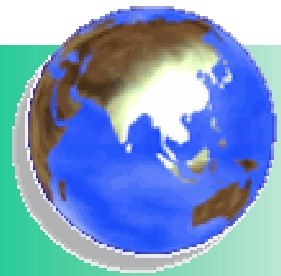
The coordination of procedures for review, approval or registration of device products before they reach the market

A dossier

- a collection of information

- a tool for communication of information

Presentation and content of submission



The degree of formality in the regulatory systems

A "Common" submission dossier for marketing authorization

Objective:

To work out an acceptable format suitable for the preparation of a well structured presentations for submission to the Regulatory Authorities in the Asian region.

Desired Outcome:

To save time and resources and to facilitate regulatory review and communication.

Path to Market

Goal

- *To get the right information to support submissions - not more, not less*

Data

- *What is needed and appropriate to product*

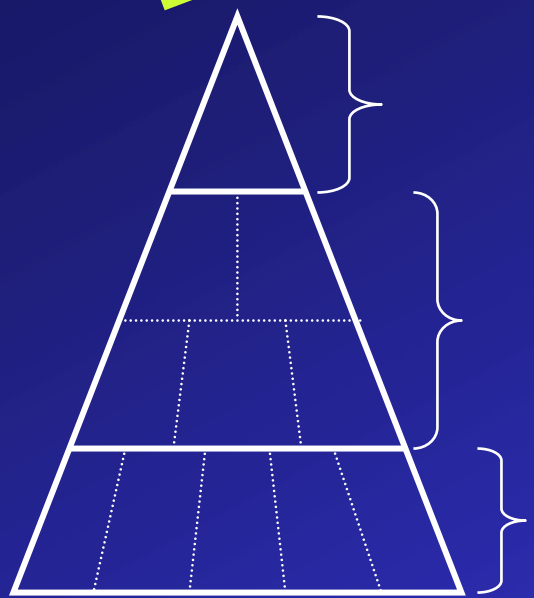
Process

- *Interactive and transparent*

Common submission dossier for marketing authorization

Strategy

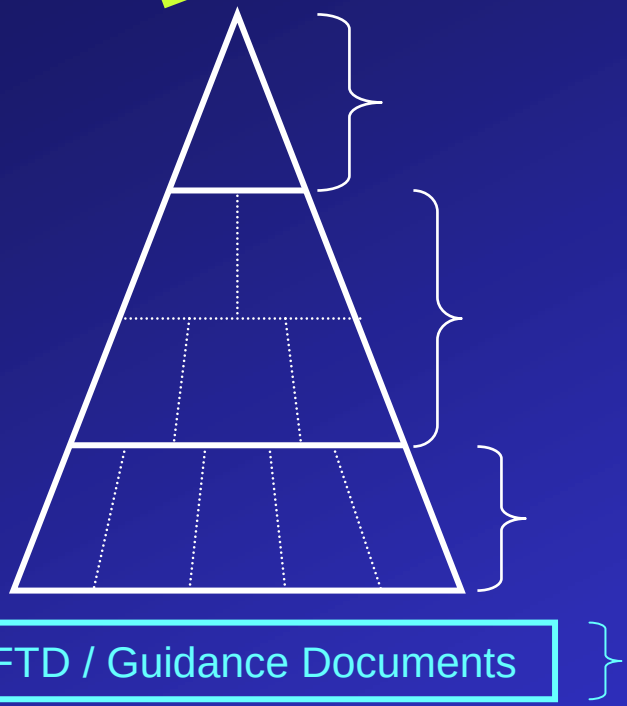
- *To define common requirements*
- *To harmonize the composition and organisation*
- *To look into structure first rather than content*



Full Technical Documentation / Guidance Documents

Sources for generating summary data for Content / Content uniformity

Common submission dossier for marketing authorization



Advantages

- ✓ *The documents in the dossier are in logical order*
- ✓ *There are sub-headings and details of the required content*
- ✓ *The order (and numbering) is specific*
- ✓ *There is clarity in requirements for the presentation of data*

Common submission dossier for marketing authorization

The Results ….

The harmonization project will bring about

- Efficiencies in processes and systems
- Timely delivery of new & innovative products
- Improved quality of life

Wish List ….
(of a Regulator)

- Exchange of information between regulatory authorities
- Parallel and joint assessments
- Dialogues and exchanges, based on the same information and references

Disadvantages

Anticipated Issues

Phases of Harmonization Project

Proposed document

- Building consensus in Regulatory & Industry working groups
- Release of proposed consensus text for wider consultation

Working draft

- Regulatory consultation & pilot trials in the region

Final document

- Adoption by Regulators
- Implementation

Common submission dossier for marketing authorization