# Adoption and Implementation of the GHTF Global Regulatory Model in Asia

***Asian Harmonization Working Party***

*11th AHWP Meeting, Pre-Meeting Workshop*

*Seoul; 13-14 September 2006*

*M. Gropp; Abbott Vascular, Brussels*



## Caveats

- Personal views
- Difficult to make general statements due to diversity across region – nonetheless general principles apply
- Presume general familiarity with work of Global Harmonization Task Force (GHTF)

Building a Prosperous Asia-Pacific through Free and Open Trade and Investment

***Source:*** *About APEC*, APEC Secretariat, 2004





Promoting the Safe and Efficient Movement of Goods, Services and People through the Asia-Pacific Region

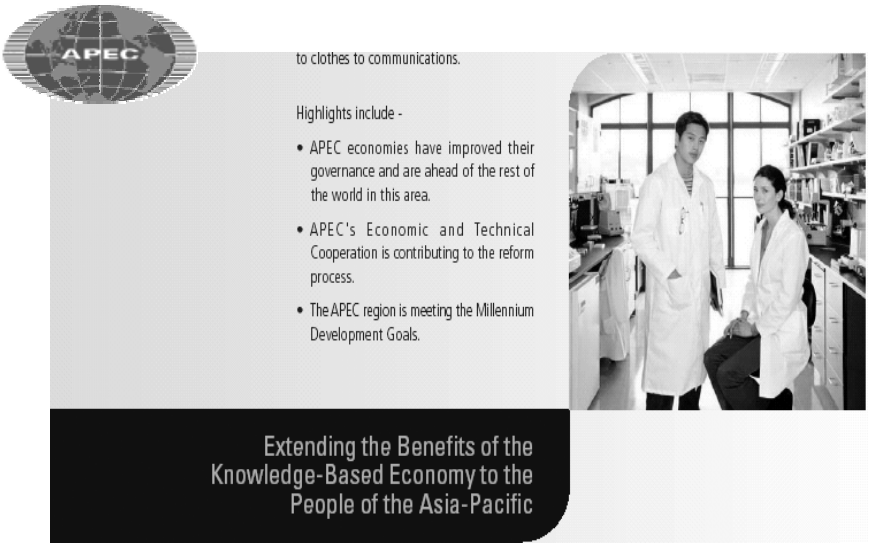
***Source:*** *APEC At a Glance*, APEC Secretariat, 2006

## European Union -- Treaty of Rome

"… an internal market characterised by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital; …"








***Source:*** *APEC At a Glance*, APEC Secretariat, 2006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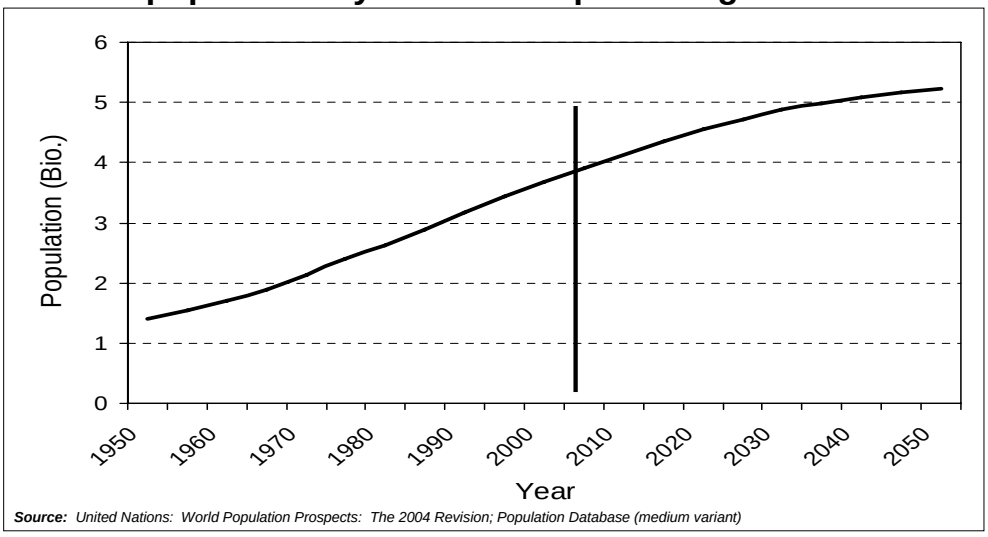
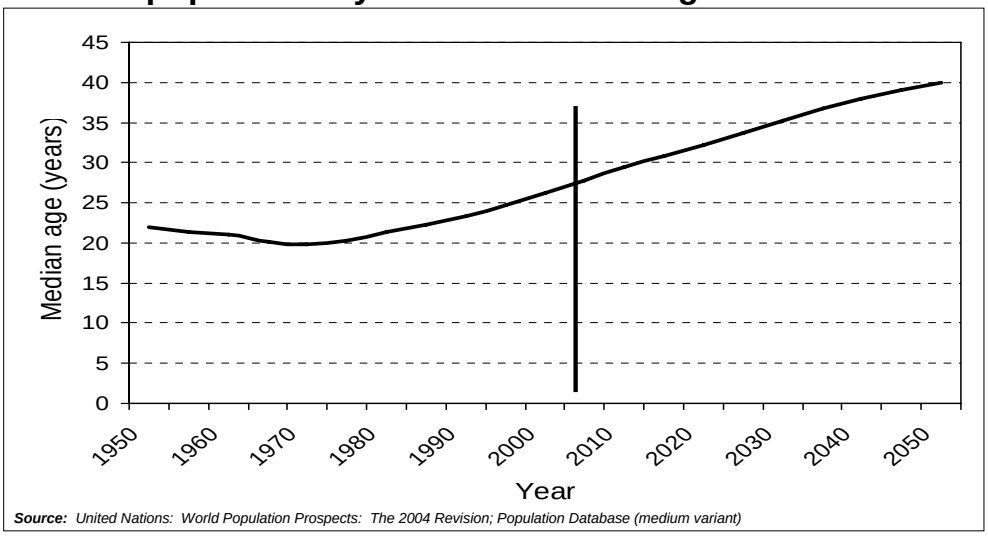
## Asia population dynamics – Population growth




***Source:*** *United Nations: World Population Prospects: The 2004 Revision; Population Database (medium variant)*

## Asia population dynamics – Median age

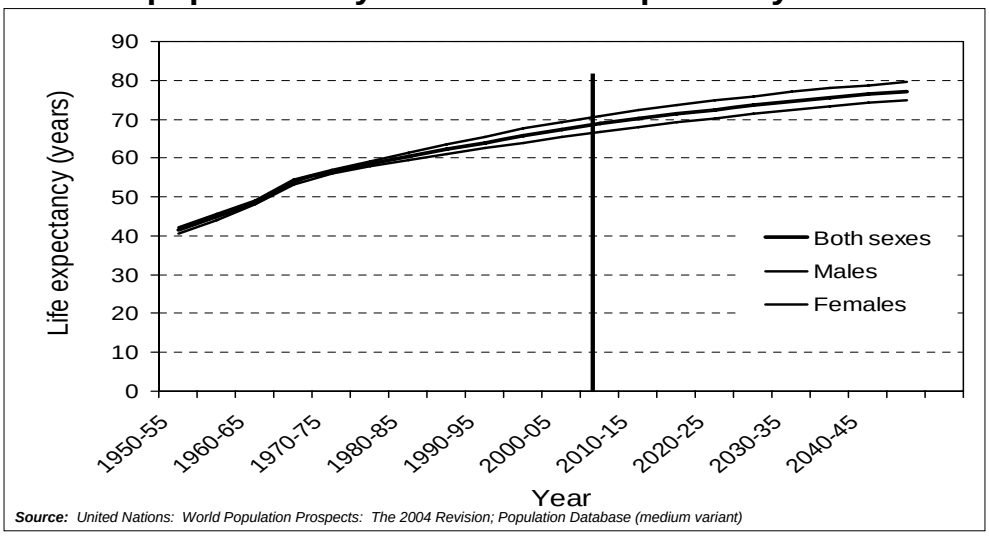



***Source:*** *United Nations: World Population Prospects: The 2004 Revision; Population Database (medium variant)*



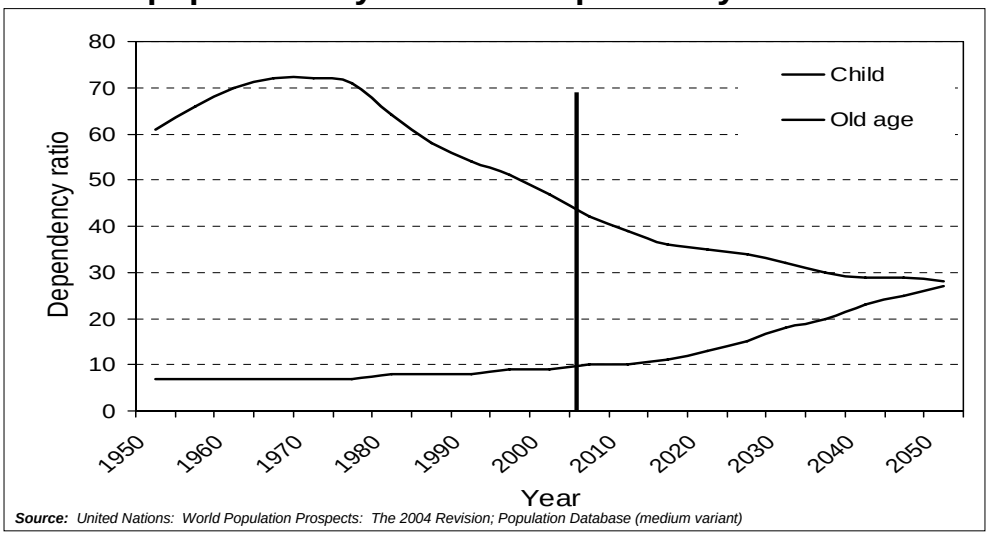


## Asia population dynamics – Life expectancy at birth




***Source:*** *United Nations: World Population Prospects: The 2004 Revision; Population Database (medium variant)*

## Asia population dynamics – Dependency ratios*



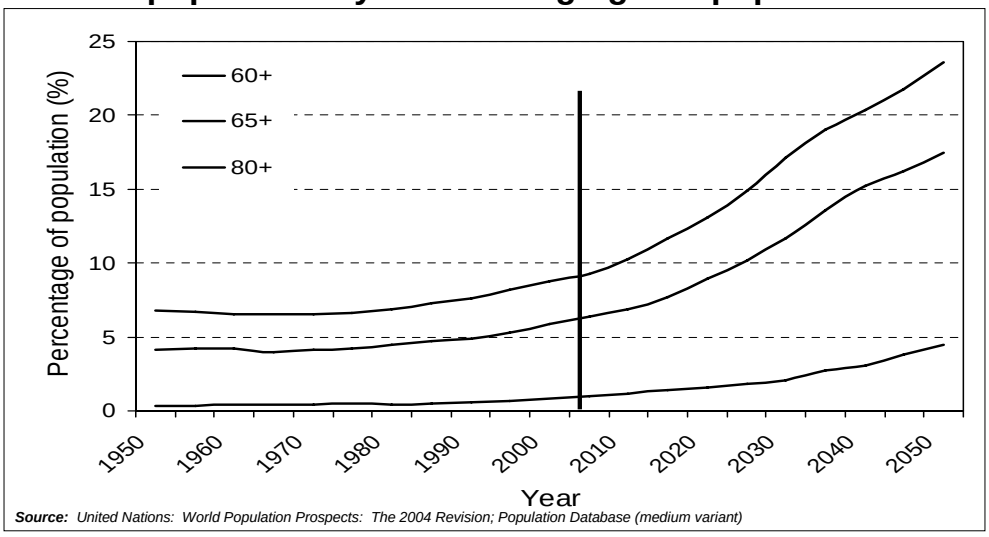

***Source:*** *United Nations: World Population Prospects: The 2004 Revision; Population Database (medium variant)*

* Population subset ratio to population aged 15-64; no. of dependents per 100 persons of working age



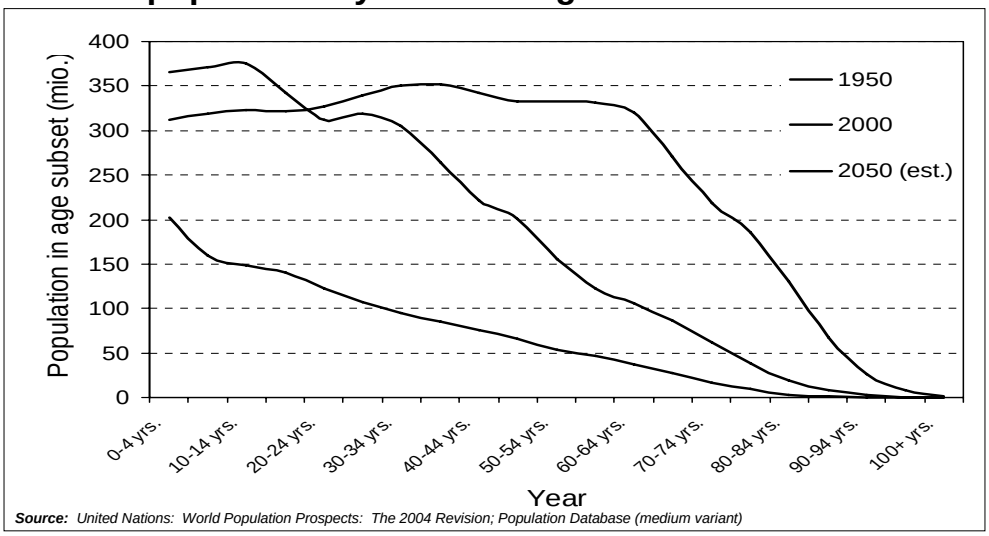


## Asia population dynamics – Aging sub-populations




***Source:*** *United Nations: World Population Prospects: The 2004 Revision; Population Database (medium variant)*

## Asia population dynamics – Age distributions over time




***Source:*** *United Nations: World Population Prospects: The 2004 Revision; Population Database (medium variant)*

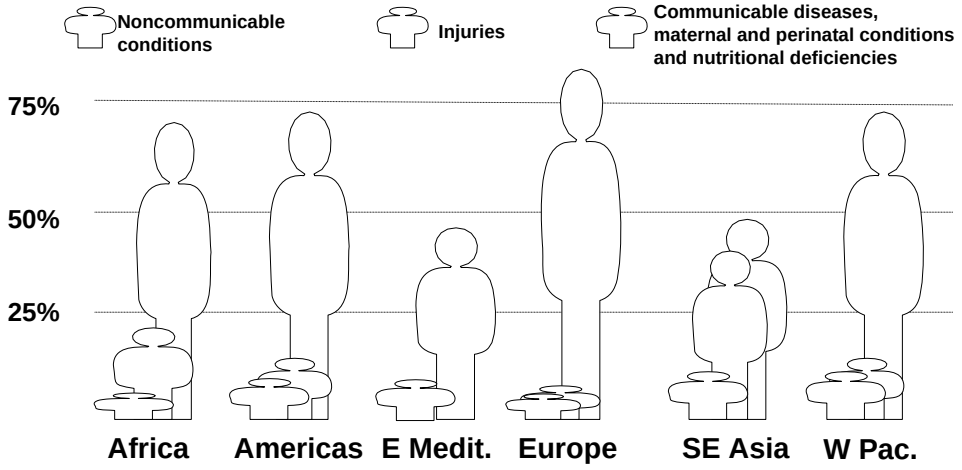




## Asia population dynamics

***Source:*** Financial Times Feb. 6, 2003

## Asia population dynamics – Disease burden

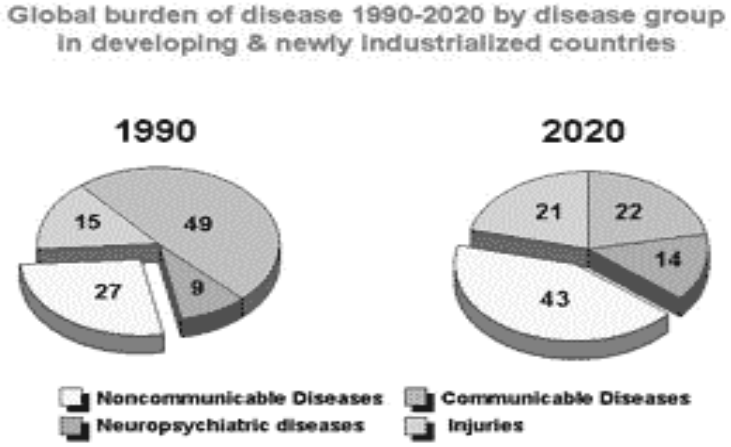



***Source:*** WHO; Courtesy of J. Epping-Jordan: Health Care for Chronic Conditions; 2003





## Asia population dynamics – Disease burden




***Source:*** World Health Organization; *Innovative Care for Chronic Conditions*; 2002

## Background

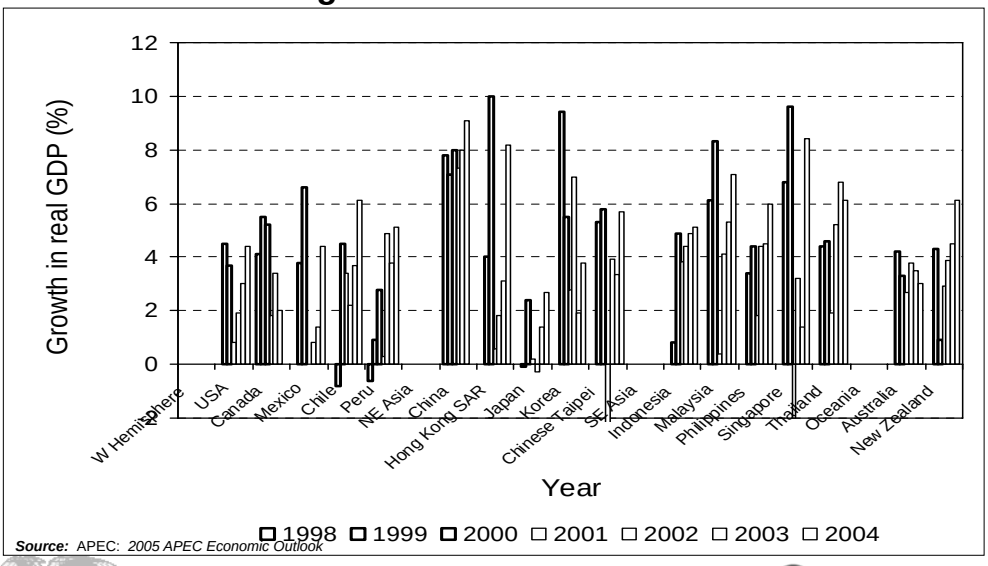
Aging populations and the greater prevalence of chronic conditions create more demand for medical diagnosis and therapy

- How do policymakers and regulators respond?





## Asia economic growth




***Source:*** APEC: *2005 APEC Economic Outlook*

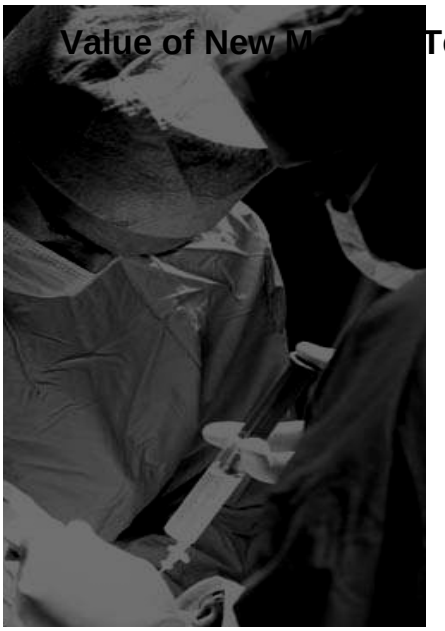
## Background

With growing prosperity come rising public expectations for improved health, reduced disability, and access to advanced diagnostic and therapeutic technologies and procedures

- How do policymakers and regulators respond?







## Value of New M Technology

**Reducing invasiveness**
- Enhanced diagnostic capabilities
- Lower complication rates
- Faster patient recovery
- Improved cost effectiveness

**Increasing effectiveness**
- Lower hospitalisation rates
- Fewer repeat procedures
- Improved quality of life

**Saving lives**
- Productive members of society
- Families stay together

**Improving performance**
- Lower cost per therapy-year

**Facilitating ease of use**
- Reduced procedure times

## Background

Growing public awareness of value of medical technology

- How do policymakers and regulators respond?





## Developing a medical device regulatory system

- Medical device regulation policy objectives
  - Protect and enhance public health
  - Promote technological innovation
  - Facilitate international trade

## Developing a medical device regulatory system

Government policies and regulations define the medical technology industry

- Requirements for safety and performance/effectiveness
- Premarket conformity assessment
- Quality management systems
- Post-marketing surveillance and adverse event reporting





## Developing a medical device regulatory system

Government policies and regulations also determine ***access*** by clinicians, patients, users, and health care systems to the benefits of safe and innovative medical technology

## Developing a medical device regulatory system

- Recognise that the characteristics and intended mode of action of medical devices differ from those of medicinal products
  - Adapt regulatory systems accordingly
- Base on local public health priorities, legal system, and industry profile
- Consider available resources





## Developing a medical device regulatory system

- Consider local needs for regulation
  - New devices placed on market
  - Remanufactured devices
  - Imported vs. domestic production
  - In-hospital “manufacturing” and reprocessing
  - Promotion and sales practices
  - Clinical investigations

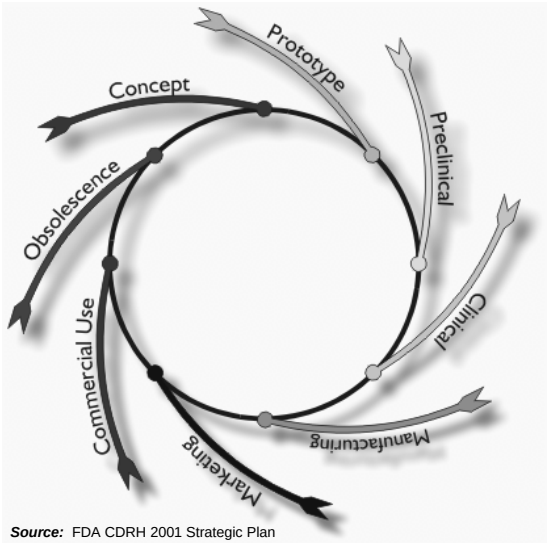
## Developing a medical device regulatory system

- Be realistic
  - Objectives
  - Transition timelines
- Consult with all stakeholders
- Ensure that adequate resources are available in public and private sector to implement proposals
- Make use of experience in other systems
- Consider where in the product life cycle is most effective point for regulatory controls





## Developing a medical device regulatory system




***Source:*** FDA CDRH 2001 Strategic Plan

## Developing a medical device regulatory system

- Start with the basic elements of market control
  - What is being placed on local market?
  - By whom?
  - Origin and history of devices?
  - Local technical support?
  - Traceability and ability to conduct timely and effective advisories and recalls?





## Developing a medical device regulatory system

- Start with the basic elements
  - Definition of “medical device”
    - Adopt GHTF guidance document
  - Adopt globally harmonised medical device nomenclature (GMDN)
  - Adopt harmonised GHTF Essential Principles of safety and performance

## Developing a medical device regulatory system

- Start with the basic elements
  - Recognise international standards
    - Evidence of conformity with Essential Principles
    - Avoid national deviations
    - Avoid creating technical barriers to trade
  - Adopt international medical device quality management systems standard 13485:2003
    - Recognise certificates of conformity issued by reputable international bodies as evidence (in whole or in part) of conformity with local requirements





## Developing a medical device regulatory system

- Start with the basic elements
  - Adopt GHTF medical device classification system
    - Basis for escalating and proportional regulatory controls
  - Develop post-marketing surveillance and vigilance systems
    - Based on GHTF guidance
    - Recognise resource needs

## Developing a medical device regulatory system

- As appropriate, and as resources are available, develop premarket conformity assessment process
  - Based on GHTF harmonised Essential Principles
  - Adopt GHTF Summary Technical Documentation (STED)
    - Or an abbreviated form of STED
  - STED depends on other elements of global regulatory model





## Developing a medical device regulatory system

- As appropriate, and as resources are available, develop premarket conformity assessment process
  - As alternative to local premarket review, consider other forms of evidence of conformity
    - Results of conformity assessments by other recognised authorities
  - Ensure availability of sufficient appropriately qualified staff and advisors to review
  - Consider regional “pooling of competence” or mutual acceptance of results of conformity assessments

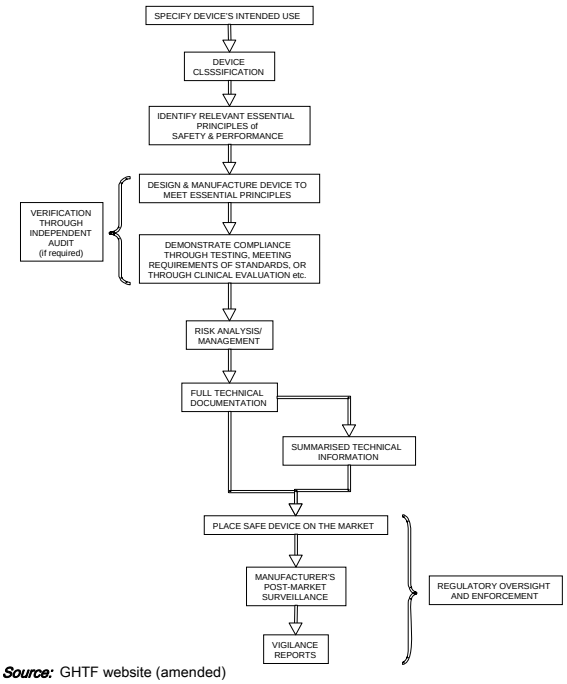
## What is the GHTF global regulatory model?

- Compilation of voluntary guidance documents developed by GHTF
- Represents consensus view of best practices based on experience gained by regulators and industry



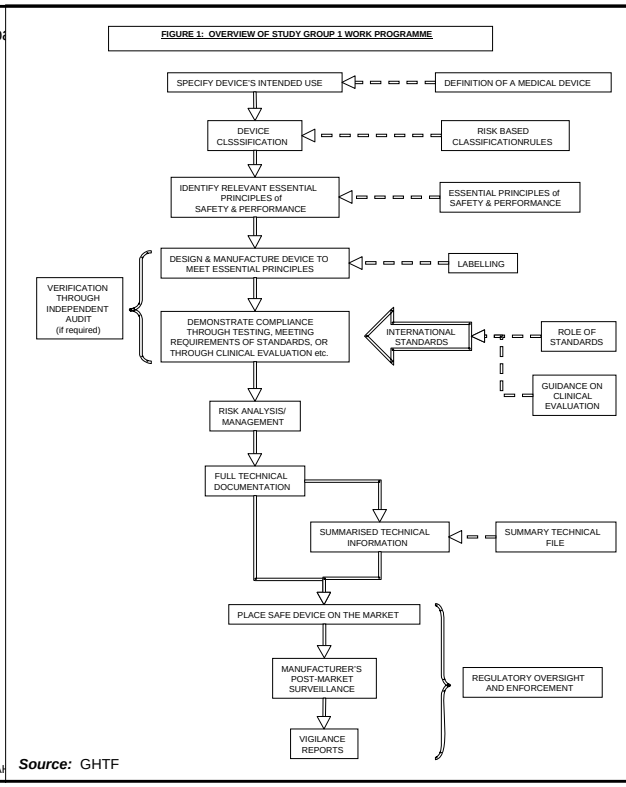


**FIGURE 1: OVERVIEW OF STUDY GROUP 1 WORK PROGRAMME**



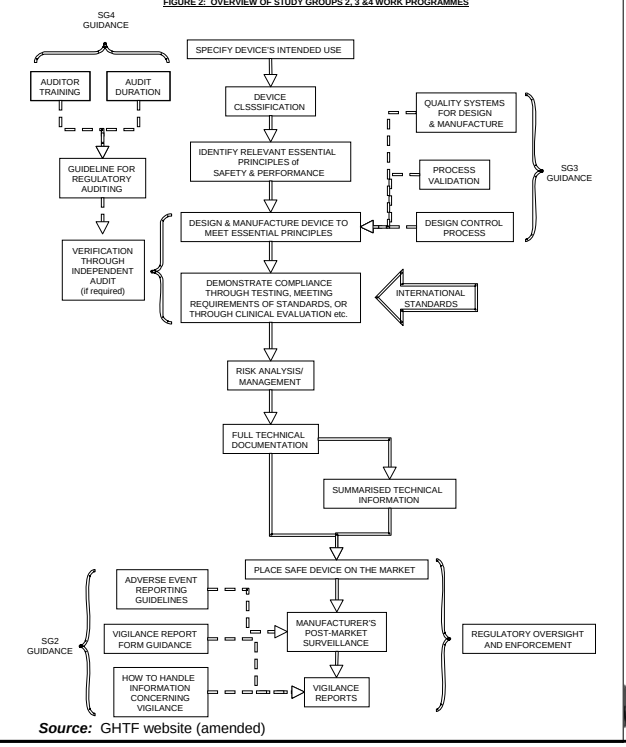

*Source:* GHTF website (amended)

Adoption of GHTF Globa



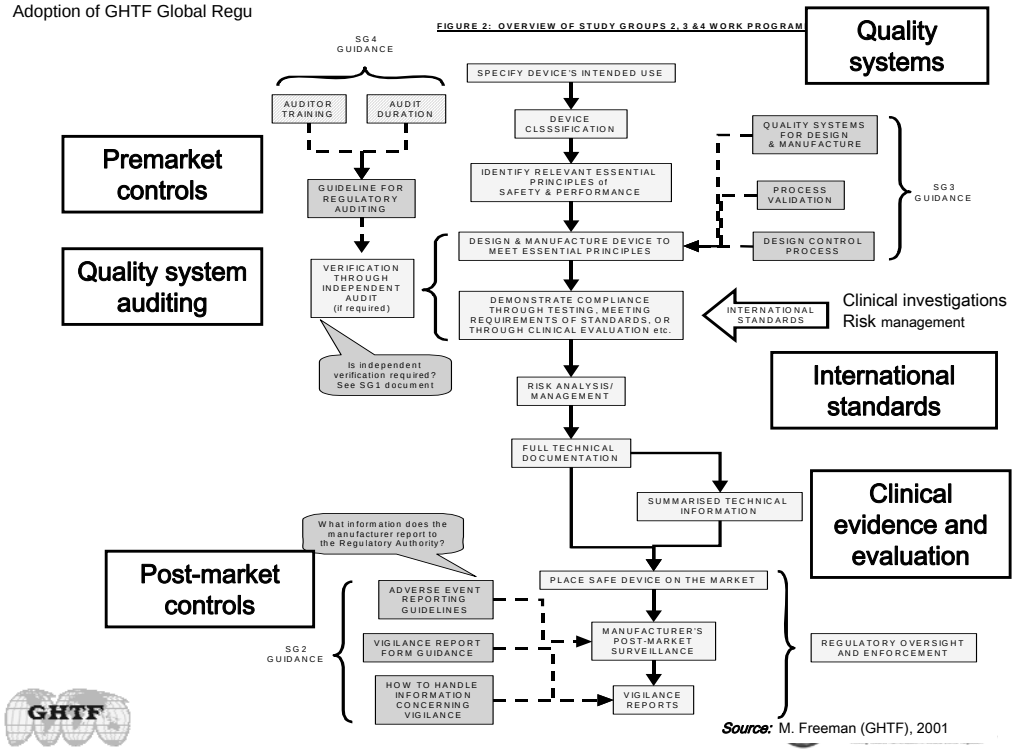

***Source:*** GHTF

Adoption of GHTF Gl




***Source:*** GHTF website (amended)

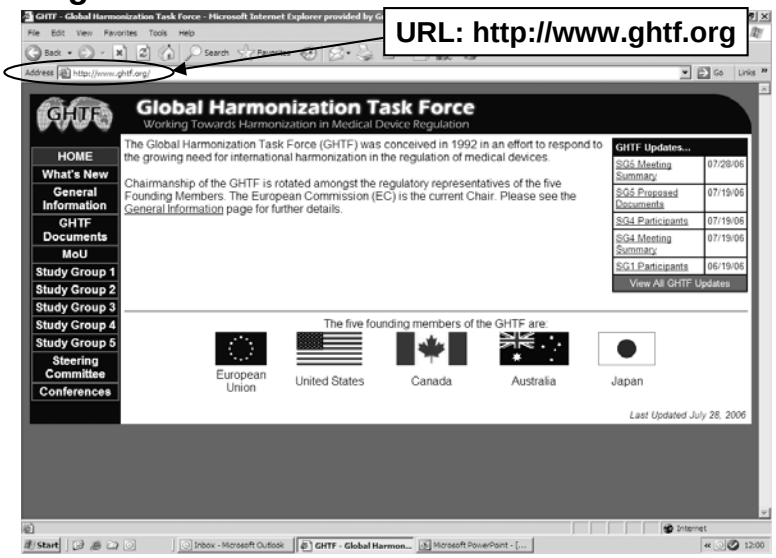
Adoption of GHTF Global Regu




*Source:* M. Freeman (GHTF), 2001

Adoption of GHTF Global Regulatory Model in Asia

## GHTF guidance



## World Health Organization guidance

"Regulatory programmes for medical devices can be developed in stages according to a country's needs as they are stated in the national policy and identified in consultation with all stakeholders …."

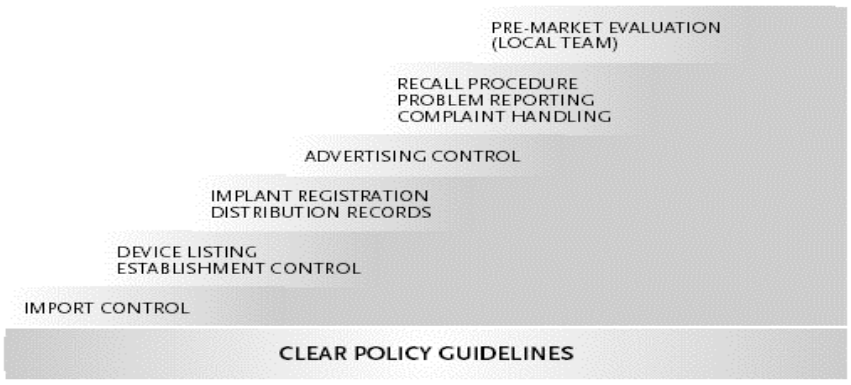
***Source:*** *Medical Device Regulations: Global Overview and Guiding Principles*; World Health Organization, Geneva, 2003





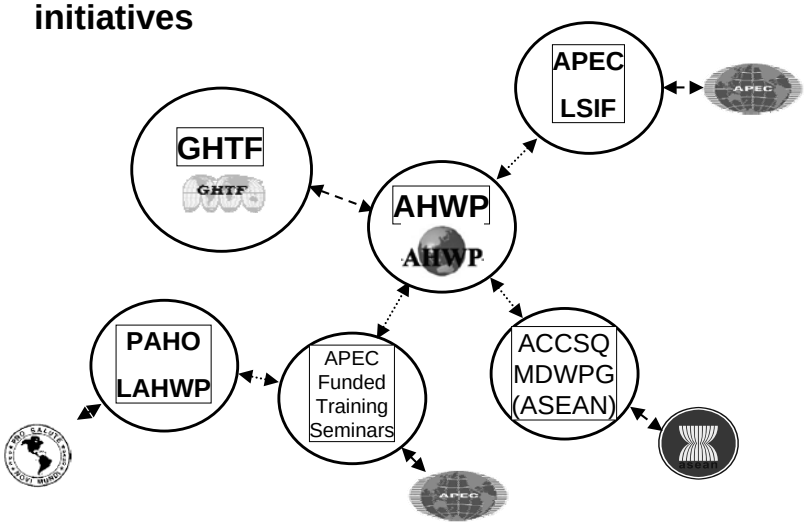
## World Health Organization guidance

*Figure 10. Suggested priorities for regulatory programme development*




***Source:*** *Medical Device Regulations: Global Overview and Guiding Principles*; World Health Organization, Geneva; 2003

## Regional medical device regulatory harmonisation initiatives








## Developing a medical device regulatory system

- Recognise that different paths and speed of implementation and harmonisation may be appropriate
  - Different laws and legal systems
  - Different administrative resources
  - Different public health priorities
  - Different policy objectives
- Promote regional regulatory “convergence”
- Is there an opportunity for greater coordination between different regional regulatory harmonisation initiatives?

## Developing a medical device regulatory system

- Ensure consistent interpretation and application of regulations and guidance documents
- Ensure that administrative decisions are made in reasonable times and transparent appeals process is established
- Avoid regulatory redundancy
- Ensure communication between government departments on requirements, e.g., MoH and customs





## Developing a medical device regulatory system

- Recognise that globally harmonised requirements and systems facilitate both imports and exports
  - Harmonisation supports industrial development policy objectives

## Developing a medical device regulatory system

- Apply international principles of good governance
  - Transparency and openness of decision-making
  - Non-discrimination
  - Proportionality, “least burdensome”, “light touch”
  - Consultation with all stakeholders
  - Periodic review
  - Application of competition principles
  - Avoidance of unnecessary trade restrictiveness
  - Use of internationally harmonized measures
  - Recognition of equivalence of other countries/regions regulatory measures



Adoption of GHTF Global Regulatory Model in Asia

## GHTF Vision

**Enhancing the health of the public worldwide and facilitating innovation by harmonising the global regulatory environment**