Convergence and capability

International health convergence, regulatory convergence, and regulatory capability

M. Gropp

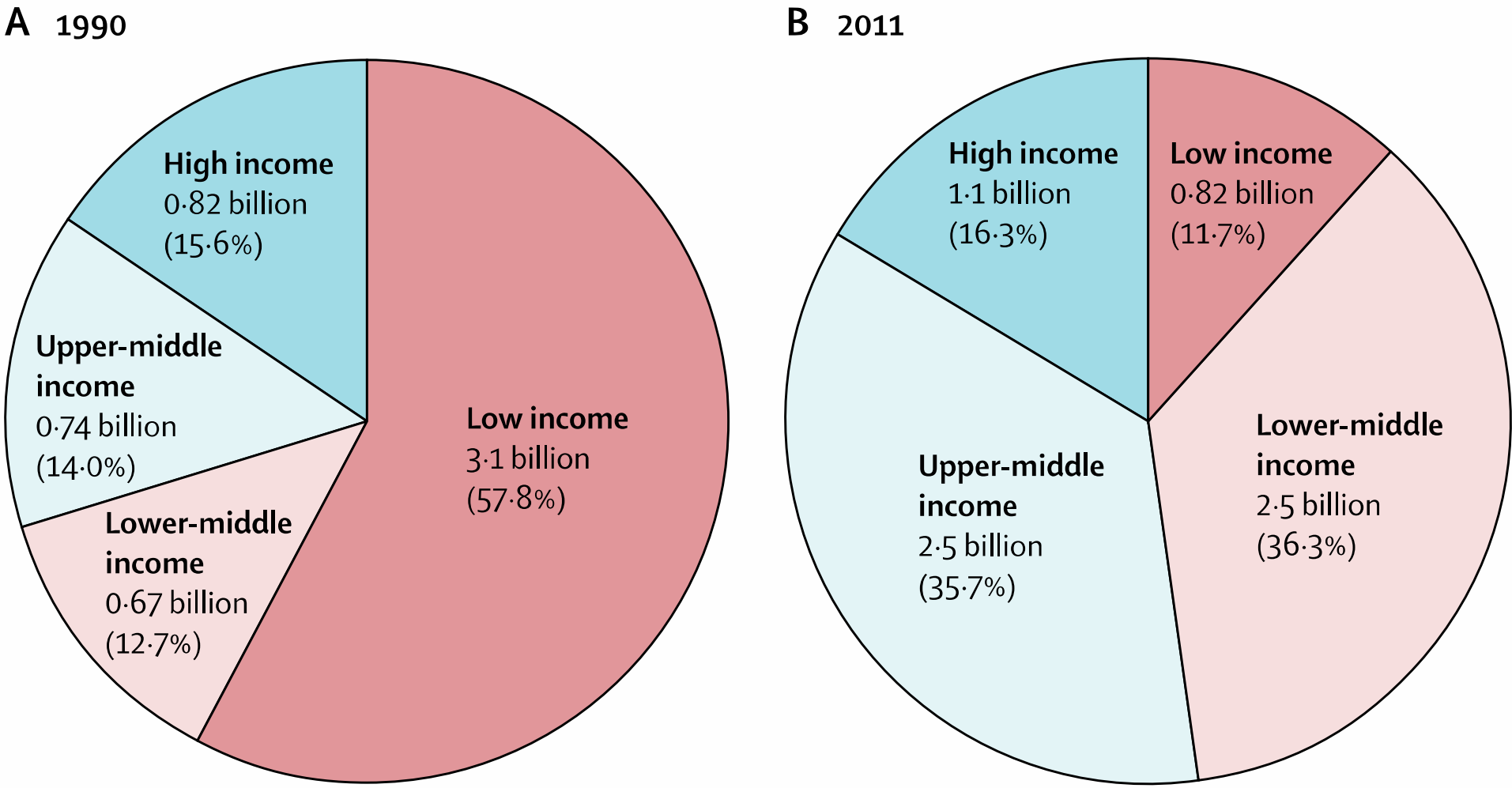
AHC-AHWP Joint Workshop
18th AHWP TC Meeting and19th AHWP Annual Meeting
18-21 November 2014, Seoul

Why regulate medical devices?

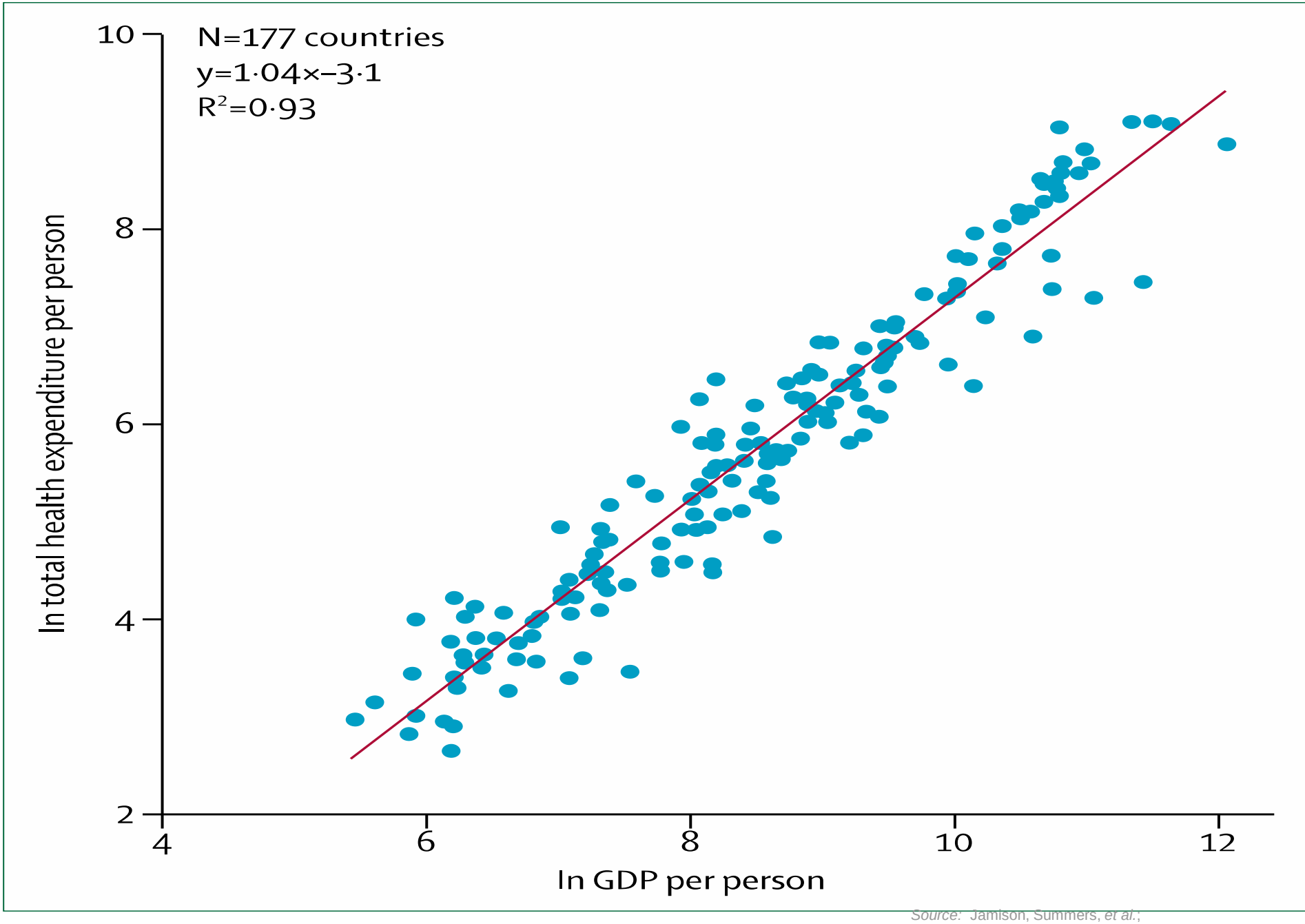
Why regulate medical devices?

Protect and promote public health

“A world converging within a generation”



Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955



Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955

Figure 21: **Relation between income and health spending**

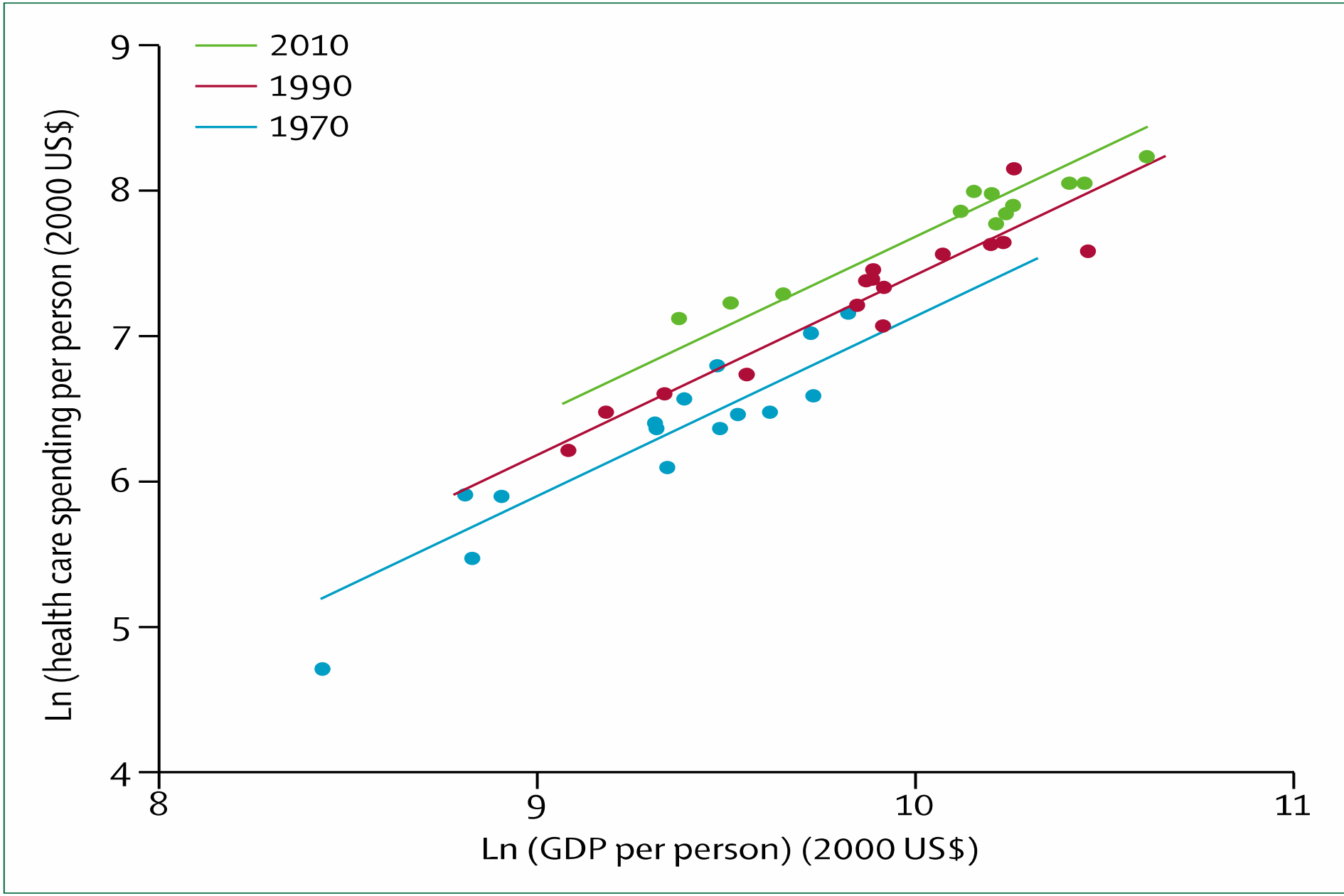


Figure 22: **The first law of health economics in Organisation for Economic Co-operation and Development countries**

Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955

"A unique characteristic of our generation is that collectively we have the financial and the ever-improving technical capacity to reduce infectious, child, and maternal mortality rates to low levels universally by 2035, to achieve a "grand convergence" in health. …

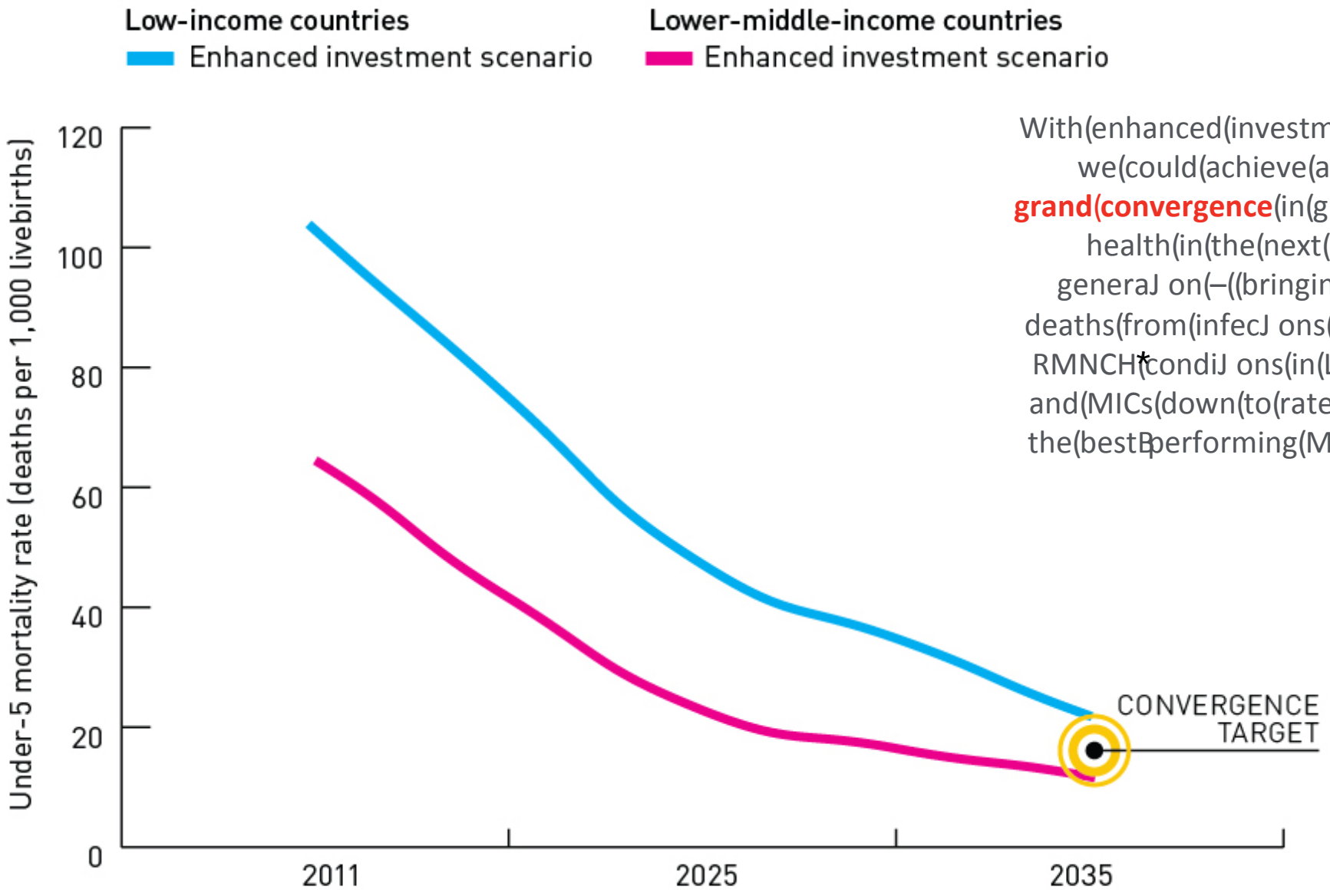
Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955

… With enhanced investments to scale up health technologies and systems, these rates in most low-income and middle-income countries would fall to those presently seen in the best-performing middle-income countries. …”

Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955

… Achievement of convergence would prevent about 10 million deaths in 2035 across low-income and lower-middle-income countries relative to a scenario of stagnant investments and no improvements in technology.”

Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955



With(enhanced(investment,((
we(could(achieve(a((
grand(convergence(in(global(
health(in(the(next(
generaJ on(–((bringing(
deaths(from(infecJ ons(and(
RMNCH*condiJ ons(in(LICs(
and(MICs(down(to(rates(in(
the(bestBperforming(MICs.(

* Reproductive, maternal, newborn, and child health

Source: Jamison, Summers, *et al.*; Global health 2013: A world converging within a generation; Lancet 2013; 382:1898-955 [adapted]

Thesis

Demand for health care and medical technologies will grow and become more widespread

Thesis

Regulation of health care products is an important element of health care ‘ecosystems’

Thesis

Regulation and regulatory practice are determinants of successful life sciences innovation

- Regulators are on life sciences “critical path”
- The efficiency and effectiveness of regulatory authorities in fulfilling their public health mandate are critical to achievement of desired life sciences outcomes

Thesis

‘Globalisation’ of R&D, clinical trials, manufacturing, and supply chains leads to growing interdependence of regulators and regulatory controls

Why regulate medical devices?

Protect and promote public health

Block or remove unsafe and ineffective products from market

Promote fair competition

Deter counterfeiting

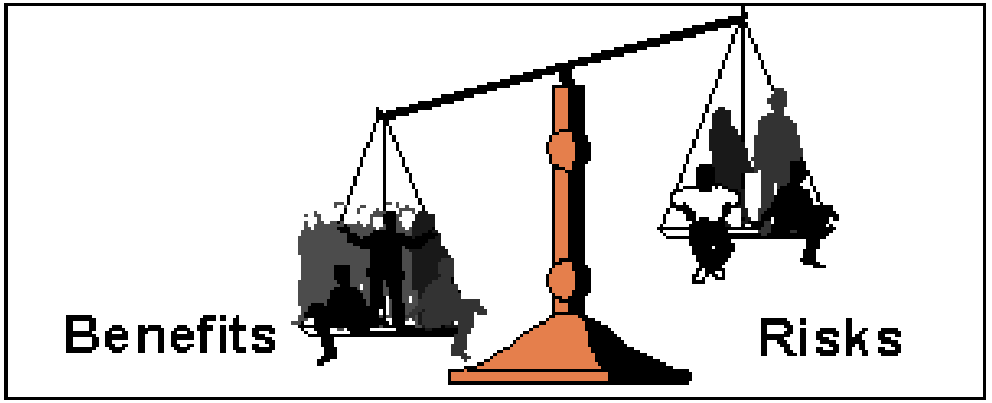
Secure supply chains

Control promotional practices

Require availability of information

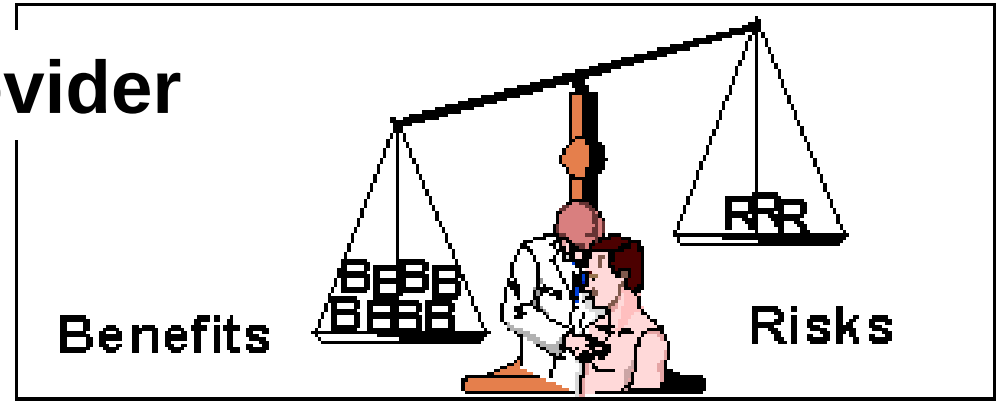
Regulator

evaluates
benefits/risks
for the population



Health care provider

evaluates
benefits/risks
for a patient



Patient

evaluates
benefits/risks
in terms of
personal values

Source: Managing the risks from medical product use; Creating a risk management framework; Report to the FDA Commissioner; May 1999 [Adapted]

Thesis

Enlightened, appropriate, judiciously applied regulation of health care products is a public good

- Good governance
- Expectation of citizens
- Public confidence in products and health care

Thesis

Many AHWP and APEC economies need appropriate and affordable regulation

… and the ability to effectively implement such regulatory systems

Regulatory convergence

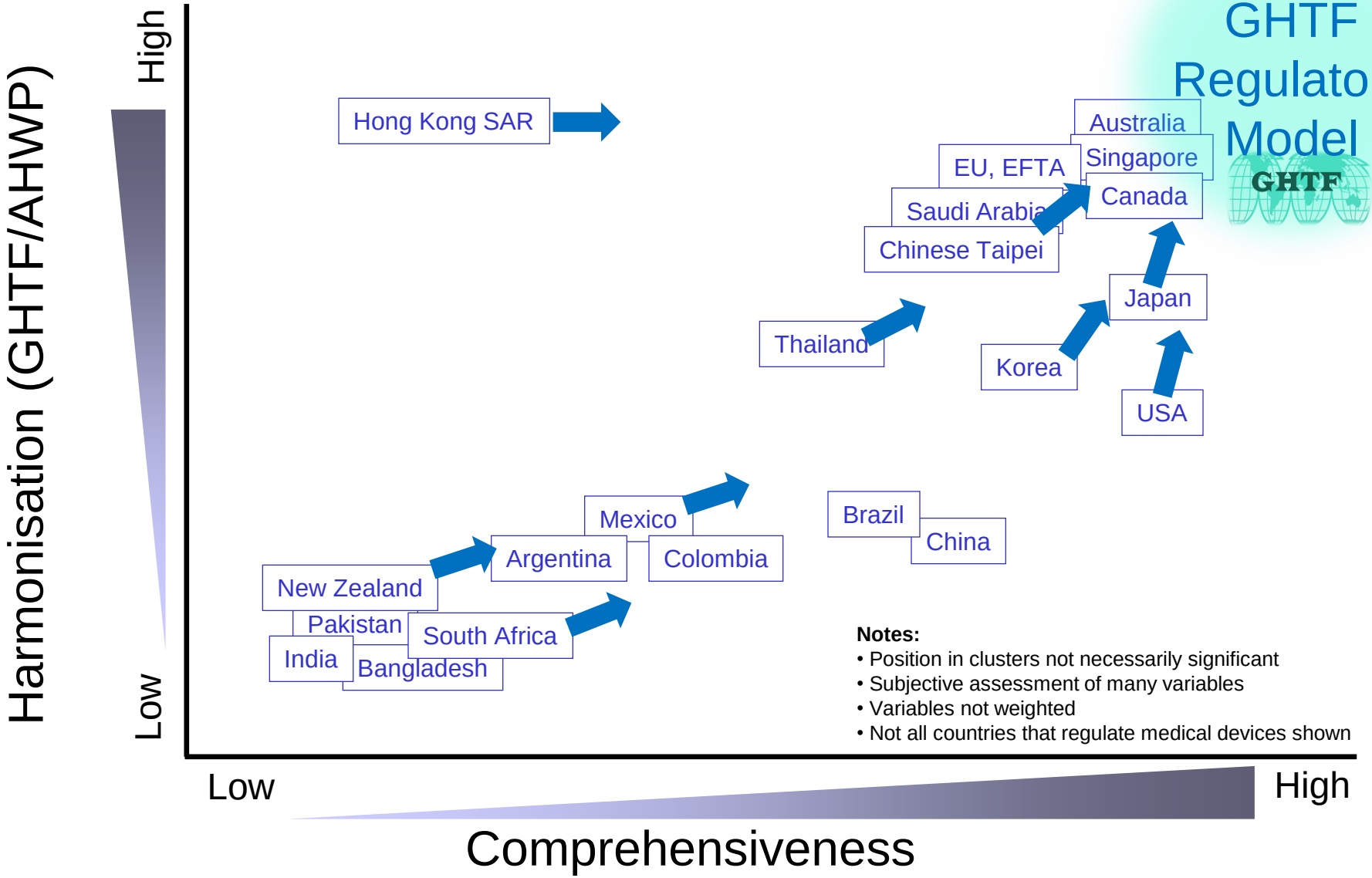
"… a voluntary process whereby the regulatory **requirements** and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and **scientific principles** (harmonization) and similar regulatory **practices** and procedures. …

Source: IMDRF Terms of Reference, 1 March 2012 [emphasis added]

Convergence of requirements → evidence → forms and format of evidence

- Not necessarily evaluation criteria or regulatory decisions

Regulatory convergence



How to regulate medical devices?

How to regulate medical devices?

Adopt and implement laws and regulations

Funding

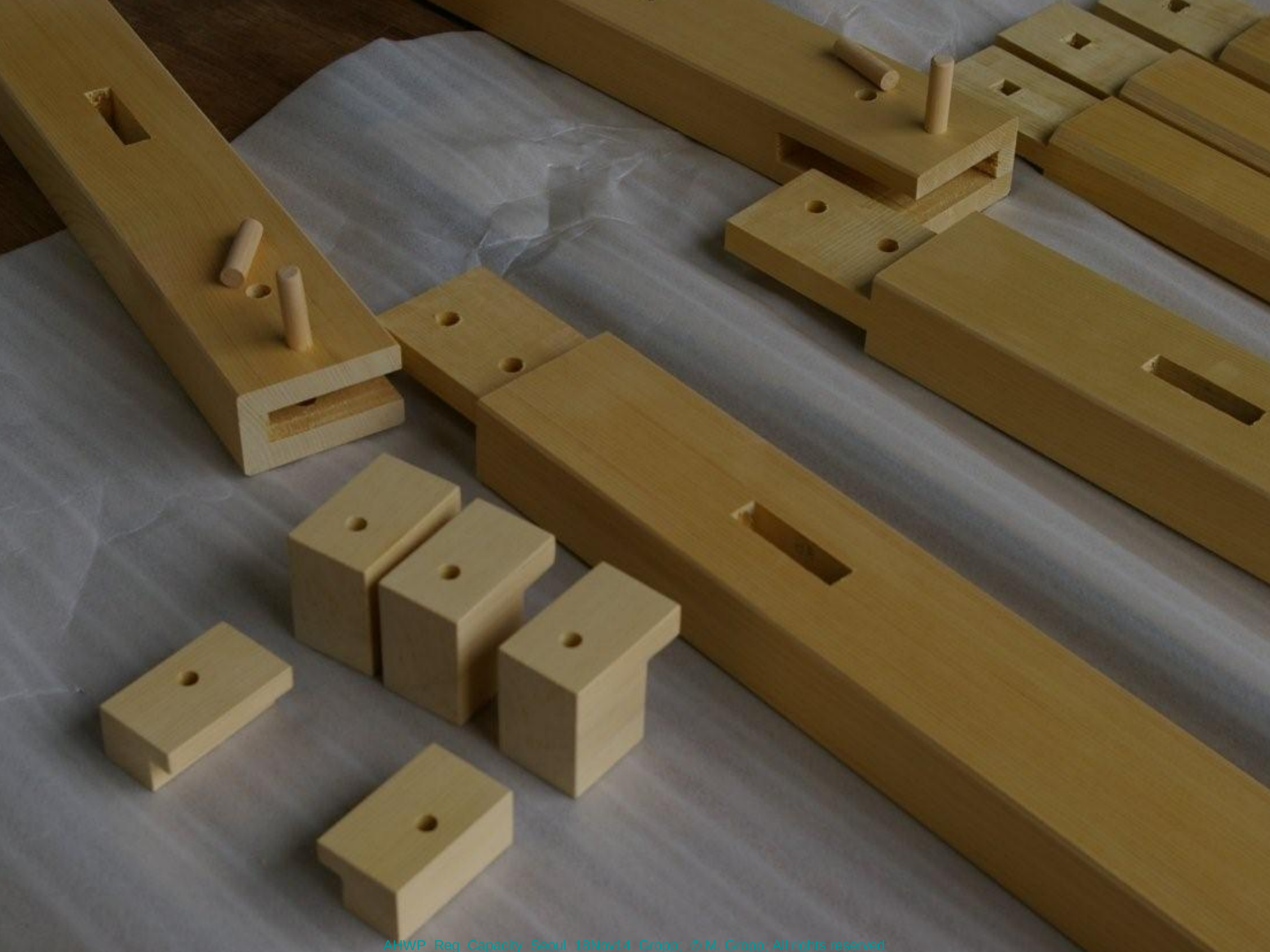
Establish regulatory authority

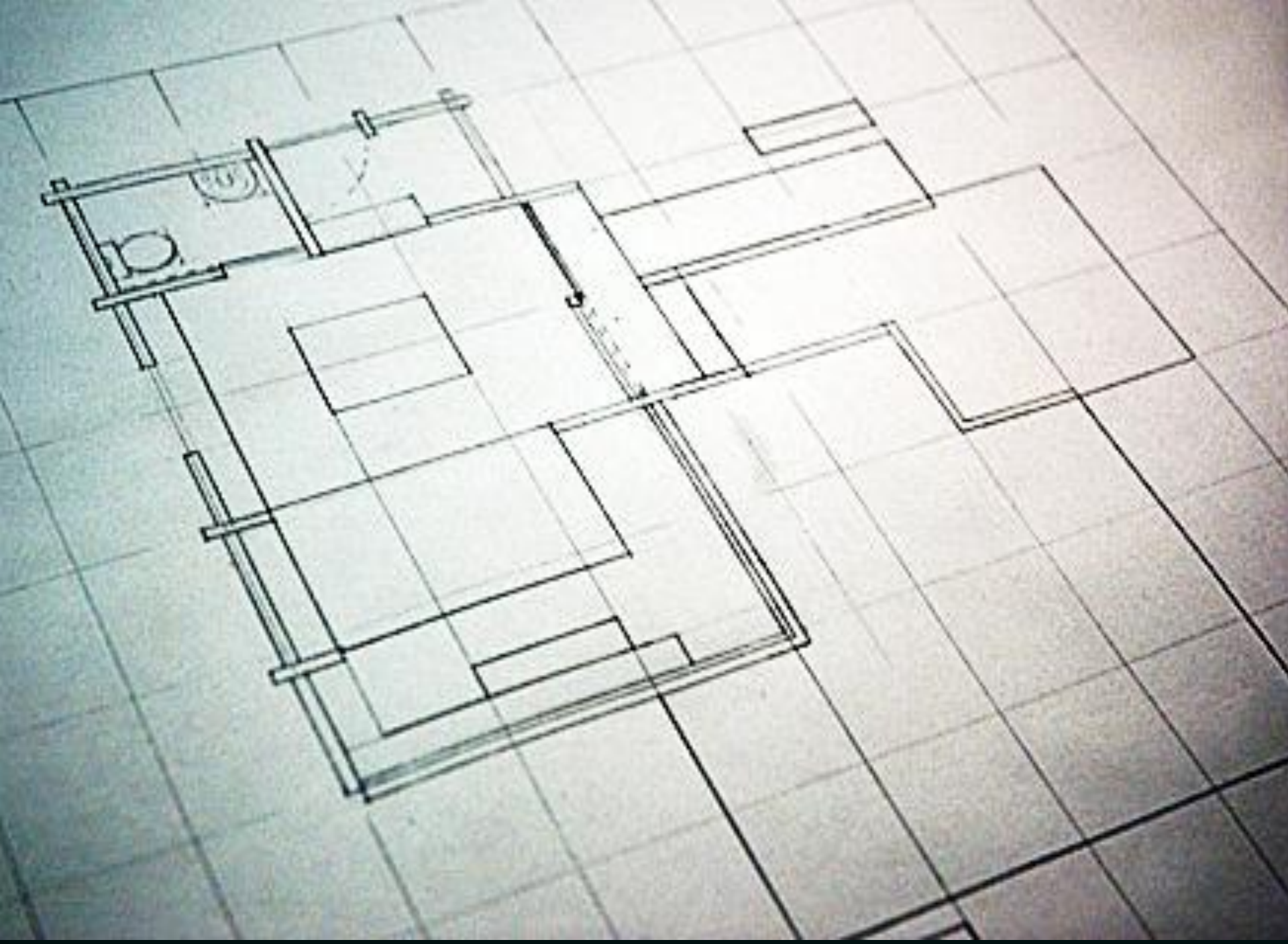
-- Systems and people

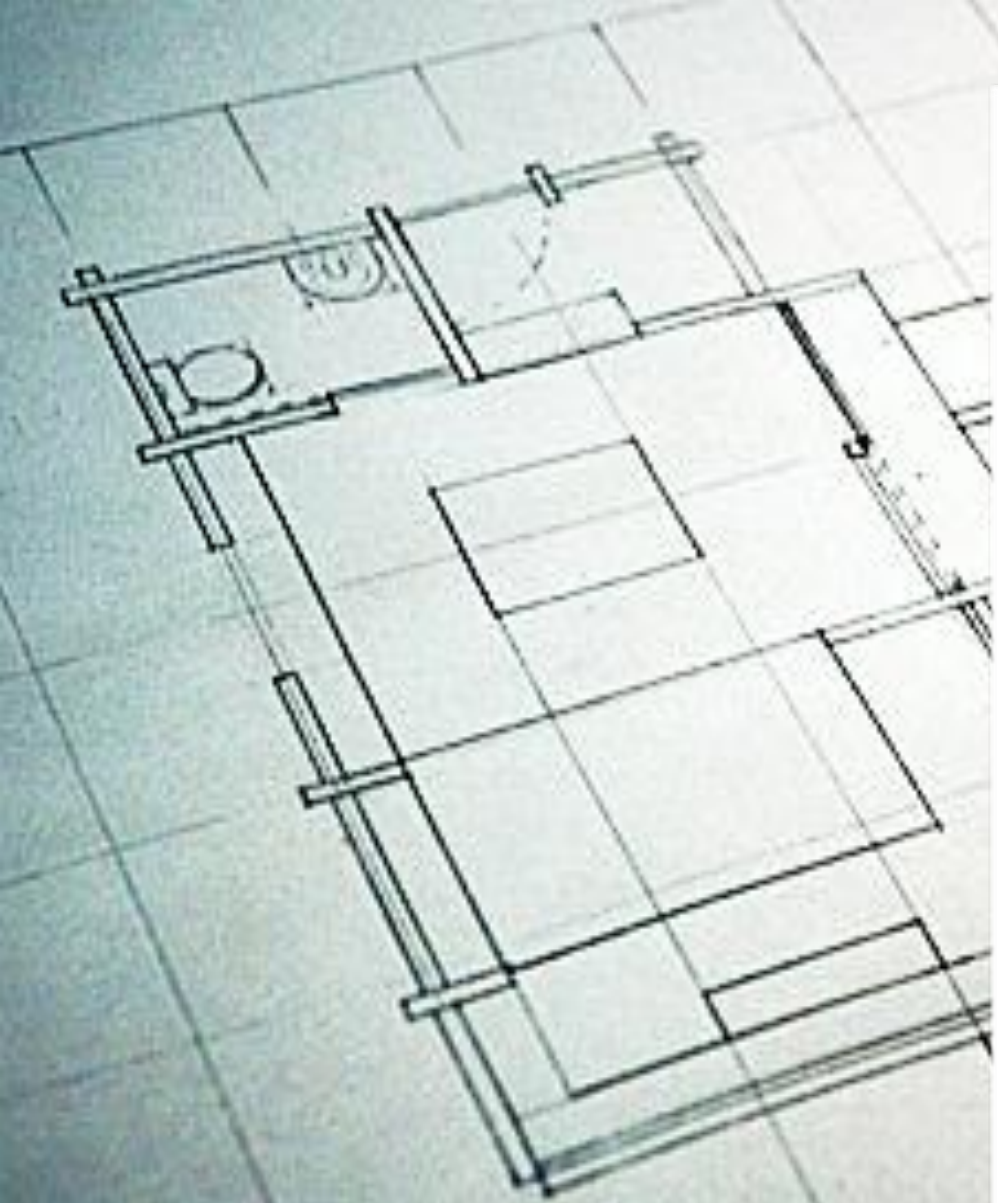
Adopt and implement regulations, ordinances, decrees

Establish market surveillance systems

Establish pre-marketing conformity assessment requirements







GHTF/AHWG-GRM/N1R13:2011

GHTF

Final Document

Title: The GHTF Regulatory Model

Authoring Group: Ad Hoc GHTF SC Regulatory Model Working Group

Endorsed by: The Global Harmonization Task Force

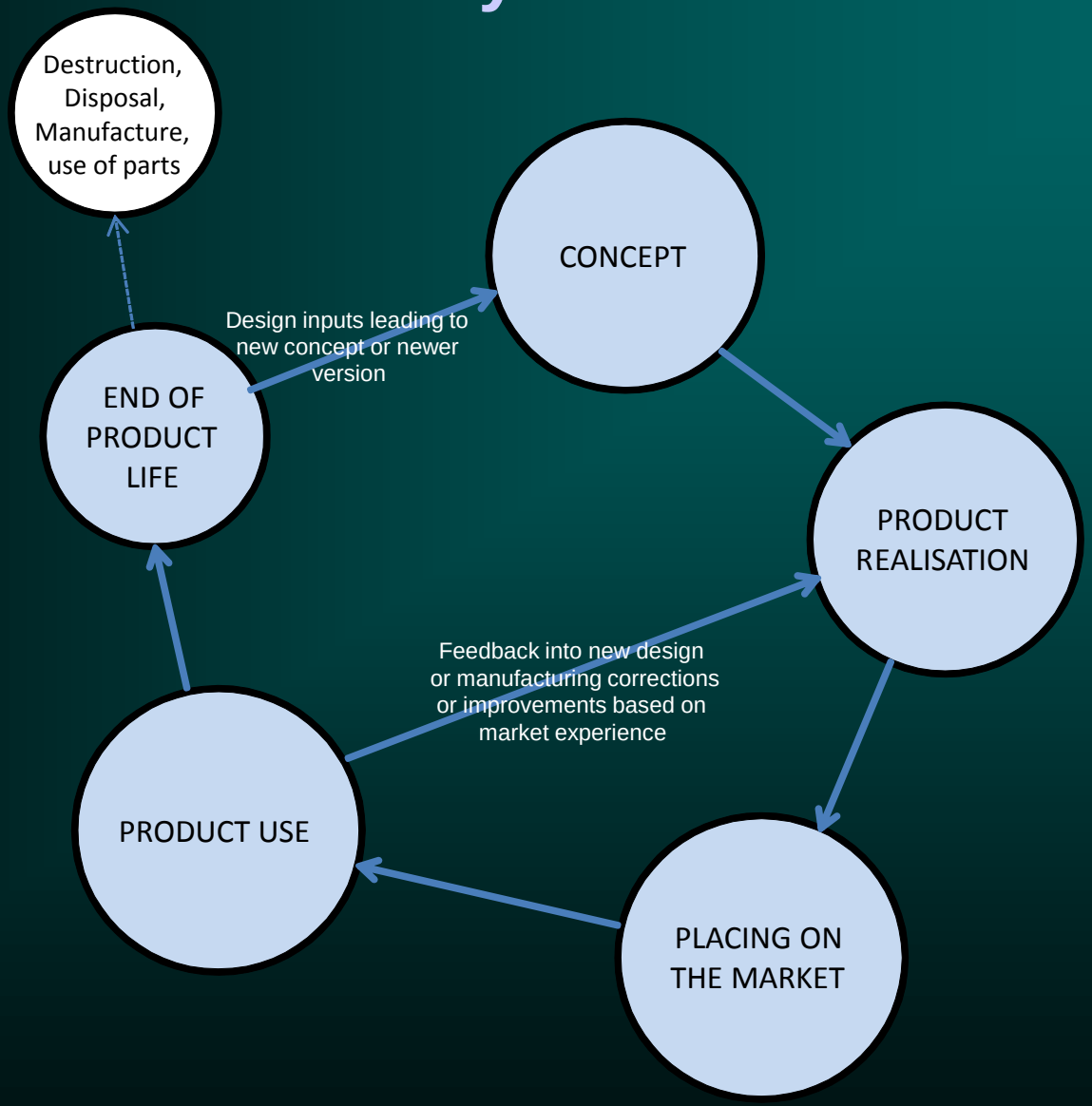
Date: 13 April 2011

[Signature], GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

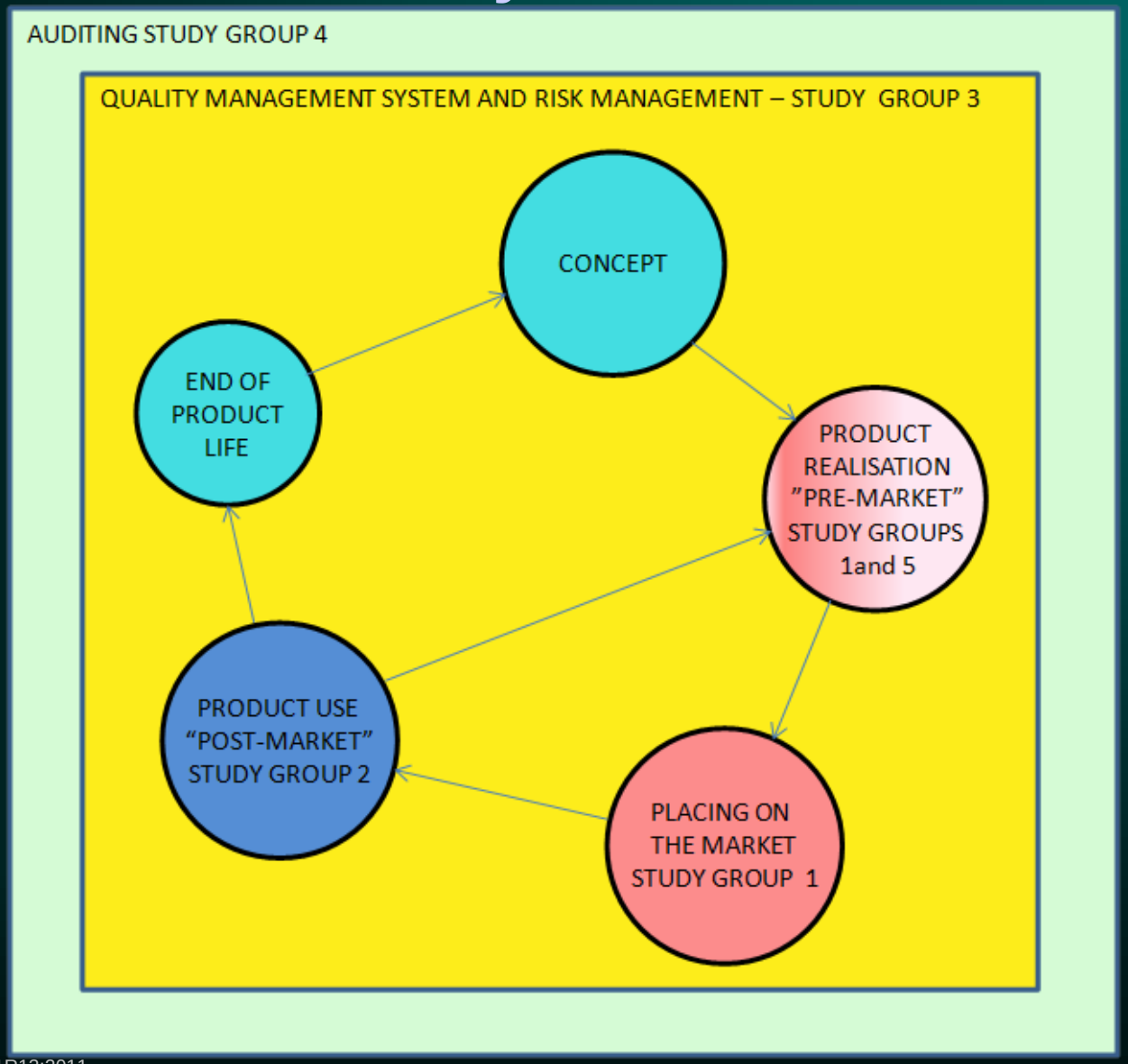
The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

Medical device life cycle



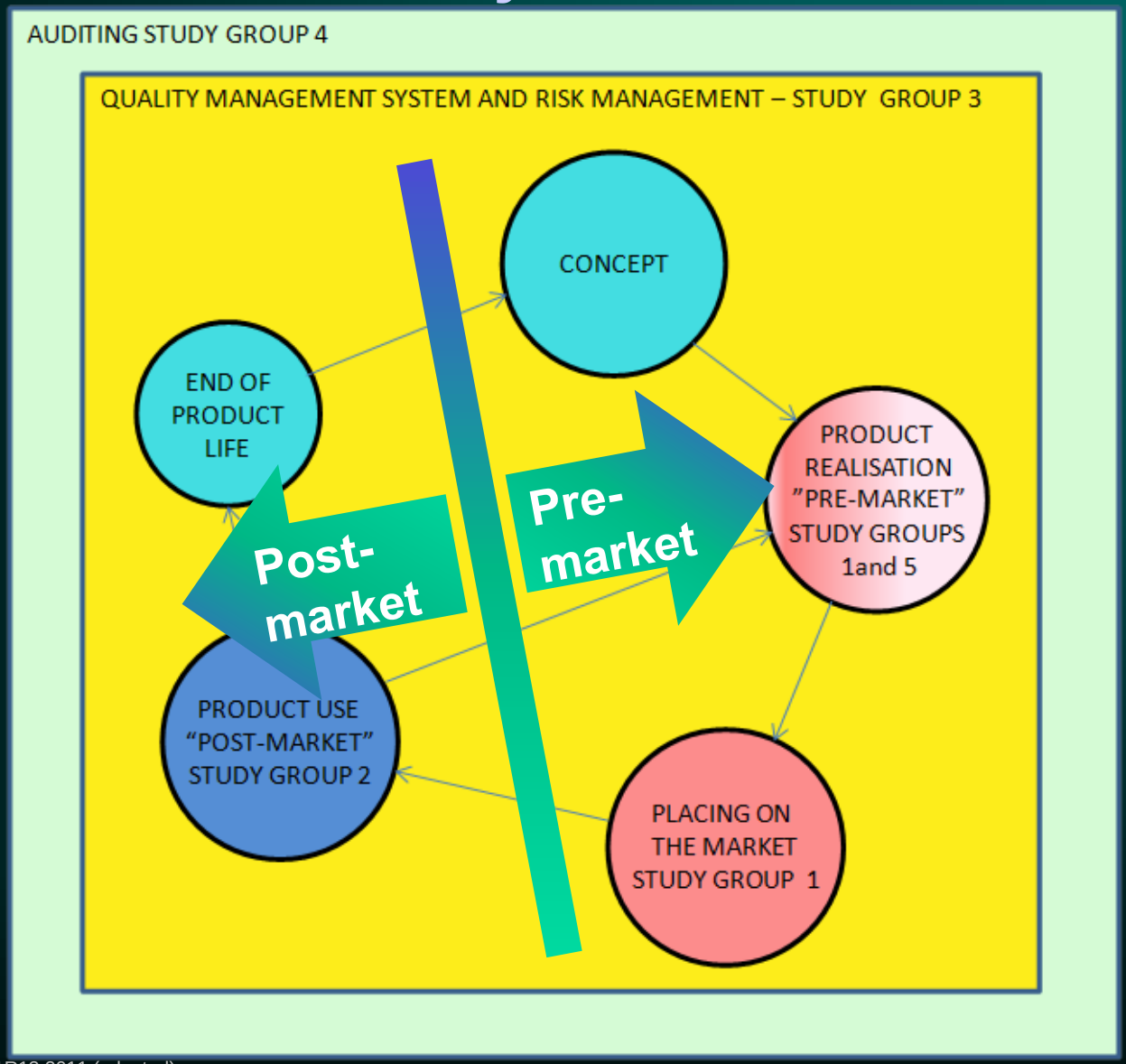
Source: Global Harmonization Task Force: *The GHTF Regulatory Model:* GHTF/AHWG-GRM/N1R13:2011 [modified]

Medical device life cycle



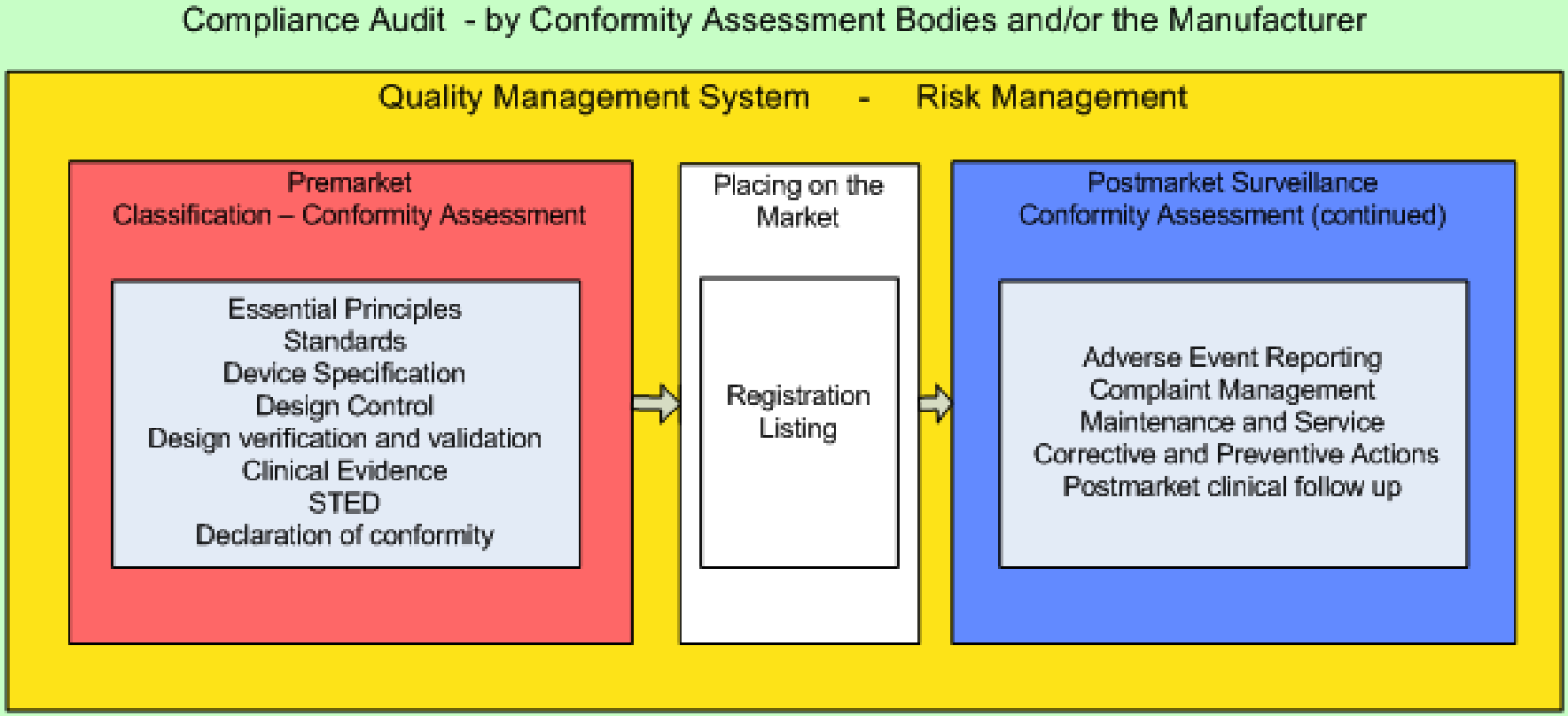
Source: GHTF/AHWG-GRM/N1R13:2011

Medical device life cycle



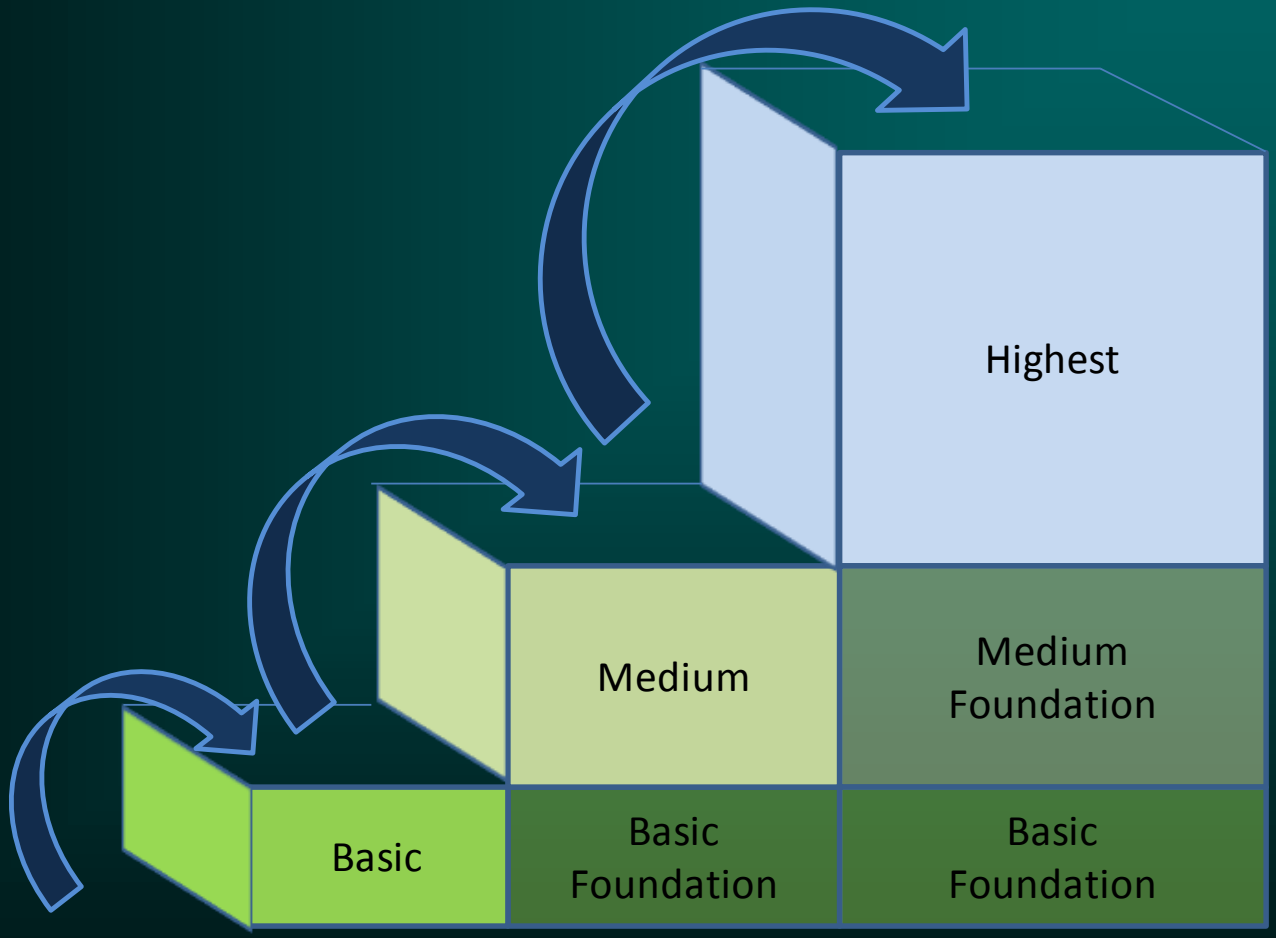
Source: GHTF/AHWG-GRM/N1R13:2011 (adapted)

Medical device life cycle



Source: GHTF/AHWG-GRM/N1R13:2011

Levels of regulatory control



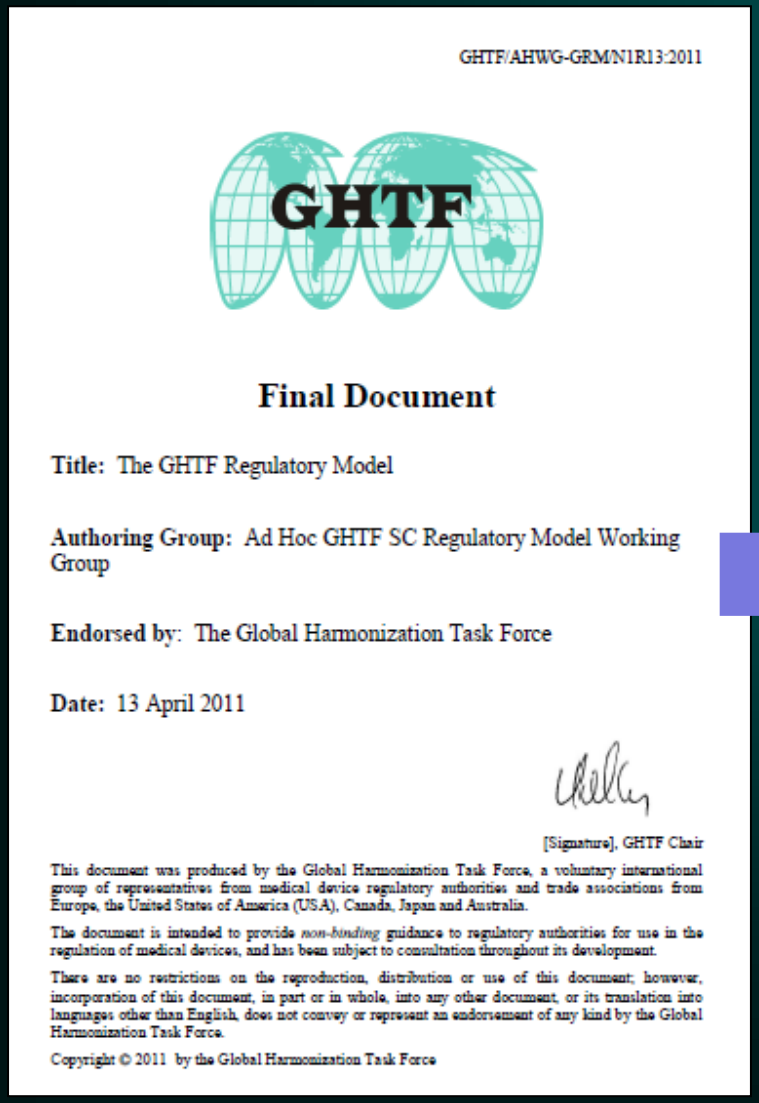
Source: GHTF: *GHTF Regulatory Model*; GHTF/AHWG-GRM/N1R13; 2011

Levels of regulatory control

Figure 10. Suggested priorities for regulatory programme development

Source: Medical device regulations: Global overview and guiding principles; World Health Organization, Geneva; 2003

Guides



GHTF/AHWG-GRM/N1R13:2011

GHTF

Final Document

Title: The GHTF Regulatory Model

Authoring Group: Ad Hoc GHTF SC Regulatory Model Working Group

Endorsed by: The Global Harmonization Task Force

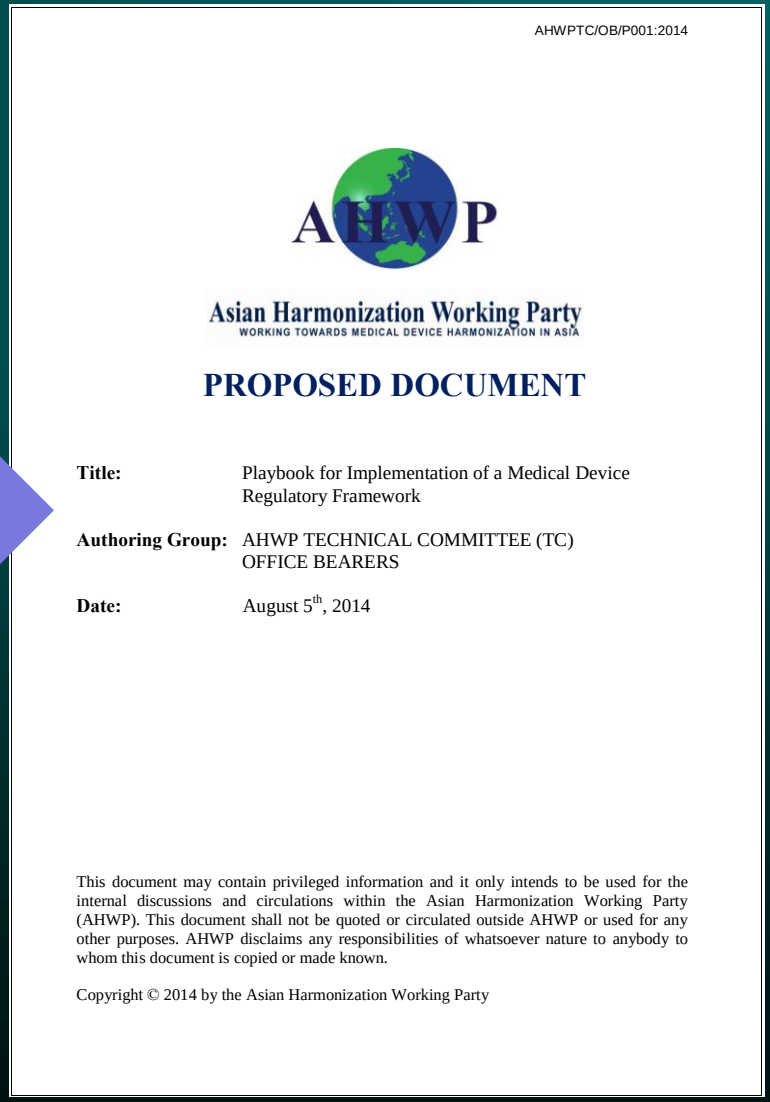
Date: 13 April 2011

[Signature], GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide *non-binding* guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the Global Harmonization Task Force.



AHWPTC/OB/P001:2014

AHWP

Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

PROPOSED DOCUMENT

Title: Playbook for Implementation of a Medical Device Regulatory Framework

Authoring Group: AHWP TECHNICAL COMMITTEE (TC) OFFICE BEARERS

Date: August 5th, 2014

This document may contain privileged information and it only intends to be used for the internal discussions and circulations within the Asian Harmonization Working Party (AHWP). This document shall not be quoted or circulated outside AHWP or used for any other purposes. AHWP disclaims any responsibilities of whatsoever nature to anybody to whom this document is copied or made known.

Enabling conditions for regulatory capability

Source: Dr. Lembit Rägo, World Health Organization; at International Regulatory harmonisation Amid Globalization of Biomedical Research and Medical Product Development; Institute of Medicine, Washington, D.C.; 13-14 February 2013 (Adapted)

Good Decision Making Practices

Good Regulatory Practices based on international guidance, alignment and effective cooperation and work sharing

Harmonisation and convergence of technical requirements in conjunction with harmonised training principles and model core curricula for regulators

Applicable modern laws and enabling legal system

General Good Governance in Public Sector, including transparency and accountability

APEC-OECD

INTEGRATED CHECKLIST

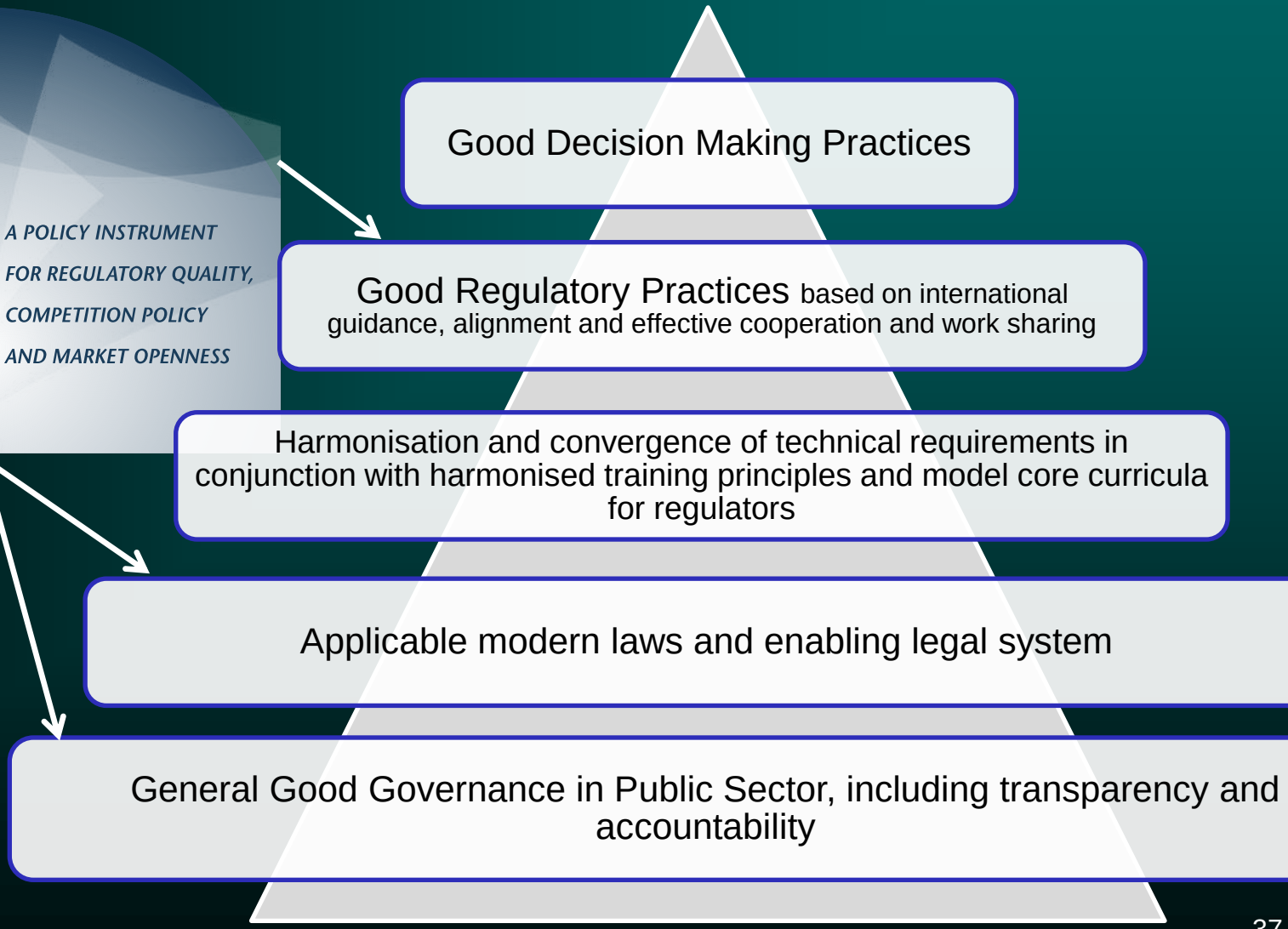
ON REGULATORY REFORM

A POLICY INSTRUMENT

FOR REGULATORY QUALITY,

COMPETITION POLICY

AND MARKET OPENNESS



Desirable attributes of regulatory capability

Desirable attributes of regulatory capability

- Integrity
- Impartiality
- Predictability
- Transparency
- Objectivity
- Safeguards against abuse of power
- Nimbleness
- Good judgment
- Efficiency
- Cost effectiveness
- Adaptability
- Outward looking
- Substantive, timely, meaningful interaction with interested parties
- Memory and learning
- Conducive to technology innovation
- Scientific and technical expertise
- Able to assess and manage risks

Desirable attributes of regulatory capability

- High quality decision making
- Linked to public health priorities
- Coordination between political levels
- Periodically reviewed and updated
- Take into account international regulatory harmonisation guidance
- Sufficient resources
- Political support
- Political accountability
- ‘Joined up’ policy making

Regulatory capability

Attributes of both systems and people

Desired attributes apply regardless of scope of regulatory systems

Capabilities of both regulators and regulated industry

General administrative policies

Law enforcement, justice policies

Consumer protection policies

Taxation policies

Securities regulation policies

Public health protection policies

Customs policies

Science and technology development policies

International trade policies

Industrial development policies

Education policies

Work force development policies

Regulator
evaluates benefits/risks for the population

Provider
evaluates benefits/risks for a patient

Patient
evaluates benefits/risks in terms of personal values

‘Joined-up’ policies

“Our overarching messages are that, the region’s competitiveness and the health and well being of our people, would benefit from

(1) a top-level **political commitment** to this sector with appropriate **resource** allocation, and

(2) an **integrated approach taken to life sciences and health care policy making**. Many different agencies have competing priorities and approaches. Coordination of these will maximize benefits to the community and efficiencies in the administration of government systems in this sector.”

Source: APEC Life Sciences Innovation Forum Strategic Plan; 2006/SOM3/LSIF/010; 6-7 Sept. 2006 [emphasis added]

Regulatory capability

Current regulatory capability and capacity needs vary across AHWP and APEC member economies

In some cases where needs for medical technology are greatest, regulatory capacity is weakest

Regulatory capability

Should all economies have same regulatory capacity?

Can a nation have “full capacity” but only in certain elements of a full “regulatory model”?

Functional cross-national network of regulators, rather than individual regulators?

Regulatory capability as intellectual capital

Skilled competent motivated regulatory affairs specialists

- Government, conformity assessment bodies, and industry

Retained experience

Institutional memory

Ethical decision-making

Continuing education and professional development

Regulatory capability as intellectual capital

Competency based training

Growing need for competence in cross-border collaboration

Capacity to participate in development and implementation of international harmonisation guidance

Opportunities for AHWP and AHC future work?

Vision of “success”

Prepare regulatory workforce of the future

Trust in ability of regulators to protect and promote public health

Confidence in industry to develop needed products

Measurable public health gains and socioeconomic development