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*Evaluation of Draft Guidelines for the Development of
Medical Device Regulations*



Workshop



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WHO mission

The attainment, for all people, of the highest possible level of health

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Purpose of the Corporate strategy

To enable WHO to make the greatest possible contribution to world health through increasing its technical, intellectual and political leadership

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Strategic direction 1

Strategic direction 2

To reduce excess mortality, morbidity and disability especially in poor and marginalized populations

To promote healthy lifestyles and to reduce factors of risk to human health that arise from environmental, economic, social and behavioural causes

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Strategic direction 3

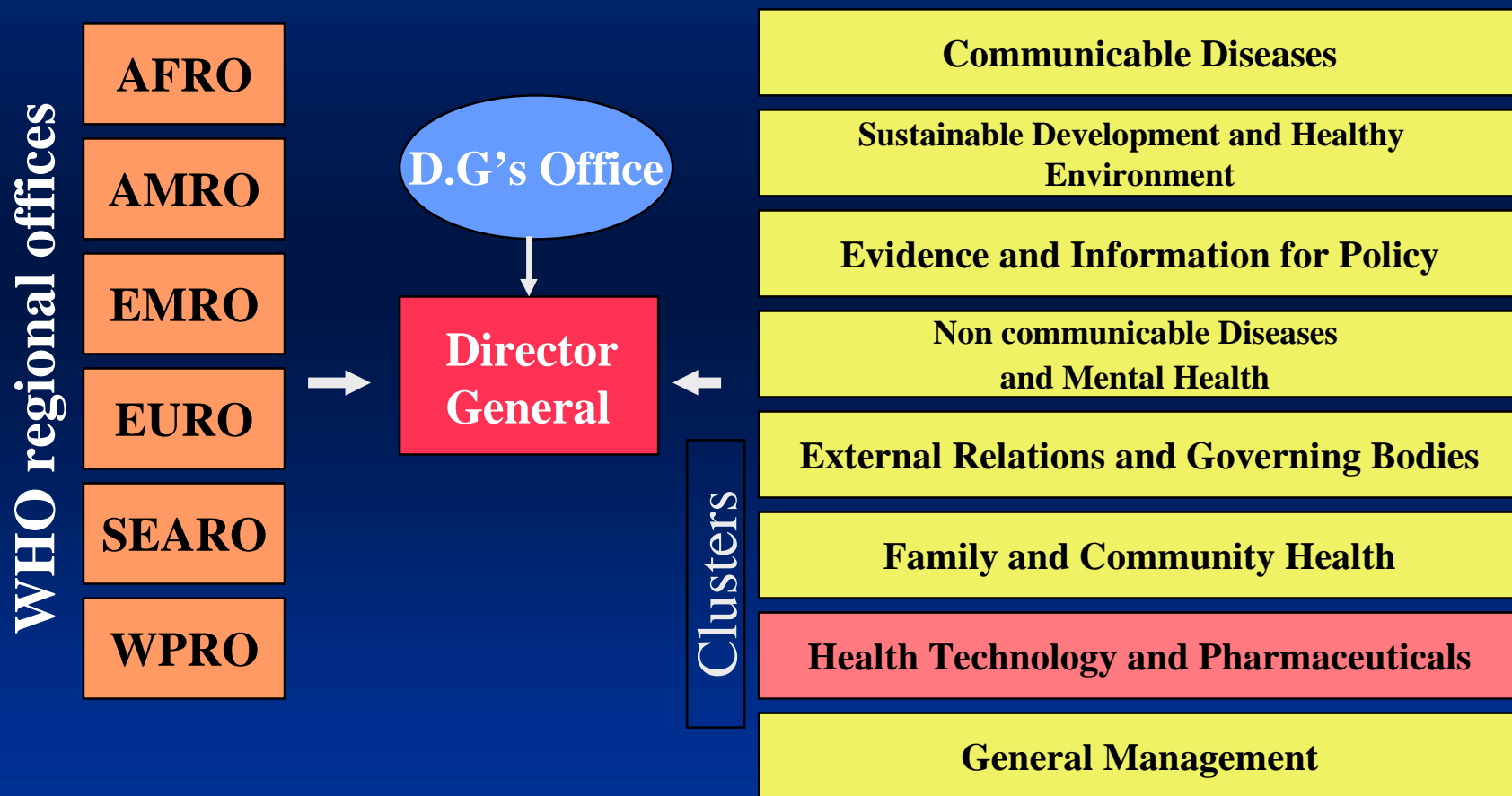
To develop health systems that equitably improve health outcomes, respond to people's legitimate demands, and are financially fair

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Strategic direction 4

To develop an enabling policy and institutional environment in health sector and to promote an effective health dimension to social, economic, environment and development policy

Structure at WHO Headquarters



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HTP mission

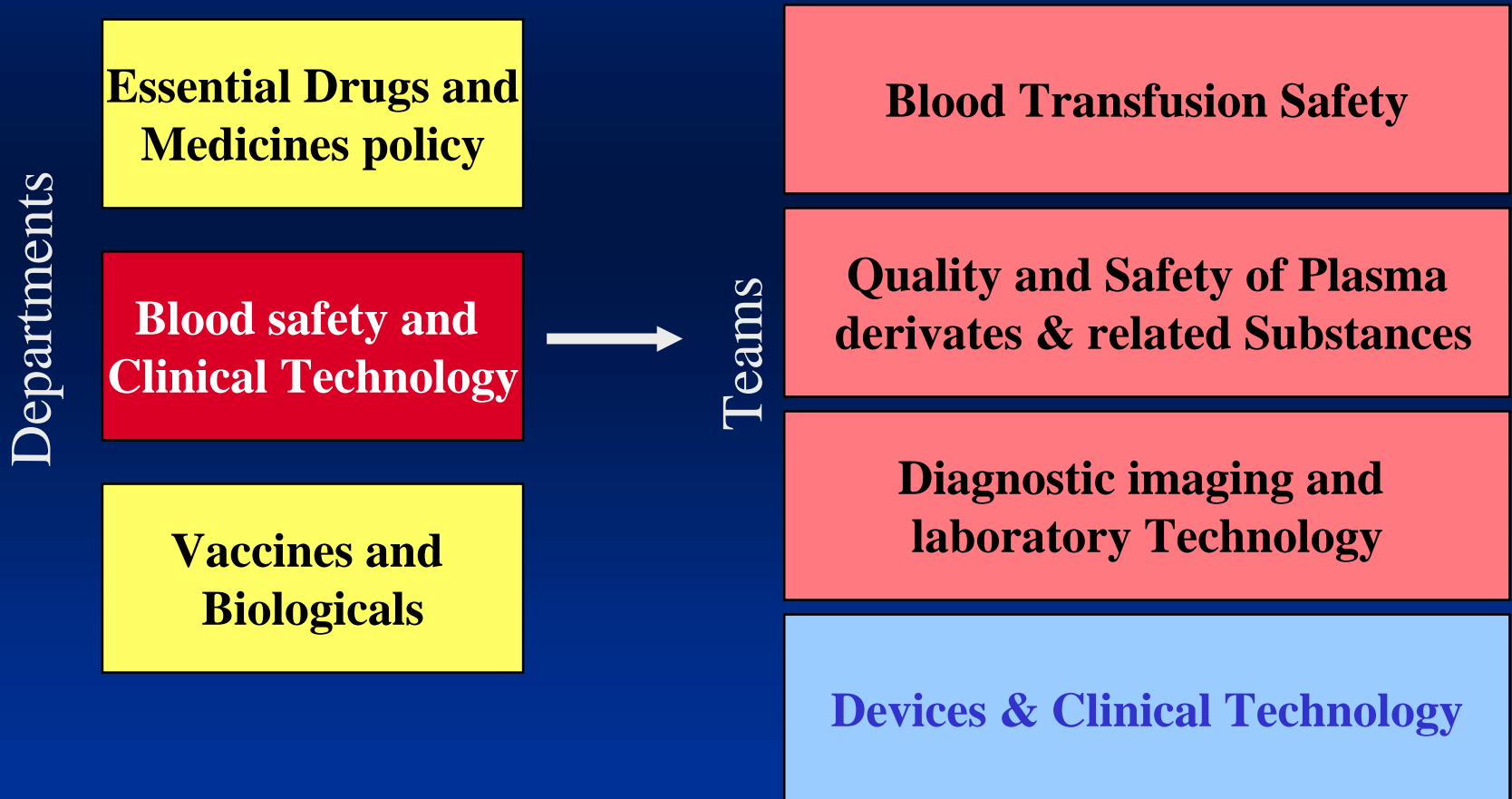
Increase access to and promote the optimal use of essential quality health technology

HTP core competencies

- **Organizing and promoting prioritized research and development**
- **Ensuring all forms of access to HTP**
- **Developing norms and standards for quality assurance in health systems**
- **Ensuring that HTP are used appropriately, rationally and cost-effectively**
- **Monitoring the impact of health interventions of all kinds**

Structure at HTP cluster

Health Technology & Pharmaceuticals



Medical devices

A medical device is an instrument, apparatus, or machine used to prevent, diagnose or treat disease.

It also serve to detect, measure, restore or modify the structure or function of the body for a given health purpose

Medical device activities

- Medical device development and technology transfer
- Specifications /Standards
- Healthcare technology management and medical equipment maintenance
- Quality of care and Vigilance /alert system
- Harmonization on medical device regulations

Specifications/Standards

- WHO specifications
- Product Information and testing
- Official link with ISO
- Collaboration with ISO/TC84

Quality of care: patient safety

WHO EB109 resolution and message to 55 WHA

- Develop global norms, standards and guidelines for the definition, measurement and reporting of adverse events
- Promote evidence-based policies to improve patient care (including product safety)
- Develop mechanisms for international accreditation of health care providers
- Encourage research into patient safety

Medical device vigilance

development of the procedure for Alerts

- Initial screening
- Technical assessment
- validation
- Circulation of information

Medical device regulations

- Answer to the specific needs of developing countries
- Link with International Trade Associations
- Link with National Regulatory Authorities
- GHTF Synergy to avoid duplication of work

GHTF/WHO collaboration

- Gap analysis (what we have /What we want to achieve)
- Join strategy
- Memorandum of understanding (MoU)
- Technical collaboration with GHTF Study group 2 on vigilance
- Nomenclature: GMDN /UMDNS

Healthcare Technology Management

Healthcare Technology Life Cycle



HTM Toolkit

- Regional HT strategy
- Guidelines for health technology policy development
- Guidelines for health technology policy implementation
- Situation analysis guideline + Health facilities audit tool
- Donation guidelines
- *Procurement guidelines*
- *HRD for HTM*
- *Guidelines for the development of medical device regulations*

Purpose

Provide Member States with basic information to promote a general understanding of medical device safety and regulatory issues for the development of basic regulatory programs

Regional edition

PAHO/AMRO activity on medical device regulation

- Work with regulatory authorities in the US and Canada
- FDA model program on medical device regulation
- in 1999: presentation of the regional edition of the guide
- Evaluation in some Latino American Member States
- 2002 : Regional edition printed
- Basis for the development of the global edition

Global edition

- Based on the Health Canada/PAHO document
- Emphasis GHTF recommendations from the last two years
- Current regulatory systems of the 5 GHTF founding members (Australia, Canada, E.U., Japan, U.S.A.)
- Majority of reviewers have agreed on the present draft
- Feedback and further suggestions for the final document

Objectives

- Provide an overview of medical device safety
- Refer to major MD regulatory systems
- Adopt global harmonization recommendations
- Promote development of post market surveillance/vigilance
- Reduce the regulatory burden of countries with financial constraints

Strategy

- Include major medical device regulations to answer the needs of all WHO regions
- Link with experts on medical device regulations
- Strengthen activities which support effective and efficient harmonization on medical device regulations

Link with GHTF

- Reference to final GHTF documents
- Call for comments on the guideline
- Proposal for a joint document
- Dissemination of the guideline
- Reference to GHTF web site

Words of advice

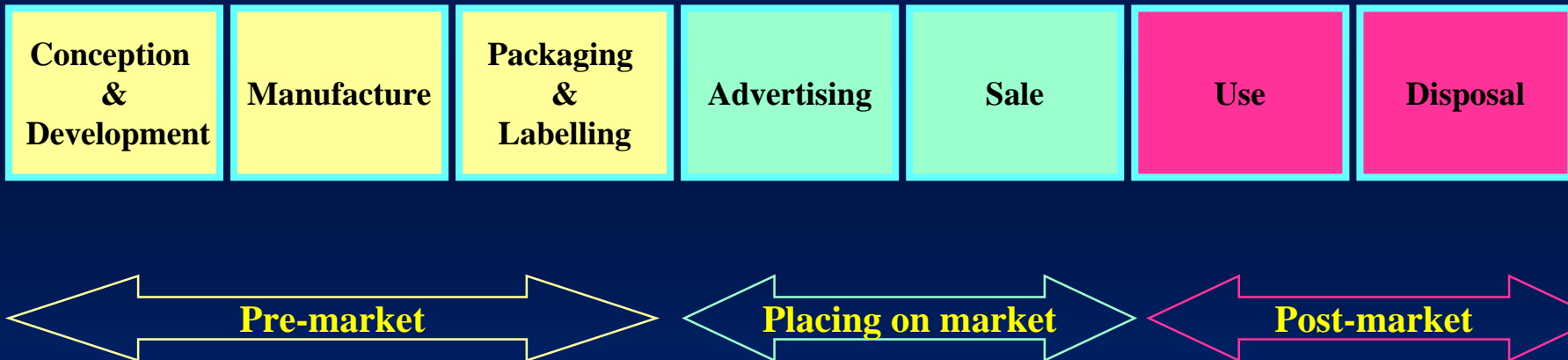
For National Medical Device Administration

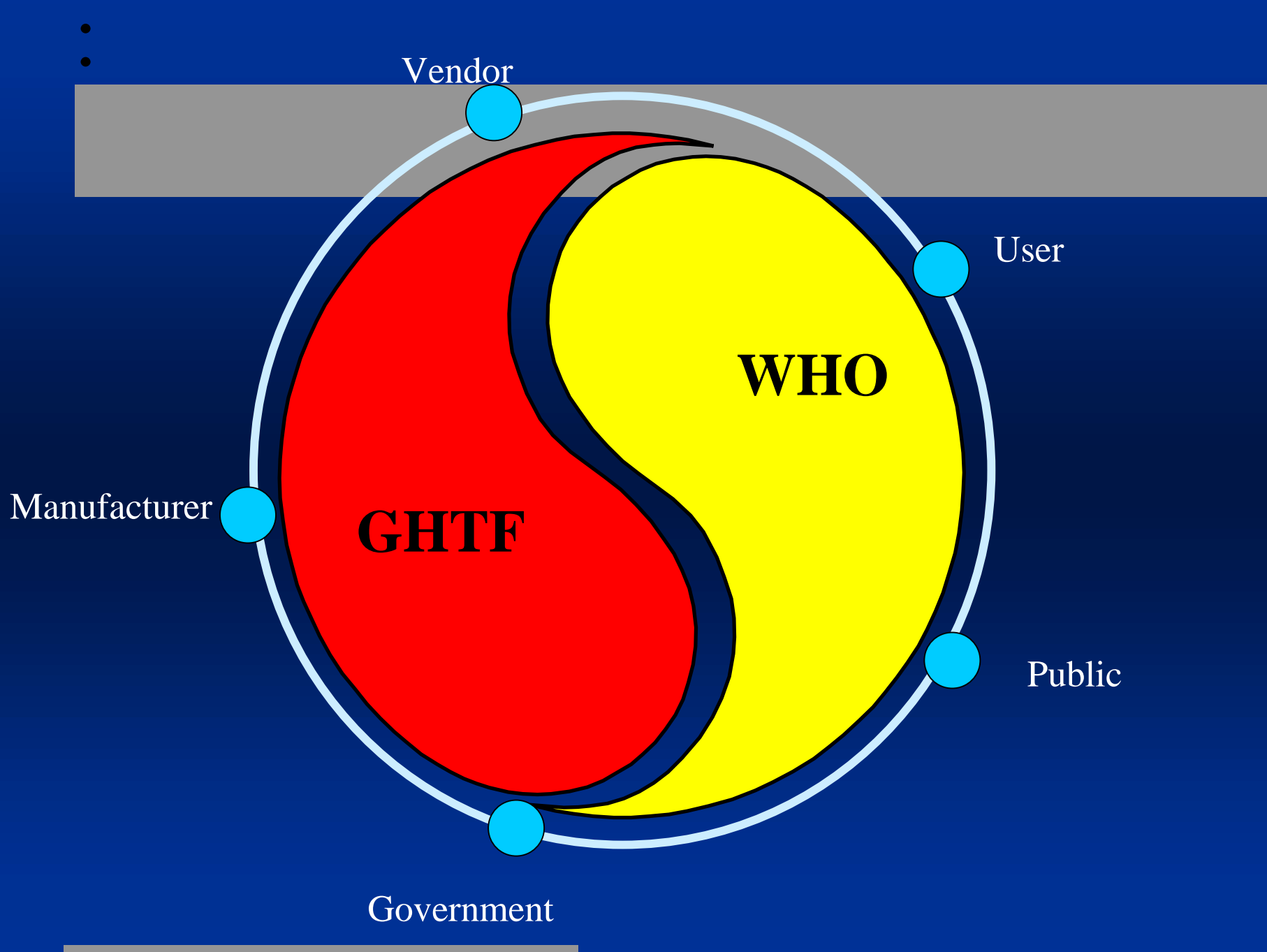
- Collaborate with all stakeholders to establish a clear and comprehensive national policy on medical devices
- Adopt recommendations on global harmonization for regulatory requirements and procedures
- Ensure that classified medical devices are manufactured in conformity with applicable quality system standards
- Link to networks that monitor medical devices and participate in post-market surveillance and medical device alert issues

Key elements

- S.... Simple
- I.... International
- N.... Non technical language
- G.... GHTF compatible
- A.... Accurate information
- P.... Periodically reviewed
- O.... Overview of medical device safety
- R.... Reference to all existing regulations
- E.... Experience based

Phases in the Life Span of Medical Devices





Vendor

User

WHO

Manufacturer

GHTF

Public

Government