Conformity Assessment
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BSI Introduction

- British Standards has a Royal Charter to act as the standards organisation for the UK. The Group now operates globally through its 3 divisions: BSI British Standards, BSI Management Systems and BSI Product Services.
- BSI Group was founded in 1901
- BSI British Standards publishes over 2,000 standards each year
- BSI has clients at 60,000 sites in more than 100 countries

- BSI Group:
  - develops private, national and international standards
  - provides product testing services
  - certifies management systems and products
  - provides training and information on standards and international trade

Jack Wong's introduction

FICCI
Federation of Indian Chambers of Commerce and Industry

Affiliations

- Secretary of Technical Committee of AHWP
- Advisory Board member of Training Committee of AHWP
- Committee Member of Medical Device Standard in China
- Chairman of Medical Device Committee in HK Association of Pharmaceutical Industry
- Adjunct Tutor in the School of Pharmacy since 1999
- Editorial Committee of China Medical Journal

Topics

- Overview
  - What does everyone want/expectation
  - What is Conformity Assessment and who does it?
  - GHTF model
- 3rd Party Conformity Assessment
- How can Governments complement the 3rd Party conformity assessment?
- Conclusion

What does everyone want?

- **Consumer (doctor/patient)**
  - Safe devices
  - Available devices
  - Access to latest devices
- **National governments**
  - Safe, cheap, state of the art medical devices
  - Strong, happy local industry
  - Healthy, happy consumers
- **Testing Lab**
  - One Standard, One Test, Accepted Everywhere

What does everyone want?

- Manufacturers
  - Minimum regulation, certainty about requirements, level playing field
  - External manufacturers want good market access
  - Local manufacturers may want guidance on requirements and/or protection

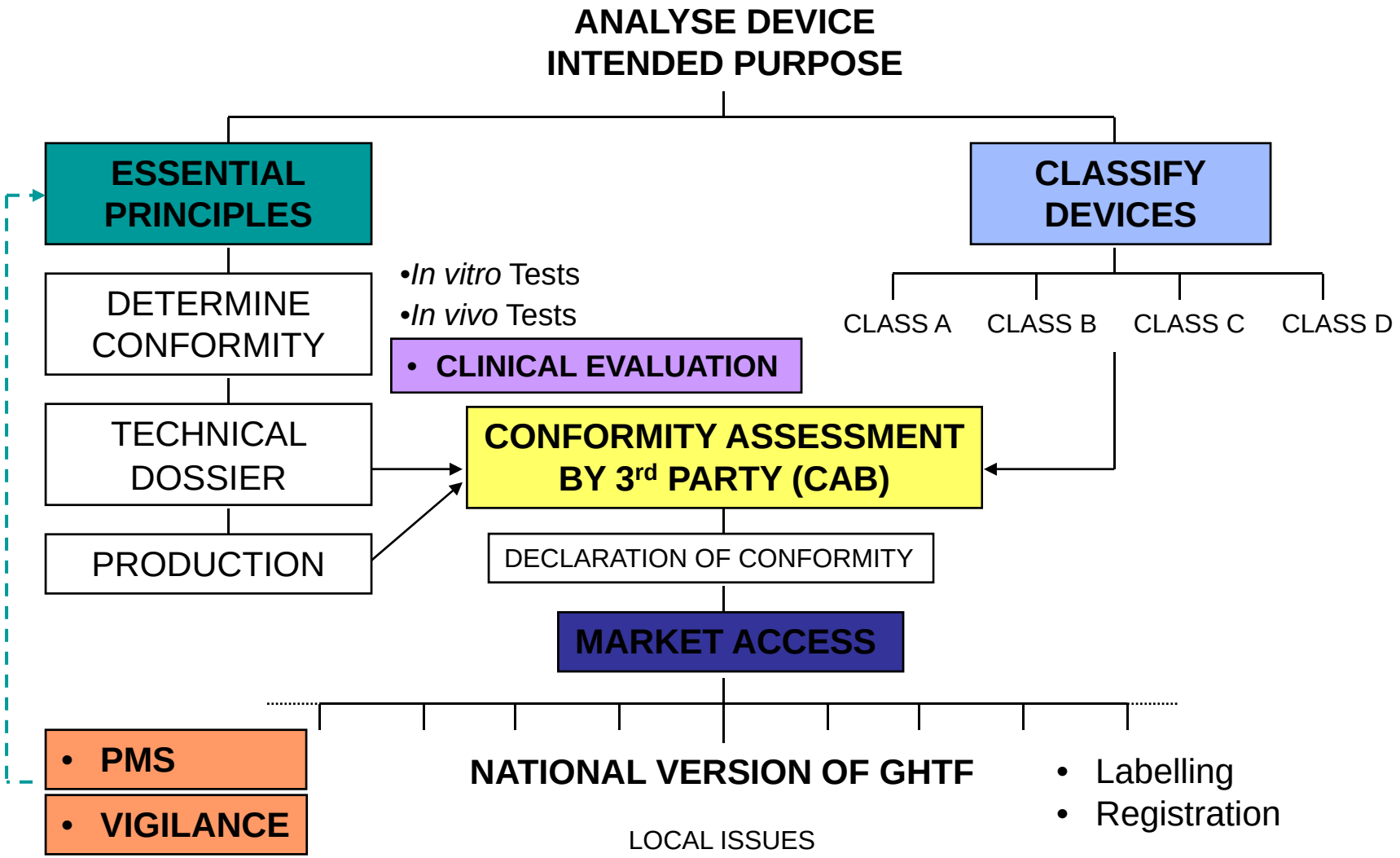
- Conformity Assessment Bodies (3rd parties)
  - Certainty about requirements, level playing field

What is conformity assessment?

- "Conformity assessment is the systematic examination of evidence generated and procedures undertaken by the manufacturer to determine that the device is safe and performs as intended by the manufacturer"
  - *Principles of Conformity Assessment - GHTF/SG1/N40:2006*

- Conformity Assessment can be done by first, second or third parties

GHTF MODEL



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Who does conformity assessment?

- Combination of:
  - First party (manufacturer)
  - Second party (usually government)
  - Third party (Conformity Assessment Body)

- **“Conformity Assessment is primarily the responsibility of the medical device manufacturer”**
  - *GHTF/SG1/N40:2006*

- But higher risk devices get more external checking than low risk devices

Important Principle

- Essential Principles and basic documentation and quality requirements are the same for all devices, regardless of classification

- All devices need
  - Clinical data
  - Technical documentation
  - A quality system
  - Post market surveillance and vigilance reporting

Risk v 3rd Party conformity assessment

This talk will cover …….

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- ✓ Overview

- **3rd Party Conformity Assessment**
  - **Risk v 3rd Party conformity assessment**
  - **What are 3rd Parties assessing against?**
  - **Role technical documentation**
  - **What do 3rd Parties do for each Risk Class?**

- How can Governments complement the 3rd Party conformity assessment?

- Conclusion

4 risk categories of medical device

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D High Risk
- Heart valves / implantable defibrillator

C Moderate-high Risk
- Lung ventilator / critical infusion pump

B Low-moderate Risk
- Hypodermic Needles / suction equipment

A Low Risk
- Surgical retractors / tongue depressors

What are CABs assessing against?

- For quality management systems
  - ISO13485:2003

- For products
  - Essential principles (as interpreted by Standards)

Quality systems – ISO13485:2003

- ISO 13845:2003 - Medical devices. Quality management systems. Requirements for regulatory purposes
  - Follows format of ISO9001
  - Can omit Design Controls for lower risk products
- CABs do factory audits
  - Specifically include manufacturer post market surveillance and vigilance reporting processes

Products: Essential Principles

- EPs define the characteristics of a “safe” device
  - risks must be acceptable when weighed against benefits
- 6 general requirements
- 11 specific requirements
- manufacturers must address each one
- Manufacturers can choose use standards which are equivalent to the EPs

EPs: bottom line

- Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended …….
- …… they will not compromise the clinical condition or the safety of patients, or …. other persons,
- … any risks … acceptable when weighed against the benefits to the patient
- and are compatible with a high level of protection of health and safety.

Technical Documentation

- …. must include:
  - description including variants
  - drawings, manufacturing methods etc
  - results of risk analysis (EN 14971)
  - method of sterilisation
  - design calculations
  - proof of compatibility with other devices in necessary
  - test reports and clinical data if necessary
  - label and IFU

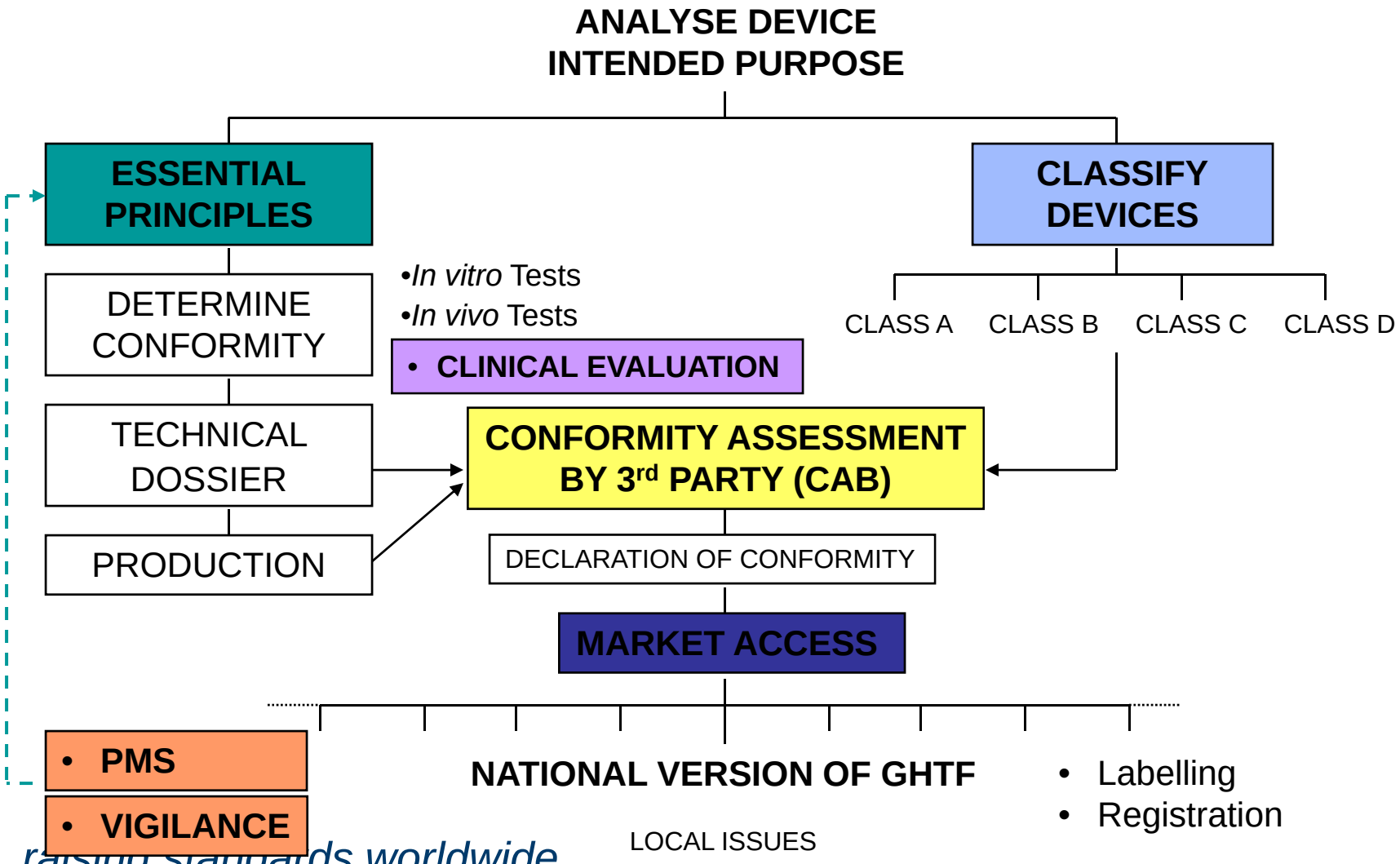
Summary Technical Documentation

- The STED is intended for conformity assessment purposes.
- The manufacturer creates the STED to demonstrate that the medical device is in conformity with the Essential Principles
- The STED can be a real or virtual set of documents, at the discretion of the manufacturer
  - Obviously, it must become “real” if used as a submission!

Design Dossier

- For high risk products, there is usually a separate examination of a “Design Dossier” which must:
  - describe the design, manufacture and performance of the product
  - include the documents needed for the Regulatory Authority or Conformity Assessment Body to assess whether the product conforms to the requirements

GHTF MODEL ….. leads to D of C

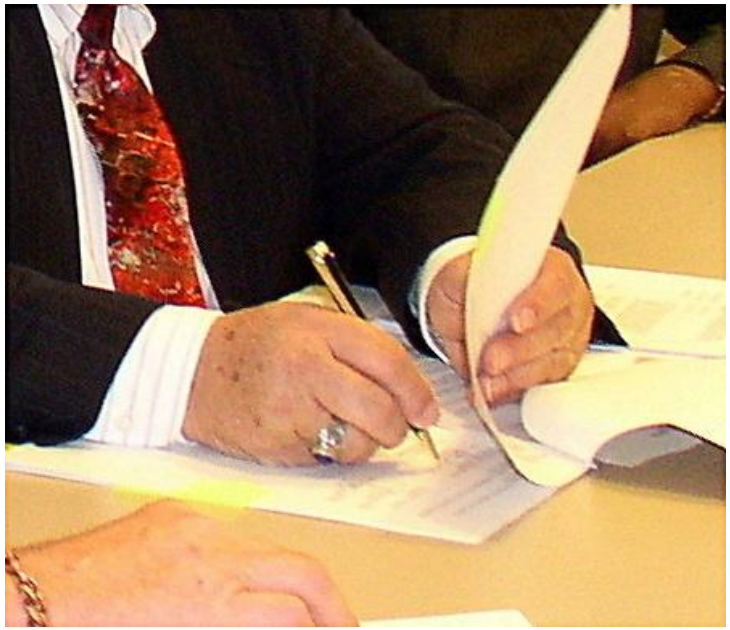


Declaration of conformity

- The manufacturer attests that the medical device complies fully with all applicable *Essential Principles for Safety and Performance ….*
- … and that all necessary conformity assessment activities are complete

Declaration of Conformity

Can be a legal document, signed by the responsible person who has been authorised on the manufacturer's behalf



Government or 3rd Party may review the Declaration of Conformity, and examine the supporting documents or evidence

Conformity Assessment Body role

- Provide 3rd Party conformity assessment services
- Usually excluded from market surveillance

- **Entire responsibility to produce a safe device remains with the manufacturer**

What do 3rd Parties do for each Risk Class?

What does the CAB check for Class A?

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What does the CAB check for Class B?

- QMS (ie ISO13485 with Design Exclusions)
  - Process control
  - Inspection and testing
  - Procedures for producing STED
    - In EU system, CABs check the actual Declarations of Conformity and STEDs on a sample basis only
- Post market surveillance and vigilance processes
- Technical evaluation of sterilisation process if applicable

What does the CAB check for Class C?

- ISO13485:2003
  - Complete QA system including design control
- Sample STED (in more depth than for Class B)
- Post market surveillance and vigilance processes
- Technical evaluation of sterilisation process if applicable

What does the CAB check for Class D?

- ISO13485:2003
  - QA system including design control
- Post market surveillance and vigilance
- Design Dossier scrutiny of each device
  - risk analysis
  - EPs addressed & relevant standards applied
  - manufacturer's solutions for each EP are checked
  - clinical data
  - Technical evaluation of sterilisation if applicable
- *(DD review can be replaced by Type Test)*

3rd Party conformity assessment

D. Manufacturing Control (including design) plus Design Dossier

C. Manufacturing Control (including design)

B. Manufacturing Control

A. Zero (manufacturer self-certifies compliance)

This talk will cover …….

- ✓ Overview
- ✓ 3rd Party Conformity Assessment
- **How can Governments complement the 3rd Party conformity assessment?**
  - **What is not covered by 3rd Parties?**
  - **Local and imported products**
  - **Registration**
  - **Market surveillance**
- Conclusion

What is not covered by 3rd Parties?

What is not covered by 3rd Parties?

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A. Lowest risk, no CAB involvement

B. Medium/Low risk

- Design process
- D of C or STED, except on a sample basis
- clinical data to justify status as a medical device or claims, except on a sample basis

What is not covered by 3rd Parties

C. Medium/High risk
- D of C, STED or clinical data for every product
- but much more is done than for Class B

D. High risk, CAB covers all aspects
- But even here, the final responsibility remains with the manufacturer

Government role?

- What do governments want?
  - Safe, cheap, state of the art medical devices
  - Strong, happy local industry
  - Healthy, happy consumers

- Often the medical device regulations are made under the Consumer Protection Laws
  - Enables surveillance and penalties to be included as for any other consumer product

- GHTF model contains provision for:
  - product registration
  - market surveillance
  - gives opportunities to complement the work of the CABS

Complementing the CAB - registration

- GHTF considers registration to be the most basic level of regulatory control
  - Identifies devices and responsible parties in the national market
  - Facilitates regulatory activity

- Regulatory Authorities can consider how much information they need to process a registration
  - eg Declaration of Conformity?
  - STED summary?

Complementing the CAB - surveillance

- GHTF has provision for Regulatory Authority audit post-market to investigate specific safety or regulatory concerns
  - can be pro-active or reactive

- Surveillance audits can cover
  - Is there clinical data to show that products meet claims?
  - Has the manufacturer classified his products properly?
  - Is the technical file complete?
  - Has the manufacturer registered all his products
  - Is he making appropriate vigilance reports?

Pro-active surveillance

- Objective is to create an “atmosphere of compliance” by sampling where there is no prior knowledge of the particular product or manufacturer, eg
  - Random sample – eg 2% of products registered
  - Targetted sample – eg 20% of products of a type which is a cause of concern

Reactive surveillance

- based on prior product knowledge, eg
  - Local user or manufacturer reports of adverse incidents
  - Recalls, advisories etc from overseas
    - FDA
    - ECRI
    - MHRA
  - Any other relevant information
- Registration system will allow assessment of relevance of overseas advisories to the local market

Local v Imported products

Locally produced	Imported into the Region
Emphasis on low risk	Range from low to high
Sometimes for local markets only	Available “worldwide”
Local manufacturers may not want FDA/EU conformity assessment	Will nearly always have FDA/EU conformity assessment – but there are gaps for Low Risk
Sometimes PMS is local market only	Subject to PMS in other countries

Government surveillance

- Benefits
  - creates an atmosphere of compliance
  - complements 3rd Party surveillance
  - especially useful for low risk products
  - can be used to help educate local industry

- Essential Principles and basic documentation and quality requirements are the same for all devices, regardless of classification
  - Manufacturers may need reminding of this ….

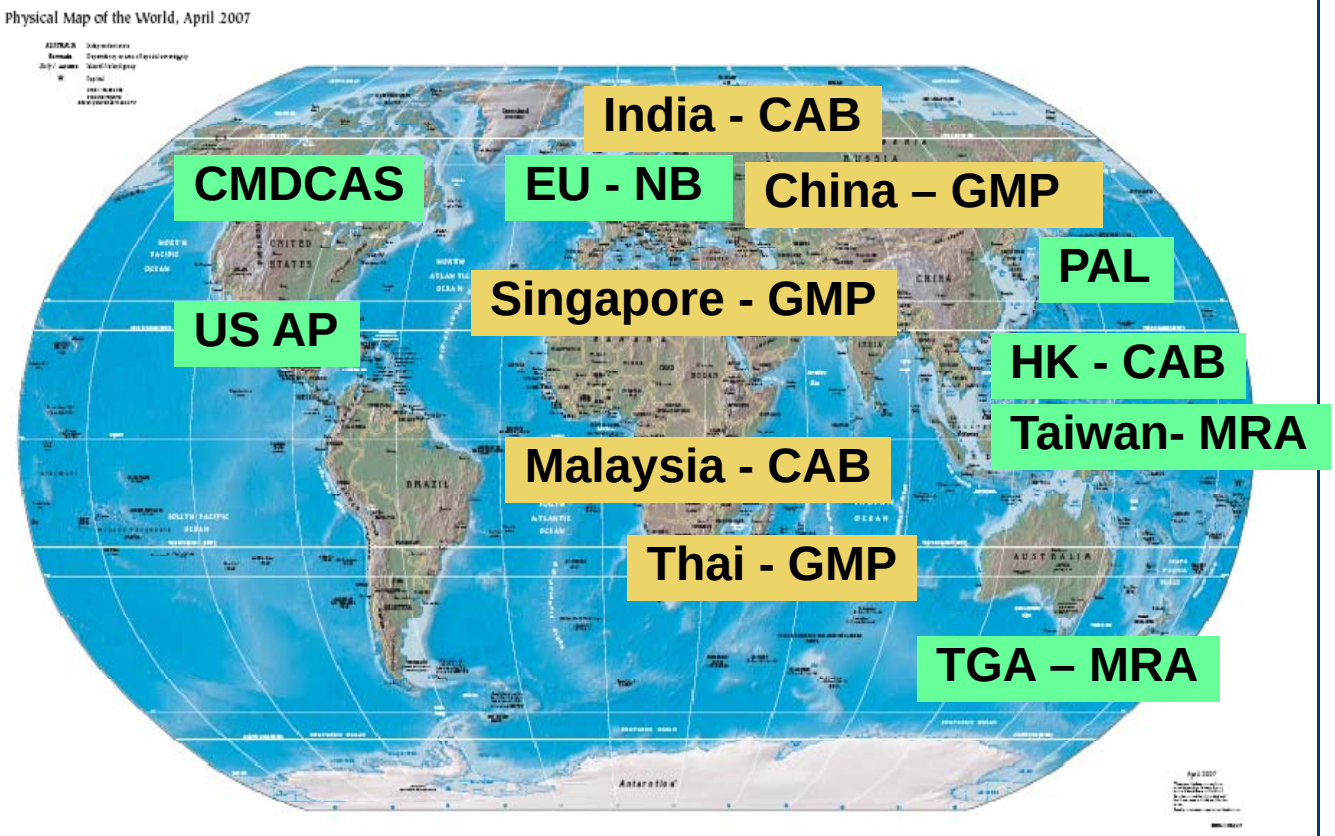
This talk has covered ….

- ✓ **Overview**
- ✓ **3rd Party Conformity Assessment**
- ✓ **How can Governments complement the 3rd Party conformity assessment?**
  - What is not covered by 3rd Parties?
  - Local and imported products
  - Registration
  - Market surveillance
- **Conclusion**

Conclusions on GHTF model

- Good but not perfect
- Requirements same for all devices but less CAB conformity assessment for Low risk
  - Manufacturers must do their part
- Regulatory Authority roles include
  - Registration schemes
  - Compliance regimes (proactive and reactive)
  - Post market surveillance
  - Monitoring recalls etc worldwide
- RAs need to create an atmosphere of compliance to complement the work of the CABs

Global Regulatory Trend - CAB



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