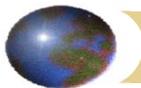


## *Global Medical Device Regulatory Overview*

Michael Flood  
Locus Consulting Pty Ltd  
Australia

*ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
March 27 - 28, 2014; San Francisco, California*

1



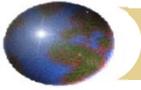
## *A little about me .....*

- Biomedical Engineer
- 40 years in the medical devices sector of Healthcare Industry
  - 8 years in commercial organisation – technical marketing and service engineering
  - 10 years public health sector – engineering services, asset acquisition and management
  - 18 years with TGA as the industry regulator
  - 4 Years as a consultant – Regulatory affairs & consulting engineering



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2



### Roles within the TGA .....

Manager, Postmarket Incident Report & Investigation Scheme (IRIS)

- Member GHTF SG 2 – Postmarket – 1996 – 1999

Manager, Device Registration and Assessment Section

- Member GHTF SG 1 – Premarket – 2000 – 2009

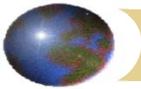
Director, Application Entry & Co-ordination

- IT systems development
- Represented GHTF on GMDN – 2000 – 2008

Policy Advisor, Office of Devices, Blood & Tissues

- Regulatory reform
  - Re-classification of devices
  - Conformity assessment activities
  - Health Technology Assessment Taskforce
  - E-health
  - Device & patient tracking

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### Other Activities

Standards Australia

- Health & Food Sector Standards Board
- Medical Electrical Equipment standards
- Medical Gas Systems standards
- Conformance marking
- Human Exposure to EME
- Medical Records

Engineers Australia

- Chairman, College of Biomedical Engineers (two terms)
- Board of Engineering Practice
- National Engineering Registration Board
- Appeals Board – Immigration Qualification Assessment

Adjunct Lecturer – ANU – Biomedical Engineering

Visiting Lecturer – several universities – regulatory affairs

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## Why regulate .....

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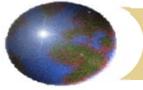
## Why Regulate .....

### **Bjork Shiley Concavo-convex Prosthetic Heart Valve**

- ~86,000 implanted world wide
- ~900 implanted in Australia
- Multiple deaths recorded as a direct result of valve failure



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## Why regulate

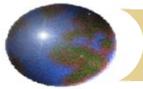
✦ To –

..... Provide for the establishment and maintenance of a national systems of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are;

- used in Australia, whether produced in Australia or elsewhere; or
- exported from Australia

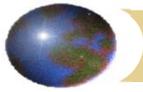
[Section 4(1) Therapeutic Goods Act 1989]

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## What to regulate .....

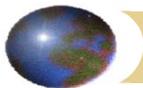
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## *Medical device ..... A definition*

- ❖ What is a medical device .....
- ❖ ..... And what is not a medical device !!
- ❖ Including IVD's

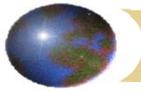
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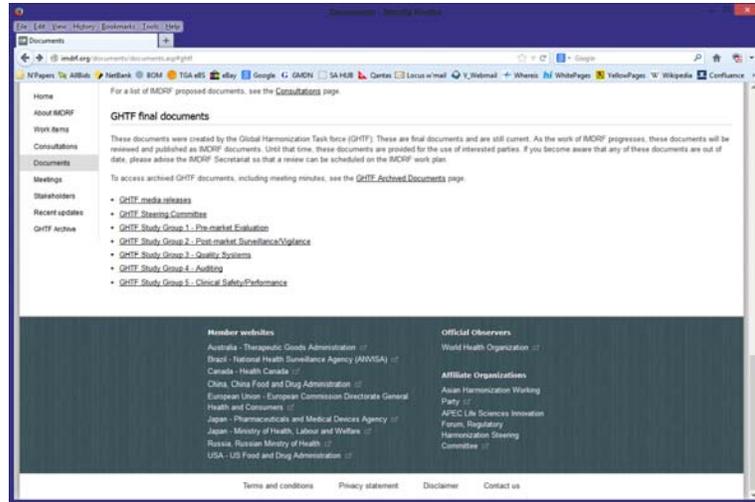
## *Medical device ..... A definition*

- ❖ SG 1 N29 R16 – 2005 - *Information Document Concerning the Definition of the Term "Medical Device"*
- ❖ What is regulated
- ❖ Who is regulated
  - Manufacturer
  - Agent
  - Distributor
- ❖ Most important is assessment regulatory path for new and emerging 'borderline' technologies

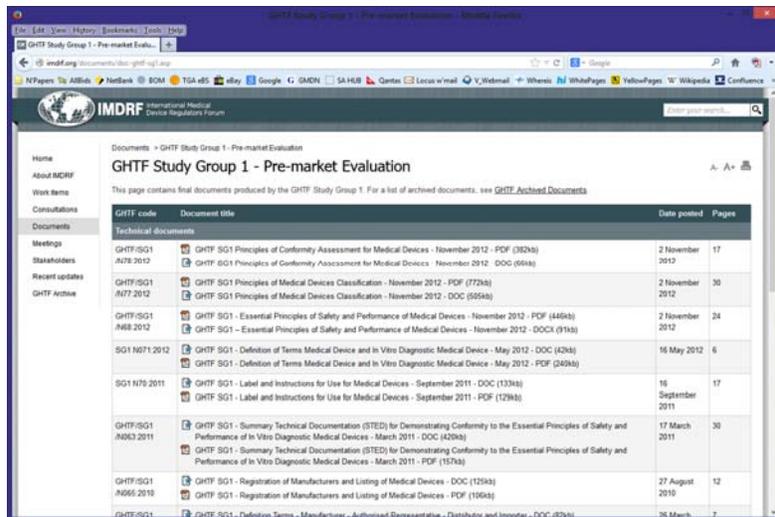
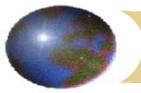
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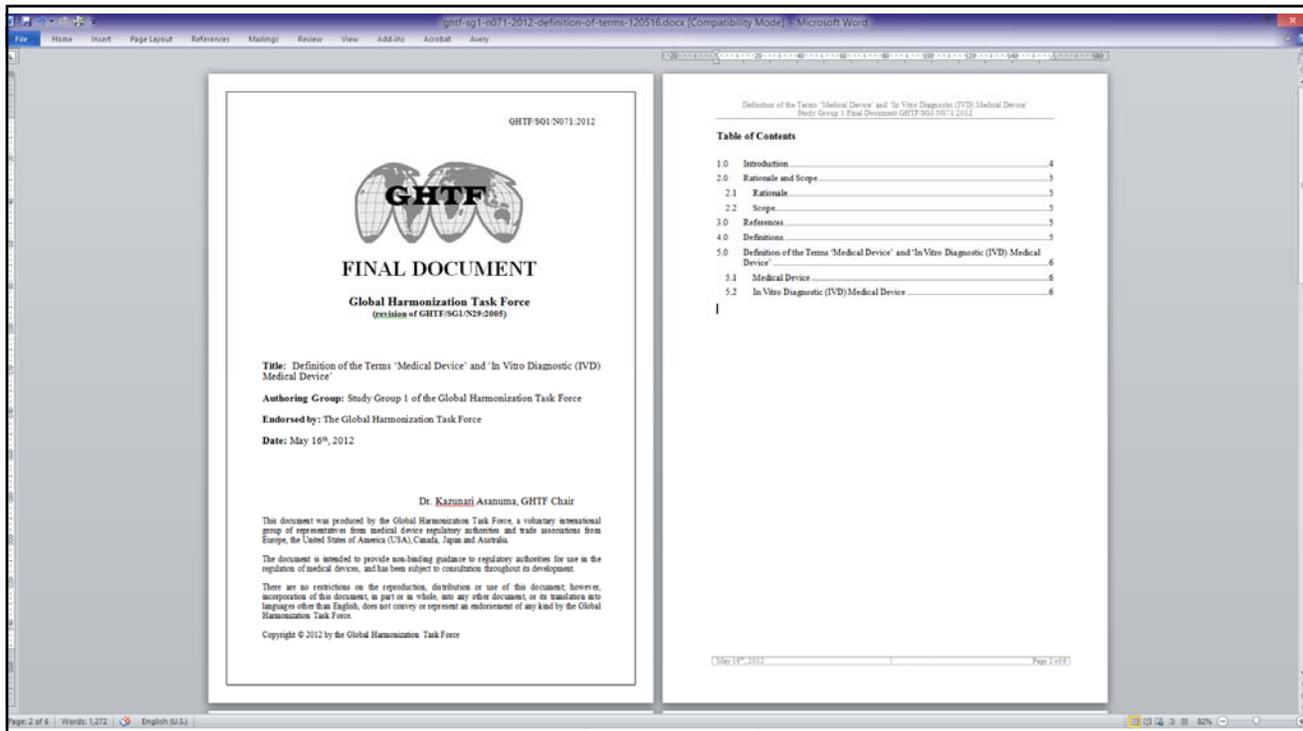
www.imdrf.org



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## Rationale for guidance

- ❑ Consistent harmonised definition of term "medical device" for use in global regulatory model
  - Benefits to manufacturer, user, patient, regulatory authorities
- ❑ Support global convergence of regulatory systems
- ❑ Eliminating differences allows patients earlier access to new technologies and reduces costs of regulatory compliance



## Scope of guidance

- ✦ .....to provide harmonized definitions of the terms 'medical device' and 'In Vitro Diagnostic (IVD) medical device'. These terms appear in guidance documents published by the Global Harmonization Task Force.
- ✦ Adopting the definitions from this document will allow a Regulatory Authority to identify the products subject to medical device regulatory controls.
- ✦ This document is intended to serve as guidance for Regulatory Authorities, Conformity Assessment Bodies and the regulated Industry.

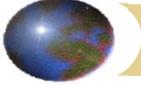
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'**Medical device**' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- ✦ intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  - investigation, replacement, modification, or support of the anatomy or of a physiological process,
  - supporting or sustaining life,
  - control of conception,
  - disinfection of medical devices,
  - providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;
- and
- ✦ which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

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- ✦ **'In Vitro Diagnostic (IVD) medical device'** means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
- ✦ **Note 1:** IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.
- ✦ **Note2:** In some jurisdictions, certain IVD medical devices may be covered by other regulations.

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17

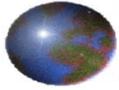


#### **NOTE -**

Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices,
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

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## Definition – Canada

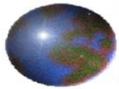
"... means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in

- (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- (b) restoring, correcting or modifying a body function or the body structure of human beings or animals,
- (c) the diagnosis of pregnancy in human beings or animals, or
- (d) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring,

and includes a contraceptive device but does not include a drug;

Source: Canada Food and Drugs Act, F27 (as amended)

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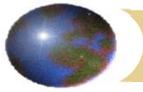
## Definition – Europe

"... any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- ❖ diagnosis, prevention, monitoring, treatment or alleviation of disease,
- ❖ diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- ❖ Investigation, replacement or modification of the anatomy or of a physiological process,
- ❖ control of conception, ....

Source: European Union Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC (5 September 2007)

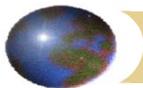
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## Definition – Europe

“... and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;”

Source: IFA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
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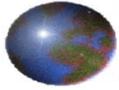


## Definition – Europe

“An **In-vitro Diagnostic** is any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures”

Source: IFA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
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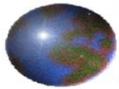


## Definition – Europe

“Specimen receptacles are considered to be *in vitro* diagnostic medical devices. ‘Specimen receptacles’ are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination”

Source: ITA-FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
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## Definition – Japan

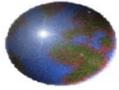
(定義) 第2条

4. この法律で「医療機器」とは、人若しくは動物の疾病の診断、治療若しくは予防に 使用されること、又は人若しくは動物の身体の構造若しくは機能に影響を及ぼすことが目的とされている機械器具等であつて、政令で定めるものをいう。

“equipments, instruments etc. specified by the government ordinance which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals, or intended to affect the structure and functions of the human or animal body”

Source: The Pharmaceutical Affairs Law; Law No. 145, dated Aug. 10, 1960, as amended by Law No. 73, dated June 11, 2003  
(unofficial translation)

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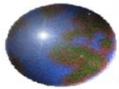


## Definition – USA

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- ✦ recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- ✦ intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- ✦ intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Source: FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
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### In-vitro Diagnostic

"... those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease of its sequelae.

Such products are intended for use in the collection, preparation, and examination of specimen taken from the human body.

These products are devices as defined in [the FD&C Act] and may also be biological products subject to ... the Public Health Service Act"

Source: FDA Medical Devices Regulatory Capacity Building Training Program for International Medical Devices Regulators  
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## Definition – Australia

“... any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

- ❖ diagnosis, prevention, monitoring, treatment or alleviation of disease;
- ❖ diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- ❖ investigation, replacement or modification of the anatomy or of a physiological process;
- ❖ control of conception; ...

Source: Australia Therapeutic Goods Act, 1989 (as amended) (at: <http://www.tga.gov.au/devices/whatis.htm> )

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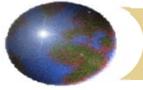


## Definition – Australia

“... and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

an accessory to such an instrument, apparatus, appliance, material or other article.”

Source: Australia Therapeutic Goods Act, 1989 (as amended) (at: <http://www.tga.gov.au/devices/whatis.htm> )  
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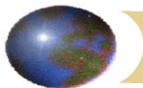
## Definition – Australia

For the purposes of paragraph (1)(a), the purpose for which an instrument, apparatus, appliance, material or other article (the **main equipment**) is to be used is to be ascertained from the information supplied, by the person under whose name the main equipment is or is to be supplied, on or in any one or more of the following:

- (a) the labelling on the main equipment;
- (b) the instructions for using the main equipment;
- (c) any advertising material relating to the main equipment;
- (d) technical documentation describing the mechanism of action of the main equipment.

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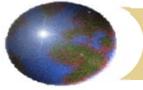
29



## Interesting words .....

- ❖ *which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means – **GHTF***
- ❖ *and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means – **Australia***
- ❖ *but does not include a drug – **Canada***
- ❖ *and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means – **Europe***
- ❖ *and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes – **US***

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## Four concepts

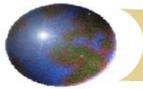
### ✦ Pharmacological means

- .... understood as an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect (EU MEDDEV)

### ✦ Immunological means

- .... understood as an action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction (EU MEDDEV)

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## Four concepts

### ✦ Metabolic means

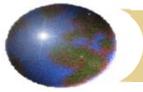
- understood as an action which involves an alternation, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function

*Note: The fact that a product is, or is not, itself metabolised does not imply that it achieves, or does not achieve, its principal intended action by metabolic means (EU MEDDEV)*

### ✦ Chemical Action

- No regulatory definition by any regulatory organisation
- Any chemical process in which substances are changed into different ones, with different properties, as distinct from changing position or form (phase) (Britannica)

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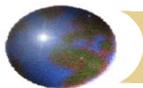


## Four concepts

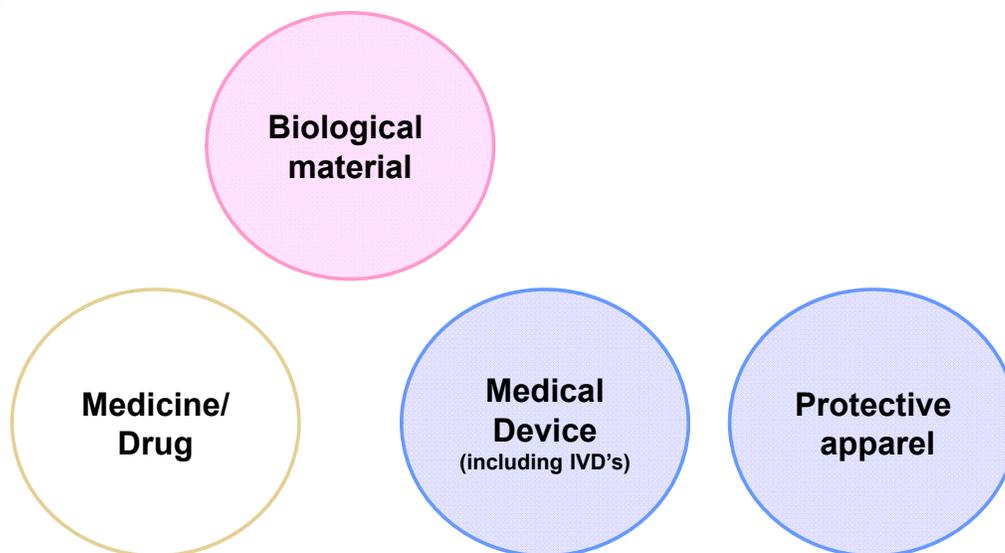
- ✦ All define the action of a medicine
- ✦ Used to exclude medicines from the definition of a medical device
- ✦ However
  - ✦ .... *but which may be assisted in its intended function by such means*

..... Combination products !!

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## Converging technologies



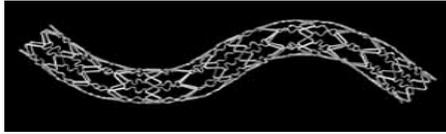
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34



## Primary intended mode of action

### Drug eluting stent



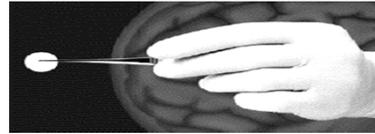
- Primary intended mode of action
  - stent opens artery
- Secondary action
  - drug reduces inflammation and restenosis of artery

➤ Regulated as a device

Source: S. Alpert, M.D., PhD. (Medtronic, Inc.); Asian Harmonization Working Party, Seoul, Sept. 2006 (adapted)

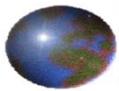
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### Drug eluting disc



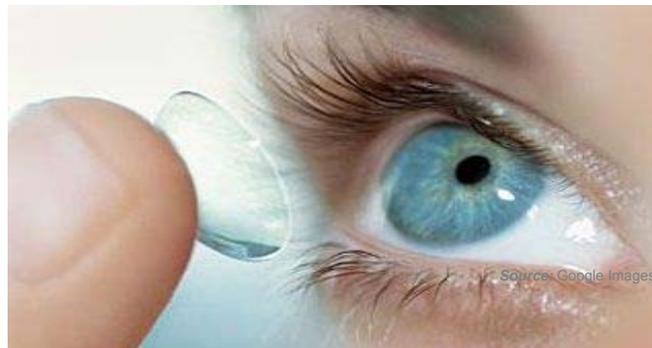
- Primary intended mode of action
  - chemotherapy for brain tumour
- Secondary action
  - local delivery of drug by device

➤ Regulated as a medicine



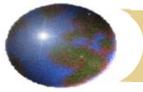
## Exercises

Is a contact lens a medical device?



Source: Google Images

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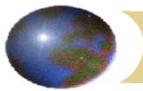


## Exercises

Is a contact lens **still** a medical device?



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## Exercises

Is a steam steriliser a medical device?



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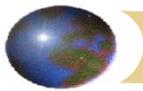
## Exercises

Is a syringe a medical device?



images

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## Exercises

Is a pre-filled syringe a medical device?



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## Exercises

Is computer software a medical device?



..... It depends.... !!

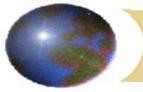
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## Conclusions

- ❖ Definition of “medical device” is essential in defining “border lines” between regulated products and systems
- ❖ Demarcation lines may be subtle
  - Guidance documents are important
- ❖ Definition turns on primary intended mode of action
- ❖ Determination depends on manufacturer claims
  - Justified and consistent with scientific evidence
- ❖ Determines regulatory framework and requirements
- ❖ Opportunity for international harmonisation

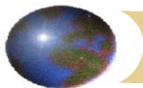
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## *How to regulate .....*

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43



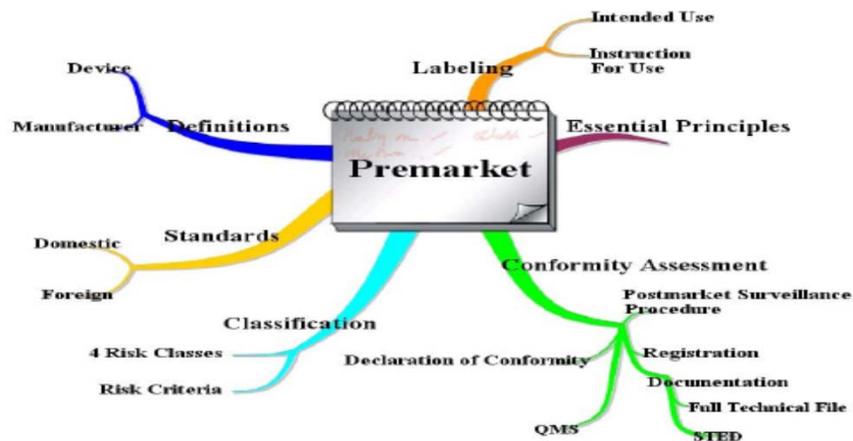
## *The Global Model*

- ✦ Published by the GHTF as a Final Document in April 2011
- ✦ Intended to link the work of the Study Groups into a cohesive framework
- ✦ Based on product life cycle

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## Pre-Market Requirements - The Global Regulatory Model



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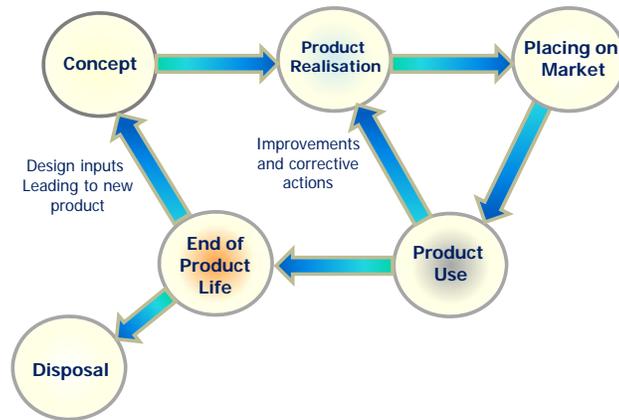
## Pre-Market Requirements - The Global Regulatory Model

- ✦ Clear Roles & Responsibilities
  - ❑ Manufacturer
  - ❑ Importer
  - ❑ Regulator
- ✦ Conformity Assessment
  - ❑ Essential principles
  - ❑ Classification
  - ❑ Technical File review
  - ❑ Quality Management Systems
- ✦ Registration of entity responsible for placing the product on the market
  - ❑ Manufacturer
  - ❑ Sponsor
- ✦ Inclusion on a Register
  - ❑ Responsible Entities
  - ❑ Medical Devices
- ✦ Post-production phase monitoring of device performance

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# Medical Device Life Cycle



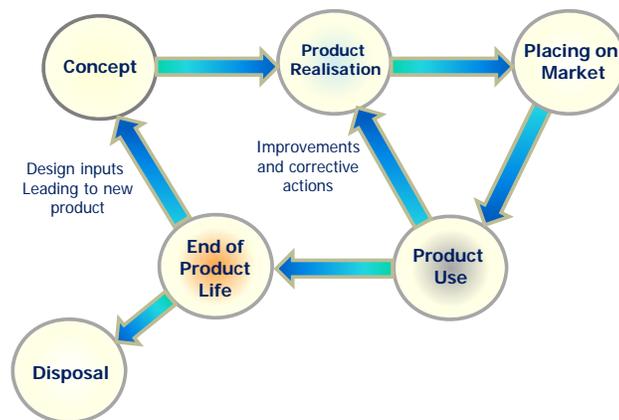
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# Life Cycle with regulatory aspects included

Auditing practice

Quality Management Systems & Risk Management



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## *Life Cycle with applied processes*

### Compliance Audit – by Conformity Assessment Body or the Manufacturer

#### Quality Management Systems & Risk Management by the manufacturer

##### Premarket Classification & Conformity Assessment

- ✓ Essential Principles
- ✓ Use of Standards
- ✓ Design inputs
- ✓ Design control
- ✓ Design –
  - ✓ Verification
  - ✓ Validation
- ✓ Clinical Evidence
- ✓ Summary Technical Documentation
- ✓ Declaration of Conformity

##### Placing on the market

- ✓ Registration
  - ✓ Entities
- ✓ Listing
  - ✓ Products

##### Postmarket Surveillance/ Vigilance

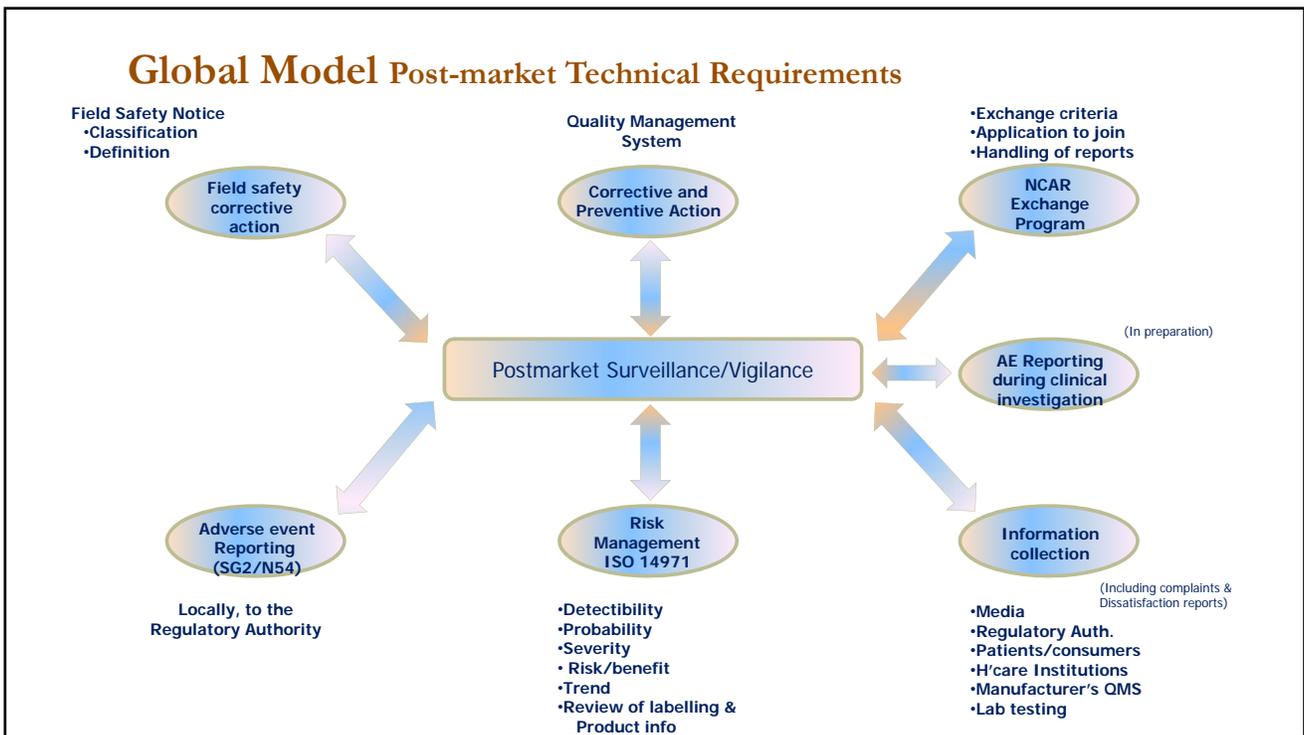
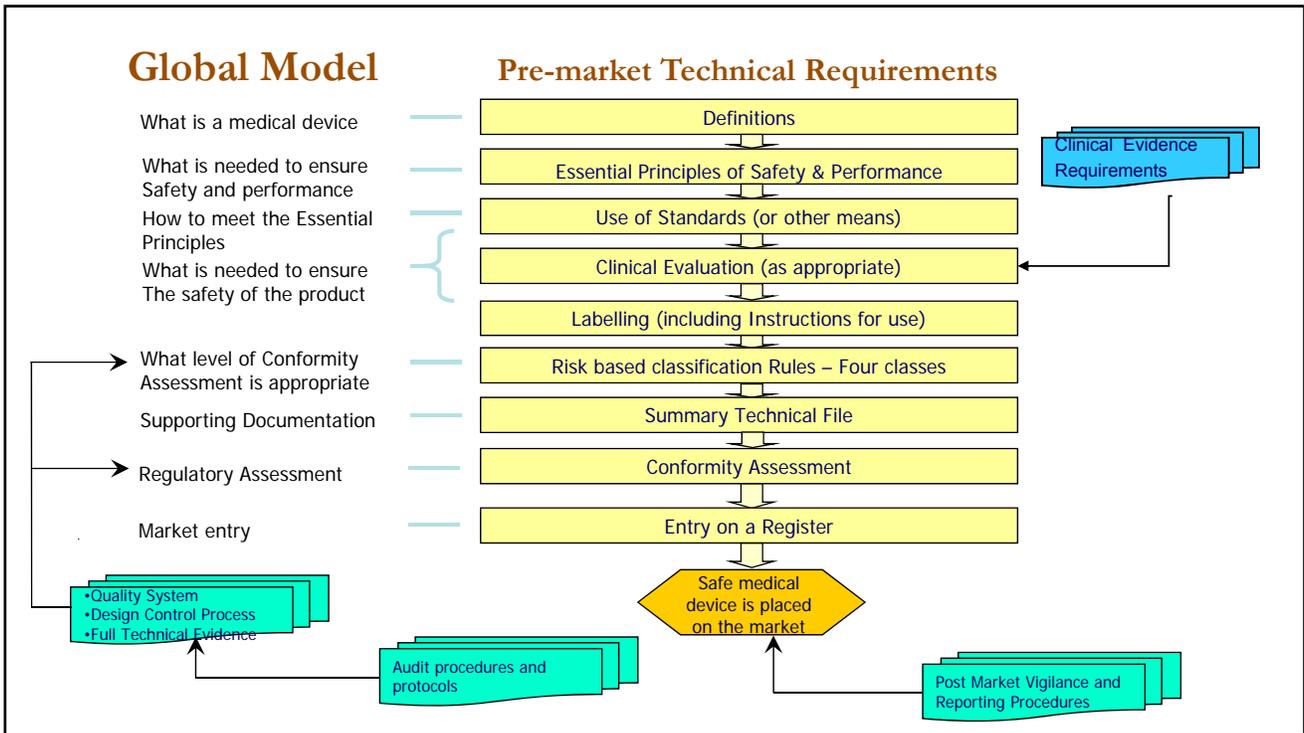
- ✓ Adverse event reporting
- ✓ Complaint management
- ✓ Maintenance & Service
- ✓ Corrective and preventive actions
- ✓ Postmarket Clinical Follow-up

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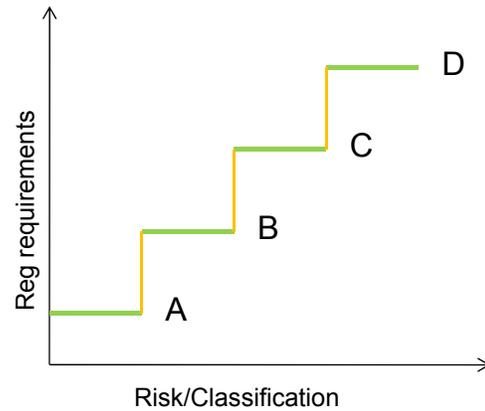
## *But how do these inter-relate .....*

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# Regulatory Controls

- ✦ Operation of a QMS
- ✦ 'Depth' of technical data
- ✦ Product testing using in-house or independent resources
- ✦ Clinical evidence
- ✦ Independent external review of manufacturer's data



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# Classification Categories

## Global Model

	Australia	Canada	Europe	Japan	USA
✦ Class A ▣ Low risk	I, Im or Is	I	I, Im or Is	I	I
✦ Class B ▣ Low – moderate risk	IIa	II	IIa	II	II
✦ Class C ▣ Moderate – high risk	IIb	III	IIb	III	III
✦ Class D ▣ Highest risk	III/AIMD	IV	III	IV	

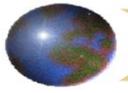
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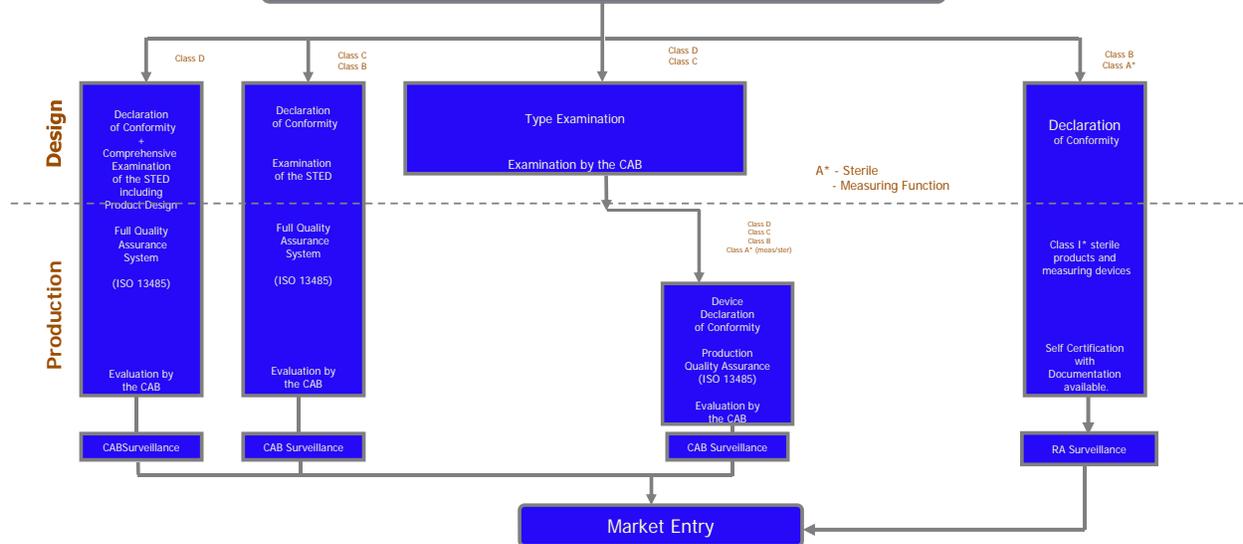
## Essential Principles of Safety and Performance

- ✦ Australia – 14 Essential Principals
- ✦ Europe – 16 Essential Requirements
- ✦ Canada – 13 Safety & Effectiveness Requirements
- ✦ Japan - ? Essential Principals
  
- ✦ All based on principles of the Global model

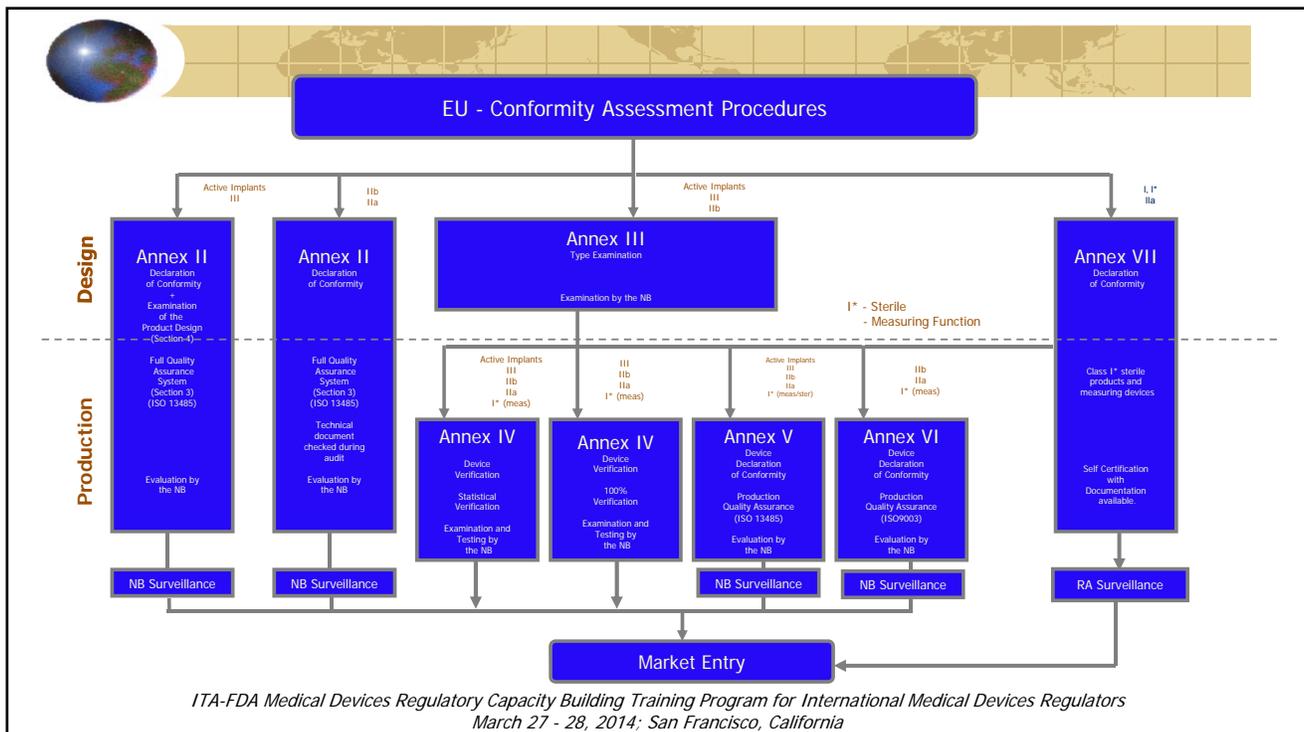
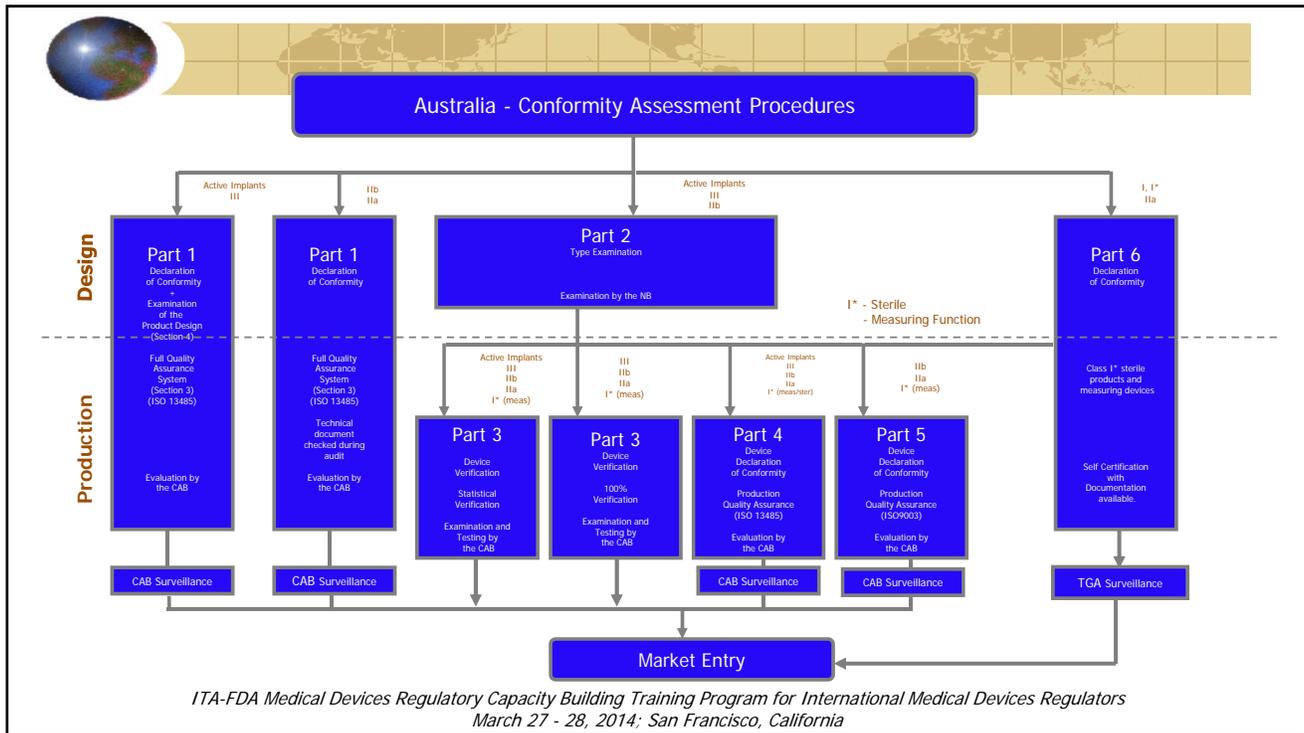
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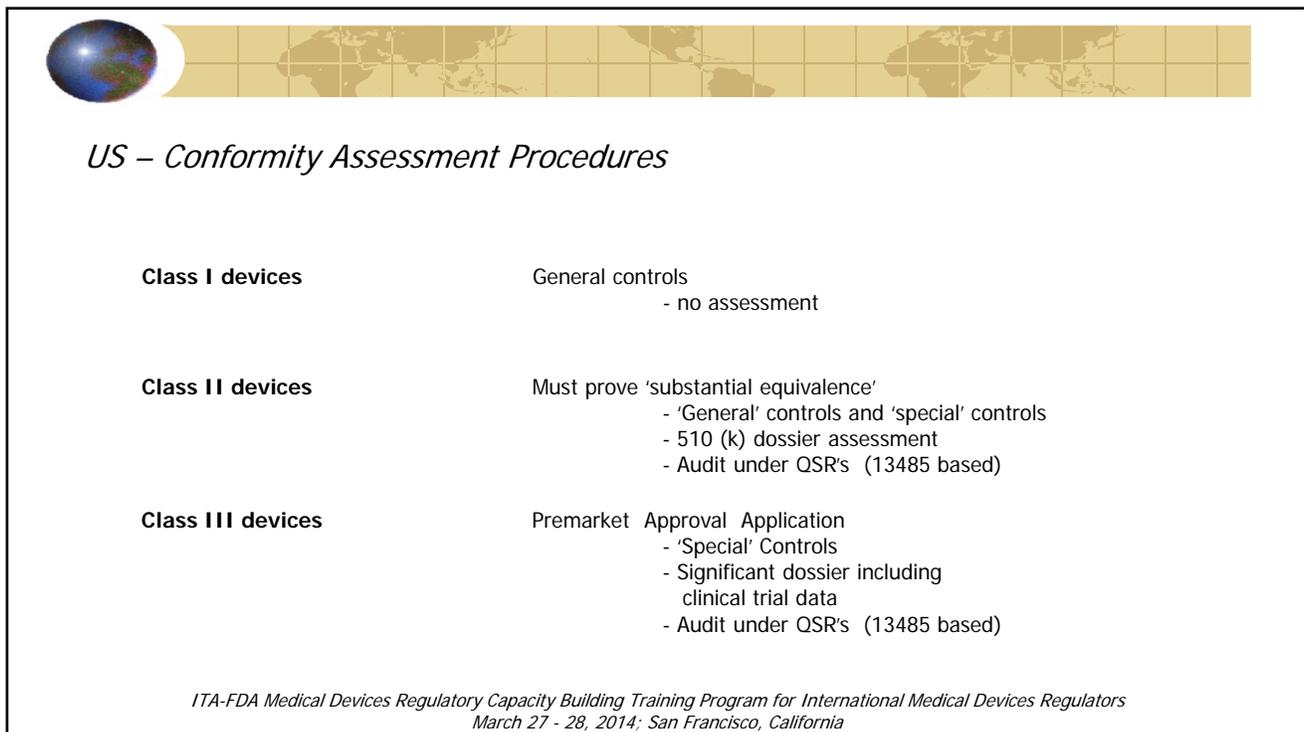
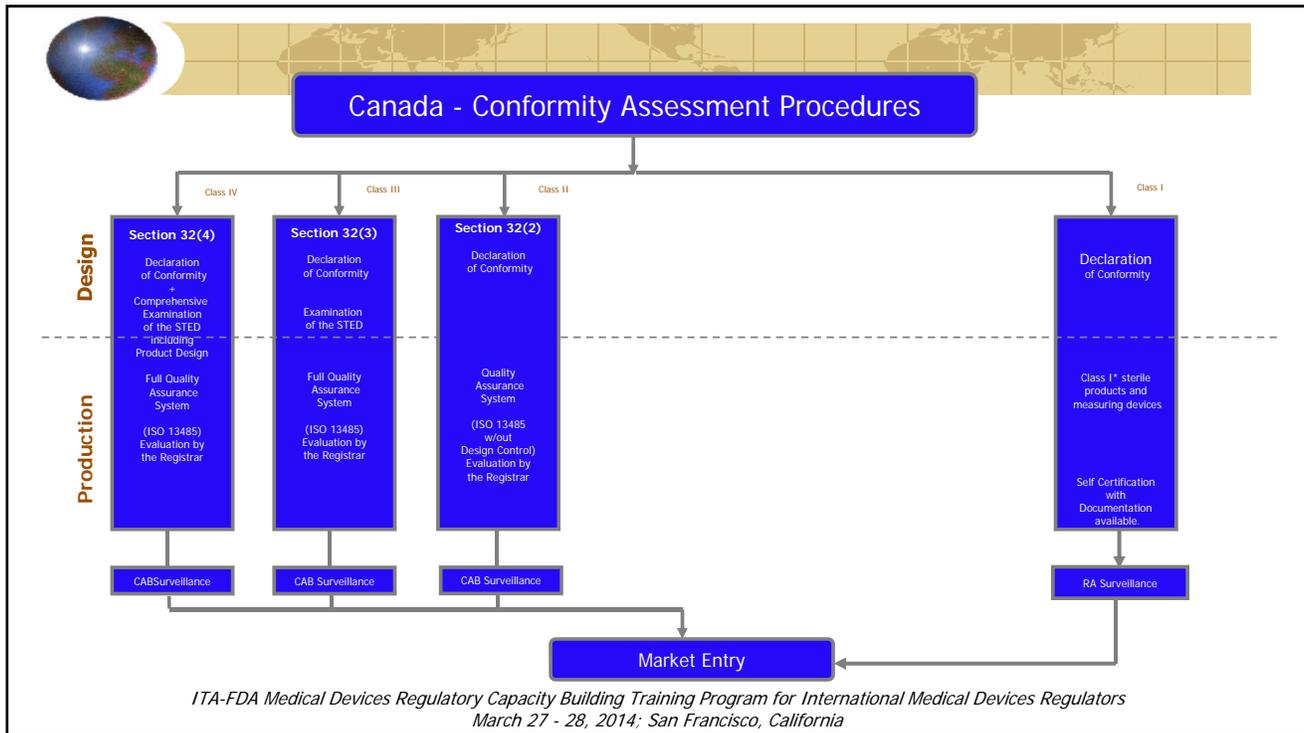


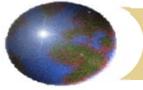
### Global Model - Conformity Assessment Procedures



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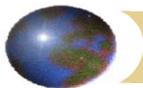


## Conformity Assessment Bodies

### ✦ Europe

- ✦ ~ 75 Notified Bodies
- ✦ Designated by one of the 27 Regulatory Authority's
- ✦ Some NB's restricted to specific categories/types of devices
- ✦ Variable levels of expertise or performance
- ✦ Regulatory decision for marketing approval is made by the NB, not the regulatory authority

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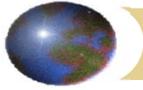


## Conformity Assessment Bodies

### ✦ Canada

- ✦ 12 Registrars, assessed and approved by Standards Council of Canada on behalf of Health Canada
- ✦ Registrar assesses only the QMS of the manufacturer for class II, III and IV devices
- ✦ Health Canada assesses the product for compliance
- ✦ Regulatory decision for marketing approval is made by Health Canada

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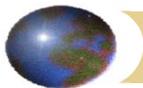


## Conformity Assessment Bodies

### ✦ Japan

- ✦ 12 Registered Certification Bodies
- ✦ Assess class II devices for which a Japanese Standard exists (~45%)
- ✦ Pharmaceutical and Medical Devices Agency assesses balance of Class II, and Class III and IV devices
- ✦ Certification Body provides a report to PMDA
- ✦ Regulatory decision for marketing approval is made by PMDA

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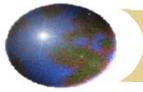


## Conformity Assessment Bodies

### ✦ USA

- ✦ 16 Accredited Persons (organisation) accepted by the FDA
- ✦ Assess the QMS and product for designated class II devices (implants and life sustaining class II's excluded)
- ✦ All other devices, and associated QMS of the manufacturer, assessed by the FDA
- ✦ Regulatory decision for marketing approval is made by the FDA

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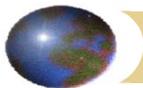


## Conformity Assessment Bodies

### ✦ Australia

- ✦ TGA issues Conformity Assessment Certificates for
  - Animal origin materials which has been rendered non-viable
  - Materials of microbial or recombinant origin
  - Incorporating stable derivatives of human blood or plasma acting ancillary to the action of the device
  - Incorporating a medicinal substance acting ancillary to the action of the device
  - **OR** are manufactured in Australia
- ✦ Changes are coming .....
- ✦ But accepts EC certificates issued by EU NB's, for all other devices
- ✦ Regulatory decision for marketing approval is made by the TGA

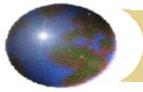
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## Labelling

- ✦ Australia
- ✦ Europe
- ✦ Canada
- ✦ Japan
  - All based on GHTF Labelling guidance  
(with language specific requirements)
- ✦ United States
  - Device Specific ( 21CFR 801,809,812 and in guidance)

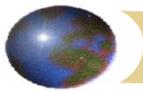
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## *Bringing it all together .....*

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67

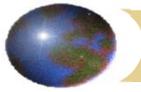


## *MRA's, MOU's .....*

### ✦ Australia has two Mutual Recognition Agreements

- ✦ European Community
  - Undefined ( ?? 17 or 27 member states)
- ✦ EFTA
  - Republic of Ireland
  - Principality of Lichtenstein
  - Kingdom of Norway
    - NOTE – Switzerland not included,  
as it joined EFTA only in 1999

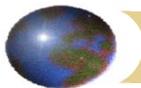
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## AU – EC MRA

- ✦ Has Country-to-country Treaty status
- ✦ Recognizes the ability of designated CAB's in each jurisdiction to assess compliance of medical devices for marketing in the other jurisdiction
- ✦ Usually contain 'Country of Origin' clause
  - ✦ Can only be utilised for product manufactured in originating jurisdiction
    - For example
      - EU CAB can only assess product originating in EU or EFTA States
      - Australian CAB (TGA) can only assess product originating in Australia or New Zealand

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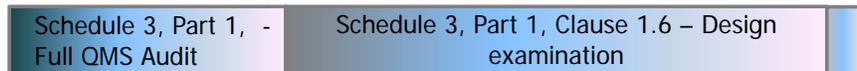


## AU – EC MRA ..... But what does it mean

- ✦ For an Australian manufacturer of a class III medical device
  - ✦ Assessment by the TGA
    - Schedule 3, Part 1, - Full QMS Audit
    - Schedule 3, Part 1, Clause 1.6 – Design examination

'Top-up' assessment of differences between TG Reg's and EU MDD

Assessment for market entry in Australia



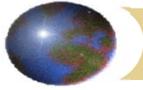
Assessment for market entry in Europe

A\$26,800

A\$52,700

~A\$3,300

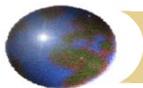
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## *MRA's, MOU's .....*

- ✦ Australia has one MoU
  - ✦ Canada
    - Assessment of Quality Management Systems

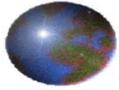
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## *AU – Canada MoU*

- ✦ Has Agency to Agency Agreement status
- ✦ Recognizes the ability of designated CAB's in each jurisdiction to assess compliance of medical devices for marketing in the other jurisdiction
- ✦ 'Country of Origin' clause
  - ✦ Can only be utilised for QMS for product manufactured in originating jurisdiction
    - Canadian Registrar can only assess QMS for product originating in Canada
    - TGA can only assess product QMS for product originating in Australia or New Zealand

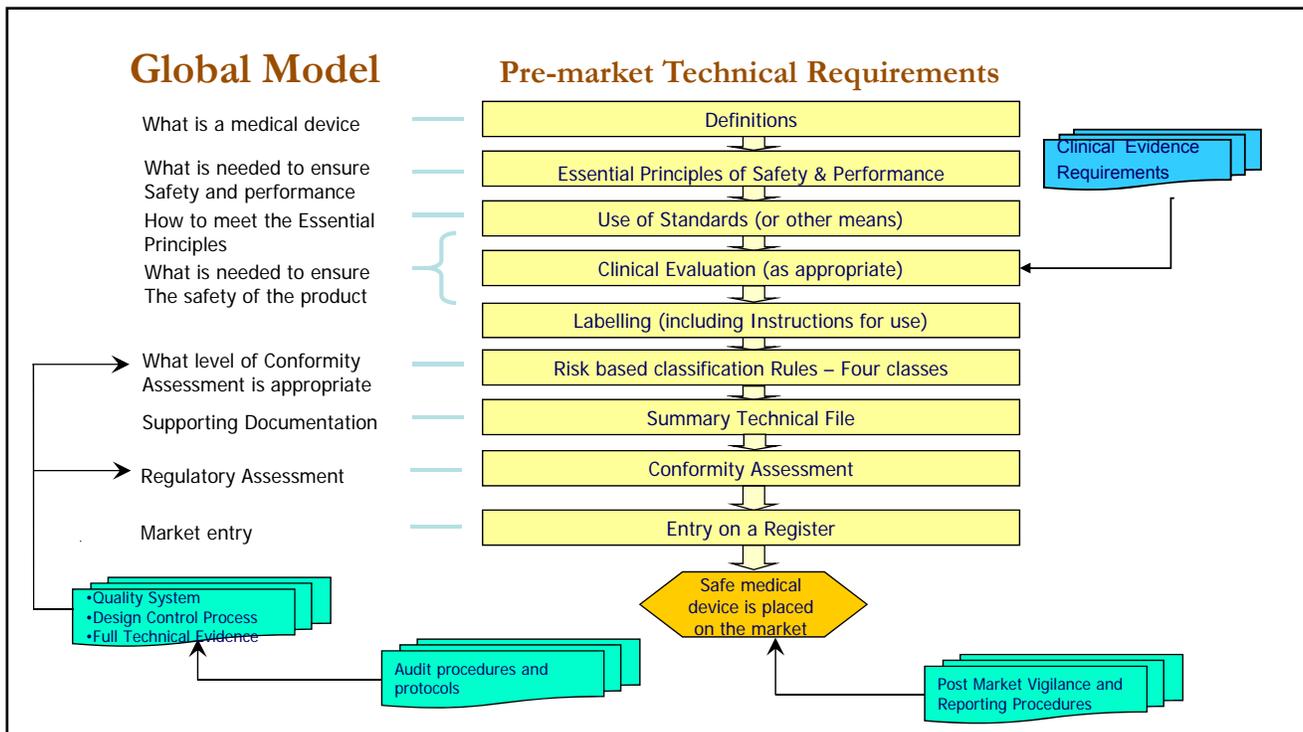
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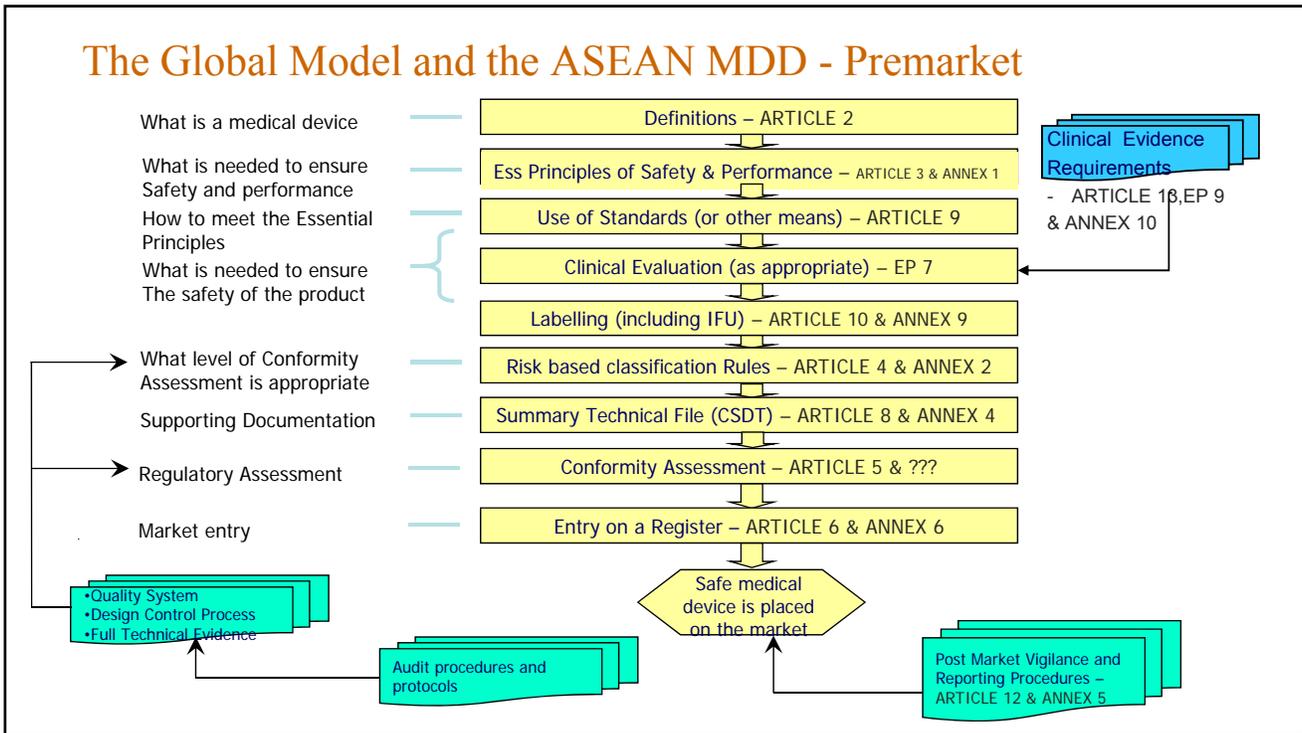


## But what about the rest of the World .....

- ✦ Association of South East Asian Nations (ASEAN)
  - ASEAN Medical Device Directive
  - GHTF based
  - Implemented by 2015 !
- ✦ Asian Harmonisation Working Party (AHWP)
  - Asian 'mirror' of GHTF
  - Very Broad membership
- ✦ Latin American Harmonisation Working Party (LAHWP)
  - Continental South America
  - Varying degrees of progress
  - GHTF based
- ✦ Arabian Harmonisation Working Party (AHWP ?)
  - Formative stages
  - Led by Saudi FDA
  - Saudi Arabia well advanced .... and progressing rapidly

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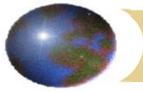




## The future .....

### IMDRF

- ❖ Medical Device Single Audit Program
  - Trial about to commence
  - Designated audit organisation
  - Single audit .....accepted by all regulators
- ❖ Regulated Submission Table of Contents
  - DRAFT Form at present
  - Replacement (??) for GHTF STED (AHWP CSTD)

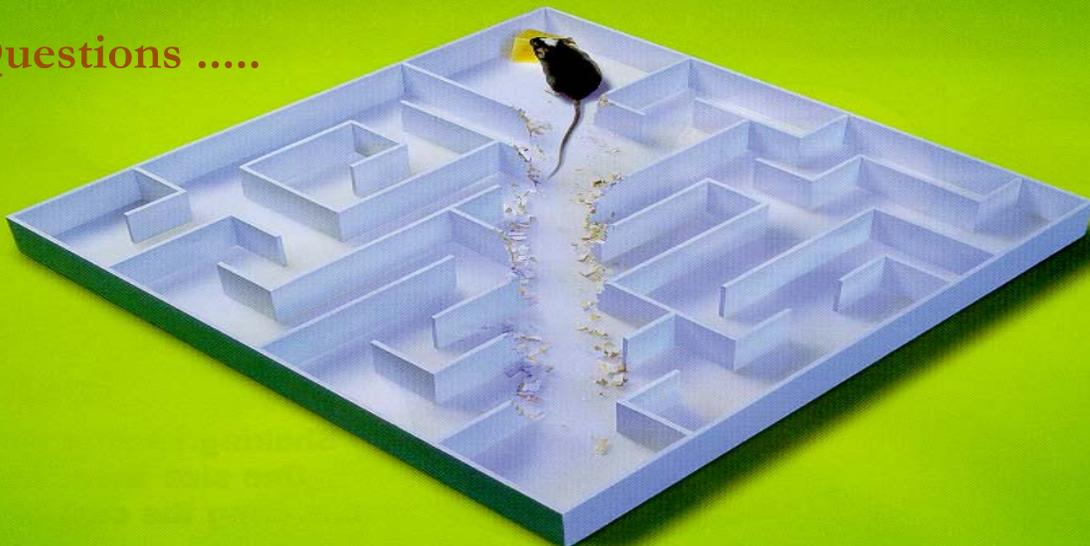


## *In conclusion*

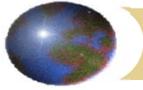
- ✦ Regulatory frameworks of Australia, Canada, Europe and Japan are closely aligned with the Global Model and with each other
- ✦ The US talks of 'convergence' rather than 'harmonisation', none-the-less, the US is adopting GHTF principles where it can
- ✦ The Global Model is in varying stages of adoption in many jurisdictions around the world
- ✦ Ultimately, MRA's and MoU's will be needed to 'stitch' these harmonised frameworks together
- ✦ There are still some differences ..... but convergence continues with the work of the IMDRF

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## Questions .....



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*Thank you .....*

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