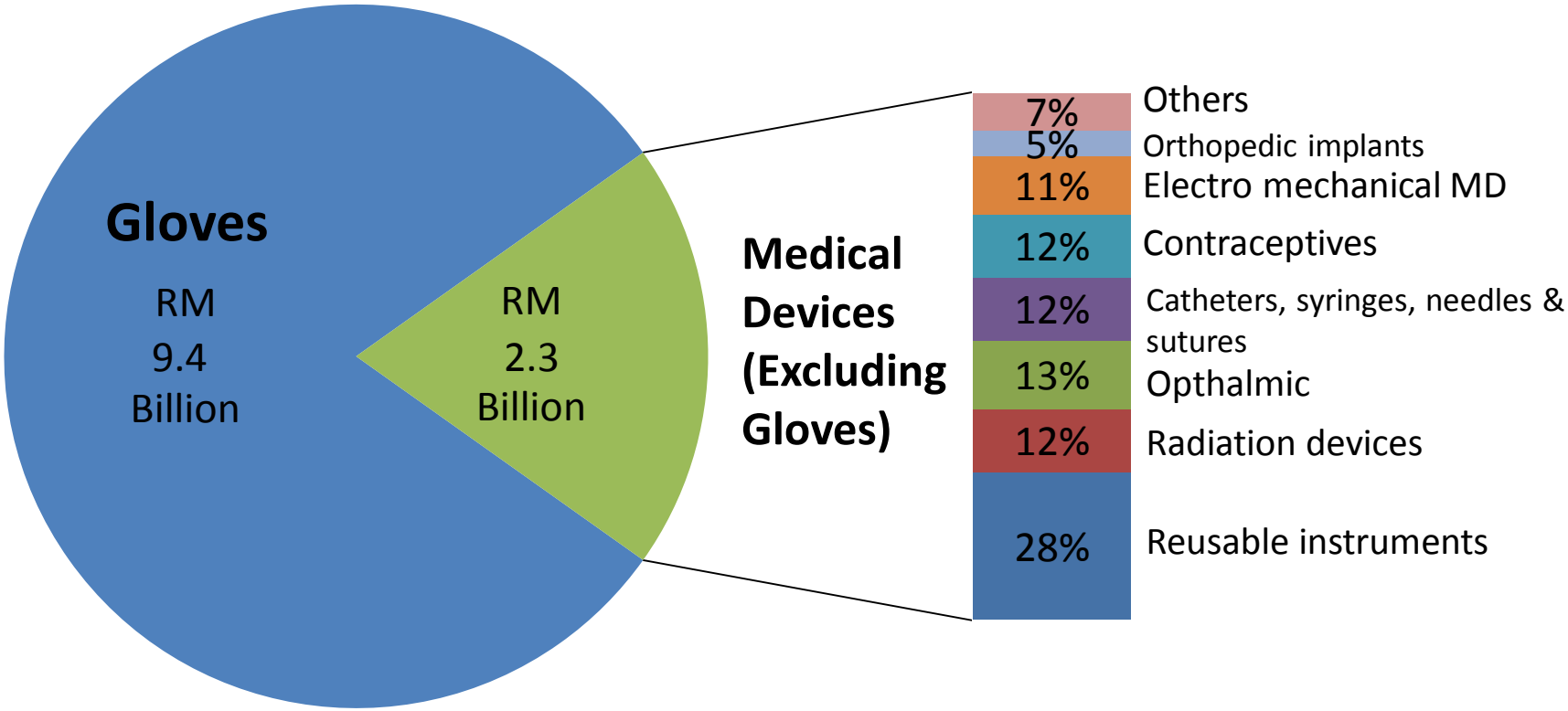
Regulation Of Medical Devices in Malaysia

National Regulatory Conference , May 2013

Malaysian Market

- Malaysia currently imports around 95% of the medical device for its consumption
- In Malaysia, the medical device industry is a highly diversified industry that produces a broad range of products and equipment ranging from medical gloves, implantable devices, orthopaedic devices and dialysers to diagnostic imaging equipment and minimal invasive surgical equipment and other devices which can be used for medical, surgical, dental, optical and general health purpose.

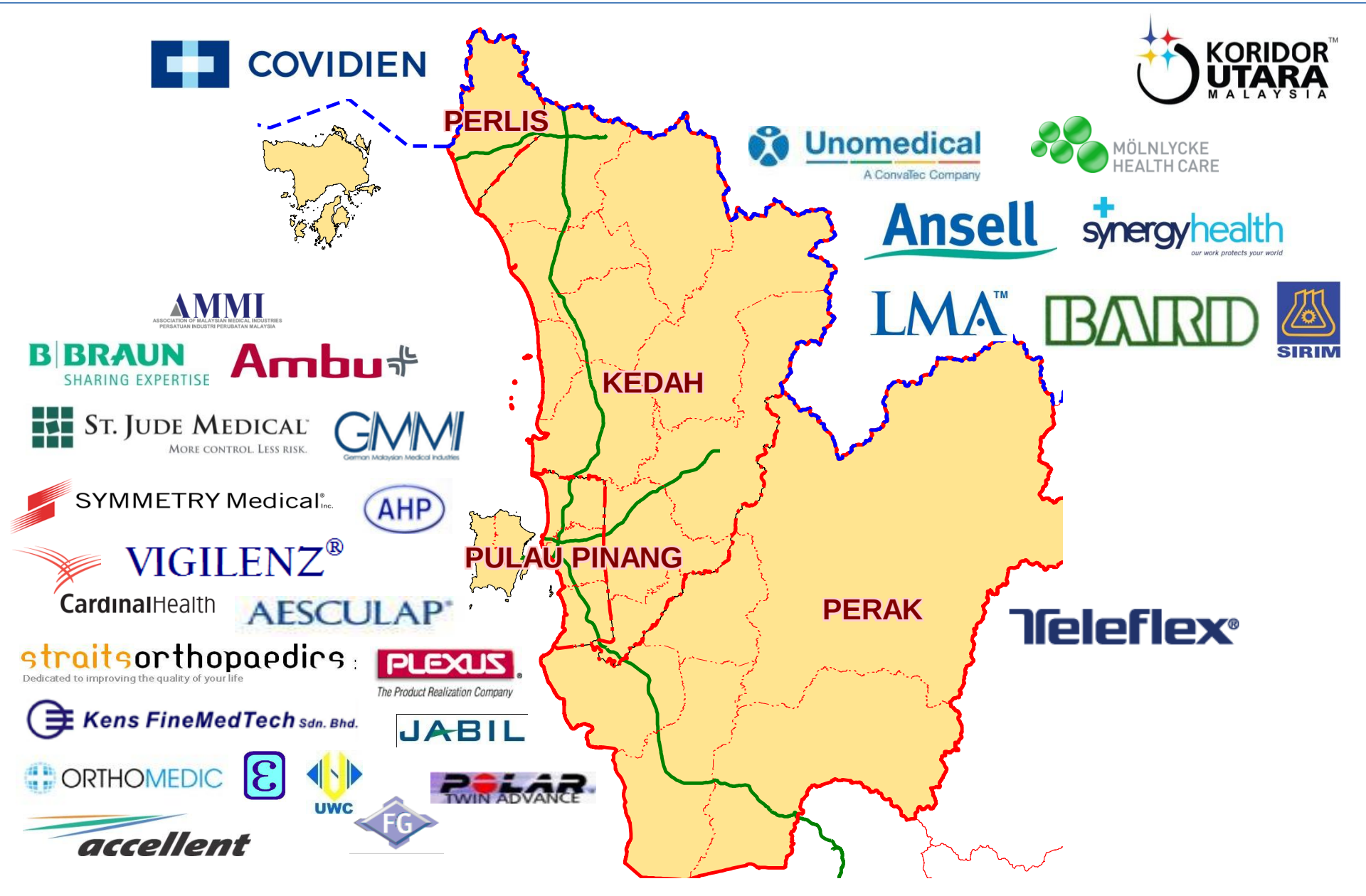
Malaysia
Exports of Medical Devices



Total Exports in 2011: RM11.7 Billion

Source: Malaysia Statistics Department, MITI, MIDA, PEMANDU

Medical Device Cluster in Koridor Utara



Why Regulate Medical Devices?

- To address public health & safety issues
  - Unavailability of *pre-market control* to assess safety, effectiveness and quality of medical devices
  - *Inadequate information* for the public and health professionals to make informed choices on medical devices
  - Lack of control over the usage of certain medical devices
  - No *post-market reporting system* to identify and monitor medical devices with problems in the market
- To facilitate medical device trade & industry
  - *To facilitate* our local manufacturers to market their products globally
  - To *provide a favourable environment* for the growth of medical device industry

World Health Organization guidance

"Governments need to put in place policies that will address all elements related to medical devices, ranging from access to high quality, affordable products, through to their safe and appropriate use and disposal. …

Policies will be unsuccessful unless they are translated into national regulations that are enforced by legislation and correlating sanctions, and that form an integral part of the overall national health system."

Source: Medical device regulations: Global overview and guiding principles; World Health Organization, Geneva; 2003
(At: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf)

Guiding Principles

- The primary goal is to *protect public health and safety*
- The level of *regulatory control should be proportional to the degree of risk*
- Expedites timely availability and access to safe and beneficial medical devices and to prevent unsafe and ineffective medical devices from entering the market
- Elements of *control from design through disposal* stages shall be put in place to ensure continued safety and quality
- In-line with *global harmonization* effort to minimize regulatory barriers, facilitate international trade, improve access to new technologies and to reduce the cost of implementing regulation

HARMONISATION (Non Tariff Barrier)

- Recommendations from the World Health Organisation (WHO)
- Recommendations from the Global Harmonisation Task Force
- In line with the World Trade Organisation's (WTO) Agreements
- ASEAN's Medical Device Directive
- Recommendations from Asian Harmonisation Working Group (AHWP)

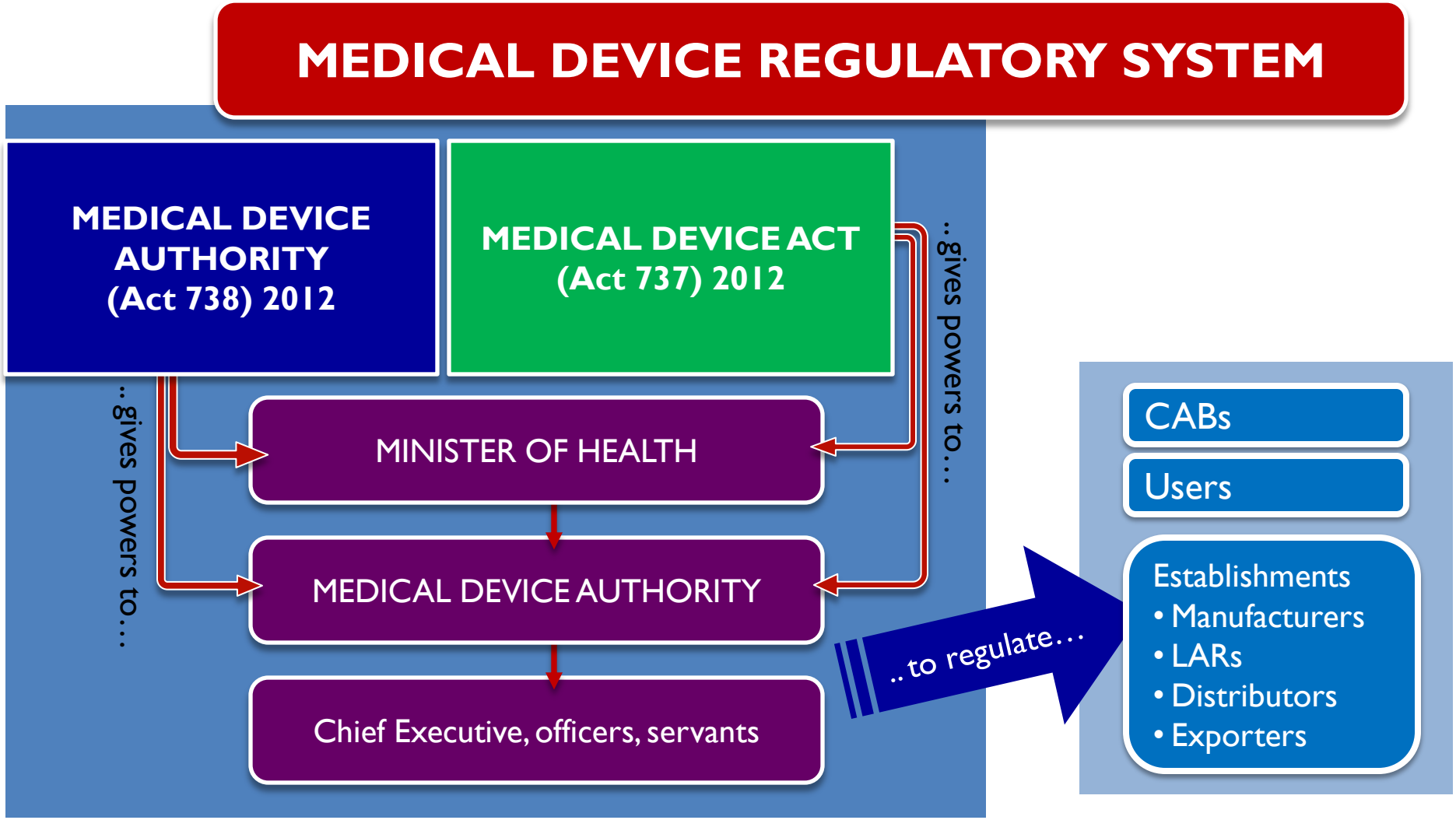
Malaysian Medical Device Act: A Harmonized Regulatory Approached

- Definition of Medical devices
- Pre-market requirements
- Requirements for placement on the market
- Post-market requirements
- Enforcement and investigation
- Miscellaneous (e.g., Standards, Designated Devices)

Current Status

- Medical Device Act (Act 737) 2012
- Medical Device Authority Act (Act 738) 2012
  - Passed by Lower House of Parliament: 3 Oct 2011
  - Passed by Upper House of Parliament: 7 Dec 2011
  - Date of Royal Assent: 30 Jan 2012
  - Date of publication in Gazette: 9 Feb 2012
    - *Appointed date for the Medical Device Authority Act is 15 March 2012*
    - *Appointed for the Medical Device Act is 30th June 2013*
- Medical Device Regulations 2012
    - *Appointed date of the Medical Device Regulations is 1st July 2013*

Institutional Structure of Medical Device Regulatory System



Medical Device Authority Act (Act 738) 2012 – The Authority

MEDICAL DEVICE AUTHORITY (MDA)

A body corporate with the following members

- DG of Health as the Chairman
- Chief Executive of the MDA
- Representative from the Min of Finance
- a representative from the Min of Health
- not more than five persons appointed by the Minister, who have expertise and experience in medical device matters

Committees appointed by MDA
- to assist it in the performance of the functions of the Authority

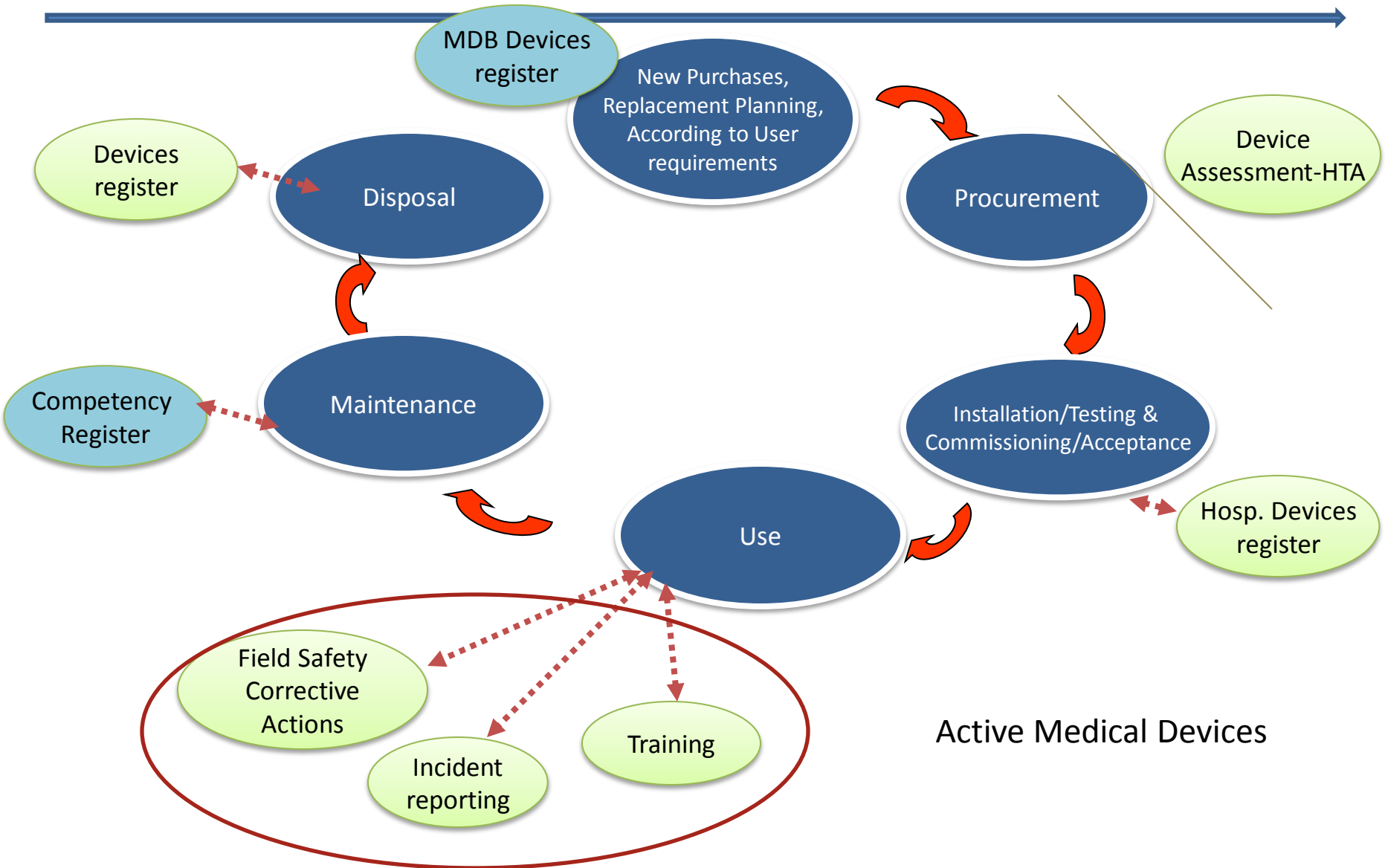
Functions of MDA

- To implement, enforce, consider and recommend reform to the medical device laws
- To perform the following in relation to medical device, its industries and activities:
  - to regulate all matters
  - to encourage & promote the development
  - to provide consultancy & advisory service and any other services
- To utilize property of the Authority in such manner as the Authority may think expedient
- To impose fees or charges for services rendered

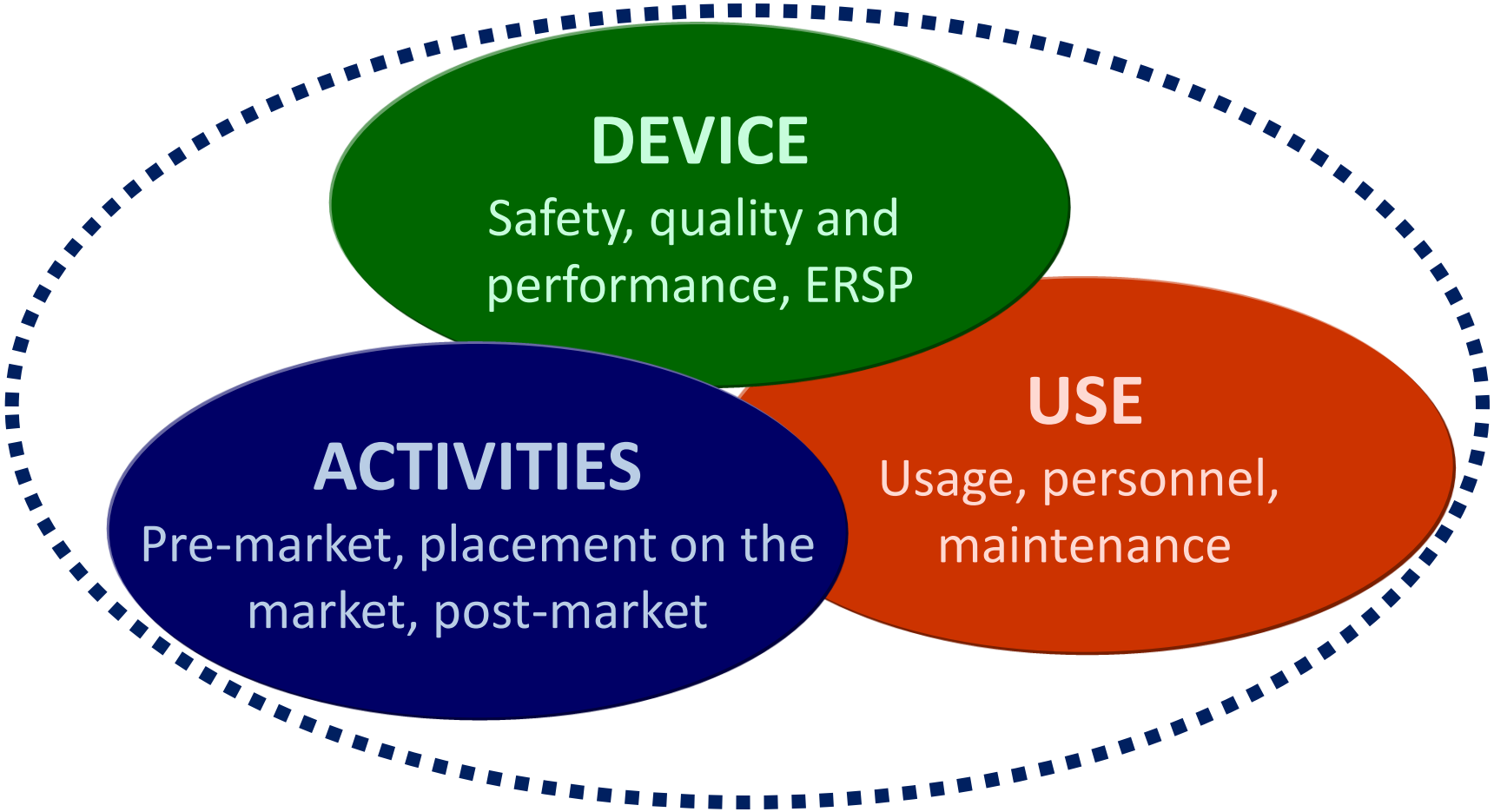
The WHO Medical Device regulatory model?

The Medical Device Life Cycle

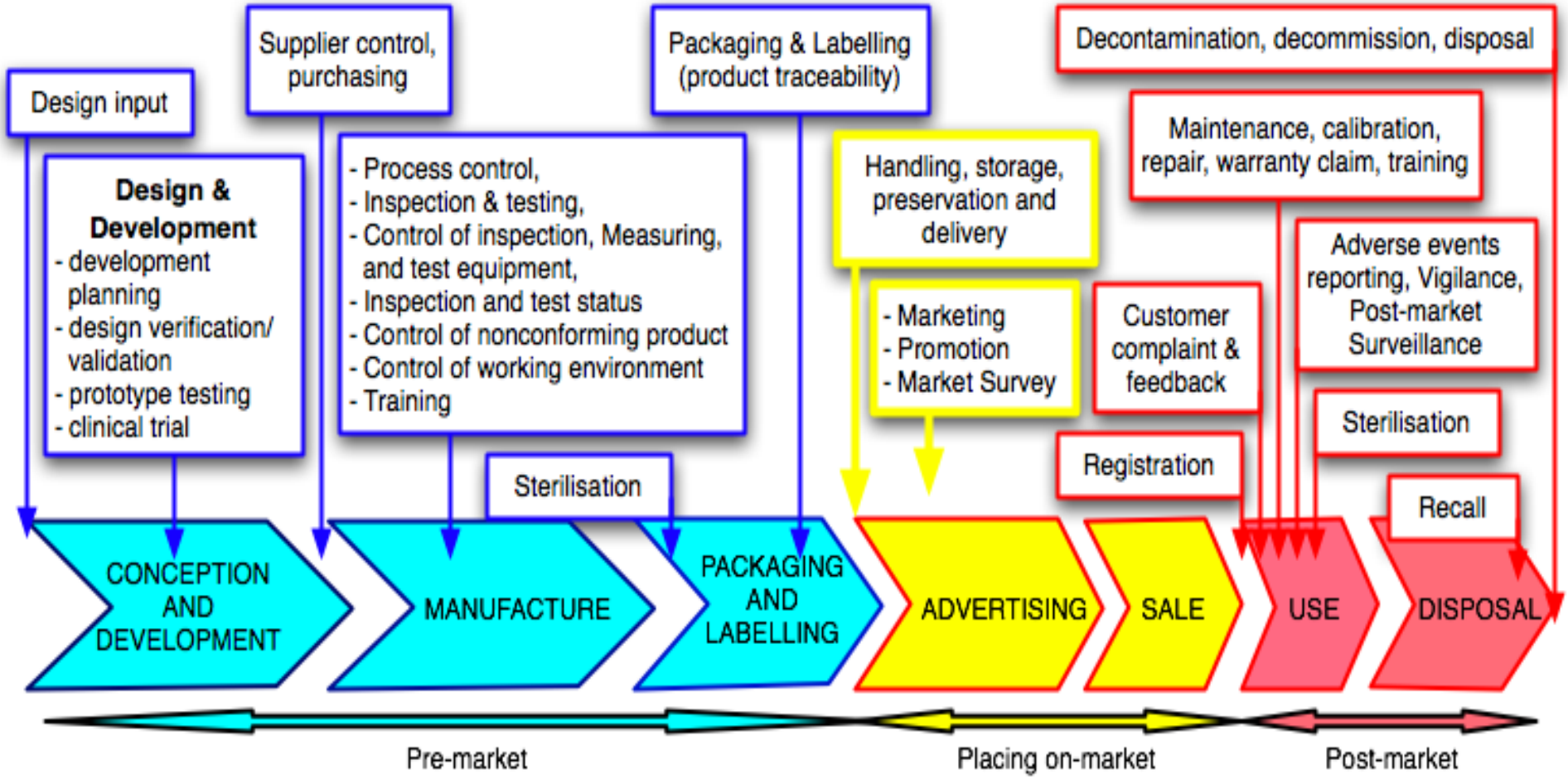
MEDICAL DEVICES LIFE CYCLE IN HEALTHCARE FACILITIES



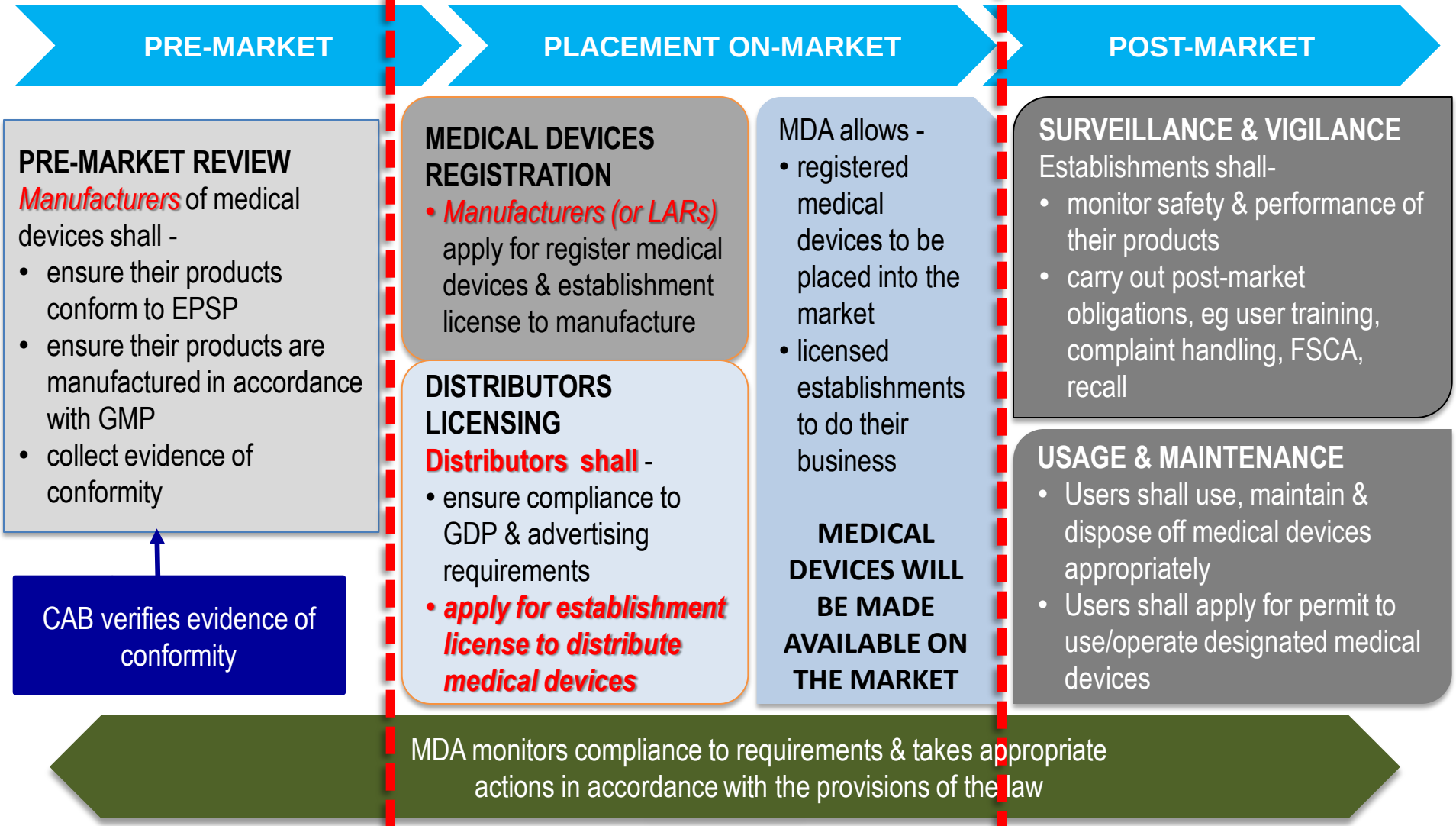
Elements of Regulatory Program



Medical Device Lifecycle – What are the Regulatory Activities?



Overview of The Regulatory System



Essential Principle of Safety & Performance

1) No compromise on clinical condition and safety of patients, health and safety of users and other persons when use under the conditions and for the purposes intended
2) In the design and construction of medical device, hazards, associated risks and foreseeable misuse from the intended use should be identified, eliminated/reduced; any residual risks that cannot be eliminated, protection measures should be taken and should be informed to users
3) Medical device should achieve the intended/specified performance and be designed, manufactured and packed in such a way that it is suitable for the functions within the scope of the definition of medical device
4) Characteristics and performances should not be adversely affected by stresses during normal conditions of use and proper maintenance
5) Characteristics and performances during the intended use should not be adversely affected under transport and storage conditions
6) The benefits outweigh any undesirable side effects

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Essential Principles of Safety & Performance

1) Chemical, physical and biological properties
2) Infection and microbial contamination
3) Manufacturing and environmental properties
4) Devices with a diagnostic or measuring function
5) Protection against radiation
6) Requirements for medical devices connected to or equipped with an energy source
7) Protection against mechanical risks
8) Protection against the risks posed to the patient by supplied energy or substances
9) Protection against the risks posed to the patient for devices for self-testing or self administration
10) Information supplied by the manufacturer
11) Performance evaluation including, where appropriate, clinical evaluation

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Definition (Scope)

What is a medical device?

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

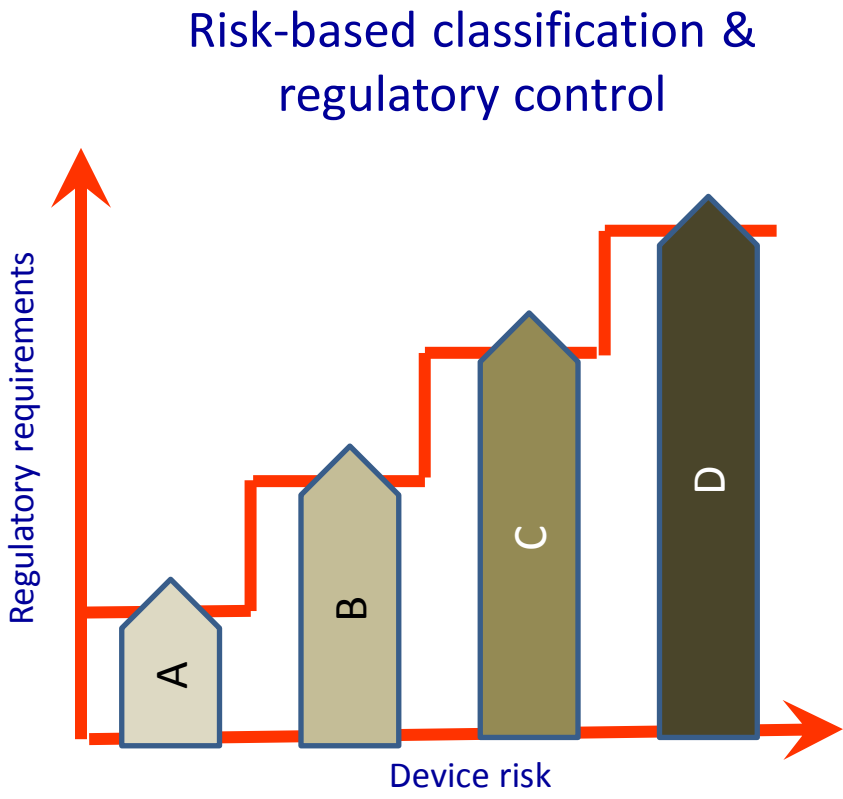
a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease;
   - compensation for an injury;
   - investigation, replacement, modification, or support of 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

b) 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

Risk-Based Classification

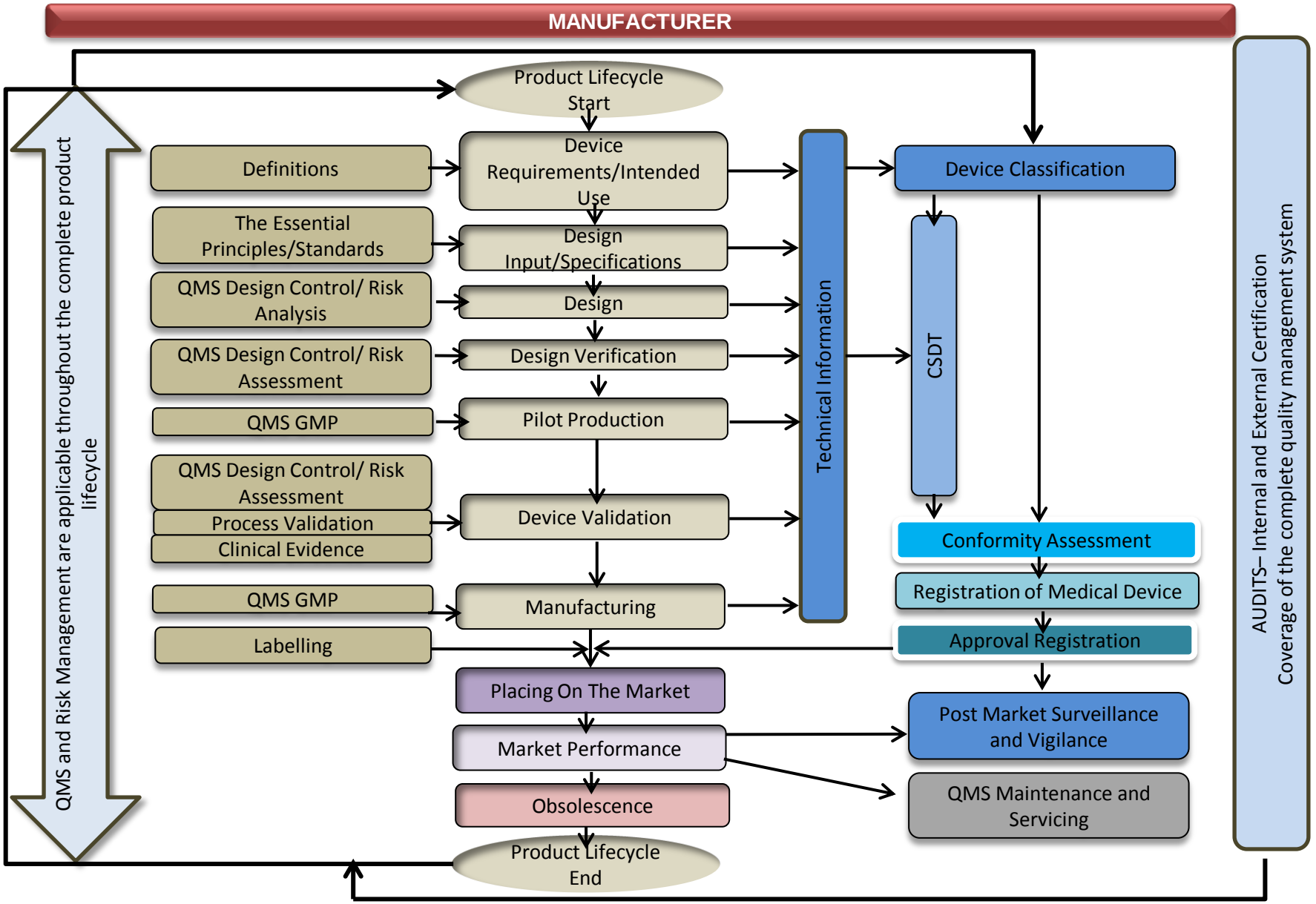
- Medical device is classified based on the risk associated with the vulnerability of the human body, the technical design and the manufacture of the medical device
- Risk-based classification;
  - Class A (low)
  - Class B (low moderate)
  - Class C (high moderate)
  - Class D (high)

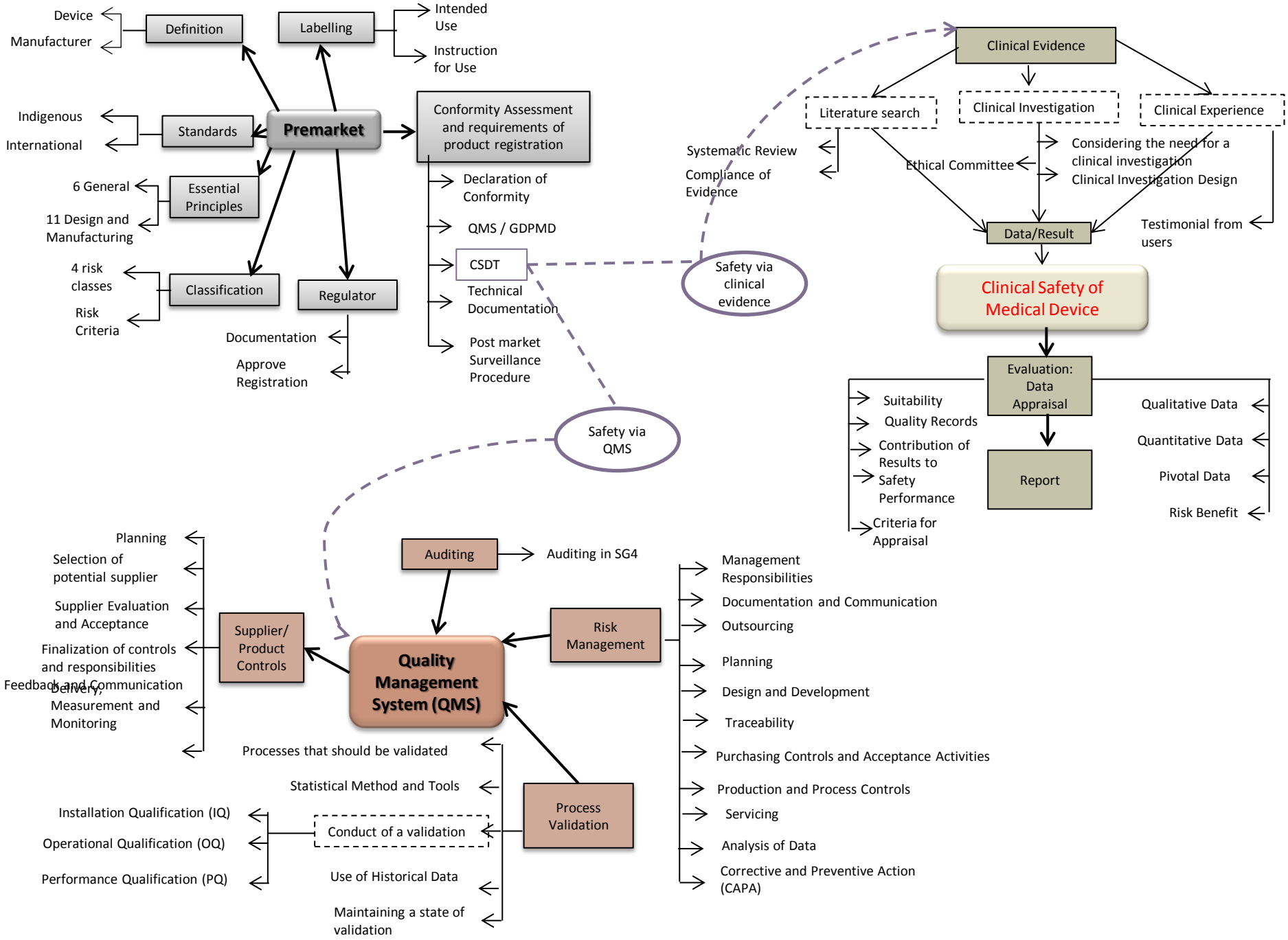


Who & What will be Regulated?

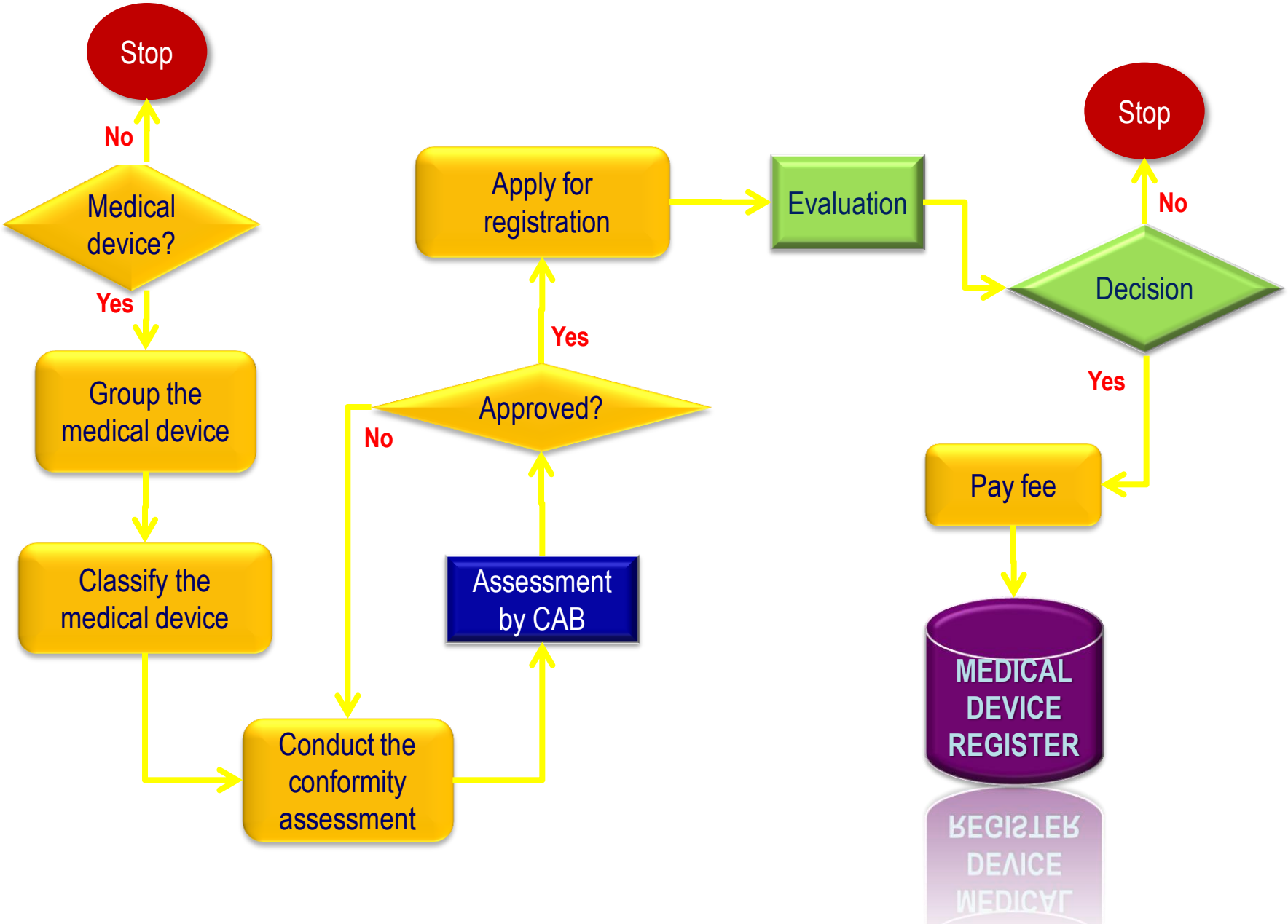
Responsible parties	Regulated activities/responsibilities
Local manufacturers	• To ensure products meet essential principles of safety & performance (EPSP) and are manufactured in accordance with good manufacturing practice (GMP) • To apply for product registration • To monitor safety & performance and to take corrective actions on problems related to products in the market
Exporters	
Local authorized representatives (LARs) of foreign manufacturers	To act on behalf of foreign manufacturers with regard to the manufacturer's responsibilities under the Malaysian laws
Importers	To ensure compliance with requirements of good distribution practice (GDP), eg cleanliness & suitability of premises, storage & stock handling, traceability, product complaints, etc
Distributors	
Conformity assessment bodies (CABs)	To verify evidence of conformity to EPSP, GMP, GDP
Users of medical devices on patients	• To ensure competencies of users & persons involve in maintenance of medical devices • To apply for permit to use designated medical devices

MEDICAL DEVICE REGULATION APPLICATION




Device
Manufacturer
Definition
Labelling
Intended Use
Instruction for Use
Indigenous
International
Standards
Premarket
Conformity Assessment and requirements of product registration
6 General
11 Design and Manufacturing
Essential Principles
Declaration of Conformity
QMS / GDPMD
CSDT
Technical Documentation
4 risk classes
Risk Criteria
Classification
Regulator
Documentation
Approve Registration
Post market Surveillance Procedure
Safety via clinical evidence
Safety via QMS
Clinical Evidence
Literature search
Clinical Investigation
Clinical Experience
Systematic Review
Compliance of Evidence
Ethical Committee
Considering the need for a clinical investigation
Clinical Investigation Design
Data/Result
Testimonial from users
Clinical Safety of Medical Device
Evaluation: Data Appraisal
Suitability
Quality Records
Contribution of Results to Safety Performance
Criteria for Appraisal
Report
Qualitative Data
Quantitative Data
Pivotal Data
Risk Benefit
Planning
Selection of potential supplier
Supplier Evaluation and Acceptance
Finalization of controls and responsibilities
Feedback and Communication
Delivery
Measurement and Monitoring
Supplier/ Product Controls
Auditing
Auditing in SG4
Quality Management System (QMS)
Risk Management
Management Responsibilities
Documentation and Communication
Outsourcing
Planning
Design and Development
Traceability
Purchasing Controls and Acceptance Activities
Production and Process Controls
Servicing
Analysis of Data
Corrective and Preventive Action (CAPA)
Processes that should be validated
Statistical Method and Tools
Process Validation
Installation Qualification (IQ)
Operational Qualification (OQ)
Performance Qualification (PQ)
Conduct of a validation
Use of Historical Data
Maintaining a state of validation

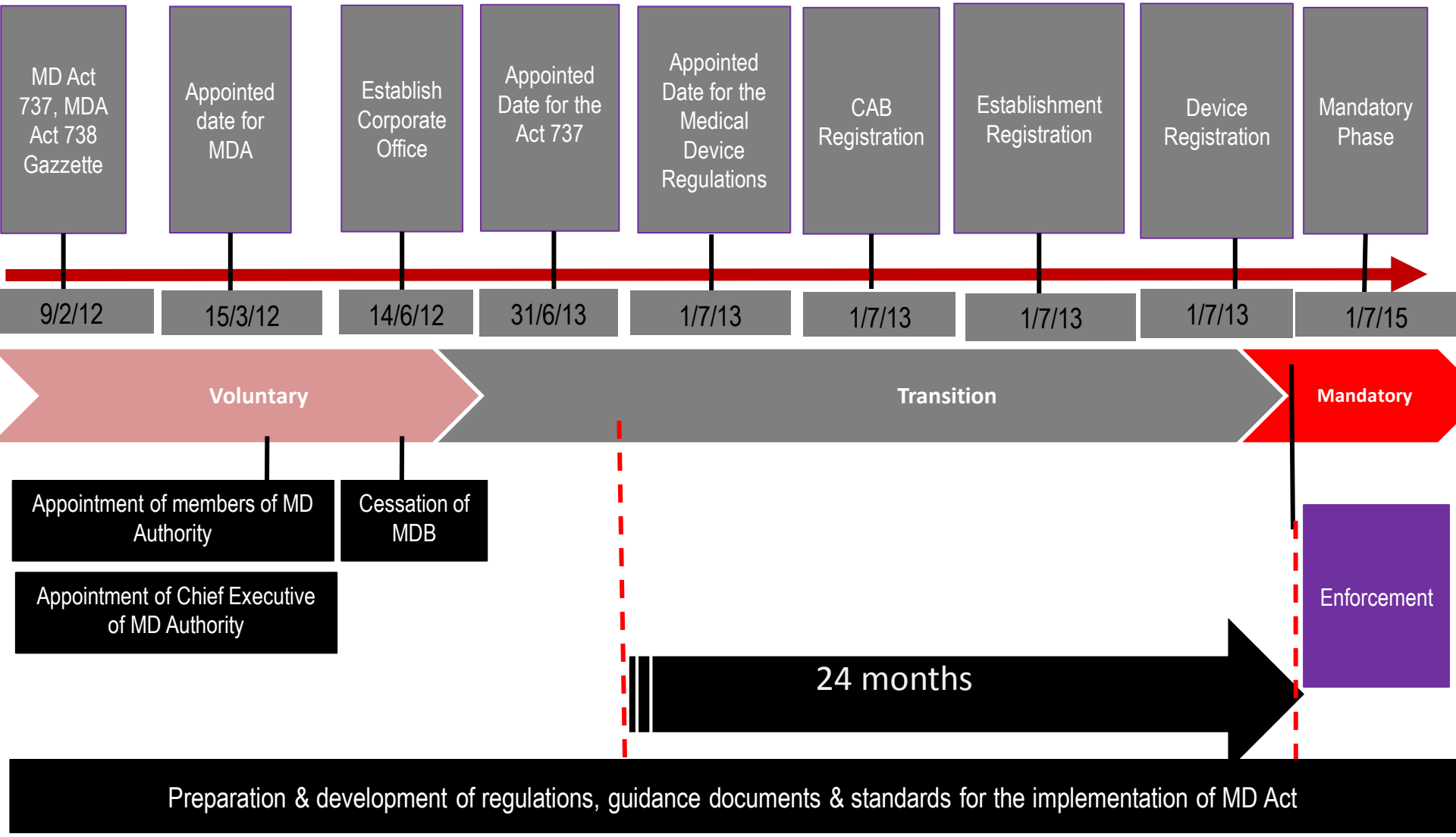
The process of medical device registration in general

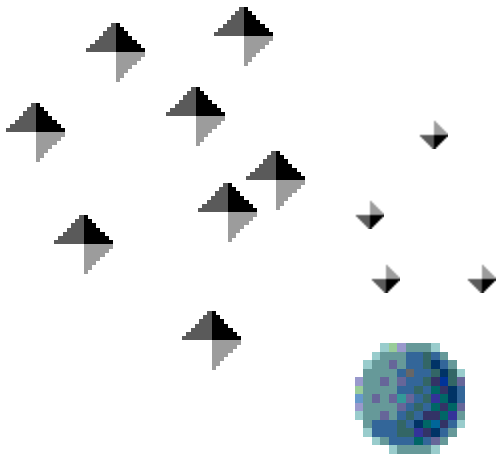


Empowerment

- Empower the industry to self declare for Class A devices
- Manufacturer themselves choose the regulatory control route of medical devices they manufacture based on the risk classification
- Conformity Assessments are carried out by third party

Now to Mandatory Phase: The Timeline





Thank You