Medical Device Review at TFDA

2012 APEC Advanced Workshop of Good Review Practice on Medical Products

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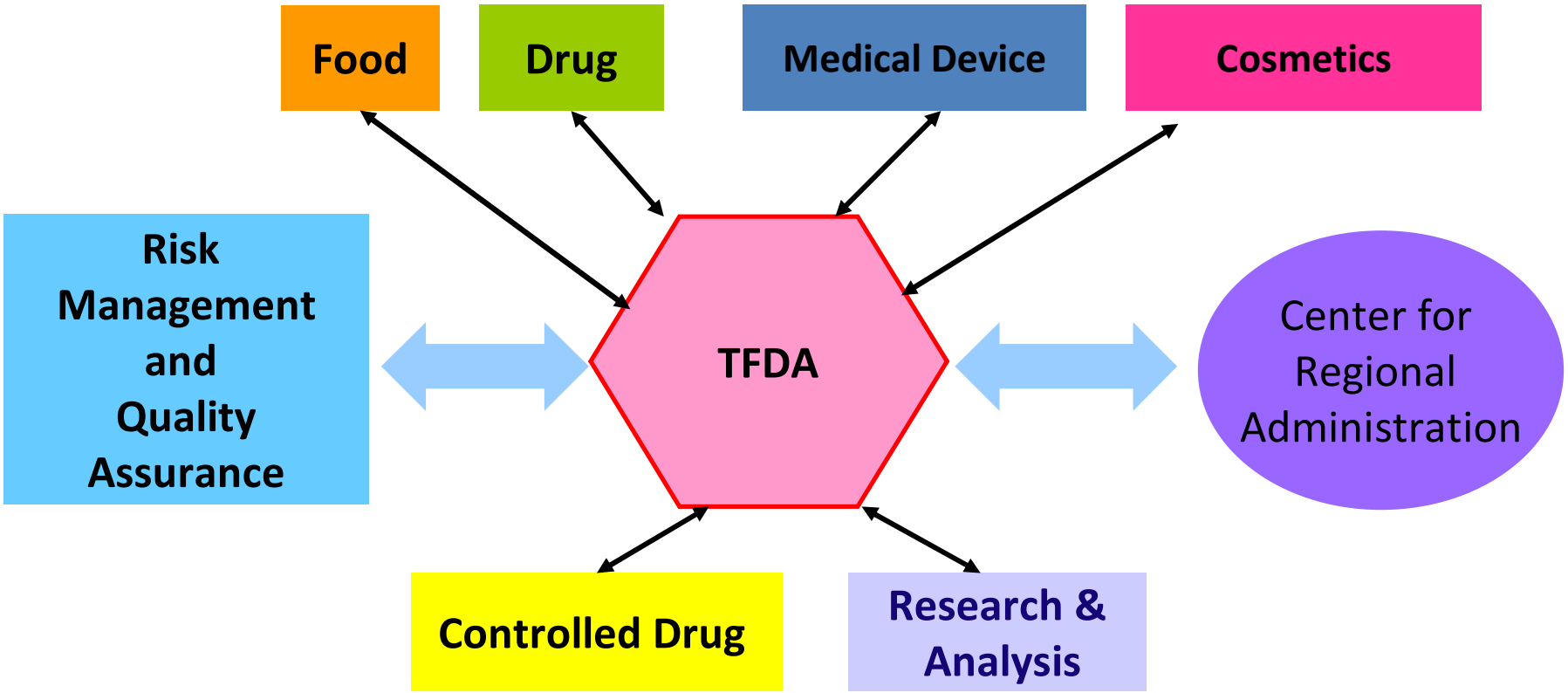
Regulatory Framework of Medical Devices

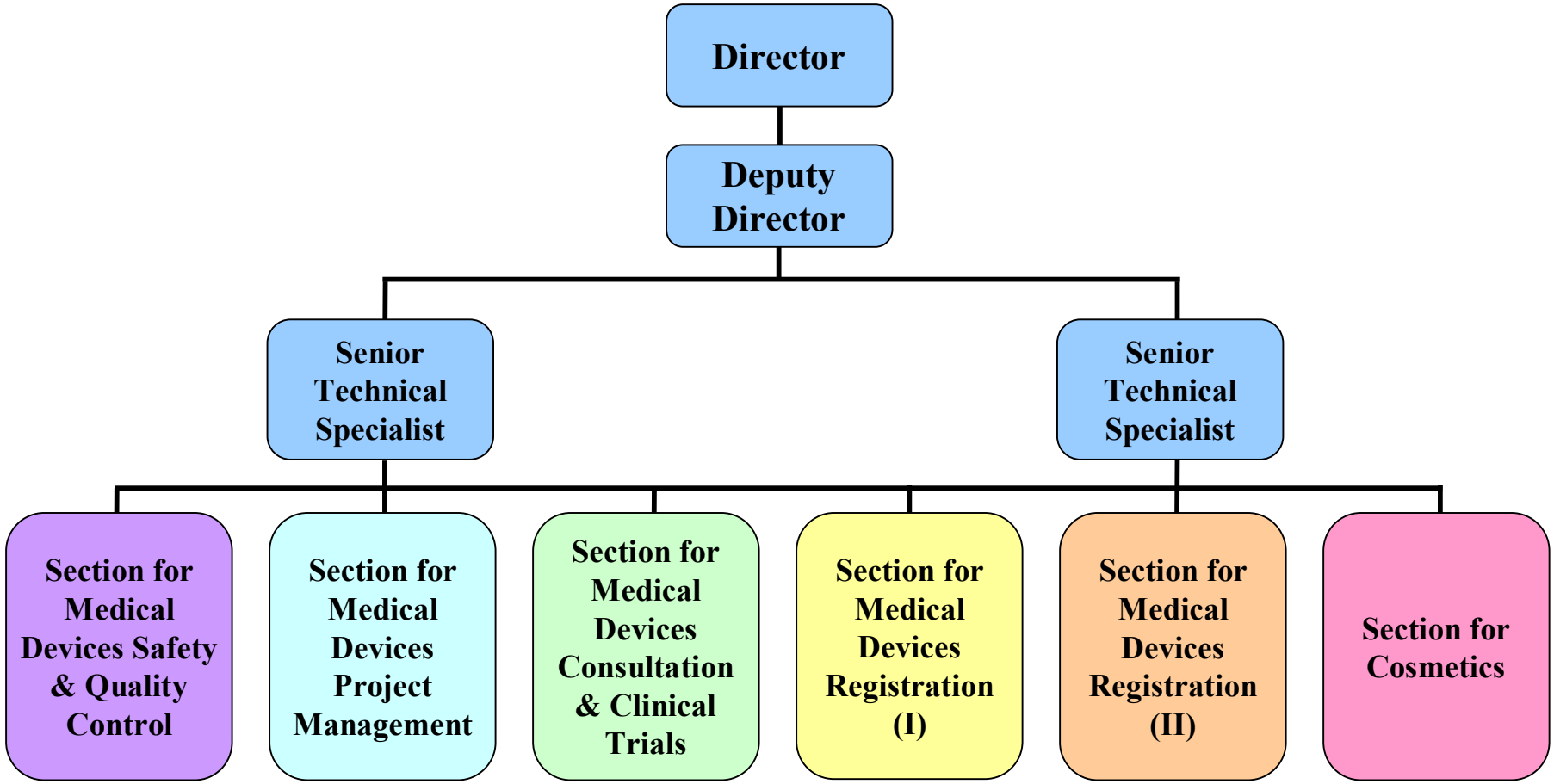
- **Food and Drug Administration (TFDA) inaugurated on Jan. 1, 2010**

- **TFDA supersedes 4 bureaus**
  - Bureau of Food Safety
  - Bureau of Pharmaceutical Affairs
  - Bureau of Food and Drug Analysis
  - Bureau of Controlled Drugs

Consolidated Food and Drug Safety Regulatory System



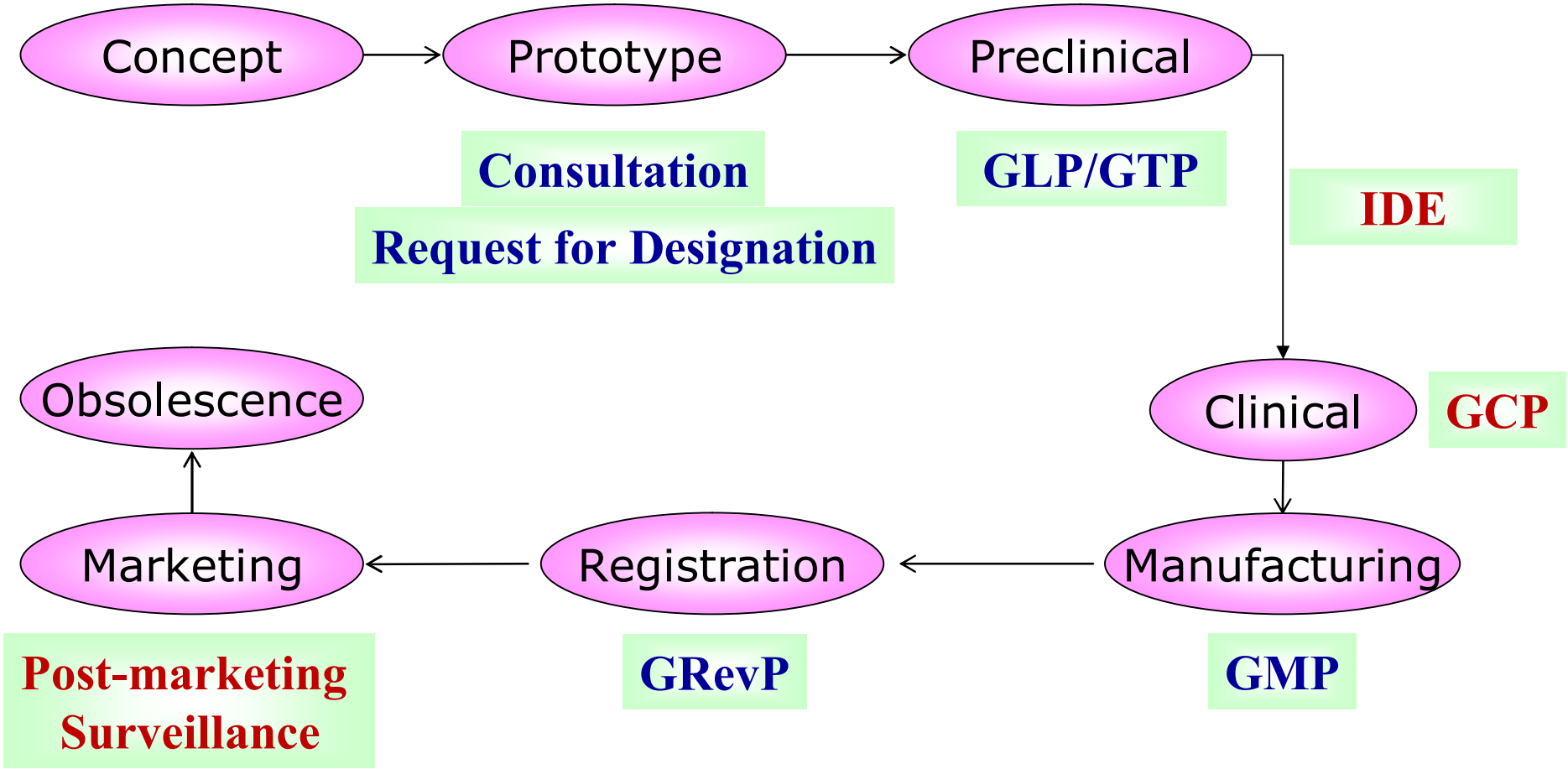
Organization Diagram of Division of Medical Devices and Cosmetics



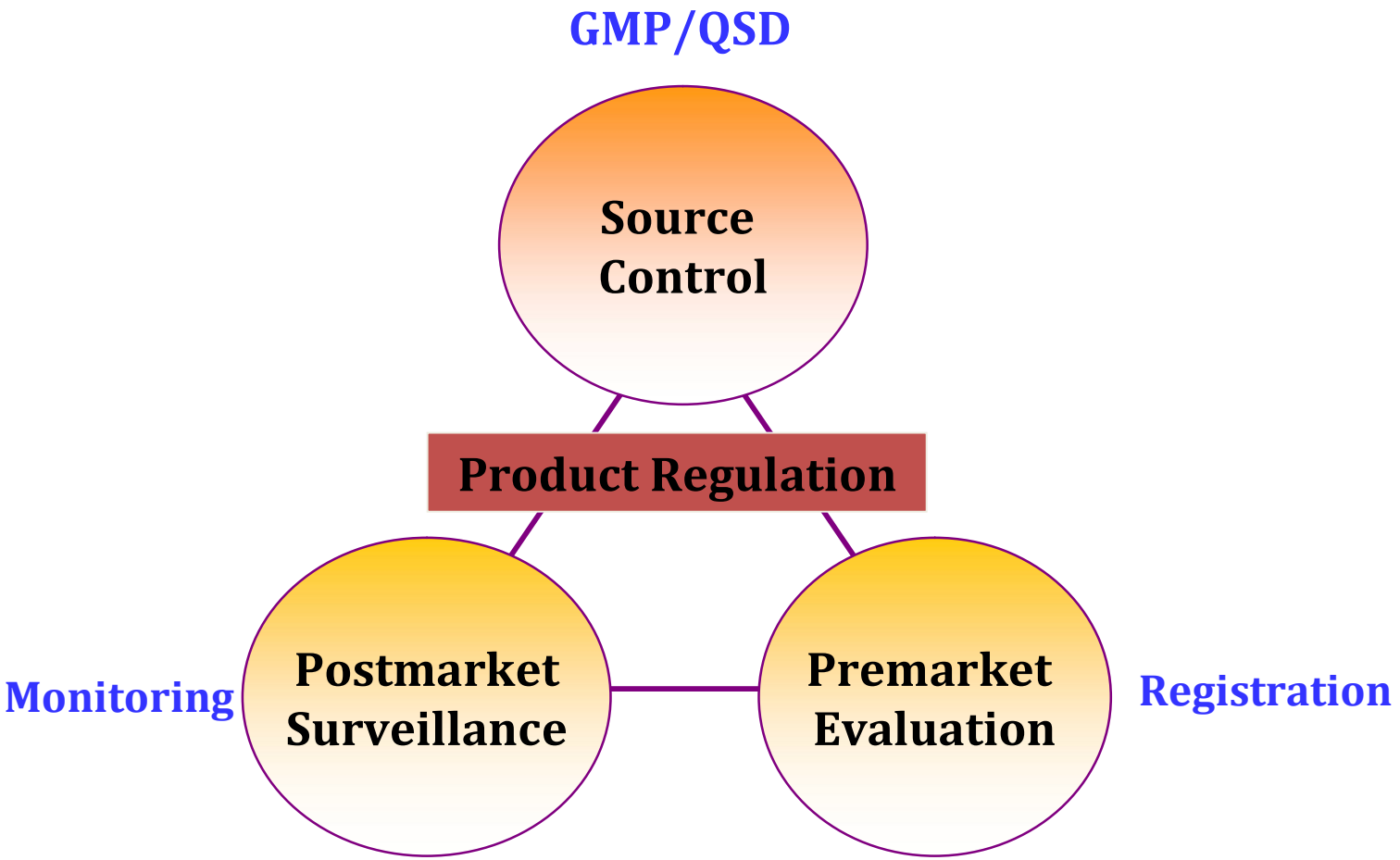
Roles of Regulatory Authorities

- **Public Health Protection**
  - Gate keeper
- **Health Promotion Through Facilitating Innovation**
  - Efficient and transparent review process
  - International harmonization of regulation
  - Consultation mechanism

A Total Product Life-Cycle Approach of Medical Device Regulation



Regulatory System

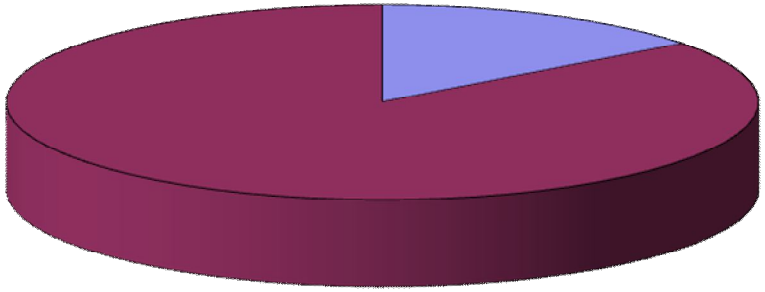


Implementation of Medical Device GMP

- Effective on February 10, 1999
- Third party inspection (contracted by TFDA)
- Domestic manufacturers: site inspection
- Importing manufacturers: quality system document (QSD) review (may also apply for overseas site inspection)

Statistics of GMP/QSD by Domestic and Imported Manufacturers

GMP (domestic)
504 (15%)

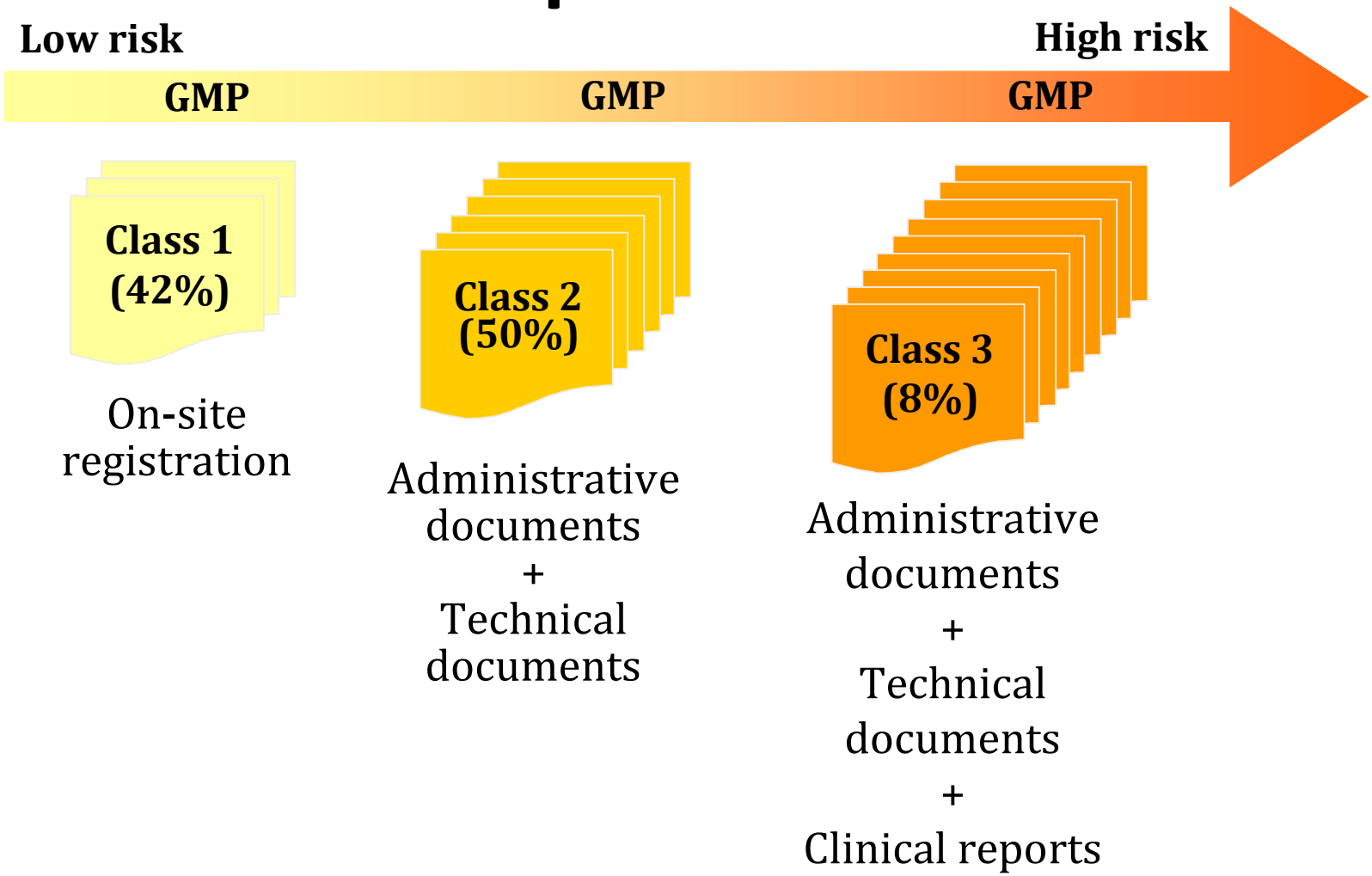


QSD (imported)
2,931 (85%)

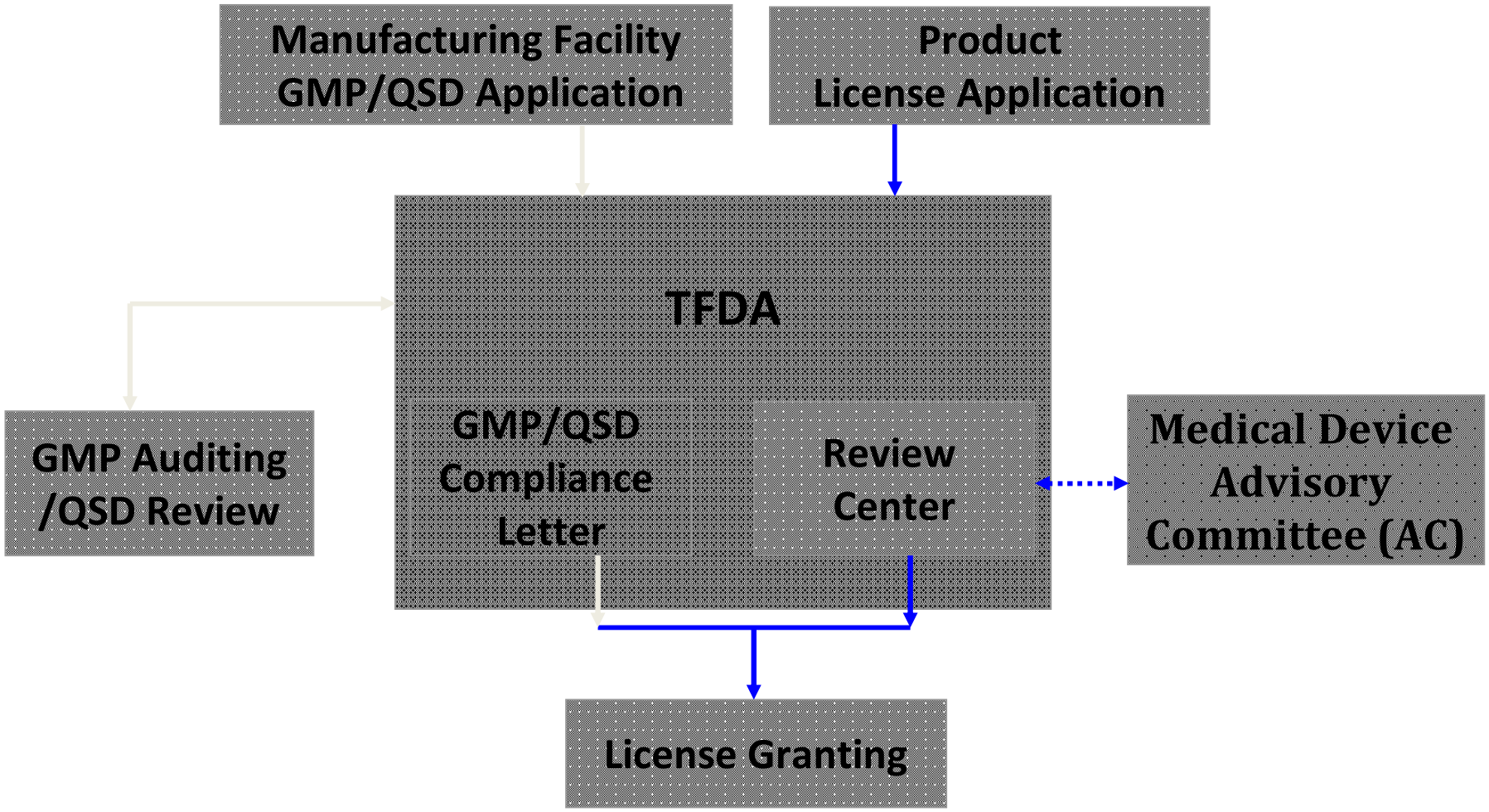
• Updated 2012.03.31

Premarket Approval

Risk-Based Registration Requirements

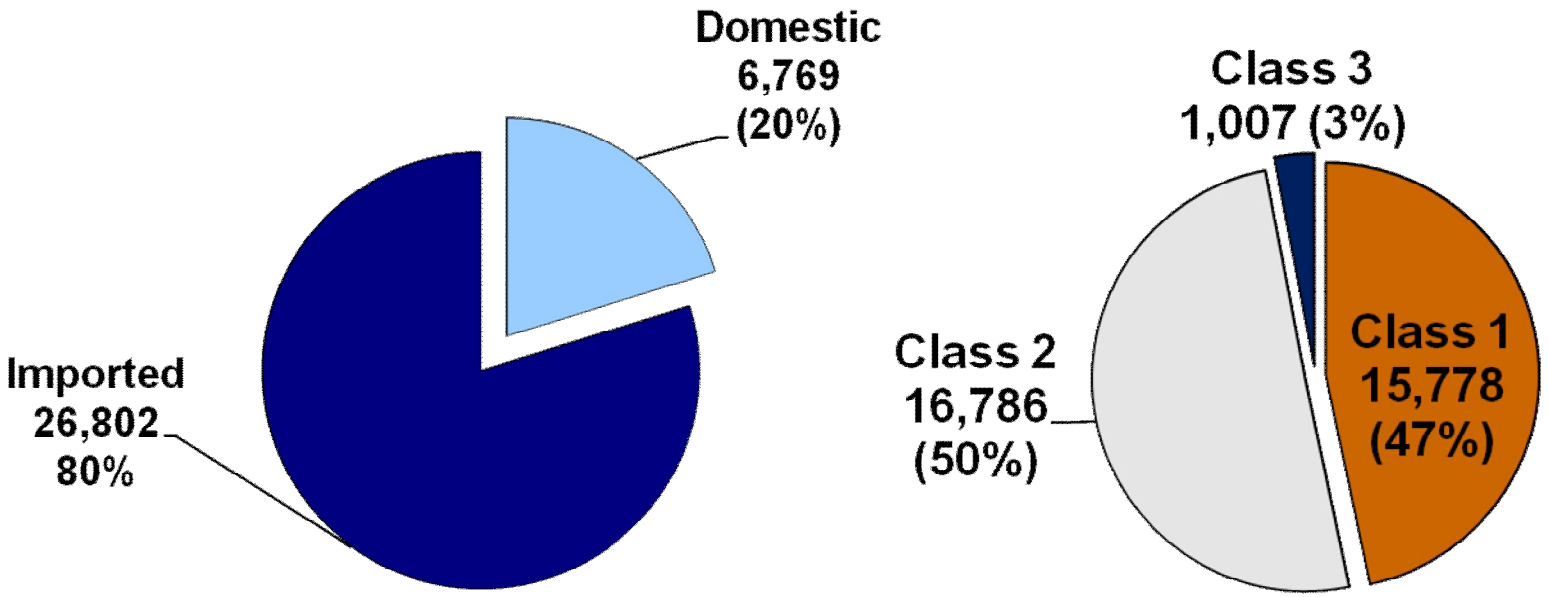


Process for Registration of Medical Devices



Number of Medical Device Licenses

Up to Dec.31, 2011, a total of 33,571 licenses were granted. It increases at a rate of >10% per year.



Reform of Pre-market Approval

Streamlined Review

- Waive testing reports for US FDA-cleared Class 2 devices.
- Summary forms of testing are accepted for certain Class 2 devices.
- Waive AC meeting for certain Class 3 devices.

Simplify pre-market review.

Shorten time to market for emerging medical devices.

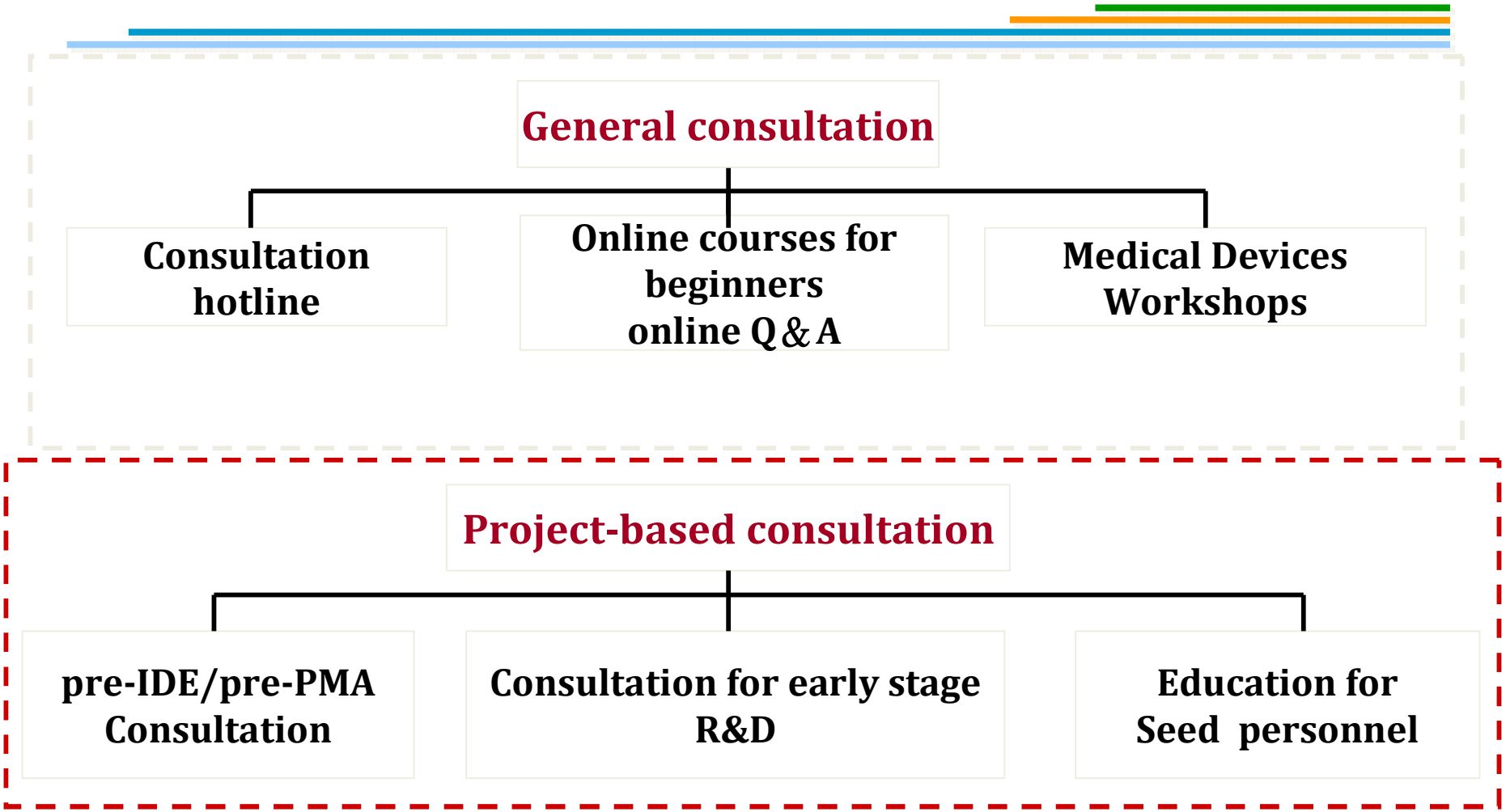
Recently Implemented Policies (I)

- “Medical device substantial equivalence decision making flowchart” issued
- Clinical reports of Class 2 new medical devices can be waived under certain circumstances
- Class 3 IVD type testing waived except some high risk items, such as blood screening products

Recently Implemented Policies (II)

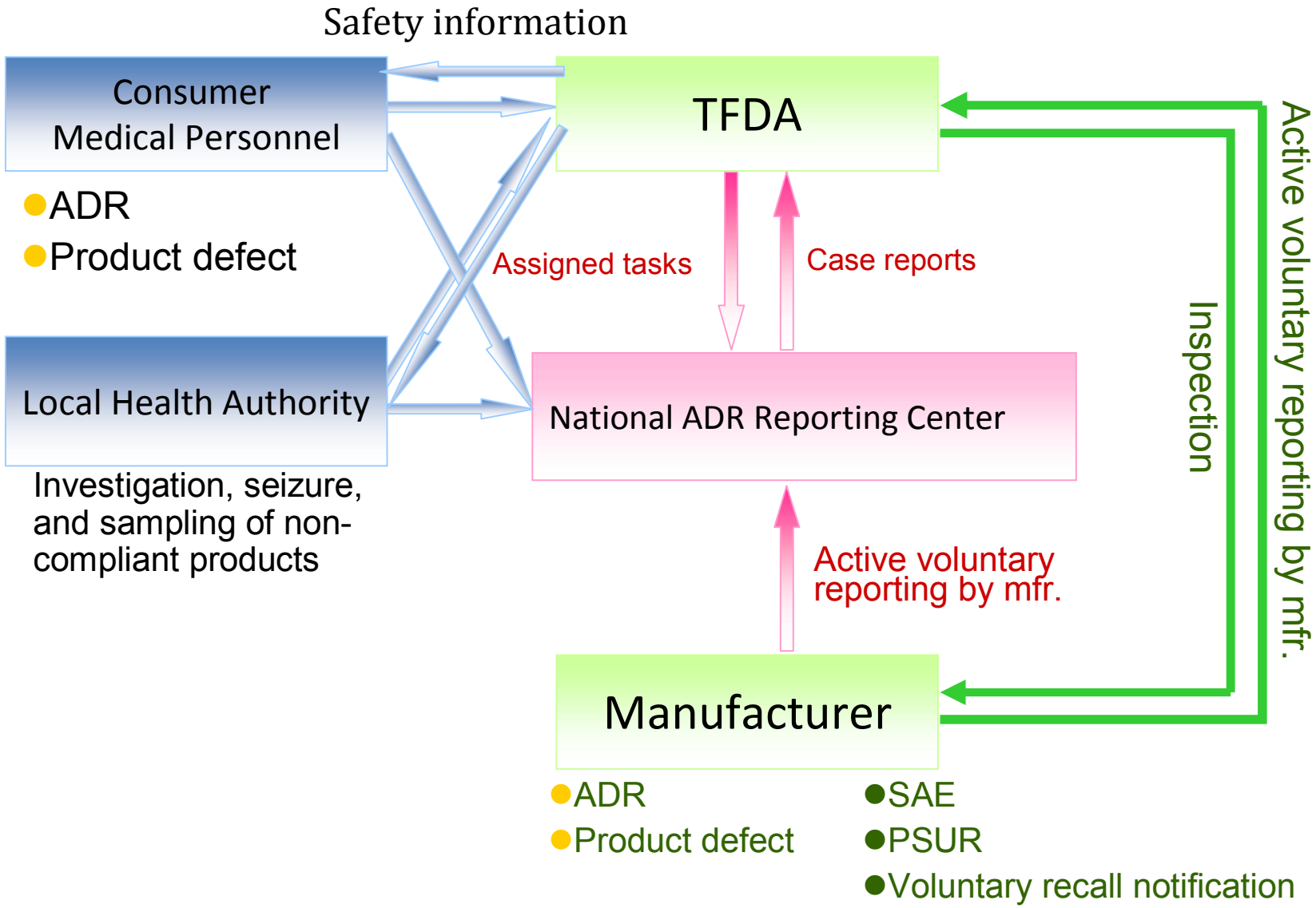
- Implemented Pre-IDE and Pre-PMA consultation system
- Seed personnel training programs for establishing regulatory consultation network
- Public notice of guidance documents (Hyaluronic acid implants, Drug-eluting stent…)

Consultation Program



Postmarket Surveillance

Flow Chart of Medical Device Reporting



Global Surveillance Participation

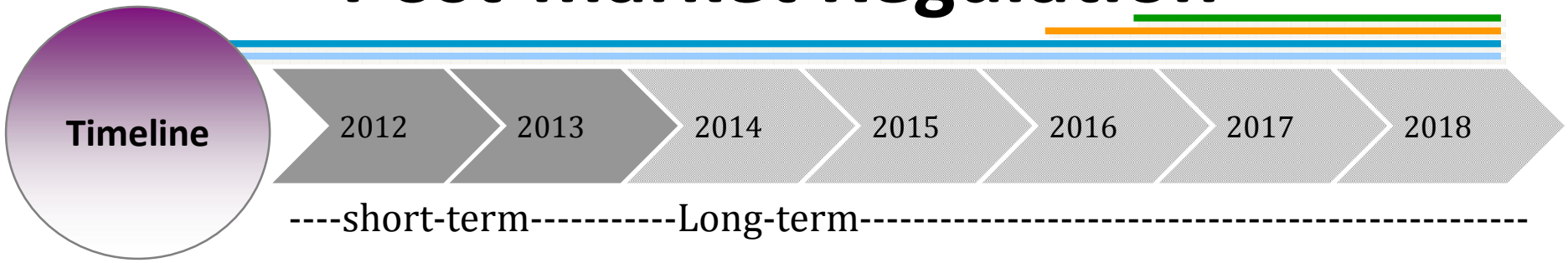
- Daily Monitoring from internet and global press (FDA, MHRA, TGA...)
- Member of GHTF National Competent Authority Report (NCAR)
- Joined AHWP Safety Alert Dissemination System (SADS)

Future Goals

Pre-market Evaluation

- **Strategy**
  - Online registration of Class 1 devices
  - Implementation of STED
    - Scheduled for Class III devices in 2013
  - Reclassification
  - Implementation of good review practice (GRevP)

Post-market Regulation



- **Strategy**
  - Strengthen license re-evaluation
  - Construct Total Product Life Cycle (TPLC)
  - Enhance illegal medical device inspection
  - Continue global surveillance activity


Thank You
for Your Attention