Regulation of Medical Devices in Hong Kong

Department of Health
The Government of the Hong Kong Special Administrative Region of the People's Republic of China

Market Status in Hong Kong

- There is no statistics about the medical device industry in Hong Kong
- Most of the medical devices used are imported
- It is estimated that there are around 100 small and medium Hong Kong manufacturers
- Most of the manufacturing sites are in Mainland China
- Most of products manufactured are OEM products

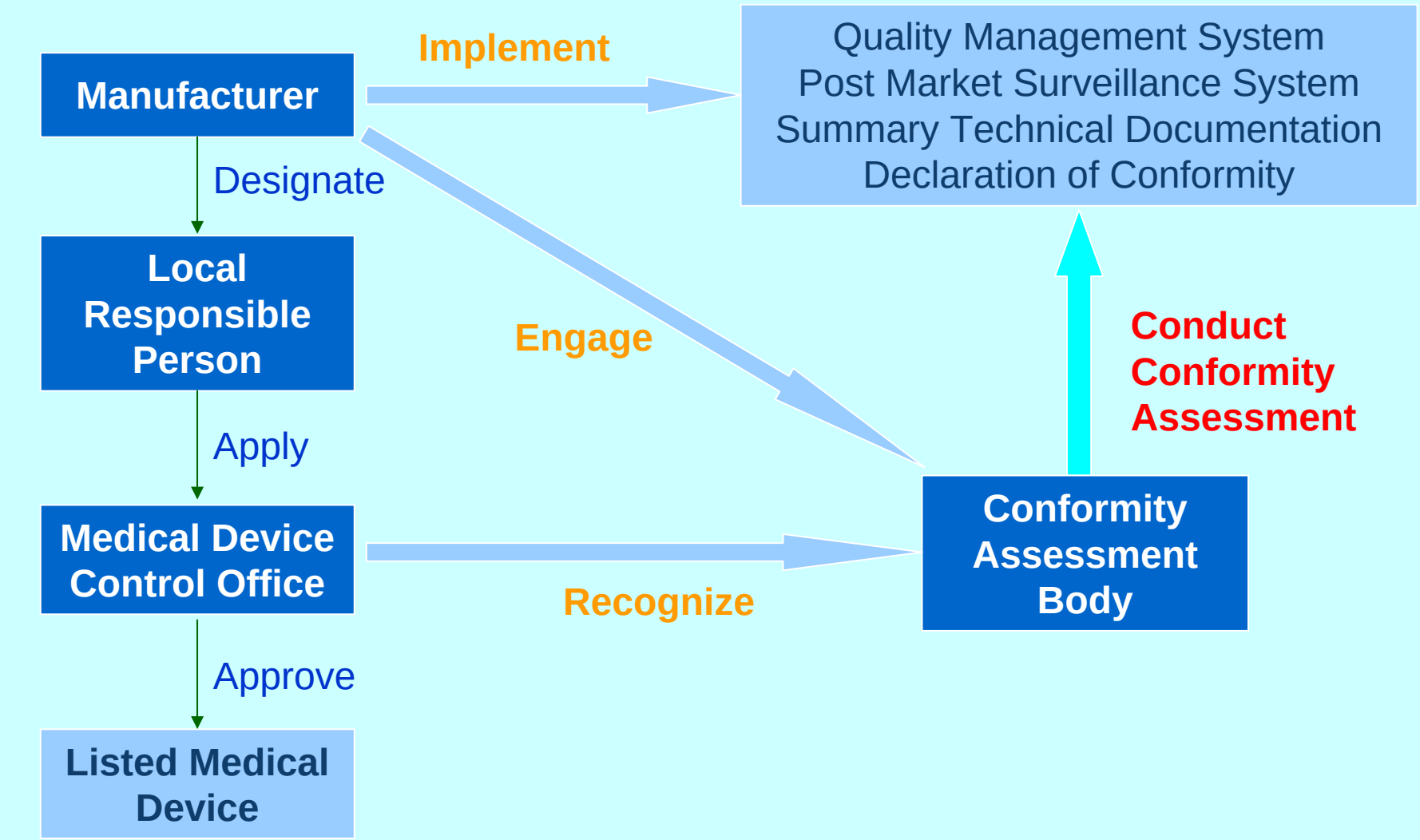
Pre-market Requirements

- There is no specific regulation for medical devices
- Some related regulations such as:
  - Electrical Products (Safety) Regulation
  - Radiation (Control of Irradiating Apparatus) Regulation
  - Consumer Goods Safety Ordinance
  - Pharmacy and Poisons Ordinance…
- Voluntary listing system in place since November 2004

Voluntary Listing System

- In line with GHTF Recommendations
  - Definition of Medical Devices
  - Essential Principles of Safety and Performance of Medical Devices
  - Principles of Conformity Assessment for Medical Devices…
- Listing system includes:
  - Classes II, III and IV medical devices
  - Conformity Assessment Bodies
  - Local Manufacturers
  - Importers

Conformity Assessment Process



Alternate Route of Conformity Assessment

- Marketing approval from GHTF founding members
  - Australia
  - Canada
  - European Union (countries have implemented European Council Directives)
  - Japan
  - USA

Post-market Surveillance

- Sources of safety information
  - GHTF National Competent Authority Report Exchange Program
  - Other governments / authorities
  - Local Responsible Persons
  - Device suppliers and manufacturers
  - Hospitals and healthcare institutions…
- Sample test of selected products

Adverse Incident Reporting

- On-line reporting through web-site by Local Responsible Persons
- Voluntary reporting by suppliers, users, the public…through letters, fax or email

Way Forward

- Regulatory Impact Assessment:

  July – December 2007

- Proposal to Legislative Council:

  Early 2008

Questions to be Addressed

- How to regulate
  - in-vitro diagnostic devices
  - borderline products
  - products from human blood and tissue
  - re-use of single-use devices
  - sale of second hand products…

Thank You!