ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

Regulation of Medical Devices in Hong Kong

A Flexible Approach

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

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Agenda
  - Facts & Estimations
  - Objectives and Principles
  - Scope
  - Flexible Conformity Assessment
  - Post-market Surveillance
  - Way Forward

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Facts & Estimations
  - Population: 7 Million
  - Models of medical devices: over 20,000
  - Trade
    - Import
      For domestic use): ~US$ 500M
      Re-export: ~US$ 1,000M
    - Domestic Export: ~US$ 50M
  - Manufacturers: ~100
  - Traders: ~700

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

Objective of Regulation

- Devices should be safe, effective and of good quality

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Principles of Regulation
  - Facilitate timely access to safe devices
  - No unnecessary burden to the trade and the government
  - In line with recommendations of Global Harmonization Task Force

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

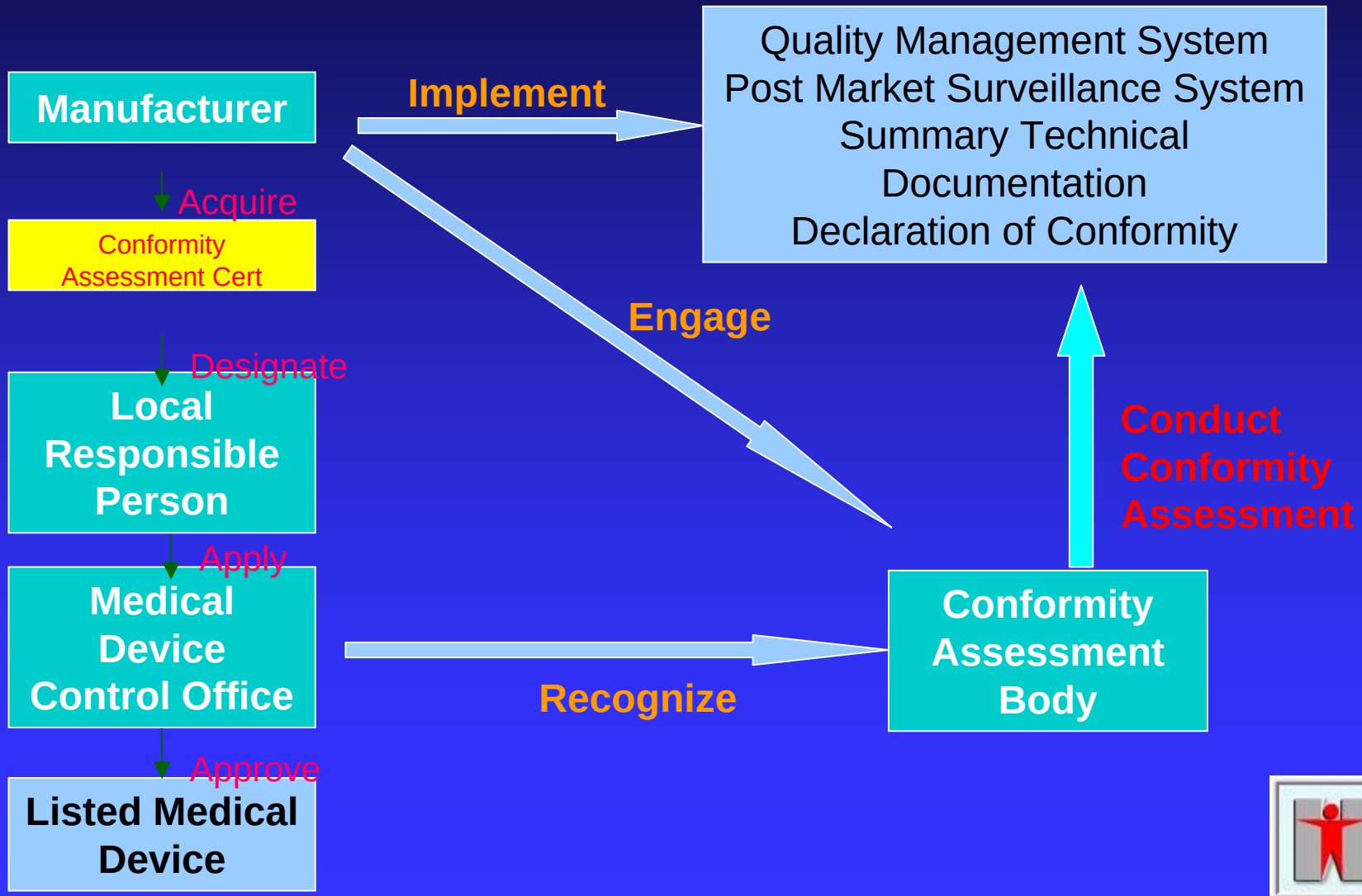
- Scope
  - Pre-market Control for Classes II, III and IV medical devices
  - Post-market Control
    - Medical Device Safety Alert System
    - Adverse Incident Reporting System
  - Control of Local Manufacturers and Importers
  - Recognition of Conformity Assessment Bodies

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Flexible Conformity Assessment
  - CABs recognised by Hong Kong Dept of Health to conduct conformity assessments for local manufacturers
  - Accepting marketing approvals from economies adopting GHTF model to avoid duplication
  - Not specifying any “recognized” standards to avoid trade barrier

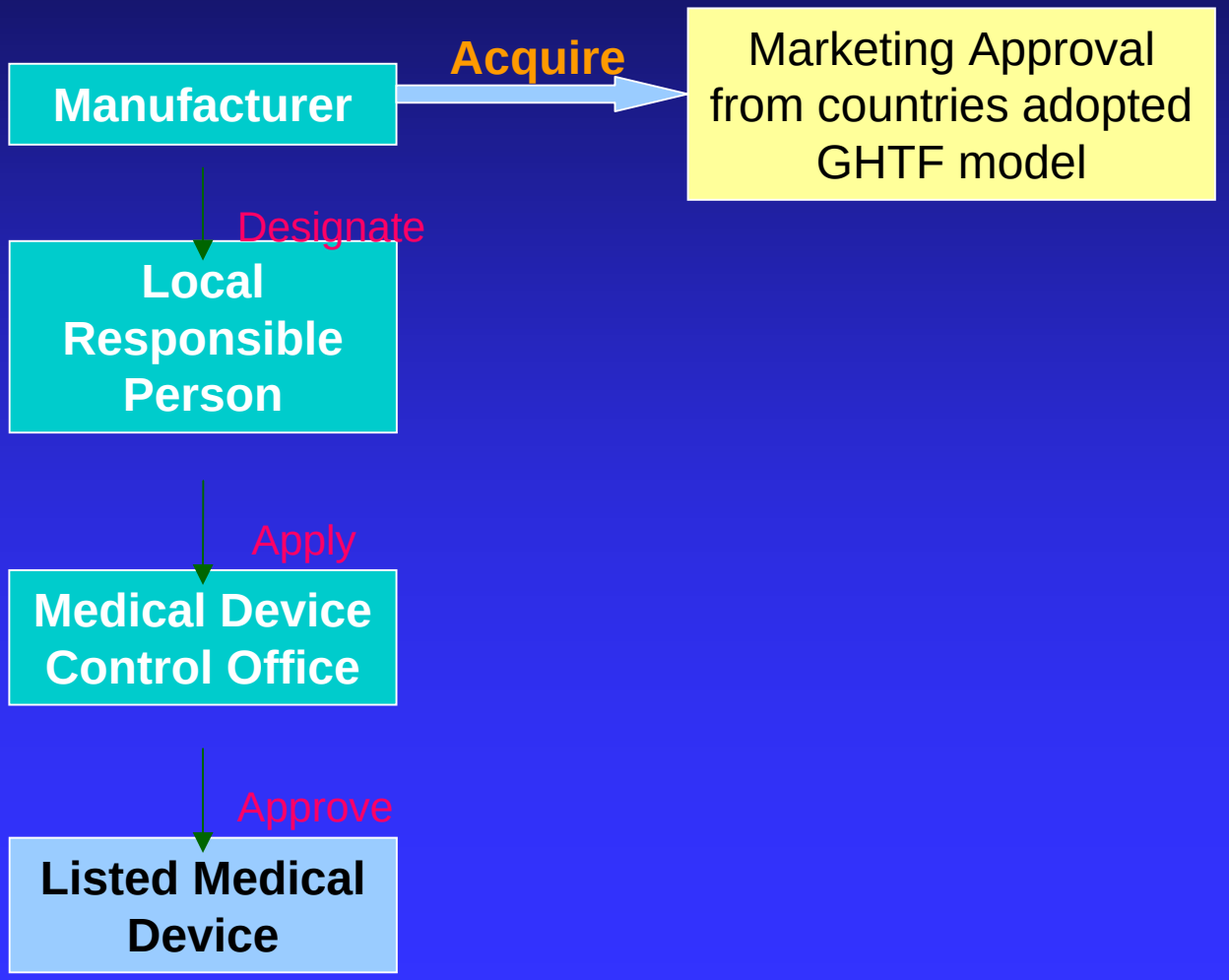
ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

Conformity Assessment by CAB



ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

Conformity Assessment by Other Marketing Approval



ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Beauty of Flexibility
  - Less resources on the part of government
  - Alternatives to suit manufacturers
  - Avoid duplication of conformity assessments
    - reduce the costs and time for placing products on market
    - Facilitate the entry of devices into the small Hong Kong market

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Certificate of Listing
  - Information on the certificate
    - Listing no.
    - Make and model
    - Device description
    - Manufacturer and address
    - Manufacturing sites
    - Local Responsible Person
    - Date of issue
    - Date of expiry

香港特別行政區政府
衞生署
醫療儀器管制辦公室
網站：www.mdco.gov.hk

Medical Device Control Office
Department of Health
Government of the Hong Kong
Special Administrative Region
Website: www.mdco.gov.hk

表列證書

CERTIFICATE OF LISTING

表列號碼 Listing No. : 050000

廠名及型號 Make and Model : ABC Model D

儀器名稱 Device Description : Glove, surgical, latex

製造商 Manufacturer : ABC, D-1234 Hong Kong

製造地點 Manufacturing Site : ABC, D-1234 Hong Kong

本地負責人 Local Responsible Person : ABC Hong Kong Limited

該證明上述產品已在衞生署的「醫療儀器行政管制制度」中表列，上述本地負責人已由製造商委任，並承諾遵守「醫療儀器行政管制制度」的規定。

This is to certify that the product described above has been listed with the Department of Health under the Medical Device Administrative Control System (MDACS). The above Local Responsible Person has been designated by the Manufacturer and has undertaken to comply with the MDACS requirements.

發出日期 Date of issue : 01 Jan 2005

有效至 Valid until : 31 Dec 2009

衞生署署長
(王春麗醫生代行)
(Dr Monica WONG)
for Director of Health

SAMPLE

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Post-market Surveillance
  - Medical Device Safety Alert System
  - Adverse Incident Reporting System

- Medical Device Safety Alert System
  - Sources of safety information
    - GHTF National Competent Authority Report Exchange Program (NCAR Program)
    - Overseas authorities
    - Local Responsible Persons
    - Device suppliers and manufacturers
    - Hospitals and healthcare institutions
    - News media…

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Classes of Safety Alerts (adapted from US FDA)
  - Class 1: reasonable chance of serious health problems or death
    → Urgent safety alert
  - Class 2: possibility causing temporary or reversible health problem
    → Monthly summary
  - Class 3: little chance causing health problems
    → No action

Dissemination of alerts

- Urgent Safety Alert Emails
- Press Releases
  http://www.mdco.gov.hk/english/press/press.html
- Urgent Safety Alerts
  http://www.mdco.gov.hk/english/recalls/recalls.html
- Monthly Summary of Safety Alerts

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Adverse Incident Reporting System
  http://www.mdco.gov.hk/english/report/report.html
  > On-line reporting
  > Reporting-form

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

- Way Forward
  - Regulatory Impact Assessment
    - July to December 2007
    - Includes public consultation
  - Report to Legislative Council - end 2007
    - Best option for statutory regulation
    - Schedule for implementation

ASEAN-U.S. Enhanced Partnership Medical Device Capacity Building Workshop

For more info on Hong Kong system, please visit

www.mdco.gov.hk