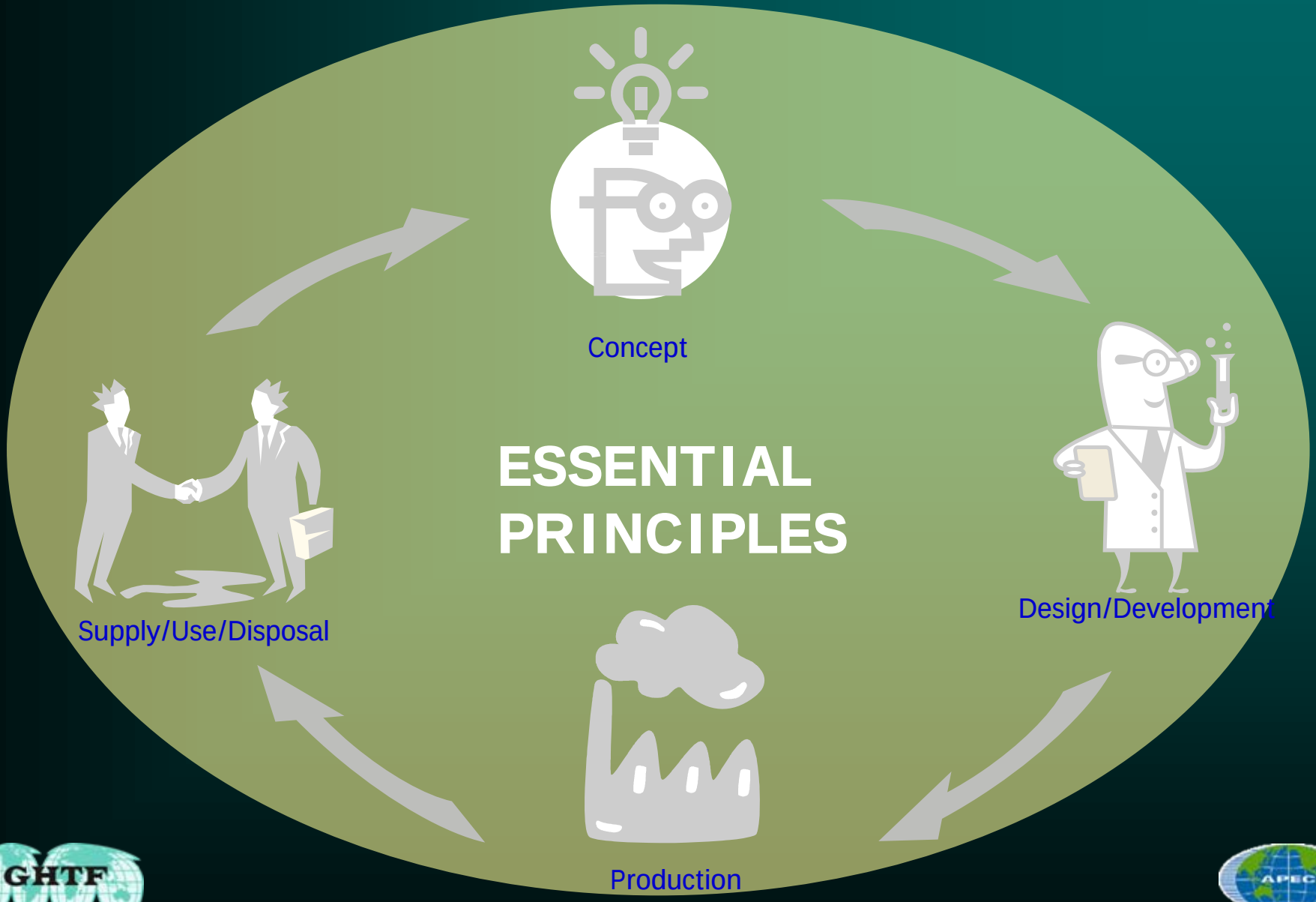
Medical Devices – Integrity in the Supply Chain

Roles and Responsibilities

Shelley Tang
Therapeutic Goods Administration
Australia

Whole of Life Cycle Approach



Manufacturer's responsibility

- In most Founding Member jurisdictions manufacturer takes ultimate responsibility for
  - Initial design
  - Compliance with Essential Principles/Safety and effectiveness requirements
  - Production
  - Ongoing monitoring of performance in the marketplace
    - Response to adverse events
    - Reporting of corrections or removal for safety reasons

Where device is imported...

- Regulatory authority in importing country needs a responsible body over which they have jurisdiction
- Manufacturer (in general) needs person(s) “on the ground” to enable manufacturer to meet obligations
- Known as importer, sponsor, initial distributor, Authorised Representative, Official Correspondent

Importer's responsibility

- Authorised by the manufacturer
- Takes legal responsibility for supply in the importing jurisdiction
- Interacts with Regulatory Authority on behalf of manufacturer
- Feeds back information on performance of the device to the manufacturer
- Keeps records of distribution

Australia

- Sponsor
  - Must hold information or have written agreement with manufacturer...
  - “includes” the device on the ARTG
  - Takes responsibility for recall and reporting
    - Annual reports
    - Serious adverse events (time frames mandated)
    - Non-compliance with regulatory requirements
  - Complies with conditions imposed on supply
  - Must give information to the TGA as required
  - TGA may inspect premises and take samples

Canada

- Importers and distributors require
  - an establishment licence
  - Documented procedures for distribution records, complaint handling and recalls
  - For Class II, III or IV devices, documented procedures for handling, storage, delivery, installation, corrective action and servicing
- Manufacturer and importer must each report serious adverse events (mandatory time-frames)
- Implant registration cards held by manufacturer

Europe

- Manufacturer works through Notified Body
- Manufacturer must have **a** designated responsible person established in the Community
- AR or importer must be identified on the label
- AR can act on behalf of a manufacturer
  - Can affix CE mark
  - Can prepare and sign DoC
- Manufacturer or designated responsible person must inform CA of address and category of devices supplied

Europe (new requirements)

From 2012

- Data to be stored in the European Databank
  - Registration of manufacturers
  - Certificates (issued, modified, supplemented, suspended, withdrawn or refused)
  - Data obtained in accordance with vigilance procedures
  - Registration of authorised representatives
  - Data on clinical investigations

Japan

- Manufacturer responsible for production only
- Market Authorisation Holder (MAH) responsible for
  - Quality and safety standards
  - Good Quality Practice
    - Shipping and receiving
    - Notifying MHLW of manufacturing changes
    - Release criteria
    - Recalls
  - Good Vigilance Practice
    - Safety of products after release into the marketplace

USA

- Foreign manufacturers must designate a US agent
- Initial importer must
  - Register establishment
  - Report serious adverse events to FDA
  - Report MDRs to manufacturer
  - Report to FDA on corrections and removals
  - Implement tracking procedures for specified devices

USA (cont)

- Distributor must keep records of complaints and make records available to the FDA
- Dealers and distributors in some cases (eg electronic products for which performance standards exist) must hold such information as is necessary to identify and locate first purchasers

Issues

- All jurisdictions know who is responsible for supply of the device
- Not all jurisdictions require address of responsible person on the label
- Most have mandatory reporting requirements
- Links between importer and manufacturer vary in strength
- Tracking requirements vary

Any Questions?