

New Australian Regulatory System for Medical Devices

Shelley Tang

TGA

New system will

- maintain TGA's standing in the international regulatory environment
- require an enhanced role for post-market to balance and complement the premarket programs
- utilise the benefits of the Australia-Europe Mutual Recognition Agreement

Framework

- adopts the principles of the GHTF as developed to date
- takes into account the concept of Total Product Lifecycle
- due to commence in October 2002

Elements of the New System

- risk based classification scheme
- Essential Principles for quality, safety and performance
- conformity assessment procedures
- medical device standards and conformity assessment standards
- market compliance program
- special access scheme

Supported by...

- Australian Register of Therapeutic Goods
- Device Electronic Application Lodgement (DEAL)
- Medical Device Advisory Committee for expert advice

Implementation

- new part of *Therapeutic Goods Act* for medical devices
- classification rules, Essential Principles and labelling requirements based on those of GHTF
- Conformity Assessment Procedures similar to those of the European MDD.
- no third party assessment

Any Questions?

