IMDRF International Medical Device Regulators Forum

Australian jurisdictional update

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Therapeutic Goods Administration

IMDRF Stakeholders Meeting

San Francisco, USA, 26 March 2014

Pre-market

1. New legislation passed
2. Premarket reforms
3. Up-classification of Class IIb joints
4. IVD framework amendments

Post-market

- Enhanced adverse event reporting
  - improved forms for reporting
  - on-line training modules for healthcare workers
  - integration in medical training curricula
  - publication of adverse event reports on TGA website
  - development of a Sentinel system