IMDRF International Medical Device Regulators Forum

Australian jurisdictional update

Dr Cheryl McRae

Therapeutic Goods Administration

Premarket

1. Expert review of regulation of medicines and medial devices
2. IVD framework amendments
3. Up-classification of Class IIb joints
4. De-regulation agenda
5. International engagement

Post market

1. Development of a new Adverse Event Management System
2. Future work includes developing a web service to allow manufactures to report directly
3. Sentinel site pilot
4. Review/consultation with stakeholders about the Recall procedure guideline