IMDRF International Medical Device Regulators Forum

Australian jurisdictional update

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Therapeutic Goods Administration

Premarket

1. Premarket reforms
2. Confidence building
3. Up-classification of Class IIb joints
4. IVD framework amendments
5. De-regulation agenda

Post market

1. Enhancements to Database of Adverse Event Notification (DAEN) currently being tested
2. Refining technical details of ‘adverse event’ definition (relevant to mandatory reporting)
3. Future work includes developing a web service to allow manufactures to report directly