IMDRF International Medical Device Regulators Forum

Australian jurisdictional update

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Therapeutic Goods Administration

Overview

- Restructure
  - TGA
  - Dept of Health

Premarket

1. Expert review of regulation of medicines and medial devices

2. IVD framework reforms

3. Reclassification of joint implants

Post market

1. Developing a new Adverse Event Management System (AEMS)

2. Developing two new device registries

3. Incident Reporting &Investigation scheme (IRIS) Sentinel Site pilot

4. Annual Charge Exemption (ACE)