IMDRF International Medical Device Regulators Forum

Australian Jurisdictional Update
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Dr Cheryl McRae

Therapeutic Goods Administration

Department of Health

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Administrative Arrangements

- Organisational change continues following the 2015 restructure of the TGA and the Department of Health – we welcomed device inspectors into Medical Devices Branch

Regulatory Update

- Recent regulatory amendment (passed through Federal Parliament) specifying TGA must be notified about custom-made devices within 2 months of manufacture or first supply in Australia

General Update

- Clinical Evidence Guidelines
- inSite pilot expanded into Sydney
- Medicines and Medical Devices Review
- Reclassification project for hip, knee and shoulder joint implants – transition period expired and applications being assessed
- Commercial IVDs have fully transitioned to the IVD framework - in-house IVDs transitioning until July 2017

Post Market Activities Update

- Pregnancy tests showing false positives
- TGA conducted lab testing on Silimed breast implants
- On-going reviews of gynaecological meshes resulting in updates to IFUs and some cancellations