IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Therapeutic Products Directorate
Health Canada

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Policy

- Medical Device Single Audit (MDSAP) Transition Plan Frequently Asked Questions (FAQ)
  - published April 22, 2016
  - document clarified that manufacturers must have valid MDSAP certificates as of January 1, 2019 to support their existing device licences and any new device licence applications going forward.

Policy

- Transition to ISO 13485:2016, published August 4, 2016

  -set March 1, 2019 as the transition date

- Re-use of Single Use Devices - Transition Period extended an additional 12 months (September 1, 2017) for all commercially reprocessed single use devices to be in compliance with the Regulations.

Regulatory Transparency and Openness Initiative

- Posting of Regulatory Decision Summaries
  - 66 (as of Aug 24) positive decisions for new Class IV medical device licence applications posted after April 1, 2015
  - 0 (as of Aug 24) negative decisions for new Class IV medical device licence applications posted after April 1, 2016

Regulatory Transparency and Openness Initiative

- Posting of List of New Safety Signals under Review and Summary of the Safety Reviews (SSR) completed
- Two SSRs posted as of April 2016

Guidance Documents

- Use of FDA Guidance Materials
- Decorative contact lenses
- Guidance for the Labelling of In Vitro Diagnostic Devices (IVDDs)

Upcoming Documents

- Finalization of Draft Guidance Document on the Preparation of a Premarket Medical Device and Licence Amendment Applications for Dermal Fillers

- Finalization of Draft Risk-Based Classification of In Vitro Diagnostic Devices (IVDDs)