IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Therapeutic Products Directorate
Health Canada

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A/Director

Medical Devices Bureau

Policy

- Medical Device Single Audit (MDSAP) Transition Plan published December 4, 2015
  - January 1, 2017- January 1, 2019: During the implementation phase, Health Canada will accept certificates issued under both Canadian Medical Devices Conformity Assessment System (CMDCAS) and MDSAP
  - January 1, 2019: Health Canada will only accept MDSAP certificates

Regulatory Transparency and Openness Initiative

Transparency Measures Introduced by Vanessa's Law

- Requires Health Canada to publicly disclose decisions on therapeutic product authorizations and details of any orders for a recall, test/ study, label change or reassessment

- Subject to regulations, requires sponsors to publicly disclose clinical trial information, such as registration and disclosure of results

- Posting of Regulatory Decision Summaries
  - Positive decisions for new Class IV medical device licence applications filed after April 1, 2015
  - Negative decisions for new Class IV medical device licence applications filed after April 1, 2016

Regulatory Transparency and Openness Initiative

- Posting of Regulatory Decision Summaries
  - 41 (as of Jan 21) positive decisions for new Class IV medical device licence applications posted after April 1, 2015
  - Negative decisions for new Class IV medical device licence applications to be posted after April 1, 2016

Guidance Documents

- Guidance for the Labelling of In Vitro Diagnostic Devices (IVDDs)
- Guidance for Health Care Professionals on Special Access and Custom-Made Medical Devices
- Guidance for the Risk-based Classification for In Vitro Diagnostic Devices (IVDDs)