IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

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Overview

- Medical Device Single Audit Program (MDSAP)
- Regulatory Review of Drugs and Devices
- Scientific Advisory Panel on Software as a Medical Device (SaMD)
- Cannabis
- Guidances

Medical Device Single Audit Program (MDSAP)

- In 2015, Health Canada announced the intention to implement MDSAP as the mechanism to demonstrate compliance with the quality management system requirements as of January 1, 2019.
- Manufacturer feedback and concerns:
  - Auditing Organization's capacity and readiness,
  - Increased audit duration and costs for smaller manufacturers
  - Health Canada's timeline to transition

Medical Device Single Audit Program (MDSAP)

- Health Canada has developed communications to ease transition which includes webinars with stakeholders and website landing page.
- Further analysis on audit duration for smaller manufacturers is ongoing.

Regulatory Review of Drugs and Devices

- Transformation into modern, agile regulatory system that supports better access to therapeutic products based on healthcare system needs
  - More timely access to drugs and devices
  - Enhanced use of Real World Evidence (RWE)

Digital Health Division

- Newly-created division will review
  - Software
  - Diagnostic, therapeutic, and cosmetic radiation devices
  - Cybersecurity
  - Artificial intelligence
  - Mobile apps
- Will also be involved in outreach and guidance development activities

Pre-Submission Scientific Advice

- Develop tools and processes that will improve pre-submission meetings:
  - Influence the design of clinical trials for devices
  - Generate appropriate data to meet regulator needs
  - Improve communication between HC and medical device industry
- e-learning tools in development
- Pre-clinical meeting pilot to be launched in Fall 2018

SAP-SaMD

- HC convened a Scientific Advisory Panel on Software as a Medical Device on January 26, 2018, to provide expert advice
- Panel members included regulator, physicians, software developers, patient group, and provided feedback on draft guidance document
- Guidance will be posted for external consultation

Cannabis

- Cannabis legalization in Canada targeted for July 2018
- New regulations being developed to address recreational and therapeutic use of cannabis
- Medical devices intended for use with cannabis (e.g., delivery devices, drug-device combination products) will be subject to additional requirements under these new regulations

Upcoming Documents

- Guidance on Software as a Medical Device (SaMD)

- Final Notice on the Reclassification of High-Level Disinfectants and Sterilants Intended for Medical Devices and associated guidance documents

Questions/comments

Thank you!