Regulatory Updates
Health Sciences Authority
Singapore

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Online Reporting System for Recalls and Field Safety Corrective Actions

- A new online system for submission of recalls and field safety corrective actions (FSCA) for medical devices has been developed
  - Enhance ease of reporting and efficiency of follow-ups

- Training videos have been developed and stakeholder feedback sessions complete

- Final usability test in progress

- To be launched in Q4 2019

MD Special Access Route Applications – Moving into our online portal

- The Special Access Route (SAR) application process for medical devices will be moving into our MEDICS online portal

- The system usability test (internal and external) to be completed in September 2019

- Updated guidance documents to be uploaded online this week

- Portal to be launched on 1 Oct 2019

Guidance Documents – New Documents in 2019

- Guidance on Requirements for Registration of Next Generation Sequencing IVD medical devices (NGS IVDs)
    - o Document published for consultation on our website.
      https://www.hsa.gov.sg/content/dam/HSA/HPRG/Medical_Devices/Updates_and_Safety_reporting/Regulatory_Updates/Requirements%20for%20NGS%20IVDs%20(for%20consultation).pdf
      Consultation period ends 31 August 2019.

- Guidance on the regulatory requirements for medical device software – a lifecycle approach
    - o In development

Guidance Documents – New Documents in 2019

- Safe use of Artificial Intelligence (AI) medical devices in Healthcare

  - There is increasing interest in the use of AI especially for clinical diagnosis and patient management as noted from the recent pre-market consultation applications we have received

  - In Singapore, HSA is working together with other Government agencies including the Ministry of Health to draft guiding principles to promote safe use of AI in our healthcare system

  - With growing interest in AI among our local research community, HSA is also working with the Academia and Research institutes to ensure safe development of AI based MDs

Thank you!