Regulatory Updates
Health Sciences Authority
Singapore

September 2019

Wong Woei Jiuang
Assistant Group Director, Medical Devices Cluster,
Health Sciences Authority, Singapore
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
  o 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
  
  o 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

  o 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

  o 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!