



IMDRF International Medical
Device Regulators Forum

Regulatory Updates Health Sciences Authority Singapore

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**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
 - 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



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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)
 - 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](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
 - 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!