Regulatory Updates
Health Sciences Authority
Singapore

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Medical Device Pre-market Registration

• Review and Redesign of our guidance documents on General medical device and IVD medical device registration
  o Clarification on specific requirements based on common queries or feedback
  o Reader-friendly format
Key changes: GN-17 and GN-18 Guidance Documents

- **Simple layout**
  - Simple
  - Reader friendly

- **Interactive**
  - Improve accessibility to information e.g. guidance documents and templates

- **Submission requirements**
  - Salient and succinct to provide greater clarity and reduce input request queries

Facilitate preparation and review of CSDT dossier

CSDT – Common Submission Dossier Template
Medical Device Pre-market Registration

• In Singapore, the pre-market submission, review and registration processes are performed on an online system called MEDICS
• Applicants submit their pre-market applications via this MEDICS portal
• The section in MEDICS where the various documents and reports from the dossier are to be uploaded, is designed as few modules.
• A submission guide that maps the various modules in our MEDICS system to the ASEAN CSDT dossier and to the IMDRF ToC has been developed to assist applicants with their online submission
Mapping the MEDIC modules to Dossiers

- E-Submission Guide for **General Medical Devices** for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS
- E-Submission Guide for **In Vitro Diagnostic Medical Devices** for ASEAN CSDT and IMDRF ToC based Submissions in MEDICS

- Specifies the appropriate modules in MEDICS for uploading of the corresponding sections of the CSDT or IMDRF ToC dossier
- Includes guidance on submitting responses to input request queries
  - To provide a written response to each input request query
  - To indicate the relevant file name(s) in the response if these are used to support the response
To facilitate review of the pre-market application

- Applicants shall ensure that the relevant section of the dossier and supporting documents are uploaded correctly under each MEDICS module.
- Document file names should also be **meaningful** and provide some indication of their content.
### E-Submission Guides

<table>
<thead>
<tr>
<th>Modules as per the ‘Dossier &amp; Supporting Document(s)’ section of the MEDICS application form</th>
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<tbody>
<tr>
<td>Brief description of the expected contents to be uploaded under each of the modules</td>
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| Data requirements for the respective evaluation routes (as per GN-15) |
| Sections of the CSDT or ToC to be uploaded under the respective module in MEDICS. |

Published online in December 2018
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
• Development of training videos and final usability tests in progress
• To be launched in June 2019
Guidance Documents – New Documents in 2019

• Guidance on the regulatory requirements for medical device software – a lifecycle approach

• Guidance on Next Generation Sequencing (NGS) based IVD medical devices
Thank you!