Health Products Regulatory Conference

Submission Excellence: Keys to Medical Device Approval

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Overview

- Importance of Good Submission
- Pre-Submission Planning and Strategy
- Common Submission Pitfalls
- Best Practices
- Tips
- Key Takeaway

Importance of Good Submission

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- S - Speed to Market
  - Faster approvals
  - Competitive advantage
  - Positive impact on company
- T - Trust Building
  - Inspire trust among stakeholders
  - Enhance the company's professional credibility
- A - Assets Optimization
  - Efficient use of resource
  - Reduced costs
- R - Results Delivery
  - Improved patient access
  - Establishes track record of successful submissions
  - Global market expansion

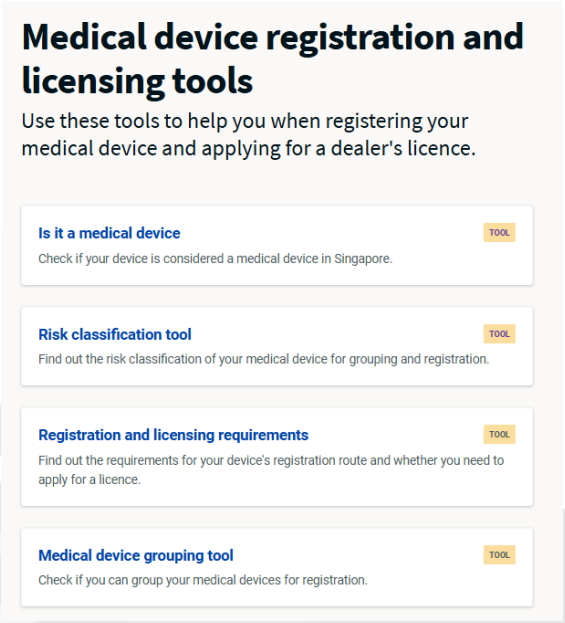
Pre-submission Planning and Strategy

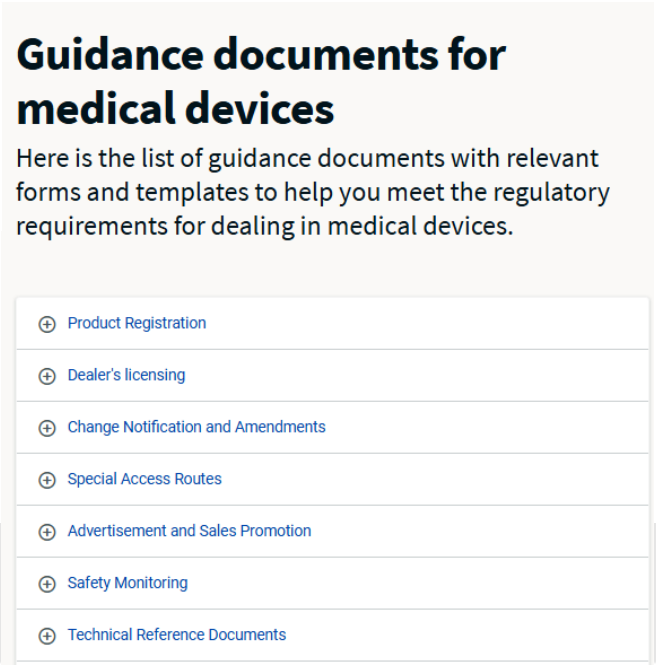

What should you do with so much information!!

Pre-Submission Planning and Strategy

3 Keys to pre-submission success in Singapore

- **Know your device and regulatory pathway**
  - ➢ Accurate device classification
  - ➢ Regulatory pathway selection
  - ➢ Understanding of guidance documents



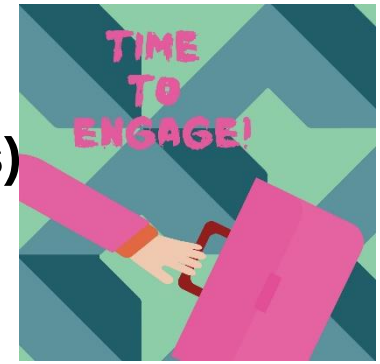


Pre-Submission Planning and Strategy

3 Keys to pre-submission success in Singapore

- **Documentation Excellence**
  - Submission Format – Common Submission Dossier Template (CSDT) or International Medical Device Regulators Forum (IMDRF) Medical device Market Authorisation Table of Contents (ToC)
  - Technical documentation completeness
  - HSA specific requirements (e.g. Letter of Authorisation, route specific documents)

- **Early Engagement with HSA (critical for new players)**
  - Pre-Submission Consultation



Common Submission Pitfalls

Common Submission Pitfalls

Documentation

- Incomplete or inconsistent documentation
- Inconsistent terminology used
- Information/data dumping
- Missing essential safety and performance requirements

Communication

- Poor organisation of responses
- Inadequate responses to queries
- Not seeking clarification on queries

Lack of submission strategy

- Unaware of regulatory requirements
- Incorrect risk classification
- Wrong regulatory pathway chosen

Best Practices

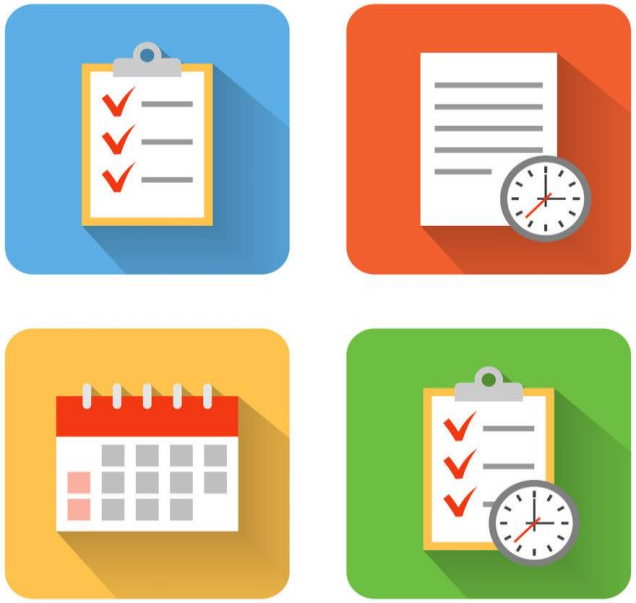
Best Practices

Preparation and organisation are critical – a well structured submission means faster approvals

Best Practices

Strategic preparation

- Key milestone and submission timeline planning
- Device classification confirmation
- Regulatory pathway selection
- Gap analysis of available data
- Be upfront with the standards used



- Documentary requirements (Summary reports vs Full reports)

Best Practices

Documentation Excellence [CSDT]

- Ensure dossier is as per the CSDT format

General Medical Device

- GN17: Guidance on preparation of a product registration submission for general medical devices using the ASEAN CSDT
- TR01: Contents of a product registration submission for General Medical Devices using the ASEAN CSDT

In-Vitro Diagnostic Device

- GN18: Guidance on preparation of a product registration submission for In-Vitro Diagnostic Medical Devices using the ASEAN CSDT
- TR02: Contents of a product registration submission for In-Vitro Diagnostic Medical Devices using the ASEAN CSDT

Best Practices

Documentation Excellence [CSDT]

- Elements of CSDT (Con't)
  - Executive summary should be on **your medical device**
  - Device description: Help us to understand your device! Pictorials, labelled diagram.
  - Essential principles checklist & Evidence of conformity
  - Device labelling
  - Risk analysis
  - Manufacturer Information

Best Practices

Documentation Excellence [CSDT]

- Elements of CSDT (Con't)
  - ➢ Design Verification and Validation

Design Verification and Validation [e.g. Biocompatibility, sterilization, software, shelf life, bench test, cybersecurity, sensitivity, interference]	✓ Clear documentation of test protocols and results ✓ Justification for leveraging existing V&V data ✓ Model representation justification ✓ Software a. Version tested should be clearly listed in the report b. Justification for version differences c. Justification for anomalies should also be included if they remain unresolved.

Best Practices

Documentation Excellence [CSDT]

- Elements of CSDT
  - ➢Clinical Evaluation

Clinical Evaluation	✓Consider referencing to *GN20: Guidance on Clinical Evaluation* ✓Clinical Evaluation Report (CER) should be clear and structured. ✓Clear identification of equivalent devices and detailed comparison table showing equivalence. ✓CER should not be a collection of literature. Ensure there are critical appraisal and quality assessment of the evidence. ✓For IVD using method comparison as clinical evidence, the comparator used must have obtained marketing clearance from HSA and/or reference agencies (EU, FDA, TGA, HC and MHLW)

Best Practices

Documentation Excellence [CSDT]

- HSA documentary requirements

Letter of authorisation	• Follow the HSA prescribed template • Product owner and registrant refers to company and not individual • Signature used should allow for traceability to ensure authenticity
Annex 2 List of Configurations	• State grouping used • Include medical devices to be registered in the application • Excel Format
Safety and Marketing History Declaration	• Route specific requirements • Declared and signed by Registrant • Signature used should allow for traceability to ensure authenticity
Declaration of labelling	• State the reference agency (s) used and the route selected • Declared and signed by Product Owner • Signature used should allow for traceability to ensure authenticity

Best Practices

Documentation Excellence [CSDT]

- Submission
  - ➢Name your file/document properly
  - ➢Upload into the applicable sections in SHARE

Tips

Tips

- Be precise. Answer straight to the point
- Consolidate all responses into a single document (e.g. word, pdf, excel).
- Name your document properly (e.g. “Query2_Software Test Report“)
- Categorize devices into groups (e.g. abutments, screws) and use tables/spreadsheet to map the device categories and applicable documents.
- Check with review officers when in doubt.
- Subscribe to HSA regulatory updates mailing list

Key Takeaway

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- Success Metrics: 3 Ps

Preparation	Precision	Proactivity
• Start Early • Plan thoroughly • Know the guidance documents	• Accuracy and consistency in documentation • Clear identification of models, versions and methods tested • Document deviations with clear justifications	• Anticipate questions • Engage early with regulators • Stay current with regulatory updates

Excellence in submissions isn't about perfection - it's about thorough preparation and clear communication

THANK YOU