Market Access To Hong Kong

Global Medical Device Consulting

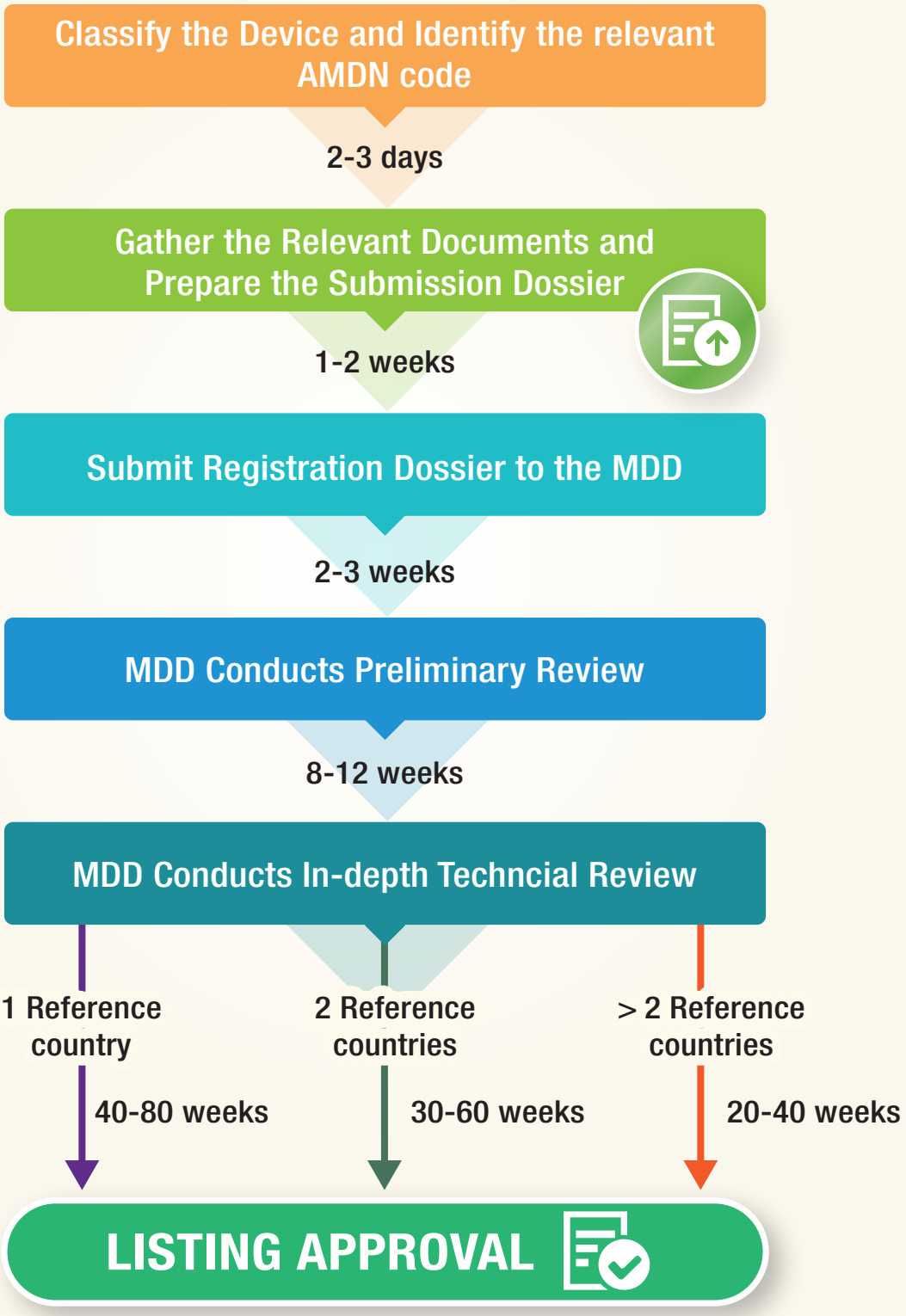
VEE CARE (ASIA) LTD

bsi ISO 13485 Quality Management for Medical Devices CERTIFIED

MD 653109

MARKET ACCESS TO HONG KONG

LISTING PROCESS



Reference Countries are: China, US, EU, Japan, Australia and Canada

MARKET ACCESS TO HONG KONG

DOCUMENTS REQUIRED

Application Requirements	Prepared by LRP	Prepared by MFR
LRP Designation Letter	✓	✓
LRP's BR	✓	
Documentation Procedures	✓	
Application Form	✓	
IFU		✓
Device Labelling	✓	✓
List of Components / Accessories		✓
ISO13485 (Manufacturer and Subcontractors)		✓
Manufacturing Flowcharts		✓
Marketing Approval (e.g., EC Certificate / 510k)		✓
EC Declaration of Conformity		✓
History of Recalls / Adverse Events		✓
Risk Management Report		✓
Bench Test Report (s)		✓
Clinical Investigation / Evaluation Report		✓
Essential Principles Conformity Checklist		✓

Vee Care provides a complete set of regulatory and compliance solutions for medical manufacturers.

Please visit our website for more information:

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