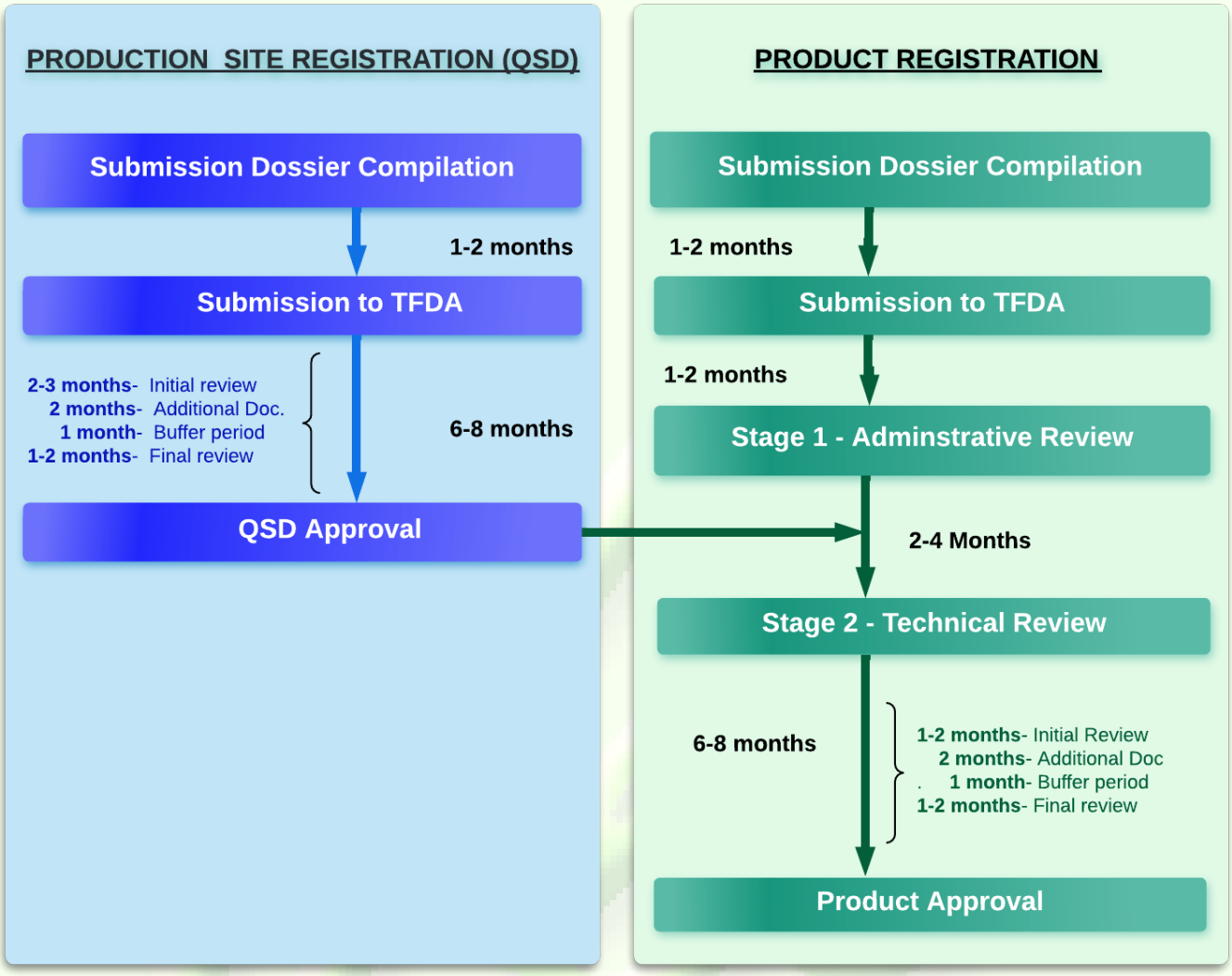
# MARKET ACCESS TO TAIWAN

## REGISTRATION PROCESS



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## DOCUMENTATION REQUIRED

| Technical Dossier | | Vee Care | Manufacturer |
|---|---|---|---|
| 1.1 | Information on previous applications | X | |
| 2.1 | Application form | X | |
| 3.1 | Safety & Performance Summary | X | |
| 5.1 | Local Drug Dealer License – License Holder | X | |
| 6.1 | Declaration Form | X | |
| 7.1 | Duly Legalized Free Sales Certificate from Home Country | | X |
| 8.1 | Letter of Authorization form Manufacturer to local license holder (original copy) | X | |
| 9.1 | Subcontractor Agreement (if any) | | X |
| 10.1 | QSD Certificate of Manufacturing Plant | X | |
| 11.1 | Packaging materials & Product Labels (2 sets) | | X |
| 11.2 | Chinese IFU / Product Manual (2 copies each) | X | |
| 11.3 | Product Photo (representative model) | | X |
| 11.4 | Original Product Manual | | X |
| 11.5 | Original IFU | | X |
| 12.1.1 | First introduction country, date, manufacturer name, site & model number | | X |
| 12.1.3 | Product structure, materials, performance and safety data | | X |
| 12.2 | Certificate on animal origin materials | | X |
| 12.3 | Operation Manual | | X |
| 12.4 | Maintenance Manual | | X |
| 13.1 | Predicate Information (Taiwan registration #, Chinese IFU, indication and specification comparison) | X | |
| 14.3 | Registration certificates or FSC other than home countries | | X |
| 15A | Bench Tests – Criteria, protocol & results | | X |
| 15B | Finished product specifications, test methods & test reports | | X |
| 16 | Principle of action report | | X |
| 17 | Clinical evaluation report (local/foreign) | | X |
| 18 | Radiation Safety Information (if applicable) | | X |
| **Quality System Documentation** | | **Vee Care** | **Manufacturer** |
| 1 | Declaration letter for the plant information (include plant name, address, list of process done by contractors....) | X | X |
| 2 | ISO 13485 certificate | | X |
| 3 | Quality Manual & Procedures stated in the Manual | | X |
| 4 | Plant layout & detail layout of the manufacturing area | | X |
| 5 | Product list and Manufacturing process flowchart | | X |
| 6 | Major Equipment list | | X |