

Medical Device

Market Entry Readiness Checklist

Key considerations to assess your readiness for regulatory approval and commercialization in a target market.



**Safer
Devices
Healthier
Lives**

01



Market Scope & Goals

- ☐ Target market(s) and launch timeline are defined.
- ☐ Intended use, claims and target patient population are finalized for the market.
- ☐ Device classification and regulatory pathway options are identified.
- ☐ Key regulatory differences (local requirements, language, standards) are understood.

02



Regulatory Requirements

- ☐ Applicable regulations and guidance (e.g., FDA, MDR/IVDR, UKCA, HC, TGA, CDSCO) are reviewed.
- ☐ Classification and product code (where applicable) are confirmed.
- ☐ Required standards (e.g., ISO 13485, ISO 14971, IEC standards) are identified.
- ☐ Regulatory gaps are assessed and an action plan is in place.

03



Technical Documentation & Evidence

- ☐ Device description, design and manufacturing information are complete.
- ☐ Risk management file is prepared and aligns with market requirements.
- ☐ Verification and validation (including software, cybersecurity, biocompatibility, EMC) are complete.
- ☐ Clinical evidence strategy is defined and the required data is available or planned.

04



Local Representation & Partnering

- ☐ Local authorized representative/agent (where required) is identified or appointed.
- ☐ Roles and responsibilities are defined in a written agreement.
- ☐ Importer/distributor (if applicable) is identified and contracted.
- ☐ Communication plan for regulatory interactions is established.

05



Registration, Labeling & UDI

- ☐ Submission dossier and required forms are prepared.
- ☐ Labeling and IFU meet local language and content requirements.
- ☐ UDI requirements are addressed (where applicable).
- ☐ Device registration, listing or licensing requirements are planned.

06



Quality System Readiness

- ☐ ISO 13485 certification (or applicable QMS) is in place or planned.
- ☐ Site and supplier controls meet market expectations.
- ☐ Regulatory inspections or audits (if applicable) are anticipated and planned.
- ☐ Ongoing QMS compliance and recordkeeping are established.

07



Post-Market Obligations

- ☐ Post-market surveillance (PMS) and vigilance reporting requirements are understood.
- ☐ Complaint handling and CAPA processes meet local requirements.
- ☐ Periodic safety update reports (PSUR) or equivalent (where applicable) are planned.
- ☐ Change management process for regulatory submissions is in place.

08



Commercial Readiness

- ☐ Go-to-market plan, key stakeholders and resources are defined.
- ☐ Insurance, reimbursement and market access considerations are assessed.
- ☐ Training and support for distributors and users are planned.
- ☐ Ongoing regulatory and quality support is established for product lifecycle management.



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