Regulatory Strategy Planning Template – FDA, EU MDR, Global Launch

Product Overview

- Device type, classification, and intended use
- Unique functionalities (e.g., SaMD, AI/ML, combination product)
- Target user population and care setting

Market Access Planning

- Primary target market (U.S., EU, APAC, etc.)
- Regulatory classification and applicable rules (FDA, MDR, TGA, etc.)
- Preferred submission type (510(k), De Novo, PMA, CE, etc.)
- Notified body/consultant engagement status

Technical and Clinical Requirements

- Pre-clinical and bench test planning
- Clinical evaluation or clinical trial need
- Biocompatibility and labeling expectations
- Standards and guidance documents to follow

Milestones & Timelines

- Regulatory roadmap aligned with design and production milestones
- Q-submission/pre-submission plan (if applicable)
- Estimated submission and approval timeline

Risk & Reimbursement Considerations

- Market-specific regulatory risks
- Impact of device claims on classification
- UDI, cybersecurity, and post-market requirements
- Reimbursement pathway research (e.g., CMS, NUB, NICE)