

Medical Device Regulatory Readiness Checklist

A practical checklist to help you prepare for a successful regulatory submission and market access.

*Safer
Devices
Healthier
Lives*

**01**

Regulatory Strategy & Planning

- ☐ Intended use, indications and target markets are clearly defined.
- ☐ Applicable regulatory requirements (e.g., FDA, MDR, UKCA, etc.) are identified.
- ☐ Regulatory pathway and classification are confirmed.
- ☐ Gaps are assessed and a clear plan is in place.

**02**

Technical Documentation

- ☐ Device description and design information are complete.
- ☐ Risk management file (e.g., ISO 14971) is prepared.
- ☐ Design verification and validation evidence is documented.
- ☐ Labeling, instructions for use and UDI requirements are addressed.

**03**

Clinical Evidence & Performance

- ☐ Clinical evaluation strategy is defined (e.g., MEDDEV 2.7/1, MDR Annex XIV, etc.).
- ☐ Clinical data or literature is collected and assessed.
- ☐ Essential safety and performance requirements are addressed.
- ☐ Benefit-risk analysis is documented.

**04**

Submission Preparation & Interaction

- ☐ Submission dossier (e.g., 510(k), De Novo, CE Technical Documentation) is complete.
- ☐ All required forms, summaries and evidence are included.
- ☐ A plan is in place to address regulator questions.
- ☐ Timelines and milestones for submission are defined.

**05**

Post-Market Readiness

- ☐ Post-market surveillance (PMS) plan is established.
- ☐ Complaint handling and vigilance processes are defined.
- ☐ Periodic reporting requirements are understood.
- ☐ Change management process is in place for future modifications.

