Health Canada Submission Checklist for Medical Devices

Regulatory Strategy & Classification

- Confirm medical device classification (Class I, II, III, IV)
- Determine licensing requirement: MDL and/or MDEL
- Appoint Canadian Regulatory Contact (if foreign manufacturer)
- Identify applicable guidance documents and policies
- Select appropriate evidence pathway (clinical, analytical, or performance-based

Technical Documentation

- Device description, intended use & indications for use
- Risk management file (per ISO 14971)
- Manufacturing & design details
- Device labeling and packaging (bilingual: English & French)
- Instructions for Use (IFU)
- Summary of Safety and Effectiveness (if required)
- Unique Device Identification (UDI) and traceability details

Clinical Evidence & Performance Data

- Safety and effectiveness evidence per classification
- Literature review or clinical trial reports (Class III & IV)
- Bio-compatibility, electrical safety, and software validation reports (if applicable)
- Equivalence data (if using predicate or comparative devices)

Quality System & Certifications

- ISO 13485:2016 certification
- MDSAP certification for Class II–IV devices
- Internal audit records and CAPA process
- Supplier and contract manufacturer controls

Submission & Post-Market Readiness

- Completed MDL or MDEL application forms
- Fees submitted via Health Canada portal
- Procedures for complaint handling and vigilance
- Post-Market Surveillance (PMS) and recall plan
- Health Canada query response and license lifecycle management