Elexes

Health Canada Compliance & Audit Readiness Checklist

Organizational & Regulatory Readiness

- Company profile and scope of activities clearly documented
- Authorized regulatory contact designated (Canada-based or via third party)
- Device classification rationale documented and justified
- Compliance matrix prepared mapping CMDR requirements to documentation
- Records of communications or inquiries to Health Canada

Quality Management System (QMS) Essentials

- Current ISO 13485:2016 certificate issued by MDSAP-recognized body
- Document control system implemented with version control
- Quality Manual and Standard Operating Procedures (SOPs) in place
- Employee training records for QMS, complaint handling, and regulatory awareness
- Procedures for handling nonconformities, CAPA, and internal audits

Establishment Licensing & Operational Controls

- Valid MDEL with correct activities and site addresses listed
- Roles and responsibilities mapped for importing, distribution, and record keeping
- Documented importation and distribution process
- Master list of suppliers, distributors, and contract manufacturers
- Annual license renewal calendar and compliance plan

Technical File Maintenance

- Centralized archive of MDL submission (if Class II–IV) and supporting data
- Bilingual labeling, packaging, and IFU maintained for all SKUs
- Evidence of changes tracked: software updates, design changes, supplier updates
- Records of device complaints and field actions (if any)
- Tracking of UDI information (if applicable) in accordance with GUDI/IMDRF guidance

Post-Market & Inspection Preparedness

- Post-Market Surveillance (PMS) procedure implemented
- Vigilance and adverse event reporting process tested/documented
- Recall procedures tested annually or after significant changes
- Mock inspection or Health Canada audit simulation performed
- Inspection readiness file or binder updated and reviewed quarterly