Elexes

Canadian Medical Device Compliance Checklist

- Understand Health Canada's classification system (Class I–IV)
- Determine if your product needs an MDL or MDEL
- If MDL needed, Obtain MDSAP certification
- Collect required documentation for MDL and/or MDEL applications. Review language, labeling, and French requirements for Canada
- Apply for MDL (if class II or III)
- Once MDL/or MDEL is granted, Complete the listing of the applicable devices in MDALL (MDEL is the only requirement for Class I)
- Determine incident reporting (along with trend analysis) requirements and Prepare Summary Reports under SOR/98-282 (Sections 61.4, 68.32).
- Plan for post-market surveillance and incident tracking
- Assess recall and adverse event reporting obligations
- Map internal SOPs to Canadian requirements