Elexes

510(k) Submission Consultants Checklist: Essential Steps to FDA Clearance

Regulatory Planning & Team Setup

- Define intended use, indications, and target market
- Assess device classification and determine 510(k) route
- Identify a suitable predicate device
- Appoint regulatory lead and build cross-functional team
- Align internal timelines with submission strategy

Design & Testing Preparation

- Ensure Design History File (DHF) is complete and traceable
- Finalize testing plan: bench, biocompatibility, software, EMC, sterilization
- Conduct risk analysis (ISO 14971)
- Confirm design and labeling align with intended use

510(k) Documentation Essentials

- FDA Forms: 3514, 3881, and Cover Letter
- Device Description and Predicate Comparison Table
- Test Reports and Validation Summaries
- Draft Labeling and Instructions for Use (IFU)
- 510(k) Summary or Statement
- Declarations of Conformity (if applicable)

Submission Execution & Communication

- Format documentation per FDA eSTAR/eCopy guidelines
- Complete internal RTA checklist before submission
- Submit via CDRH Portal or physical eCopy
- Track submission status and respond to FDA queries

Post-Submission & Launch Prep

- Review clearance letter and finalize labeling
- Register device and list it with FDA
- Train internal teams on cleared use and claims
- Initiate post-market surveillance activities