Elexes

FDA Pre-Submission (Q-Sub) Essentials

Device & Regulatory Details

- Clear device description and intended use
- Classification and regulatory pathway rationale (510(k), De Novo, PMA)
- Summary of product development stage

Technical & Clinical Documentation

- Device design overview with key specifications
- Proposed test protocols (bench, software, clinical, usability)
- Risk management summary (if available)
- Draft labeling, Instructions for Use (IFU), and packaging

FDA Engagement Strategy

- Well-structured questions for FDA (clinical, nonclinical, regulatory)
- Preferred method of feedback (written or teleconference)
- Suggested meeting agenda and discussion topics

Administrative Content

- Cover letter and contact details
- Table of contents and document structure per FDA guidance
- Confirm submission format (electronic via eCopy or CDRH Portal)
- Requested reviewers or division (if known and justified)