Elexes

Medical Device Change Control Checklist (FDA-Aligned)

1. Define the Change

- What is changing? (Software / Design / Process / Labeling)
- Why is the change being made?
- Which product/version is affected?

2. Assess Impact

- Does it affect intended use?
- Does it impact safety or performance?
- Does it introduce or modify risk?
- **If YES to any → Move to submission check**

3. Check Evidence Requirements

- New verification testing needed?
- New validation required?
- Is existing evidence still valid?

4. Submission Decision (FDA Focus)

- Significant impact on safety/effectiveness?
- Change in intended use?
- Aligns with 510(k) change guidance?
- **Decision: Submission required → Document internally with justification**

5. Update Documentation

- Risk Management File
- Design / Technical Documentation
- Labeling / IFU
- Software / Validation records

6. Quick Red Flags

- “Minor change” assumed without assessment
- Missing documentation or weak rationale
- Over-submitting due to uncertainty
- QA / RA / Eng misalignment