

12 Critical Checks Before You Submit: Medical Device Submission Consistency Checklist

- Intended use consistency across all documents
- Claims alignment between clinical, labeling, and technical files
- Clinical evidence versus risk management correlation
- Risk controls versus labeling warnings consistency
- Data consistency across tables and summaries
- IFU and labeling claim validation
- Indications for use alignment
- Device description consistency
- Terminology standardization
- Cross-reference verification
- Regulatory pathway alignment
- Final readiness review checks