Elexes

12 Critical Checks Before You Submit Your Medical Device to FDA or EU MDR

1. Regulatory Pathway Confirmed

Ensure the correct submission pathway and device classification are selected.

2. Intended Use Consistency

Verify intended use statements match across all documents.

3. Technical Documentation Complete

Check for missing sections, evidence gaps, or incomplete files.

4. Clinical Evidence Reviewed

Confirm clinical evidence supports device safety and performance claims.

5. Risk Management Alignment

Ensure RMF, CER, labeling, and technical documents are aligned.

6. Software Documentation Ready

Validate cybersecurity, software validation, and lifecycle records if applicable.

7. Labeling and IFU Checked

Review warnings, symbols, claims, and regulatory labeling requirements.

8. Cross-Document Consistency Verified

Ensure no conflicting information exists across submission files.

9. Verification & Validation Evidence Included

Confirm all required testing reports and summaries are available.

10. Submission Structure Reviewed

Check formatting, indexing, traceability, and file organization.

11. Regulatory Expectation Alignment

Review alignment with FDA guidance, EU MDR, and applicable standards.

12. Final Readiness Validation Completed

Perform a final expert review before submission.