

Medical Device Documentation Maintenance Checklist

Risk Management File (RMF) – Update Triggers

Update your risk management file medical device when:

- Design inputs or intended use change
- New hazards are identified
- Risk control measures are modified
- Verification results impact risk acceptability
- Post-market data introduces new risks
- Complaints or CAPAs relate to safety
- Standards or regulatory expectations change

Section 2: Design History File (DHF) – Update Triggers

Update DHF when:

- Design changes are implemented
- Design reviews are conducted
- Verification or validation activities are updated
- Test failures require design modifications
- New product variants or SKUs are introduced
- Software updates (for SaMD) are released
- Engineering change orders (ECOs) are approved

Section 3: Labeling & IFU – Update Triggers

Update labeling when:

- Intended use or indications change
- Risk controls impact warnings or precautions
- Market-specific regulatory requirements change
- New regions or geographies are added
- Product variants require differentiation
- Post-market feedback affects usability or safety

Section 4: Traceability – Update Triggers

Update traceability matrices when:

- Design inputs are revised
- Risk controls are updated
- Verification or validation results change
- Links between design ↔ risk ↔ testing are incomplete
- Documentation ownership or systems change