

15 Critical RMF Checks Before Audit

- Risk Management Plan approved and current
 - Hazards linked to risk controls
 - Controls linked to verification evidence
 - Residual risks properly justified
 - RMF aligned with CER conclusions
 - PMS data reflected in risk updates
 - Traceability maintained across documents
 - Risk acceptance criteria clearly defined
 - Verification evidence complete and accessible
 - Software/cybersecurity risks assessed
 - Foreseeable misuse evaluated
 - CAPA and complaint trends reviewed
 - Document versions controlled
 - RMF structure aligned with ISO 14971
 - Audit/submission readiness verified
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