MDSAP Checklist:
Process, Docs & Country Scope

Audit Preparation

- MDSAP country scope reviewed (US, Canada, Brazil, Japan, Australia)
- Internal gap assessment to MDSAP audit model conducted
- SOPs mapped to audit tasks (per MDSAP Companion Document)

Required Documentation

- QMS manual aligned with ISO 13485 and MDSAP
- Design & development plan and DHF in place (if applicable)
- Risk management file maintained per ISO 14971
- Internal audits and management reviews performed
- Complaint handling , CAPAs, NC reports up-to-date
- Purchasing, supplier control records audited
- Market authorizations and registrations documents
- Records of the adverse events reports are available and timeline for adverse event reporting is in
- Evidence that the design changes that follow documented, review and approval.
- Process validation records, envirnomental control monitoring records, training records for operators, production and services.
- Training and competency records for all roles that impact quality.

Nonconformity Management

- Grading system for NCs understood (Grade 1 vs Grade 2)
- CAPA procedures established for MDSAP-specific findings
- Historical remediation evidence retained