

Be Audit-Ready for MDSAP: 10 Key Preparatory Steps

- **Understand MDSAP Requirements** – Review audit model, regulatory scopes, and participating country rules.
- **Map Your QMS Processes** – Align all procedures with MDSAP process-based audit structure.
- **Conduct a Gap Assessment** – Identify gaps weaknesses against MDSAP requirements and address them early.
- **Update Documentation** – Ensure SOPs, records, and forms are current, controlled, and compliant.
- **Strengthen Risk Management** – Maintain ISO 14971-aligned risk files with clear traceability.
- **Verify Training & Competence** – Ensure all staff are trained and aware of audit expectations.
- **Review CAPA Effectiveness** – Close old CAPAs, verify effectiveness checks, and improve root-cause practices.
- **Audit Internal Processes** – Perform internal audits mirroring the MDSAP approach.
- **Prepare Objective Evidence** – Organize records for design, production, complaints, and PMS.
- **Set Up an Audit Logistics Plan** – Assign process owners, schedule availability, and prepare audit spaces.