MDSAP Audit

Readiness Checklist | Manufacturer Preparation

Device / role: _____ Reviewer / date: _____

Mark Ready, Gap or N/A. Reference evidence and justify N/A decisions.

1. Scope, jurisdictions and audit arrangements

- ☐ Confirm products, sites, roles, outsourced processes and intended supply markets.
- ☐ Justify exclusions/non-applicability against the current Audit Approach.
- ☐ Confirm recognized AO, audit stage, scope, dates and responsible contacts.

2. Management and risk-based oversight

- ☐ Check quality objectives, responsibilities, competence and management review.
- ☐ Connect risk decisions, document controls and resources with process evidence.

3. Market authorization and regulatory reporting

- ☐ Check applicable device authorizations, facility registrations and change obligations.
- ☐ Check adverse-event and advisory-notice procedures for applicable jurisdictions.
- ☐ Confirm responsibilities with sponsors, MAHs, importers and other relevant parties.

4. Measurement, analysis and improvement

- ☐ Link complaints, quality data, nonconformities and risk review to appropriate action.
- ☐ Check internal audits, corrections, corrective/preventive action and effectiveness.

5. Design, production/service and purchasing

- ☐ Check applicable design planning, reviews, verification, validation and change evidence.
- ☐ Check production acceptance, required validation, identification and traceability.
- ☐ Check relevant cleanliness, sterile-device, installation and servicing controls.
- ☐ Check supplier selection, monitoring, purchasing and outsourced-process controls.

6. Team preparation and finding follow-up

- ☐ Sample connected records; confirm process owners can retrieve and explain evidence.
- ☐ Prepare responses with correction, cause analysis, action and evidence as appropriate.
- ☐ Confirm AO deadlines; track implementation and effectiveness through the audit cycle.

Priority gap / evidence reference / owner / target date:

_____

Initial readiness aid, not a certification audit. Confirm scope against current MDSAP AU P0002.011 and applicable regulations. The recognized AO conducts certification audits and decides certification. Reviewed October 12, 2026.