Elexes

Medical Device Complaint File Audit-Readiness Checklist

Use this checklist to ensure your complaint file contains the documentation and evidence auditors expect.

1. Complaint Information

- [ ] Complaint details, dates and reporter information are complete.
- [ ] Device identification information is documented.
- [ ] Patient/user outcome and use context are recorded.

2. Investigation & Reportability

- [ ] Investigation findings are supported by evidence.
- [ ] Missing information and follow-up attempts are documented.
- [ ] Reportability assessment and rationale are clear.
- [ ] Applicable markets and timelines were considered.

3. Risk & Quality Actions

- [ ] Similar complaints and trends were reviewed.
- [ ] CAPA need was assessed and documented.
- [ ] Risk-management impact was evaluated.
- [ ] Supplier, product or process actions are linked where applicable.

4. Closure & Traceability

- [ ] Closure rationale is documented.
- [ ] Required approvals are completed.
- [ ] Open actions have owners and due dates.
- [ ] Related records are traceable from the complaint file.