Elexes

Medical Device Complaint-to-CAPA Checklist

Complaint Assessment

- What happened and what was the outcome?
- Is the failure mode understood?
- Is the event isolated or recurring?

Risk and Extent

- Could recurrence cause greater harm?
- Are other units, lots or markets potentially affected?
- Did an existing risk control fail?

Systemic Assessment

- Is there a design, manufacturing, supplier or process issue?
- Has a similar issue occurred previously?
- Was a previous corrective action ineffective?

CAPA Decision

- Is formal corrective action required?
- Is effectiveness verification needed?
- If CAPA is not opened, is the rationale documented?
- Are related actions traceably linked?