Elexes

Medical Device Complaint Downstream Action Checklist

Complaint & Investigation

- Is the investigation complete and the patient/user outcome documented?
- Is the failure mode and investigation conclusion clearly documented?
- Have similar complaints, recurrence, and trends been reviewed?
- Are any investigation limitations or uncertainties documented?

Risk Management

- Does the complaint identify a new hazard or hazardous situation?
- Could the probability or severity of harm differ from the current risk assessment?
- Has an existing risk control failed or become ineffective?
- Does the risk-management file require review or update?

Product & Engineering

- Could other devices, lots, models, components, or configurations be affected?
- Is engineering review or product action required?
- Is a design, software, process, or specification change needed?
- Would the proposed change require verification or validation?

Supplier & Maintenance

- Is a supplier, component, material, or outsourced process involved?
- Is supplier corrective action or containment required?
- Could maintenance, calibration, or servicing prevent recurrence?
- Do maintenance or service procedures require revision?

Labeling, Training & CAPA

- Did labeling, instructions, training, or usability contribute to the issue?
- Are labeling, training, or user-control updates required?
- Has the need for CAPA been assessed and documented?
- If CAPA is opened, are effectiveness measures defined?

Regulatory, PMS & Traceability

- Has regulatory impact and reporting been assessed?
- Does the finding affect post-market surveillance or trend monitoring?
- Are all required actions assigned to an owner with a due date?
- Are actions linked to controlled records and traceable to the complaint?