Elexes

Medical Device Incident Reporting Checklist

Awareness date is documented

- When did the responsible reporting entity first become aware of the event?

Patient or user outcome is assessed

- Did the event involve death, serious injury, serious deterioration, or another significant outcome?

Device malfunction is evaluated

- Could the malfunction cause or contribute to serious harm if it occurred again?

All relevant markets are identified

- Which jurisdictions need a separate reportability assessment?

Responsible reporting party is confirmed

- Manufacturer, importer, sponsor, user facility, licence holder, or another regulated entity?

Applicable reporting category is determined

- Which event classification and reporting requirement applies in each market?

Deadline is calculated correctly

- Is it measured in hours, calendar days, or work days, and what is the applicable Day 0?

Shortest applicable deadline is prioritized

- If several jurisdictions apply, which report requires action first?

Initial reporting need is confirmed

- Is a report required while the investigation is still ongoing?

Follow-up and closure are tracked

- Are supplemental information, investigation updates, corrective actions, and final-report obligations being monitored?