

MDR Vigilance Report

Use this template to regulatory vigilance report assessment for [event_id].

Template Metadata

Field	Details
Category	Medical Devices
Owner	[Team or owner]
Version	[Version number]
Effective Date	[Date]
Review Cycle	[Monthly / Quarterly / Annual / Event-based]
Status	[Draft / In Review / Approved]

Event Summary

State event ID, awareness date, source, country, complaint link, and concise event description.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Device Details

Identify device name, model, UDI, lot or serial number, software version, and distribution status.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Patient or User Impact

Describe injury, treatment, outcome, exposure, and whether the device was available for evaluation.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Reportability Assessment

Document decision logic for death, serious injury, malfunction, serious public health threat, and regional criteria.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Investigation Status

Summarize current findings, DHR review, returned device analysis, and root cause status.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Corrective Actions

List containment, CAPA, field action, labeling, or risk file updates.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Submission Controls

Define report type, authority, due date, submitter, follow-up schedule, and records retained. Use regulatory assessment language and avoid unsupported conclusions.

Item	Details	Owner	Status
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]
[Item or requirement]	[Describe the relevant detail, evidence, or decision]	[Owner]	[Open / Complete]

Notes

[Add context, assumptions, exceptions, evidence links, screenshots, calculations, or reviewer comments.]

Review and Signoff

Document review conclusions, approvals, unresolved items, and next review date.

Role	Name	Date	Notes
Preparer	[Name]	[Date]	[Notes]
Reviewer	[Name]	[Date]	[Notes]
Approver	[Name]	[Date]	[Notes]