

Product Complaint Investigation

Use this template to quality complaint investigation for [product_name] complaint [complaint_id].

Template Metadata

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

Complaint Intake

Record complaint ID, receipt date, reporter, event description, sample availability, and seriousness.

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.]

Product and Batch Details

Identify product, strength, batch, expiry, packaging, distribution, and retain sample availability.

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.]

Initial Risk Assessment

Assess patient risk, quality defect potential, escalation needs, and immediate containment.

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 Activities

Review batch records, retains, deviations, stability, distribution, manufacturing data, and returned samples.

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.]

Root Cause and Disposition

State confirmed or probable root cause, complaint confirmation status, batch impact, and product disposition.

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.]

Regulatory Assessment

Document recall, field alert, defect notification, pharmacovigilance, or no-report rationale.

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

Item	Details	Owner	Status
[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.]

Closure

Summarize customer response, CAPA linkage, trend code, approvals, and closure date. Use concise quality investigation language and tables where evidence is compared.

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]