

Pharmaceutical Adverse Event Reporting Checklist

Event Identification & Initial Assessment

Gather initial information about the adverse event and determine its potential severity.

Date of Event Occurrence

Time of Event Occurrence

Brief Summary of the Event

Initial Severity Assessment

- Mild
- Moderate
- Severe
- Life-Threatening

Patient Age (years)

Enter a number...

Reporting Source

- Patient
- Healthcare Professional
- Caregiver
- Other

Patient Information Verification

Confirm patient identity and relevant medical history.

Patient Full Name

Write something...

Date of Birth (YYYY-MM-DD)

Enter a number...

Patient Medical Record Number

Write something...

Gender

- Male
- Female
- Other
- Prefer not to say

Relevant Medical History (Brief Summary)

Write something...

Patient Contact Method Preference

- Phone
- Email
- Mail

Product Information Confirmation

Verify the specific pharmaceutical product involved and lot number.

Drug Name

Write something...

Lot Number

Enter a number...

Expiration Date (YYMMDD)

Enter a number...

Quantity Administered

Enter a number...

Dosage Form

- Tablet
- Capsule
- Solution
- Injection
- Other

Product Packaging Photo (if available)

 Upload File

Event Description and Timeline

Document detailed information about the event, including onset, duration, and resolution (if applicable).

Detailed Description of Adverse Event

Write something...

Date of Event Onset

Enter date...

Time of Event Onset

Date of Event Resolution (if applicable)

Enter date...

Time of Event Resolution (if applicable)

Duration of Event (in hours/minutes)

Enter a number...

Sequence of Events Leading Up to the Adverse Reaction

Write something...

Severity of Event (e.g., Mild, Moderate, Severe)

- Mild
- Moderate
- Severe

Medical Intervention & Outcome

Record any medical interventions performed and the patient's response.

Describe the medical interventions performed (e.g., medications, procedures).

Write something...

Dosage of medication administered (if applicable).

Enter a number...

Date of intervention.

Enter date...

Time of intervention.

Describe the patient's immediate response to the intervention.

Write something...

Overall Outcome of Intervention

- Improved
- Stable
- Worsened
- No Change

Describe any long-term effects or sequelae observed.

Write something...

Physician/Healthcare Provider Confirmation

Obtain confirmation and supporting documentation from the treating physician or healthcare provider.

Physician/Healthcare Provider Signature

Date of Confirmation

Enter date...

Physician/Healthcare Provider Name

Write something...

Physician/Healthcare Provider Credentials

Write something...

Summary of Physician Assessment (e.g., Causality Assessment, Severity)

Write something...

Causality Assessment (e.g., Definite, Probable, Possible, Unlikely, Not Related)

- Definite
- Probable
- Possible
- Unlikely
- Not Related

Severity Score (if applicable, per internal scoring system)

Enter a number...

Regulatory Reporting Requirements

Determine applicable reporting requirements (e.g., FDA, EMA).

Reporting Jurisdiction

- United States (FDA)
- European Union (EMA)
- Canada (Health Canada)
- Other (Specify in Long Text)

Reporting Form Type

- 3500A
- 15-Day Report
- Annual Report
- Other (Specify in Long Text)

Specific Regulatory Guidelines Applied

Write something...

Reporting Deadline (Days)

Enter a number...

Submission Date

Enter date...

Supporting Documentation (Regulatory)

 Upload File

Internal Reporting and Documentation

Complete necessary internal forms and enter data into relevant systems.

Case/Incident ID

Enter a number...

Date of Internal Report

Enter date...

Summary of Adverse Event (for internal records)

Write something...


Severity Assessment (Internal)

- Minor
- Moderate
- Severe
- Life-Threatening

Affected Departments

- Manufacturing
- Quality Assurance
- Pharmacovigilance
- Medical Affairs

Supporting Internal Documents (e.g., lab reports)

 Upload File

Internal Notes/Comments

Write something...

Review and Approval

Ensure accuracy and completeness of the report before submission.

Reviewer Signature

Review Date

Review Outcome

- Approved
- Requires Revision
- Rejected

Reviewer Comments (if applicable)

Revision Count (if applicable)

Submission and Tracking

Submit the report to the appropriate regulatory agency and track its status.

Submission Date

Submission Time

Submission Method

- Online Portal
- Email
- Mail

Tracking Number (if applicable)

Write something...

Confirmation Code (if applicable)

Enter a number...

Notes on Submission (e.g., communication with agency)

Write something...

Submission Status

- Submitted
- Received (Agency)
- Under Review
- Accepted
- Rejected