Deviation - an overview

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What is Deviation?

- Deviation is a departure from approved procedure or specification.

- A deviation is an activity performed differently and/or modified than that specified in an approved document.

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Types of deviation :-

• There are two types of deviations
  ➢ 1) Planned Deviation.
  ➢ 2) Unplanned Deviation.
Types of deviation..

1) Planned Deviation -

Planned deviations, which are described, and pre-approved deviation from the current operational document/system, covering a specified period of time or number of batches.

- Planned deviation shall be approved before execution.
2) Unplanned Deviation -

Unplanned deviations also called as incident.

Incident can be defined as unplanned or uncontrolled event in the form of non-compliance from the designed systems or procedures at any stage of manufacturing, packaging, testing, holding and storage of drug product due to system failure or equipment breakdown or manual error.
Types of deviation ...

2) Unplanned Deviation (Contu..)

Incidents are again of two type.

- i) Quality Impacting Incident
- ii) Quality Non-impacting Incident
Types of deviation ...

2) Unplanned Deviation (Contu..)

i) Quality Impacting Incident :-

Quality impacting incidents are errors or occurrences during execution of an activity which will affect the Quality, Purity, Strength of the drug product.

ii) Quality Non-impacting Incident :-

Quality Non-impacting incidents are errors or occurrences during execution of an activity which may have no impact on the quality, purity and strength of a drug product.
1) Planned deviation

- Who will raise the deviation?
  - Concerned department officer/executive or above can raise the deviation by all details which are mentioned in deviation form.

  Details like –
  1) Document/Material/Product description
  2) Item code /Document No./ A.R No./ Batch No.
  3) Current procedure
  4) Proposed Deviation
  5) Reason for Deviation and Justification for deviation
1) Planned deviation

- Who will review and authorize the deviation?
  - Concerned department head shall review deviation. In case of any additional information required on the deviation, department head send back the form to the initiator.
  - If the deviation is found acceptable, Department Head shall make the comments on the deviation and send to QA for further evaluation.
1) Planned deviation

- Who will approve the deviation?
  - QA Manager is responsible for approve or reject.
  - On receipt of the deviation, QA Manager shall allocate a number to the deviation report.
  - QA Manager shall evaluate the deviation and send the deviation format to other departments (QC/Engineering /SCM/RA), if require for their opinion.
  - Respective Department Heads shall write their comments on the deviation report by evaluating the impact of deviation.
  - QA Manager shall evaluate the deviation report along with the opinion of the other Department Heads for the impact of deviation.
1) Planned deviation

- **Who will approve the deviation?** (Continued)
  - On complete evaluation of the content of the deviation, QA Manager shall either approve or reject with comments.
  - On receipt of the deviation, shall allocate a number to the deviation report.

  ✓ While indicating the corrective and preventive actions it shall be ensured that the actions committed are with timelines.
  ✓ On confirmation of the corrective action as mentioned in the deviation report by QA Executive, QA Manager shall close the deviation and the same shall be recorded in the Deviation Log

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Flow chart for Handling of deviations

Initiator (Officer/Executive)

HOD

Approved

QA Manager

Rejected

Approved

Implementer from QA

Close Notification

Comments from Marketing

Comments from SCM

Comments from Engg.

Comments from Any other Dept.

RA, Validation

FR&D

Marketing

SCM, Engg

Any other Dept.

Comments from RA

Comments from Validation

Comments from FR&D

Return

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2) Unplanned deviation/Incident Report

- Whenever any incident occurs, the identifier together with the department head shall evaluate the impact of the incident on the Quality, Purity and Strength of the Product. Based on the evaluation, the incident shall be classified as Quality impacting or Quality non-impacting.

- For the Quality impacting Incident, the identifier shall immediately notify the QA, and shall raise the incident report by filling the relevant information in the incident format.

- QA officer/Executive shall register the incident in the Incident Log.

- Concerned Department Head shall carry out detailed investigation immediately after the occurrence of the incident.

- All documents or operations which give an information about the cause of the incident shall be investigated.

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2) Unplanned deviation/Incident Report (Contu...)

- To identify the root cause five generic causes shall be considered and investigated according to that
  a) Material
  b) Method
  c) Personal
  d) Equipment
  e) Environment

- Identify the probable causes, which may be the reason of incident. evaluate the probable causes and summarize to conclude and identify the root cause.

- Details of investigation, conclusion shall be recorded by concerned department head

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2) Unplanned deviation/Incident Report (Contu...)

- Based on the investigation, evaluation and conclusion, concerned department head shall take the immediate actions.
- CAPA shall be mentioned to avoid the recurrence of the incident.
- Concerned department head shall submit the incident report to QA Manager for evaluation and disposal.
- QA manager or designee shall monitor the CAPA and on ensuring the compliance, the incident shall be disposed.
- Once the planned CAPA have been executed, QA officer/Executive shall close the Incident report.
- If preventive action is planned in phased manner, the incident report shall remain open till the preventive action(s) is completed.

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2) Unplanned deviation/Incident Report (Contu...)

- For Quality Non impacting incident, the identifier shall register the incident by filling the relevant information in format.

- The identifier and the concerned department head shall carry out the detailed investigation.

- All operations/analysis/documents which give an information about the cause of the incident shall be investigated.

- The details of investigation, conclusion shall be recorded by initiator/concerned head.

- Based on the investigation, concerned HOD shall mention the CAPA to avoid the recurrence of the incident and the same shall be recorded.

- After taking corrective and Preventive actions, the Incident Report shall be disposed by concerned department head.
Flow chart for Handling of Incident

Incident Identification and classification

Quality impacting
- Notify QA and Raising of Incident Report
- Logging of Incident by QA
- Detailed Investigation by concerned Department Head
- Based on investigation Immediate Correction Done by Department Head
- CAPA By Department Head
- Evaluation of CAPA by QA
- After compliance, disposition of incident by QA
- Closing of incident in Incident Log

Quality Non impacting
- Logging of incident by department
- Detailed Investigation by concerned Department Head
- Based on Investigation CAPA by Dep. Head
- Evaluation of CAPA by Department Head
- After compliance, disposition of incident by Department Head
- Closing of incident in Incident Log

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What are the contents of ideal Deviation format?

- Deviation no.
- Department
- Document /Material /Equipment/ Product
- Document No. / AR No. / Item Code No. /Equipment No./ Batch No
- Current Procedures & Proposed procedures
- Reasons & Justifications.
- Corrective and Preventive Action
- Initiator Name, signature and date.
- Comments with Signature and Date of initiator department head, RA head and other department head (if applicable)
- QA Manager opinion : Approve/Reject.
- Verification of CAPA by QA team.

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What are the contents of ideal incident format?

- Incident no.
- Department.
- Date of Occurrence & date of report.
- Document /Material /Equipment/ Product.
- Document No. / AR No. / Item Code No. /Equipment No./ Batch No.
- Brief description of incident - description and Observer and QA officer sign and date.
- Investigation & Conclusion.-description and concerned officer and concern department head sign and date.
- Immediate correction done & CAPA. –description and concern department head sign and date.
- Evaluation and Disposition by QA Manager.

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THANK YOU