Centre for cGMP

PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA
(Set up by Ministry of Commerce & Industry, Govt. of India)

MANIPAL ACADEMY of HIGHER EDUCATION
(Institution of Eminence Deemed to be University)

Our Inspiration

Founder : **Dr. T M A Pai,** Padmashree awardee

Manipal College of Pharmaceutical Sciences | **In Association with IDMA and Pharmexcil**

Centre for cGMP presents to you "cGMP AWARENESS SERIES" (2025/03)

THINK cGMP – cGMP is LIFE

Commitment | Adherence | Creating Quality Culture

Topic: Deviation and its Management

Procedure and general requirements

- A deviation is a variance in a process. All variances should be avoided or mitigated to establish good manufacturing practices.
- Whenever a deviation occurs in a manufacturing facility, contact Quality Assurance (QA) immediately.
- A deviation record is initiated in the organization's quality system to document the event.
- Perform suitable analysis (Eg: Gemba analysis) with subject matter experts (SMEs) on the day of deviation occurrence. This includes a walkthrough of the place where deviation took place and understanding how and why the incident might have occurred.
- Perform initial impact assessment (IIA) of the deviation, on the product quality, safety, identity and purity. The IIA should be completed within 48 hrs of deviation opening in the quality system.
- The IIA will help understand the risk and impact level of deviation i.e., high, medium or low.
- Once IIA is approved by QA, it is critical to identify what all temporary actions need to be taken to continue operations without putting the product at risk.
- A deviation record reflects the quality of a pharmaceutical organization, on how they handle variations in the process and improve the quality of manufacturing.

Procedure and general requirements

INITIAL IMPACT ASSESSMENT (IIA):

- The IIA is imperative to any deviation record, as it helps understand the team, the risk and impact level of the deviation on the product quality.
- The IIA should be reviewed and approved by SMEs of all cross-functional groups and at the end by QA.
- The IIA also helps determine the requirement and extent of root cause analysis of the deviation.

DESCRIPTION OF THE DEVIATION:

- It is critical to outline the description of the event and should consist of answering questions in a manner it occurred. For example, what happened, when it happened, how it happened and what should have happened.
- The team should refrain from making assumptions and conclusions during description stage on why the event took place.
- Post description, implement immediate temporary actions which were taken by operations team to avoid this type of incident occurring again in rest of the operations.

DEVIATION INVESTIGATION:

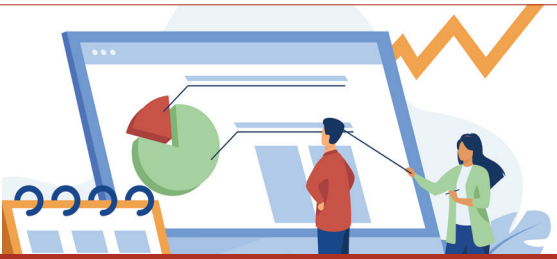
- Outline the input of the investigation. The outline should entail review of SOPs, interview of personnel involved during the deviation, RCA, CAPA analysis and QA recommendation.
- **CAPA:** Corrective action Preventive action

Root Cause Analysis (RCA)

RCA is paramount to any deviation. A robust analysis helps the organization take decisions to improve quality and prevent deviations or variance in the process. There are various tools to conduct RCA i.e., Ishikawa diagram/5 Whys/ 6Ms (Materials, Methods, Manpower, Mother nature, Measurements and Machine) etc.

Important Note:

Once RCA is completed and the root cause is identified, perform CAPA assessment with QA to determine how this deviation can be corrected/ prevented in the future. Quality Assurance is responsible for providing a recommendation on how cGMP should be conducted in accordance with the regulations and whether the CAPA needs an effective check within a year or not.



Visit Manipal cGMP Museum

Images by freepik