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Review on Deviation Management in Pharmaceutical Industry.

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Abstract:

Any departure from a proved instruction or established standard or any incident that would have an effect on Product quality or a reliability of record. There are so many deviations incidence occur throughout manufacturing process which are affect on quality management system of pharmaceutical industry so handling of deviation is one of vital step in quality management. This Article introduce you procedure for handling of deviation with its categorizing, Raise of Deviation, Investigation.

Keywords: Deviation, CAPA, Root cause analysis, Pharmaceutical.

Introduction:

Deviations are the measured variations between the observed and expected or normal values for a product or method condition or a departure from a documented standard or procedure. A deviation may occur during sampling and testing, raw materials- and finished product acceptance and manufacturing. Deviations may additionally be triggered by customer complaints or comments when the customer company's standards do not meet critical attributes as delivered per certificate.[1]

Types:

1. **Critical**
2. **Major**
3. **Minor**

1.Critical:

When the deviation affects a quality attribute, Critical process parameter, an equipment or instrument critical for process or control of action the impact on patient is highly probable as well as life threatening scenario or when deviation adversely affect the safety, Identity, strength, purity and quality of product average integrity of data. Critical deviation requires immediate action, investigation and documentation as such by the appropriate SOP.

Possible consequences: Rejection of batch or CAPA**.**

2.Major:

When the deviation affects a quality attribute a critical process parameter, an equipment or instrument critical for or control, of which the impact to patients is unlikely and or that might adversely affect the safely, identity, strength, purity and quality of product and documented as by process appropriate SOP.

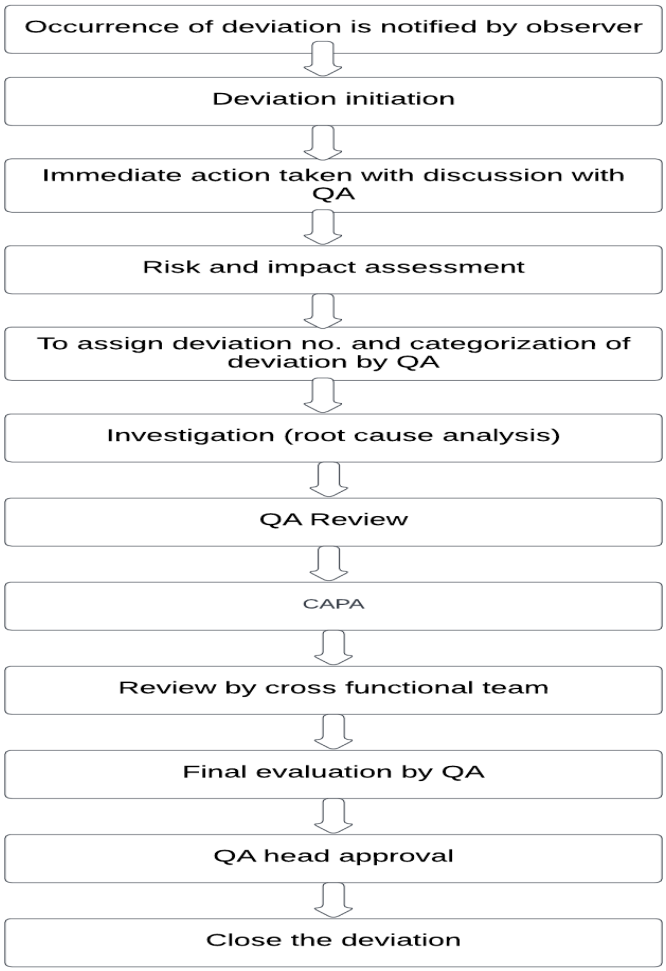
Possible consequences: Rejection of batch or CAPA**.**

3.Minor:

When the deviation does not affect any quality attribute a critical process parameter or an equipment or instrument critical for process or control and that does adversely affect the safety, identity, strength, purity and quality of product it would be categorized as minor.

Possible consequences: Need for improvement of conditions, practice and process.[2]

Flowchart:



How to raise?

- As soon as any deviation observed department head and discussed with QA about the deviation and take the decision as per its severity like immediate action and stop further process.
- After that record that deviation with sop instruction with process, person, timing, production stage, department, category.
- After this investigation process are started.[3]

Step of investigation:

1.Immediate notification of deviation on detection to respective user department.

2.Preliminary analysis.

3.Evaluate all currently available information.

4.Interview appropriate people.

5.Immediate measure or remedial action shall we planned based on preliminary evaluation.

- Basic knowledge and experience of incidents and Investigation.
- Understanding of process and the systems

6.Investigation process and data collection:

- Review of records and documentation.
- Review of similar incidence in last 5 years.
- History of products interview with operating person.[4]

ROOT CAUSE ANALYSIS

Genchi Genbutsu

Brainstorming Fishbone/Ishikawa Diagram

why analysis

Fault Tree Analysis

Genchi Genbutsu:

The meaning and procedure of this technique is mentioned below:

"Genchi Genbutsu" means "Go" and "See" i.e. Go and see for yourself to thoroughly understand the situation.

Root cause is identified by using the below mentioned steps.

1. Observe the problem/situation first hand, personally (not to rely on the report of others).
2. Talk to those at the sharp end (counselling).
3. Explore the contributing visible and invisible factors.
4. Analyse each factor and conclude probability.[5]

Brainstorming:

1. The details of Brainstorming are mentioned below.
2. Brainstorming one of the creative problems solving method that allows the people to come-up with suggestions/ ideas that could solve the problem/situation.
3. A meeting with Cross Functional Team may be called to brain storm on problem/situation.
4. Revelent people shall ask to think and share their views /suggest ideas to overcome the problem All views and suggestion shall analyse to identify the cause of problem.[5]

Fishbone/Ishikawa Diagram:

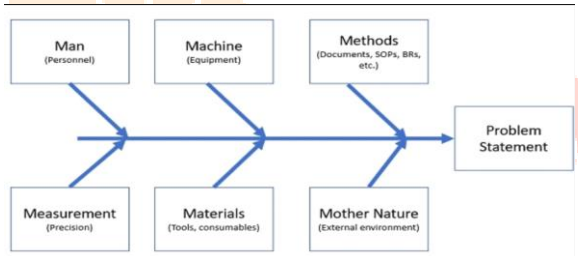
The fishbone diagram identifies many possible causes for an effect or problem.

The Fishbone diagram includes the potential cause of the problem and is used in order to find the real causes.

This tool is mainly categorized in 6M i.e., Man, Materials, Machine Method, Measurement

Mother Nature. Below are the main 6M causes:

1) Man: Responsible persons who involved in the process or activity.
2) Materials: Raw materials, items, parts used or involved in the process or activity.
3) Method: It includes all procedures, rules, policy, regulation, and specific requirement for the activity or process
4) Measurements: Data generated during a process which measures the quality of products.
5) Machines: Any equipment, instrument involved in the activity or process
6) Mother nature: This includes environmental conditions like temperature, humidity, pressure differential etc. and culture which process or activity performed.[6]



5. why analysis:

1. 5W1H (who, what, where, when, why, how) is a method of asking questions about a process or a problem taken up for improvement.
2. Four of the W's (who, what, where, when) and the one H is used to comprehend for details, analyse inferences and judgment to get to the fundamental facts and guide statements to get to the abstraction.
3. The last W (why) is often asked five times so that one can drill down to get to the core of a problem.
4. 5W1H of Six Sigma explains the approach to be followed by exactly understanding and analysing the process, project, or problem for improvement.[6]

Fault Tree Analysis:

Fault tree analysis is a tool to find out the root cause analysis for the deviations. This helps to evaluate the failure of system one at a time and sometimes, by identifying the casual chain of events, multiple causes can be combined.

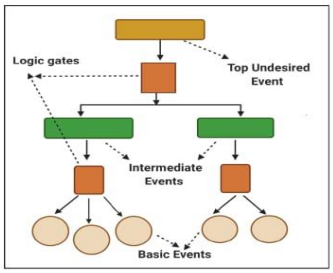


Fig. 4: Fault tree analysis

Conclusion

The results of these events are represented pictorially in the tree form. FTA is used to investigate the deviations and complaints to understand the root cause and to make improvements so that it does not lead to further problems.

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