

CAPA and risk management

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The pharmaceutical company should have a system for implementing corrective actions and preventive actions resulting from the; investigation of complaints, Product rejections, Non-conformances, Recalls, deviations, Audits, Regulatory inspections and findings, and Trends from process performance and product quality monitoring. A structured approach to the investigation process should be used with the objective of determining the root cause. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk, In line with ICH Q9 "Quality Risk Management".

CAPA methodology should result in product and process improvements and enhanced product and process understanding.

Corrective Action: Corrective action is aiming to correct an existing non-conformity and to avoid reoccurrence of the same non-conformity. Corrective action may arise, from manufacturing deviations, OOS investigations, complaints, audit findings, recalls.

A systematic investigation should be performed to determine the reason(s) for the non-conformities and to agree upon appropriate corrective action.

All Agreed corrective actions should be closely followed-up and monitored till completion.

Management should be notified about the costs and impact of failure including the respective corrective actions.

Preventive Action: Preventive action should be aiming to avoid the initial occurrence of non-conformity by proactively implementing improvements. Preventive action may result from trending of in process data, of analytical data, of audit findings, Trending of root causes for non-conformities or complaints, From product quality reviews (annual product reviews), Quality risk analyses, etc.

Similar to corrective actions, All Agreed Preventive Actions should be closely followed-up and monitored till their completion. Effectiveness of preventive actions should be reviewed regularly, as part of the product quality review (annual product review).

Effective CAPA Process, CAPA Challenges & CAPA Management Software are the key factors.

Biography

Rucha Majmundar Mehta is an independent GCP Auditor (Freelancer) since 6 years. She developed a Clinical Research Site in a privately owned small sized hospital and was heading the site till 2007. She provides QA consultation and training to various study sites and QA department of Pharmaceutical Companies, and conducts GCP Sessions during Investigators Meeting globally. She was practicing as a Clinical Nutritionist prior to changing her profession to Clinical Research. She has done post-graduate studies in Clinical Nutrition from G S Medical College Bombay - India. She received her training in clinical research from NIH - US, and has done GCP auditing course from BARQA-UK.

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