Course Description:

This 4-hour course is designed to provide participants with a comprehensive understanding of Corrective Actions (CA) and Preventive Actions (PA) within the context of quality management systems. Through interactive discussions, case studies, and group exercises, participants will learn how to effectively identify, implement, and manage CAPA processes to improve organizational performance and compliance with regulatory requirements.

Course Objectives:

1. Understand the purpose and importance of CAPA in quality management.
2. Differentiate between Corrective Actions (CA) and Preventive Actions (PA).
3. Learn how to effectively investigate and root cause analysis for CAPA.
4. Develop skills to implement and monitor CAPA plans.
5. Explore best practices for documentation and communication in CAPA processes.

Course Outline:

1. Introduction to CAPA
   1. CAPA definitions
   2. Overview of CAPA principles and its role in quality management.
   3. Regulatory requirements (e.g., FDA, ISO) related to CAPA.
2. Differentiating CA and PA
   1. Definition and purpose of CA and PA.
   2. Examples of CA and PA in various industries (e.g., healthcare, manufacturing).
3. CAPA Investigation and Root Cause Analysis
   1. Techniques for conducting effective investigations.
   2. Root cause analysis tools (e.g., 5 Whys, Fishbone diagram).
4. Developing and Implementing CAPA Plans
   1. Developing action plans based on investigation findings.
   2. Implementing and tracking CAPA effectiveness.
5. Best Practices in CAPA Documentation and Communication
   1. Documenting CAPA processes and outcomes.
   2. Communicating CAPA findings and actions to stakeholders.
6. CAPA Scenario and Working Group Exercise
   1. Presentation of a realistic CAPA scenario.
   2. Breakout groups to analyze the scenario, develop CA and PA plans, and present findings to the class.
7. Case Studies and Examples
   1. Review of real-world CAPA case studies.
   2. Discussion of lessons learned and best practices from case studies.
8. Q&A and Discussion
   1. Open forum for questions, discussion, and sharing of experiences related to CAPA.
9. Conclusion and Recap
   1. Summary of key concepts and takeaways from the course.
   2. Feedback and evaluation of the course.

X. Post-Course Assessment (Optional). crossword

Optional assessment to test participants' understanding of CAPA concepts covered in the course.

Materials Required:

* Presentation slides
* Case studies and scenarios
* Flip charts or whiteboards for group exercises
* Handouts or worksheets for exercises
* Evaluation forms for feedback

Target Audience:

* Quality assurance professionals, regulatory affairs personnel, auditors, and anyone involved in implementing or managing CAPA processes in their organization.

Prerequisites:

* Basic understanding of quality management principles and familiarity with quality management systems is recommended but not required.
* If an RCA class was utilized in a previous training, that RCA can dovetail into the CAPA material