Root Cause Analysis (RCA) and CAPA for GMP Deviations Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA) play pivotal roles in ensuring compliance and continuous improvement in Good Manufacturing Practices (GMP). In industries where quality control is non-negotiable, RCA and CAPA provide systematic approaches for investigating, analyzing, and addressing deviations, ultimately preventing recurrence and improving operational processes. Root Cause Analysis (RCA) and CAPA for GMP Deviations Training Course equips professionals with the knowledge and tools needed to investigate GMP deviations effectively, identify root causes, and implement corrective and preventive measures. By integrating key methodologies and industry best practices, this course empowers organizations to maintain compliance, enhance product quality, and ensure operational efficiency.

The training will explore the practical aspects of performing RCA and CAPA, focusing on proven techniques that drive improvement in a regulated environment. Participants will learn to utilize modern analytical tools, explore case studies, and develop strategies to streamline processes and mitigate risks. With a structured approach to investigating GMP deviations, professionals will be better positioned to contribute to a culture of quality within their organizations. Whether in pharmaceutical manufacturing, biotechnology, or other GMP-compliant sectors, this course offers actionable insights that can lead to tangible improvements in quality systems and operational performance.

Programme Curriculum

Root Cause Analysis (RCA) and CAPA for GMP Deviations Training Course

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Course Duration

10 days

Course Objectives

1. Understand the principles and methodologies behind Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA) within GMP contexts.
2. Identify and mitigate the causes of GMP deviations, improving quality control and operational integrity.
3. Develop critical thinking skills for effective problem-solving in deviation management.
4. Learn to conduct effective RCA through data analysis, interviews, and structured methodologies.
5. Apply CAPA strategies to prevent recurrence of GMP deviations and enhance operational performance.
6. Familiarize with regulatory standards for RCA and CAPA, including FDA, EMA, and ISO guidelines.
7. Integrate modern tools and technologies in RCA and CAPA processes for better traceability and transparency.
8. Utilize failure mode effects analysis (FMEA) and other risk management tools to analyze deviations.
9. Understand the significance of root cause verification to ensure long-term corrective measures.
10. Develop and implement effective training programs on RCA and CAPA for cross-functional teams.
11. Explore continuous improvement techniques using RCA and CAPA in the GMP environment.
12. Learn best practices for documentation, reporting, and compliance in RCA and CAPA processes.
13. Analyze and solve real-world case studies, applying RCA and CAPA techniques to GMP deviations.

Target Audience

1. Quality Assurance (QA) Managers
2. Regulatory Affairs Professionals
3. GMP Compliance Officers
4. Manufacturing Managers
5. Pharmaceutical Engineers
6. Production Supervisors
7. Process Improvement Specialists
8. Auditors in GMP environments

Course Modules

Module 1: Introduction to RCA and CAPA

- Understanding the basics of RCA and CAPA
- Importance of RCA and CAPA in GMP environments
- Case study: The role of RCA and CAPA in product quality
- Regulatory frameworks and compliance standards
- Key terminologies in RCA and CAPA

Module 2: Investigating GMP Deviations

- Types of GMP deviations
- Step-by-step approach to deviation investigation
- Tools for identifying deviations
- Collecting data for root cause analysis
- Case study: GMP deviation investigation in a pharmaceutical plant

Module 3: Root Cause Analysis Techniques

- Overview of RCA methodologies
- Fishbone diagram (Ishikawa)
- 5 Whys technique
- Fault Tree Analysis (FTA)
- Case study: Using RCA tools to identify root cause

Module 4: Corrective and Preventive Actions (CAPA) Overview

- Defining corrective and preventive actions
- The importance of timely CAPA implementation
- CAPA planning and execution process
- Aligning CAPA with risk management strategies
- Case study: Effective CAPA implementation in a manufacturing facility

Module 5: Risk Management in RCA and CAPA

- Risk-based approach to RCA
- Failure Mode Effects Analysis (FMEA)
- Hazard analysis and risk assessment
- Applying risk management tools in CAPA
- Case study: Risk mitigation strategies in CAPA

Module 6: Documenting and Reporting RCA and CAPA

- Best practices for documentation
- CAPA report structure and contents
- Record-keeping requirements for GMP compliance
- Electronic documentation and regulatory considerations
- Case study: Compliance audit and CAPA documentation

Module 7: Regulatory Guidelines and Standards

- Understanding FDA, EMA, and ISO requirements
- How regulatory bodies view RCA and CAPA

- Key GMP guidelines on deviation management
- CAPA audit preparedness and strategies
- Case study: Meeting regulatory standards in CAPA

Module 8: RCA Tools and Technologies

- Leveraging software for RCA and CAPA tracking
- Automation in deviation tracking
- Data analytics for RCA insights
- Integrating RCA tools with quality management systems
- Case study: Implementing RCA software in a pharmaceutical company

Module 9: Continuous Improvement through RCA and CAPA

- Aligning RCA and CAPA with continuous improvement
- Kaizen methodology in GMP environments
- The role of feedback loops in RCA
- Measuring the effectiveness of CAPA actions
- Case study: Continuous improvement through CAPA

Module 10: Effective CAPA Implementation

- Steps to implement CAPA
- Root cause verification in CAPA
- Monitoring and tracking CAPA results
- CAPA effectiveness assessment tools
- Case study: Successful CAPA implementation post-deviation

Module 11: Managing CAPA Resources

- Resource allocation for CAPA projects
- Cross-functional collaboration in CAPA implementation
- Training for CAPA teams
- Managing CAPA timelines and milestones
- Case study: Managing CAPA resources in a biopharmaceutical setting

Module 12: Performance Metrics in RCA and CAPA

- Key performance indicators for RCA and CAPA
- Measuring the success of corrective actions
- Statistical tools for RCA performance metrics
- Analyzing CAPA effectiveness through data
- Case study: Using metrics to improve CAPA processes

Module 13: Cross-Functional Collaboration in RCA and CAPA

- Roles of various departments in RCA and CAPA
- Collaborating with production, quality control, and engineering
- Communication strategies for RCA and CAPA teams
- Creating a culture of quality and accountability
- Case study: Cross-functional collaboration in deviation resolution

Module 14: CAPA Effectiveness and Monitoring

- CAPA monitoring systems
- Techniques for ongoing CAPA tracking
- Identifying recurring issues for long-term solutions
- The role of CAPA in audit readiness
- Case study: Monitoring CAPA effectiveness in a pharmaceutical lab

Module 15: Audits and Inspections for RCA and CAPA

- Preparing for RCA and CAPA audits
- Internal vs. external audits in deviation management
- Best practices for audit trail and inspection readiness
- Role of CAPA in GMP inspections
- Case study: Audit findings and CAPA responses

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.com or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to FINESKILL TRAINING CENTER account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000
28 Sep 2026	09 Oct 2026	Online	$4,000
05 Oct 2026	16 Oct 2026	Online	$4,000
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

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