Practical Guide for Root Cause Investigations

Methodology & Tool Kit

Overview

This engaging two-day workshop teaches a step by step, proven process ideal for researching any change/decline in the performance of a product or work process/system, whether it be physical or virtual. It is appropriate for individuals new to this discipline, as well as those who are seasoned veterans looking to improve/refresh their skills, regardless of industry or function within the organization. Simply put, this is one of the most practical and applicable trainings available!

On day one, the participants are introduced to the seven step methodology. A Roadmap is provided to guide the participants through the steps and suggest appropriate tools to ensure the right questions are being asked, the right data is being collected, and the right documentation is being made. After each step is presented leveraging an instructor case study, the participants immediately apply the learning on their own case study (which is based upon a real life investigation). **On day two,** several hours are devoted to strengthening the participants' skills leveraging the methodology through practice on another, more complex, real life case study. As the participants work on this case study they will compare their work with that of the investigation conducted by the real team.

Participants will be emailed a set of electronic templates. These templates, plus the Roadmap, guide the investigator through the methodology and provide the basis for documentation.

Who Should Attend:

Alumni of this program typically (though not exclusively) have a background in:

- Quality
- Risk management
- Regulatory affairs
- Compliance
- Manufacturing
- Product development
- CAPA
- Supply chain & purchasing
- Production
- Engineering
- Project management
- R&D
- Fraud management
- and more

Learning Objectives:

Upon completion of the workshop, participants will able to immediately, effectively, and efficiently apply the methodology to:

- Identify the technical root cause(s), that is, the change(s) that occurred.
- Identify systemic root cause(s), that is, any underlining breakdown in the organizations broader systems that allowed the change(s) to occur.
- Implement a comprehensive corrective and/or preventive action plan to restore performance.
- Implement a control plan to minimize and/or prevent recurrence.

Rob Weaver, *President of Weaver Consulting*

Founded in 2003, Weaver Consulting is a two-person enterprise comprised of Tom Weaver and Rob Weaver. They are quality and operations improvement consultants who focus their business exclusively on root cause analysis. With a combined 40+ years' experience and a client base that expands worldwide, they have helped organizations across a multitude of highly regulated industries, including pharmaceutical, medical device, aerospace, defense, financial services, food & beverage, consumer products, automotive, telecommunications, semiconductors, and many more, successfully implement their premier root cause analysis methodology, Root Cause Investigation for CAPA. Both Tom and Rob held titles of Vice President in their respective careers before joining the firm, Tom with Baxter Healthcare and Rob with Wells Fargo & Company.

Thursday, 8 Nov 2018   9:00 – 18:00

9:00   **Welcome & Introduction**
- Define technical CAPA problem
- Common investigation mistakes
- Investigation Roadmap template
- Introduce 1st participant real life case study

10:00   **Step 1: Define the Performance Problem**
- Introduce instructor case study
- Problem statement
- Problem description

10:30   **Coffee Break**

11:00   **Step 1: Continued**
- Problem description continued
- Workshop
- Flow chart process(es) being investigated & identify key inputs
- Workshop
- Time of events
- Team charter including performance & cost savings goals

12:00   **Lunch Break**

13:00   **Step 2: Collect Data**
- Determine data needed
- Data collection tools & techniques
- Data measurement plan
- Workshop

15:00   **Coffee Break**

15:30   **Step 3: Identify Possible Causes**
- Time of changes
- Differences between Is & Is Not facts
- Workshop
- Changes associated with identified differences
- Review risk analysis
- Brainstorming techniques
- Workshop

16:30   **Step 4: Test Possible Causes**
- Test possible causes against facts
- Summarize testing leveraging contradiction matrix
- Historical perspective of investigations
- Workshop

17:30   **Step 5:**
Identify Technical & Systemic Root Causes
- Verify assumptions
- Conduct studies/experiments
- Identify technical root cause(s)

18:00   **End of Day 1**

Friday, 9 Nov 2018   9:00 – 16:30

9:00   **Step 5: Continued**
- Identify systemic root causes

9:30   **Step 6:**
Determine Corrective/Preventive Actions
- Mistake proofing techniques
- Variation reduction & optimization techniques
- Corrective/preventive actions
- Acceptance criteria

10:30   **Coffee Break**

11:00   **Step 6: Continued**
- Risk mitigation
- Control plan
- Workshop

11:45   **Step 7: Verify Corrective/Preventive Actions**
- Implement & measure corrective/preventive actions
- Evaluate control plan
- Determine additional preventive actions

12:00   **Lunch Break**

13:00   **Second Participant Real Life Case Study**
- Introduction
- Workshop to develop problem statement, problem description, identify possible causes
- Workshop to collect data
- Workshop to test possible causes

15:00   **Coffee Break**

15:30   **Second Participant Real Life Case Study Continued**
- Workshop to determine corrective/preventive actions including risk mitigation, control plan, acceptance criteria

16:00   **Closing Remarks**
- Compare/contrast this investigation methodology with traditional approach
- Shortcuts
- Simple investigations
- Difficult investigations
- Investigation report
- Return on investment
- References

16:30   **End of Course**