

*root cause analysis
investigations*

By

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Introduction

- ▶ Regulations
 - FDA/CFR
 - Out of Specifications Results
 - ISO
 -
- ▶ Good Business Practice

Out of Specification Results

- ▶ Assessment of laboratory's data
- ▶ Errors identified, repeat test, using same solution, if possible
- ▶ No errors identified, complete investigation required

OOS Results - Lab Investigation

- ▶ Analyst knowledge of the procedure
- ▶ Examine raw data
- ▶ Confirm performance of instruments
- ▶ Reference standards, solvents, reagents, etc.
- ▶ Performance of testing method (I.e., as validated)

Lab Investigation (cont.)

- ▶ Retesting original sample
- ▶ Test new sample from batch
- ▶ Resampling testing data
- ▶ Use of outlier
- ▶ Averaging

OOS Results: Full Investigation

- ▶ Manufacturing process sequences
- ▶ Documentation review
- ▶ Problem occurred previously
- ▶ Other batches/products possibly affected

Interpretation of Results

- ▶ Laboratory error, suspect result invalidated
- ▶ Possible OOS result, use result in evaluating quality of batch
- ▶ Confirmed OOS, reject and properly dispose

Root Cause Analysis

- ▶ Systematic investigation of a problem to determine actual cause
- ▶ Leads to a plan for corrective and preventive action

Recognizing Root Causes

- ▶ Process
- ▶ Equipment
- ▶ Personnel/Training
- ▶ SOPs
- ▶ Raw Materials
- ▶ Sampling
- ▶ Vendors

Recognizing Root Causes

- Design
- Formulation
- Environment
- Distributor
- User
- Other

Investigating Root Causes

- ▶ In-process/final inspection data
- ▶ Yield data
- ▶ Process control
- ▶ Scrap
- ▶ Incoming testing and inspection
- ▶ History records

Investigating Root Causes

- ▶ Training records
- ▶ Change control records
- ▶ Rework/reprocessing
- ▶ Complaints
- ▶ Nonconforming materials reports
- ▶ Audit reports
- ▶ Other

System Related Issues

- ▶ Underlying system related causes
- ▶ Corrective and Preventive action for the root causes/system causes identified

Integrate with other Programs

- ▶ Corrective and Preventive Action System
- ▶ Complaint procedure
- ▶ Recall procedure
- ▶ Adverse event procedure
- ▶ Medical device reporting
- ▶ Servicing
- ▶
- ▶

Integrate with other Programs

- ▶ Internal/external audits
- ▶ Supplier control
- ▶ Nonconforming materials
- ▶ Other
- ▶
- ▶
- ▶

Thorough, Credible, Effective

- ▶ First-hand knowledge
- ▶ Management support
- ▶ Consistent analysis
- ▶ Previous experience
- ▶ Literature review?
- ▶ System not individual
- ▶

Corrective and Preventive Action

- ▶ Appropriate to the magnitude of the problem and any associated risk
- ▶ Responsible person(s)
- ▶ Method for measuring results
- ▶ Completion date
- ▶ Verify/validate

Team Leadership

- ▶ Strong communication skills
- ▶ Ability to see opportunities
- ▶ Ability to lead groups of people through aggressive timelines
- ▶ Understand business

Communication

- ▶ Questioning
- ▶ Listening
- ▶ Observing
- ▶ Recording

Questioning

- ▶ Closed Questions
- ▶ Open Questions
- ▶

Listening

- ▶ Focus on the response and clarify
- ▶ Show interest, not emotion
- ▶ Active listening

Observation

- ▶ Environment
- ▶ Housekeeping
- ▶ Frequent interruptions
- ▶ Body language
 - Eyes
 - Posture
 - Mouth

Case Study

- ▶ Practice what learned
- ▶ Find root cause
- ▶ Corrective/preventive action

Thinking

- ▶ No problem can stand the assault of sustained thinking

Voltaire