Investigations & Compliance

Improving root cause investigations, risk assessment, and addressing common audit findings

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Why this matters?

- Weak investigations create repeat failures
- Strong RCA prevents recurrence and supports compliance
- Investigation maturity = quality culture indicator

What Auditors Expect

- Timely initiation and closure
- Evidence-based conclusions and documented rationale
- Product impact assessment
- Effective CAPA
- Management oversight and trending

Top 10 Audit Findings – RCA & Investigations

Common Finding	What Auditors Usually Observe	Regulatory Concern
Superficial root cause ("human error")	Operator blamed with no system analysis	Failure to identify true cause
No documented investigation methodology	No 5-Why, fishbone, fault tree, timeline etc.	Investigation not scientifically justified
CAPA does not address root cause	Retraining only, no system/process fix	Recurrence risk remains
Repeat deviations with no trending	Same issue, multiple times	PQS and/or prior RCA ineffective
Delayed investigations/overdue closure	Events left open too long	Risk not controlled promptly and poor quality culture indicator
Poor impact/risk assessment	No product impact or batch risk review	Potential unsafe/nonconforming product released
Incomplete scope of investigation	Related batches/equipment/materials ignored	Extent of issue unknown
No effectiveness checks for CAPA	CAPA closed without verification	No proof problem solved
Weak data evidence	No review of logs, EM data, calibration, trends	Conclusions unsupported
QA oversight inadequate	Investigations approved without challenge	Governance weakness

Human Error is not a Root Cause

- Need to address:
  - Why was it possible?
  - Process robustness?
  - Control adequacy?

Your SOP could be your Root Cause

- Weak SOP → weak RCA
- Strong SOP → structured thinking
- QA oversight required

Improving Root Cause Analysis (RCA)

- Define what effective RCA looks like
  - Establish clear expectations for analysis
- Use structured tools
- Risk-based depth
- Use data and expand scope

CAPA and Governance

- Link CAPA to cause
- Avoid retraining-only or “Toolbox” talks
- Implement prevention
- Verify effectiveness

DMAIC Framework

- Use DMAIC as a thinking framework, not just a checklist.
  - Define – clear problem statement
  - Measure – use data
  - Analyse – structured, system-based RCA
  - Improve – preventive / sustainable CAPA
  - Control – verify effectiveness
- SOP to define each process stage
- Form to capture outcomes

Audit Examples

Scenario: ***Raw material "X" appeared degraded, there was no investigation on cause or impact of continuing use.***

- Investigate transit/storage damage, moisture, packaging, shelf life
- Quarantine, test, supplier investigation request, batch impact review

Scenario: ***Recall due to fungal growth investigation did not identify root cause or impact to other batches.***

- Needs source identification
- Look-back to other lots / batches, room(s), equipment, shift, operators

Scenario: ***EM trend data is not investigated.***

- EM upward trends below limits still require investigation
- Waiting for failure **is not** contamination control

Audit Examples cont'd…

Scenario: ***Temperature probe review identified multiple excursions of greater than 30°C. Product must be stored below 30°C. No investigation or impact reviewed for the product.***

- Assess lots impacted, stability risk, HVAC, alarm process, maintenance, CAPAs

Scenario: ***There were six (6) sterility failures of batch "Y", with no investigation of trend or common cause.***

- Six (6) failures treated separately
- Trend review should assess room, operators, shifts, organism, utilities
- Escalate contamination control review and EM intensification

Strong vs Weak CAPA

- Weak:
  - Retraining and/or toolbox talks
- Strong:
  - Redesign process
  - Automate checks
  - Segregate labels
  - Add verification
- Verify effectiveness after implementation

Key Takeaways

- Stop accepting human error as a Root Cause
- Design SOPs and Forms for RCA
- Use data
- Focus on prevention
- Verify effectiveness

THANK YOU!

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