You’ve Completed Your Root Cause Analysis, Now What?

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Take Away:

- Leveraging RCA to update our procedures or work instructions
- RCA outcomes can drive predictive preventive actions
- Advanced level critical thinking based on trend analysis and data
- Data driven automation of solution
- Element of post-market surveillance, risk management practices and continuous improvement
- Q&A
POLL 1

After an effective RCA, I am aware of what to do with the data and information resulted from RCA.

A. Yes
B. No
Let's begin by asking a few questions
Let's Begin by Asking a Few Questions

1. What happens once an RCA is done?

2. Does the output end here or is there a better way to utilize the data and information generated during the analysis?

3. Can it become an input to the next internal audit?

4. Are we able to conclude an effective solution proofing future error?

5. Will the RCA outcome help us recognize a different approach if the problem continues?

6. Have we safeguarded future audit failures, time and cost etc.?
Updating Process or System

- **REVIEW & APPROVAL**
  - QMS
    - Quality Management System
  - SOP
    - Standard Operating Procedures

- **TRAINING**
  - WI
    - Work Instructions
  - RECORDS/FORMS

- **CHANGE REQUEST**
  - DHR/BATCH RECORDS

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Correlation Between Processes

- **RCA**
  - Data
  - Information

- **Trend Analysis**
  - MRM
  - Internal Audit

- **Process Improvement**
  - SOP/QMS
  - CAPA
  - AQL

- **Risk Management**
  - Risk documentation
  - New Controls
  - IFU

- **Technical Documentation**
  - Device File
  - PMS
  - CER
MRM and Internal Audit

INTERNAL AUDIT:
Are we ensuring the information being utilized during internal Audit?

MANAGEMENT REVIEW MEETING:
Are we ensuring the information being discussed in a management review meeting
Impacting Technical Documentation

- Risk management
  - Update risk documentation
  - Residual Risk
  - New Controls
  - Label/IFU

- Quality Management System
  - Procedures/SOP/WI
  - Validations
  - Design changes

- Clinical Evaluation Report
  - Updates
  - Risk information
  - Quality Inspections
  - CAPA

- Post Market Surveillance
  - Customer Feedback
  - Complaints
  - CAPA
  - Product Failures
  - Registry/Recall database
Revalidation

**PROCESS**

1) Revise the study plan as a whole
2) Changes in sampling size
3) Update inspection Plan
4) Revalidation methodology

**PRODUCT**
POLL 2

I understand digitalization and EQMS will automate our processes and reduce inefficiencies?

A. Yes
B. No
Risk Profile and Management

- Does RCA outcome trigger changes in Risk documentation?
- Does it bring in new residual risk?
- Will the risk documentation cause changes in IFU or Label?
- Does the RCA information demands a completely different control?
- Is it causing changes in processes that results new risk?
Post Market Surveillance and Clinical Evaluation

RCA outcomes will suggest update in Risk Management, Quality Inspections, CAPA, IFU, Label

PMS results new data that includes safety reports, results from published literature, registries, PMCF studies, and other data about device usage

Clinical evaluation requires PMS data to evaluate safety and performance
Predictive Preventative Actions

Outcome (Data & Information)

Outputs from RCA

Predict the most accurate actions required

Supports planning & maintenance
On the Manufacturing Floor

Manufacturing

Accident Analysis
- Health and Safety
- Work environment

Maintenance Analysis
- Proactive Maintenance

Failure Analysis
- Process Monitoring
- Process Control

Operational Planning
- Efficient production
- Optimum resource utilization
Automation Towards Solution

Data > Learning >
Updating > Automation >
Predictive Actions >
Failure Prevention >
Save cost  > Save Time
Winding up!

“Data driven decision tends towards a solution, else its merely just another discussion”

Without data you’re just another person with an opinion.

— W. Edwards Deming, engineer, professor, author, lecturer
Feedback
About ComplianceQuest
AI-powered cloud platform for Clinical, Quality and Safety management solutions

INTEGRATIONS
- CRM
- EBR
- ERP
- HRMS
- LIMS
- MES
- MOM
- PLM
- RIMS
- Others

CLINICAL MANAGEMENT
- Clinical Trial Operations
- Study Start-Up
- CTMS
- eTMF
- EDC
- Safety & Pharmaco-vigilance
- Decentralized Clinical Trials

MARKET SURVEILLANCE
- Complaint Management
- Regulatory Assessment
- Regulatory Reporting
- MDR eGateway
- Field Service Connector

QUALITY MANAGEMENT
- Audit
- CAPA
- 5 Why RCA
- Change Control
- Deviation
- Equipment
- Investigation
- NC
- OOS/OOT
- Product Inspection

SUPPLIER MANAGEMENT
- Audit
- On/Off-Boarding
- Accreditations
- Deviations
- SCAR
- 5 Why RCA
- Supplier Central
- Inspections
- PPAP
- Document Exchange
- Supplier Ratings
- Score Cards
- Permit to Work

RISK MANAGEMENT
- Audit
- Risk Register
- Process Inspection
- JSA
- Permit to Work
- Investigation

WORKFORCE DIGITALIZATION
- Document Management
- SOP Enforcement
- Training
- Change
- Learning Portal

HEALTH AND SAFETY
- Injuries, Vehicle, Security, Property
- Claims Management
- Safety Observations
- Near Miss
- Investigation
- 5 Why RCA
- Regulatory Forms
- Inspections
- JSA
- Permit to Work
- Management of Change
- Toolbox Talk

ENVIRONMENT & SUSTAINABILITY
- Spills and Releases
- Sustainability
- Permits
- Regulatory Library
- Notice of Violation
- Audit

INTEGRATIONS

PLATFORM POWERED BY

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THANK YOU

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