Building a CAPA Strategy to Drive Continuous Improvement

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CAPA = Corrective And Preventive Actions

RCA = Root Cause Analysis
• Importance and Benefits of Effective Root Cause Analysis (RCA)
• Steps in Root Cause Analysis
• Developing & Implementing Corrective and Preventive Actions (CAPA)
• Automation for Speed in Improvements
• Continuous Improvement Lifecycle
• Challenges and Best Practices
• Case Studies
Importance & Benefits of Root Cause Analysis (RCA)

• Immediate Causes
• Underlying Causes
• Continuous Improvement
Importance & Benefits of Root Cause Analysis (RCA)

- Reduced downtime
- Improved quality
- Enhanced safety
- Cost savings
- Data-driven decision making
- Continuous improvement culture
- Compliance and risk-mitigation
Steps in Root Cause Analysis

• Identify the Problem
• Collect Data
• Identify the Root Cause
• Analyze the Root Cause
• Develop Corrective and Preventive Actions
Developing Corrective and Preventive Actions (CAPA)

- Root Cause Understanding
- Actionable Solutions
- Allocation of Resources
- Ownership and Accountability
Implementing Corrective and Preventive Actions

- Implementation Plan
- Monitoring and Measurement
- Documentation and Reporting
- Monitoring and Reviewing
Automation for Speed in Improvements

- Data Integration & Visualization
- Issue Tracking Systems
- Quality Management Software
- Automated Alerts, Reminders, Notifications
Continuous Improvement Cycle

- Plan
  - Identify areas for improvement
  - Set goals
- Do
  - Execute plans
  - Implement changes
- Check
  - Analyze data
  - Assess impact
- Act
  - Take appropriate actions
Poll Time!

What has been your biggest challenge with building and implementing a CAPA strategy into your organization?

- Lack of cross-functional collaboration
- Overcomplicated processes
- Lack of management/leadership support
- Resistance to change
- I don’t know where to start!
- Something else
Challenges

• Lack of Cross-Functional Collaboration
• Overcomplicated Processes
• Lack of Management Support
• Resistance to Change
Best Practices

• Data Quality
• Adaptable Automation
• Regular Review & Audits
Case Study #1

- **Machines**
  - Irregular maintenance

- **Materials**
  - Substandard raw materials
  - Variations in supplier quality

- **Manpower**
  - Inadequate training
  - Insufficient staffing
  - Absent quality checks
  - Lack of SOPs

- **Methods**
  - Ineffective defect monitoring
  - No clear performance metrics

- **Environment**
  - Poor lighting
  - Temperature fluctuations

- **Measurements**
  - Inaccurate QC measurements
Case Study #1

- Standardized machine calibration process
- Employee training
- Regular audits
- Automated alerts
Problem Statement: High number of customer complaints about software bugs and slow response times from support team

• Why are there software bugs and slow response times?
  • Because customers are experiencing technical issues with the software

• Why are customers experiencing technical issues with the software?
  • Because there are unresolved software defects affecting functionality

• Why are there unresolved software defects affecting functionality?
  • Because the development team is not effectively identifying and prioritizing software defects.

• Why is the development team not effectively identifying and prioritizing software defects?
  • Because there is a lack of clear communication between customer support and the development team regarding bug reports

• Why is there a lack of clear communication between customer support and the dev team?
  • Because there’s no established process for documenting and conveying bug reports, leading to misunderstandings and delays in addressing issues

Case Study #2
Case Study #2

- Creation of centralized knowledge base
- Communication platform
- Automated ticketing system
Key Takeaways

• A strong RCA and CAPA program is a must-have – for EVERYONE!
• Countless benefits to customers and employees
• Continuous improvement is important
• Understand your challenges
• Getting buy-in and support is critical
• Have fun!