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)

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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

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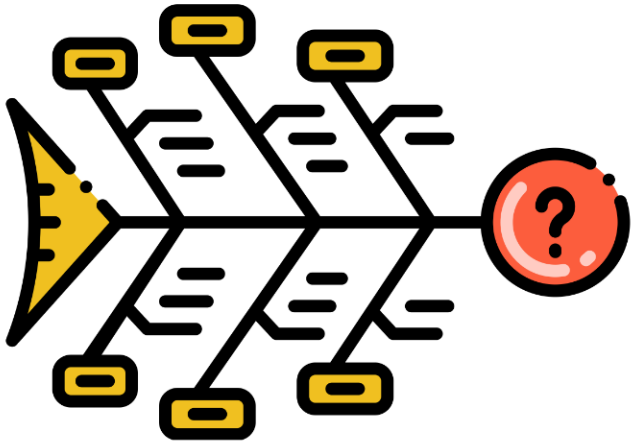
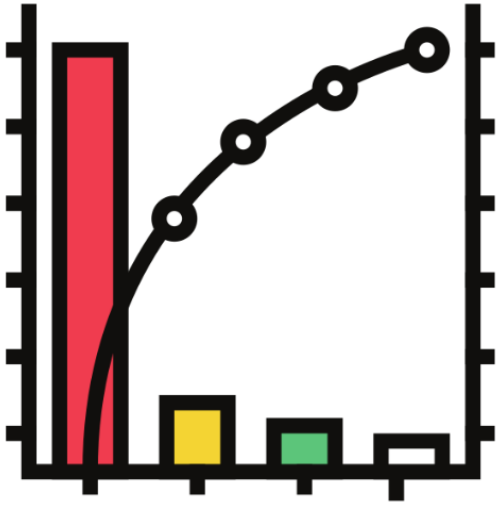
Steps in Root Cause Analysis

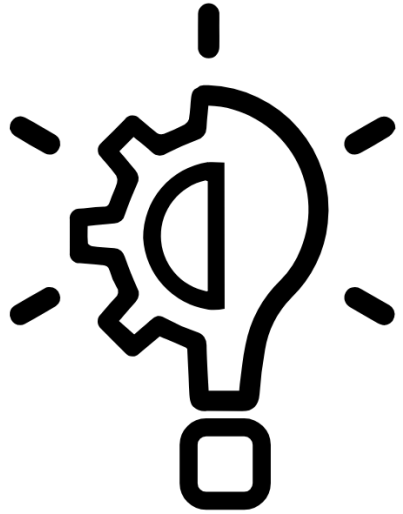
- Identify the Problem
- Collect Data
- Identify the Root Cause
- Analyze the Root Cause
- Develop Corrective and Preventive Actions





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

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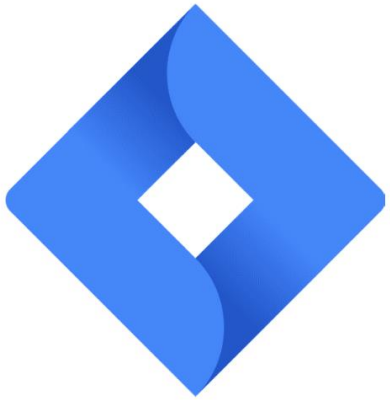
Automation for Speed in Improvements

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



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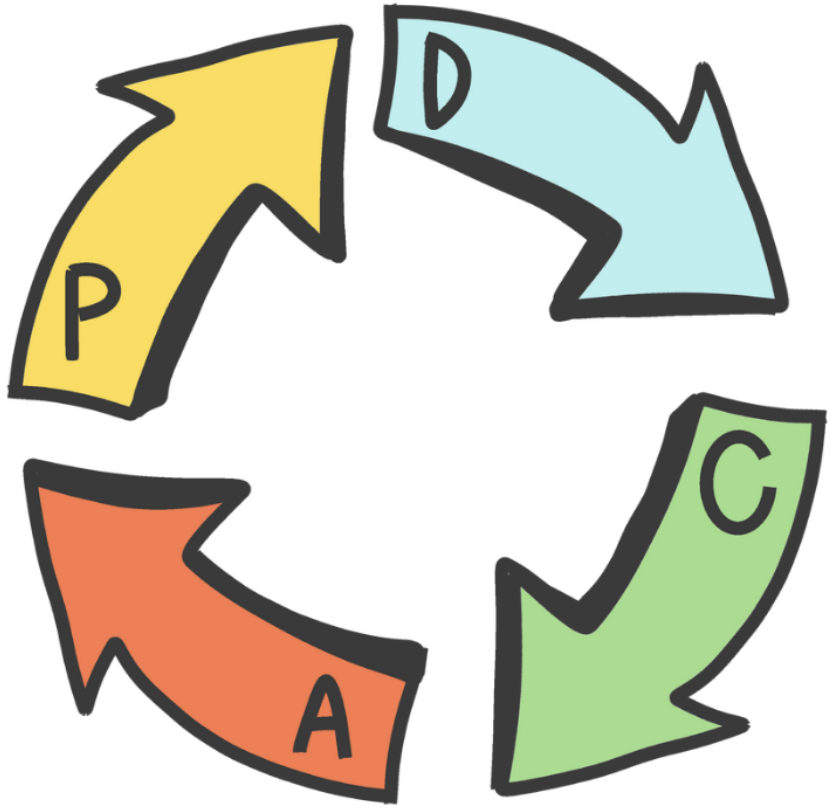
Continuous Improvement Cycle

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



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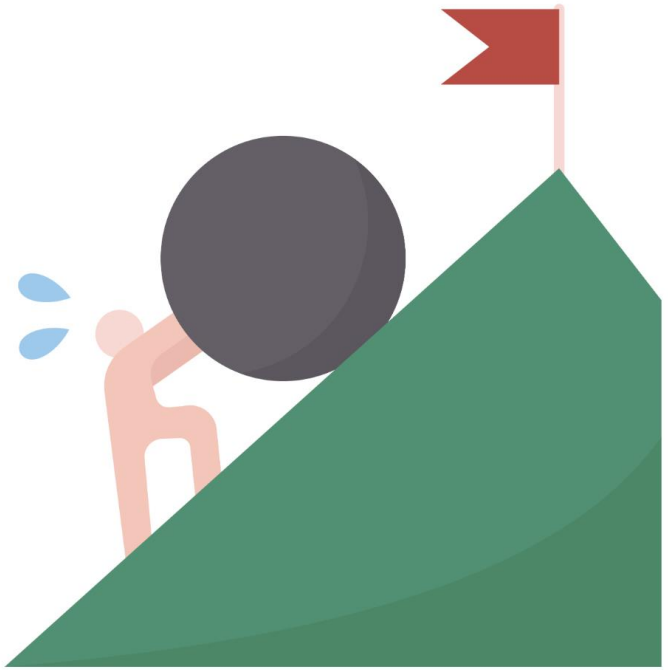
Poll Time!

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



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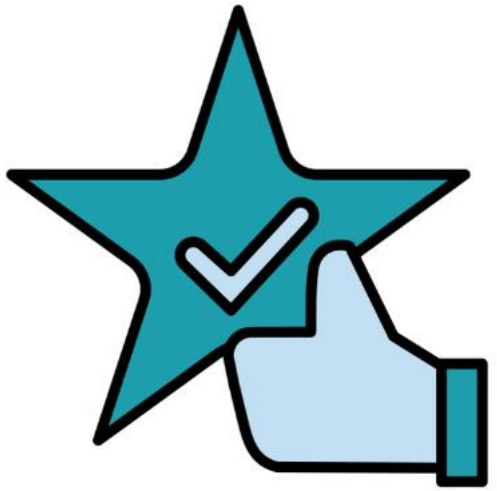
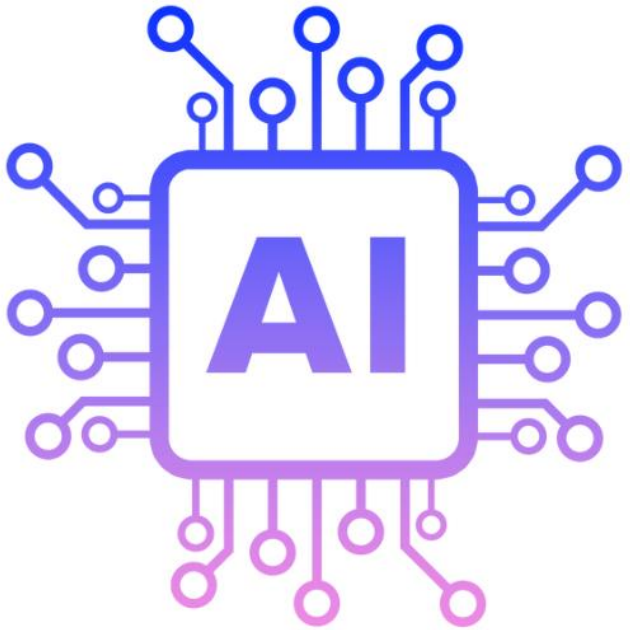
Best Practices

- Data Quality
- Adaptable Automation
- Regular Review & Audits





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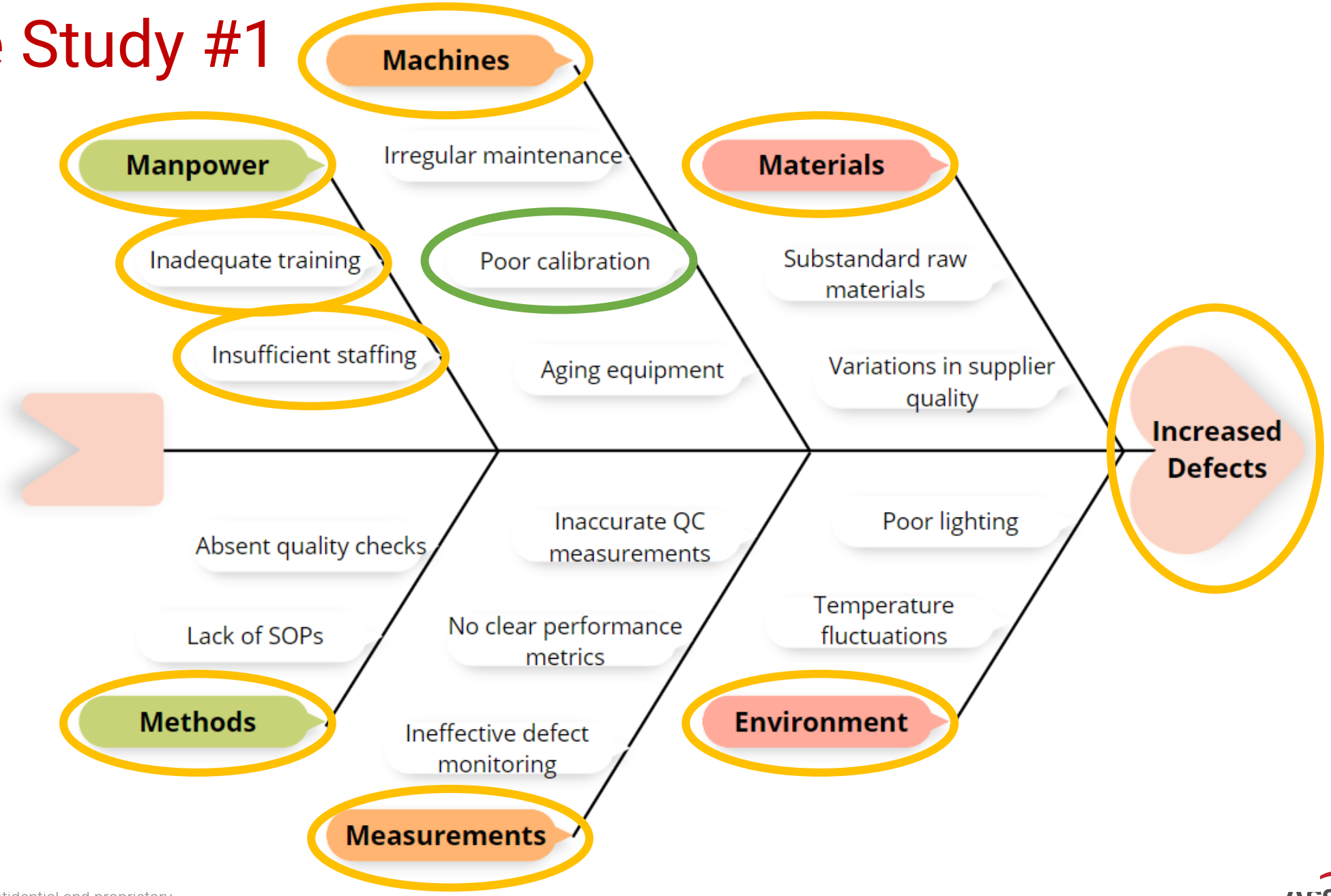
Case Study #1



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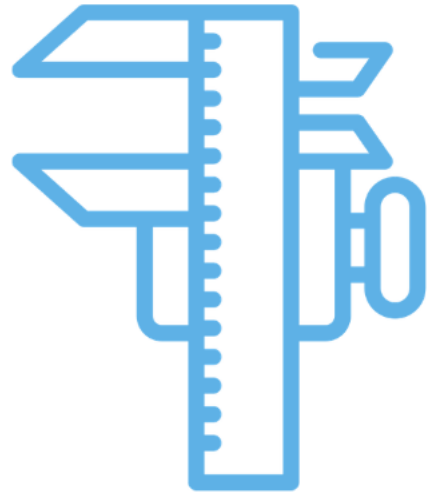
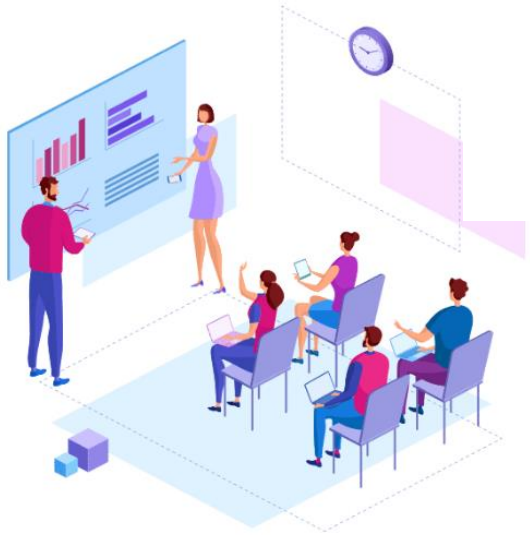
Case Study #1

- Standardized machine calibration process
- Employee training
- Regular audits
- Automated alerts





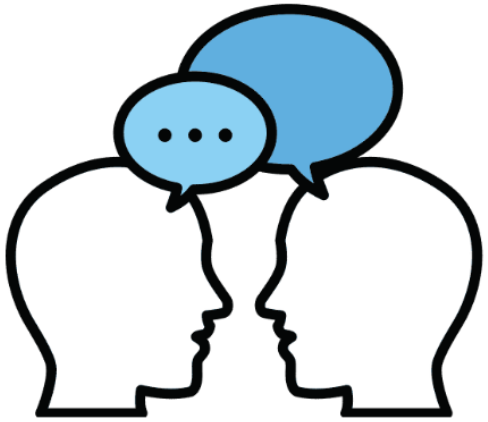
Case Study #2

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

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



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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!

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