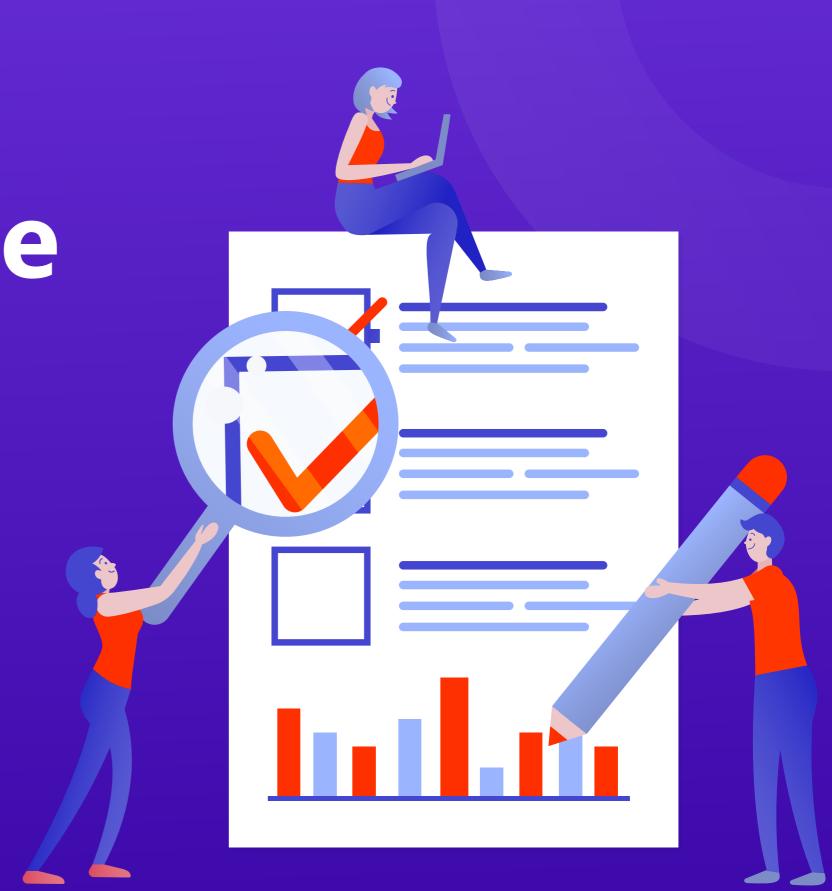
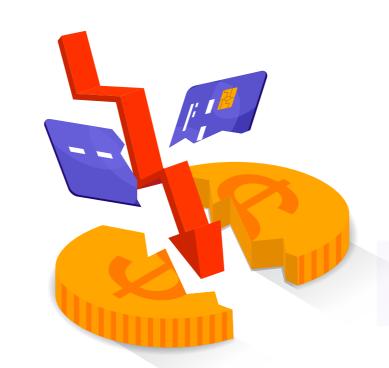
The Lifecycle of Nonconformance Management

Nonconformance (NC) refers to any deviation from established standards, regulations, or customer expectations in processes, products, or services.

- 75% of quality issues in manufacturing stem from unresolved nonconformances.(Source: ASQ)
- The cost of poor quality (COPQ) can range from 5% to 35% of total sales revenue due to defects, rework, and compliance failures. (Source: IISE)







The Cost of Poor Nonconformance Management

Financial Impact:

- ✓ The average cost of non-compliance for organizations is \$14.82 million, including fines, business disruptions, and lost revenue. (Source: The Access Group)
- ✓ 5% of annual revenue is lost due to unaddressed quality issues. (Source: ASQ)

Reputation Impact:



The Nonconformance Management Process

Identification

Sources: Internal audits, customer complaints, supplier quality issues, employee observations, process monitoring.

Example: A manufacturing defect is discovered during quality control.

80% of recurring quality issues stem from unidentified root causes. (Source: ISO 9001:2015)

Containment & Impact Assessment

Immediate containment actions to prevent the defect from spreading or causing further damage.

Risk assessment using Failure Mode and Effects Analysis (FMEA) or risk

matrices.

Example: Temporarily halting production to prevent faulty products from reaching customers.

50% of nonconformances lead to costly rework or recalls if not contained early. (Source: Harvard Business Review)

Corrective & Preventive Actions (CAPA)

- Corrective Actions: Immediate fixes to address the identified issue.
- Preventive Actions:

 Long-term process
 improvements to
 prevent recurrence.
- Example: Updating SOPs retraining employees, or modifying production equipment.

Companies with strong CAPA systems *reduce nonconformances by 40%* annually. (Source: Quality Management Institute)





Report (NCR) detailing:

Issue description

Documentation

Issue descriptionAffected process/product

Create a Nonconformance

Responsible departmentInitial impact assessment

Why It's Important: Proper documentation helps track trends and prevent future occurrences.
Companies using structured NCRs *reduce resolution time by 30%.* (Source: Quality Digest)

Root Cause Analysis

Investigate using methodologies like:

(RCA)

- ✓ 5 Whys Analysis Asking Why?" five times to uncover root cause.
- Fishbone (Ishikawa)
 Diagram—
 Categorizing
 potential causes.
 Pareto Analysis —

Identifying the most frequent problems.

90% of nonconformance issues can be traced back to process or human errors rather

than material failures.

(Source: ASQ)



Verification & Follow-Up

- Effectiveness check: Ensuring corrective actions successfully eliminate the root cause.
- Process improvement:
 Updating Standard
 Operating Procedures
 (SOPs) based on findings.
- Monitoring: Implementing automated tracking systems to detect future issues faster.

systems reduce recurrence rates by 50% compared to manual tracking. (Source: IISE)

The Role of Digital Quality Management Systems (QMS)

nonconformance management process.

Using a structured QMS ensures a streamlined, compliant, and efficient

Centralized Data Management: Provides a single source of **E-Signature Compliance: Cross-Module Integration:** truth for all quality-related Meets regulatory requirements Seamless communication records. such as FDA 21 CFR Part 11 between nonconformance and ISO 9001. reports, CAPA, audits, and training modules. 06 03 01 **Automated Email Notifications:**

Automated Workflows:
Reduces manual
intervention and
speeds up NCR
resolution.

Document Control Features: Ensures version control and compliance with industry standards.

in real time to accelerate corrective actions.

Keeps stakeholders informed

Companies implementing digital QMS reduce nonconformances by 45% and improve compliance reporting by 60%. (Source: Quality Digest)

Be Proactive, Not Reactive!

A structured *Nonconformance Management Cycle, supported by a robust QMS*, minimizes risks, ensures compliance, and enhances operational

efficiency.

Simplify Nonconformance Tracking and Resolution with BizPortals QMS

Book a Free Consultation Today