COMPLIANCEQUEST
Complete Quality Transformed

Integrating Core QMS Insights: A Year-End Review for Future Excellence

Presented by | Sundeep Agarwal

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Speaker Introduction

SUNDEEP AGARWAL

Medical Device Expert & Consultant

An expert in medical and IVD devices & life sciences, Mr. Sundeep Agarwal is a speaker, trainer and consultant in the field of Quality Assurance, Regulatory Affairs, QMS, GMP, Software Validation, Artificial Intelligence, Combination Devices, GCP, Design & development, Risk Management and Industrial Manufacturing. He is a lead auditor for medical devices and has expertise in ISO 13485, EU MDR, IVDR, CE Certification, CER, PMS, USFDA, 510(K), ISO 14971, MDSAP.

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W. Edwards Deming

William Edwards Deming (October 14, 1900 – December 20, 1993) was an American business theorist, engineer, management consultant, statistician, and writer. Educated initially as an electrical engineer and later specializing in mathematical physics. He is also known as the father of the quality movement and was hugely influential in Japan post-WWII.

“Quality is everyone's responsibility.”

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Key Takeaways:

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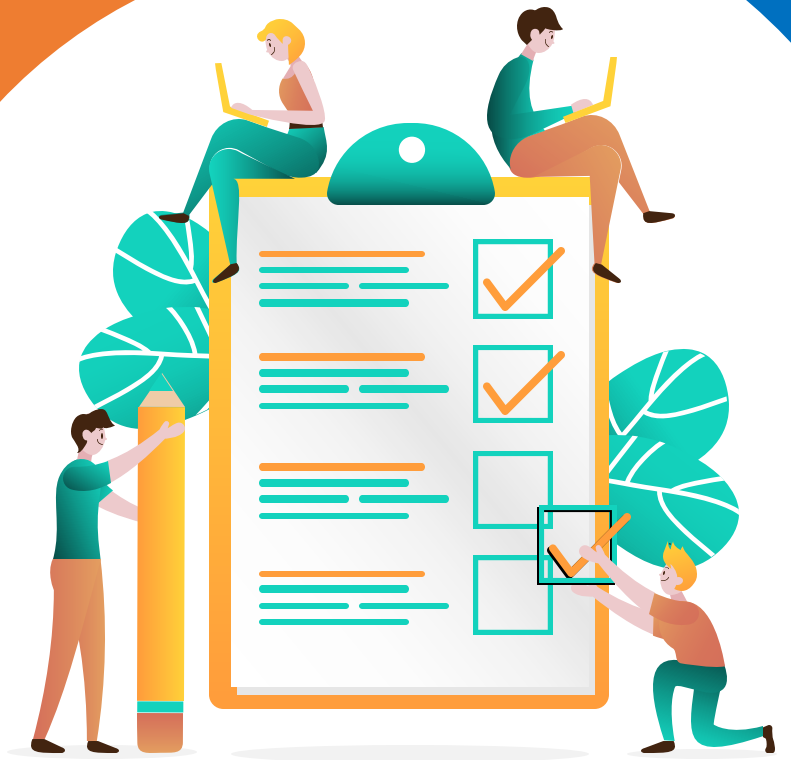
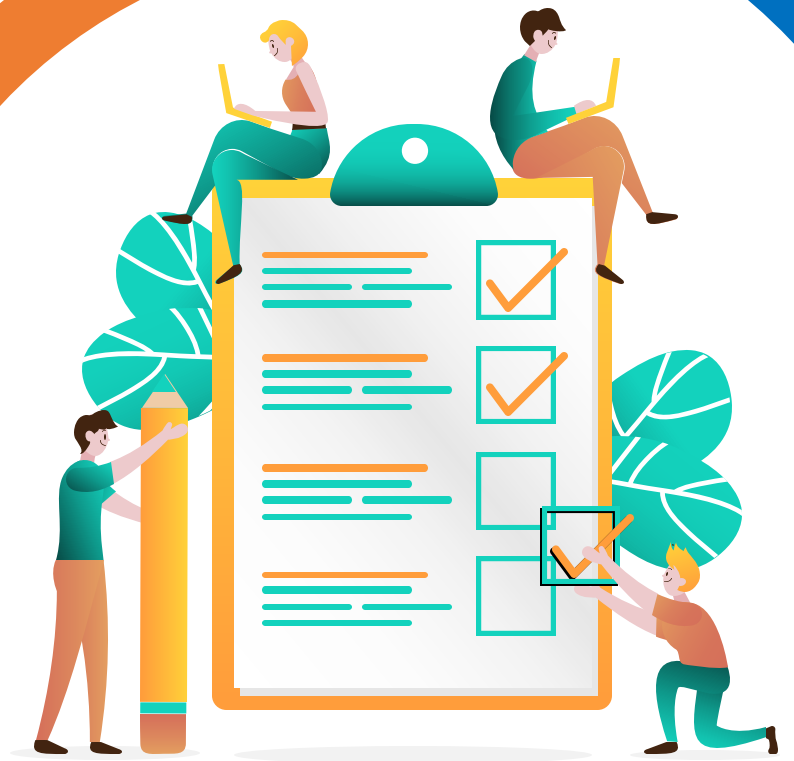
Standard Operating Procedures (SOPs)



Standard Operating Procedure:

A standard operating procedure (SOP) is a written **set of instructions** (or defined procedure) for carrying out a particular **task or work**.

SOPs seek to **minimize ambiguities** and failure to **adhere to regulatory requirements** while increasing **effectiveness**, high-quality output, and **consistency of performance**.



Well-structured SOPs minimize errors, deviations, and inefficiencies: General Content of an SOP

Purpose
- Standardized

Scope
- Coverage
- Limitations

Responsibilities
- Who
- What

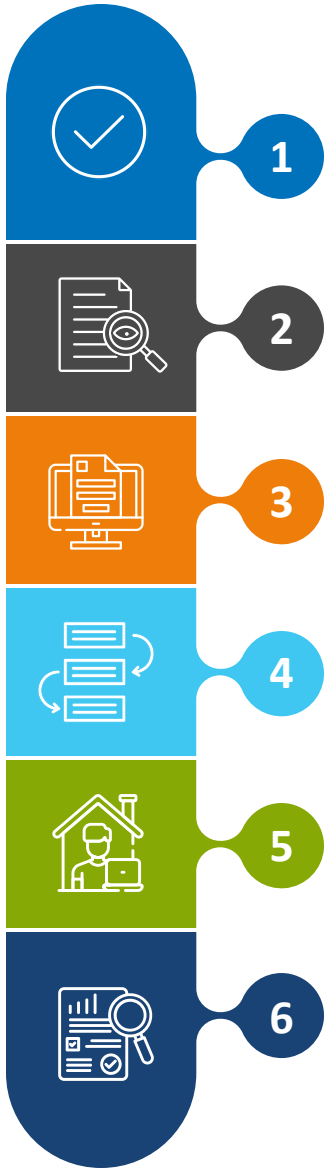
Procedure
- Steps
- Consistency

Referencing
- Internal
- Regulatory
- Standards
- Guidance

Document History/Changes
- Changes
- Continuous improvement

Reviewer & Approver
- Reviewed
- Approved
- Dated

Standard Operating Procedure (SOP): Best practices



1. **Clear and Concise:** Easy to understand, State the purpose. Be specific
2. **Well-Structured (and preferably digitalize using an EQMS):** Numbered steps, East Navigation, Access digitally
3. **Appropriate Detail and Sequence:** Adequate but avoid excessive detail. Chronological order, Practical, Incorporate Visual Aids
4. **Roles & Responsibilities:** Clearly defined for each process or task.
5. **Compliance and Regulations:** Address relevant regulatory, and industry standards. Aligns with legal and quality standards.
6. **References, Version Control, Approver and Reviewer, Document History.**

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Poll Question no. 1

“We have all SOPs in place but now require updating them based on today's learning”

A. Yes

B. No

Root Cause Analysis (RCA)

What is Root Cause Analysis (RCA):

RCA is a process to analyze problems or events to identify (What happened, How it happened, Why it happened) to determine the exact cause(s) of the problem to conclude the most appropriate solution for the problem.

Root cause analysis is not a one-size-fits-all methodology.

Root cause analysis is part of a more general problem-solving process and an integral part of continuous improvement.

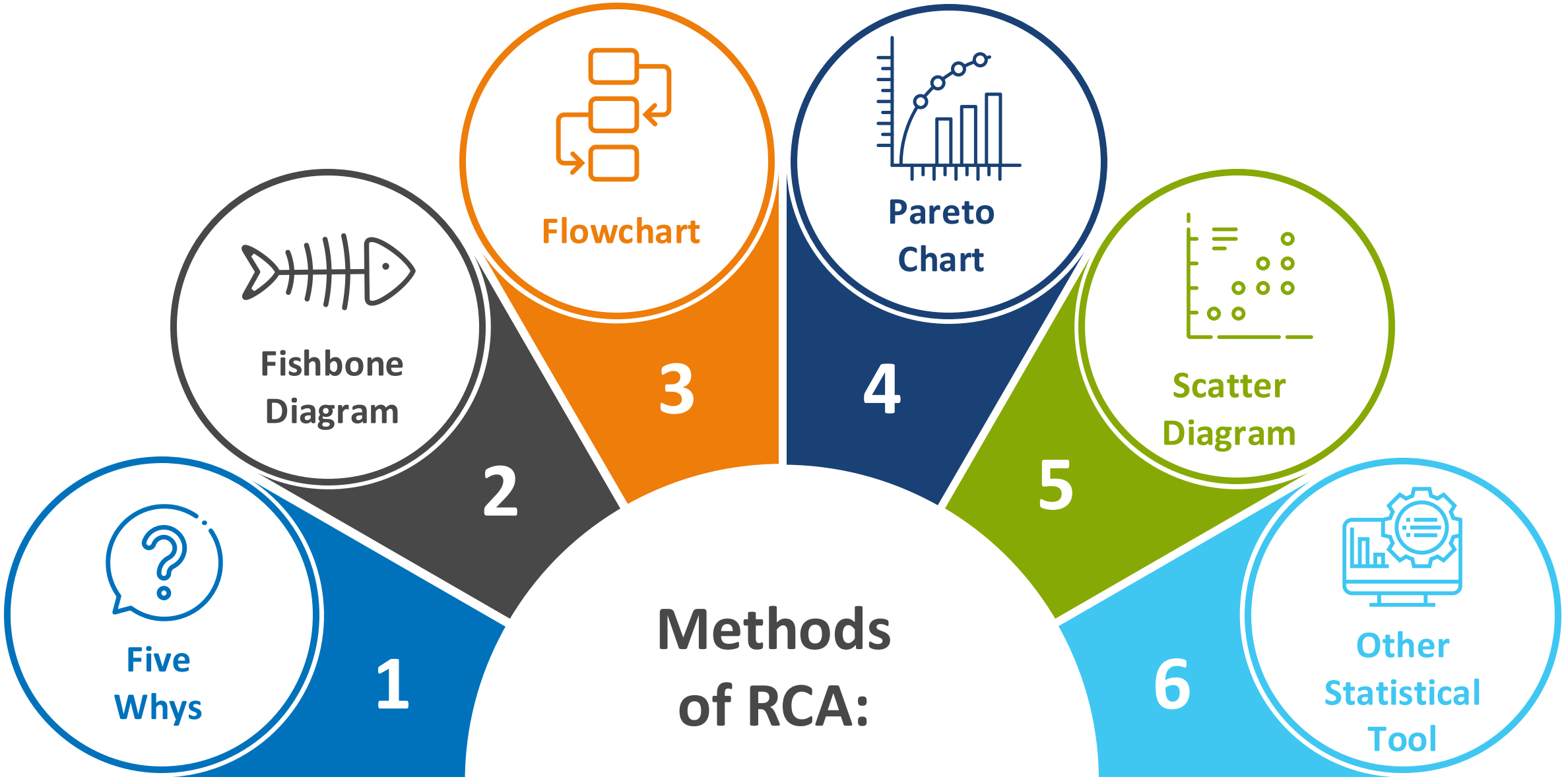
What are practical sources that triggers potential problems?

INTERNAL

1. Nonconforming raw material report
2. Process Control Data
3. Mistakes in production process
4. Test/Inspection data
5. Out of specification (OSS) products
6. Device History Records/Batch records
7. Internal Audits
8. Nonconforming material reports
9. Faulty machines and measuring equipment’s
10. Rework and Scrap/Yield Data,
11. Untrained employees/workers
12. Management Review Meetings
13. Risk Analysis

EXTERNAL

1. Supplier Controls
2. Raw material inspection
3. Customers Complaints
4. Servicing repairs
5. Adverse Event
6. Regulatory Authority findings
7. External Audits
8. Similar products/devices from competitors
9. Risk Analysis
10. Usability problems


Methods of RCA:
1
Five Whys
2
Fishbone Diagram
3
Flowchart
4
Pareto Chart
5
Scatter Diagram
6
Other Statistical Tool

Corrective and Preventive Action (CAPA) Process

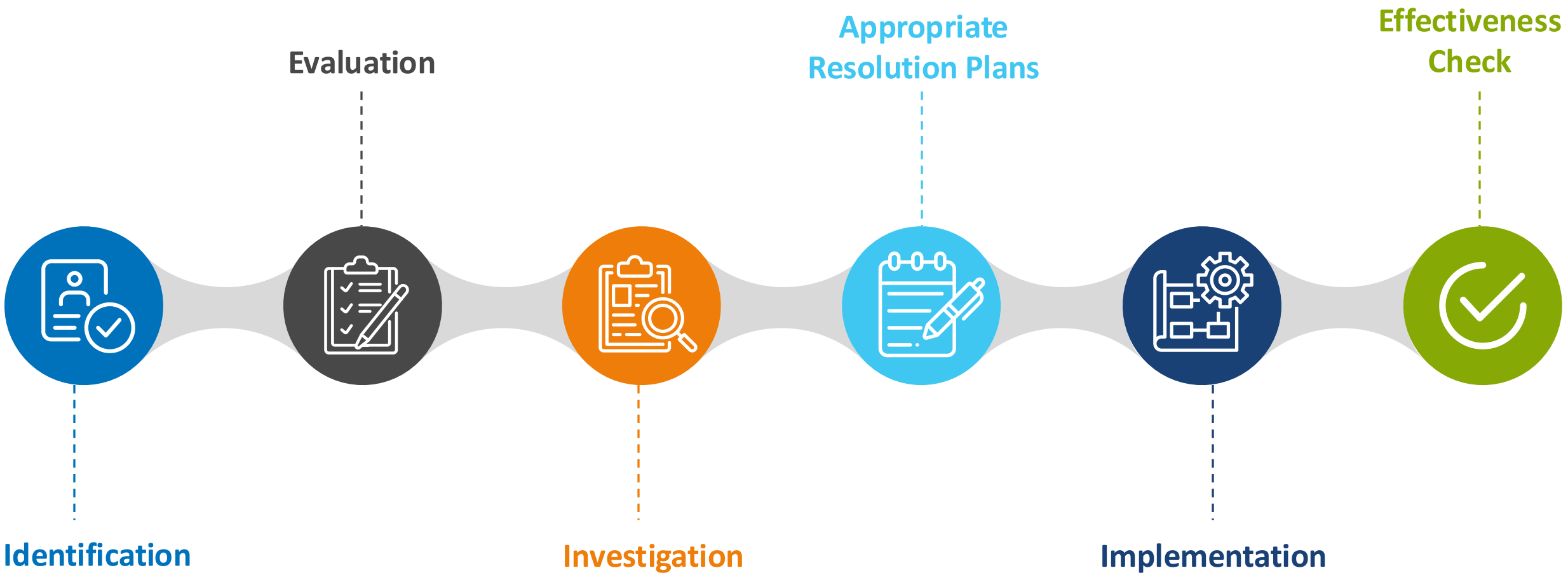


Image Source: https://www.compliancequest.com/capa-corrective-and-preventive-action/

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Poll Question no. 2

“As an organization, currently we do face a lot of problems investigating and handling CAPA”

A. Yes

B. No

Internal audits

Internal and External Audits: Spot the 5 differences

Internal Audit	External Audit
Conducted by trained personnel within the organization	Audit involves an independent third party, a regulatory body
Verify organization QMS processes and procedures adhere to internal policies, industry standards, and regulatory requirements.	Ensures the organization's QMS complies with industry regulations, standards, and customer requirements.
Assessment: Efficiency and effectiveness of organization's QMS.	Determination: Organization's QMS meets the criteria for a specific certification or accreditation.
Risk Identification: Identifying potential risks and vulnerabilities within the QMS	Supplier Evaluation: Customers may perform audits to assess their suppliers' QMS
Continuous Improvement: Using audit findings to implement corrective and preventive actions (CAPA) to enhance processes and prevent issues from recurring.	Credibility and Assurance: External audits provide stakeholders, including customers and regulatory bodies, with independent assurance that the organization maintains a robust QMS

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Poll Question no. 3

Are you stressed or tensed?

Please have a look at the image and honestly answer if this is something you feel every time when it comes to audit.

A. Yes

B. No

Image Source: www.newtimes.co.rw

Management Review Meetings (MRM)

Meaning of MRM:

Management Review Meeting Is

An essential process to holistically review the systems and processes (DISCUSSIONS)

To evaluate the insufficiency and adequacy (INPUTS & OUTPUTS)

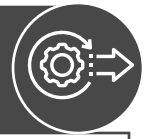
While promoting continual improvements (PLAN & ACTIONS)

MRM – Inputs & Outputs:

INPUT

- Customer satisfaction, complaints, feedback
- The extent to which quality objectives have been met
- Process performance and conformity of products and services
- Monitoring and measurement of processes, products & their results
- Corrective actions & preventive actions
- Internal results, third party inspections, regulatory authority audits and their outcomes
- The performance of external providers, suppliers and subcontractors' evaluation
- Opportunities for improvement
- Issues and applicable new or revised regulatory/legal requirements,
- Environmental, social, occupational health and safety performance of the organization (if applicable)
- Any adverse or severe adverse events, vigilance, FSCA activities (if applicable).

OUTPUT



- Any improvement, or technology or method needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes
- The need for changes to quality management system supporting continual improvement including, equipment's, machineries, infrastructure, resources (including manpower) and requirements.
- Changes needed to respond to applicable new or revised regulatory requirements/legal / environmental /Occupational and health safety
(if applicable).

Best Practices:

STEP 1
Plan and define MRM

STEP 2
Agenda with review inputs & outputs

STEP 3
Fix the date & time.
Send out MRM Agenda

STEP 4
Encourage active participation.
Auto generate reminder if possible

STEP 5
Initiate with previous minutes, if applicable

STEP 6
Discussion and Documentation (or recorded)

STEP 7
Prefer virtual MRM at periodic interval without fail.
Digitally capture the minutes of the meeting (audio & report)

Cost of Quality (CoQ)

W. Edwards Deming

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“The biggest cost of poor quality is when your customer buys it from someone else because they didn't like yours”

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Measuring Cost of Quality

The basic equation for Cost of Quality is the sum of Cost of Good Quality (CoGQ) and Cost of Poor Quality (CoPQ).

CoQ = CoGQ + CoPQ

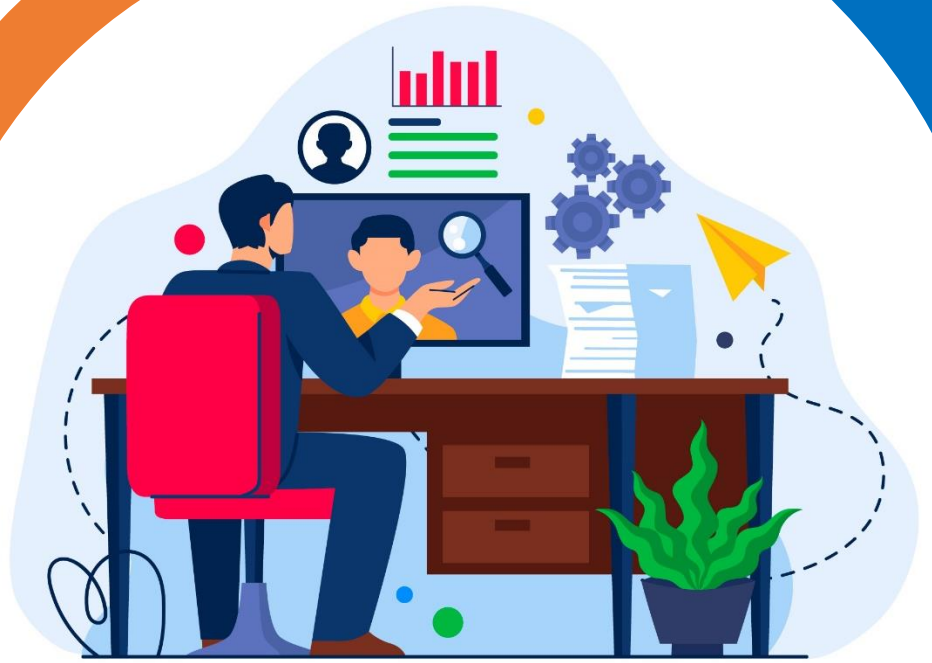
CoGQ = PC + AC (Prevention Cost, Appraisal Cost)

CoPQ = IFC + EFC (Internal Failure Cost, External Failure Cost)

Cost of good quality (CoGQ) vs cost of poor quality (CoPQ):

What is the Cost of Good Quality (CoGQ)?		What is the Cost of Poor Quality (CoPQ)?	
The Cost of Good Quality (CoGQ) represents investments made to prevent poor quality and ensure high-quality products and services.		The Cost of Poor Quality (CoPQ) denotes the financial setbacks incurred by a company resulting from subpar products or services. It encompasses all expenses tied to errors, defects, and inefficiencies throughout the production and delivery process.	
Prevention Costs	**Appraisal Costs**	**Internal Failure Costs**	**External Failure Costs**

Remote Audits



Remote Audits:

Remote audits refer to the use of information and communication technologies (ICT) to gather information, interview an auditee, etc., when "face-to-face" methods are not possible or desired. (ISO 19011).

Remote audit

Audit performed off-site through the use of information and communication technology [Synonyms: E-audit, virtual audit].

Remote Audits

A joint survey (August 2021) of **4320** people took part on both sides of the audit, assessment and evaluation process (by the IAF, ILAC and ISO) shows that many are ready to embrace new methods and procedures in remote audits, assessments and evaluations.

79 % said that they would like to see blended (remote and on-site) or remote procedures used in the future.

80 % agreed that remote procedures give the same confidence as on-site audits.

91.5 % felt that a substantial increase in remote techniques will stimulate the use of new processes.

97.5 % agreed to some extent that new technologies and alternative techniques should be used.

Source: https://www.iso.org/news/ref2737.html
https://www.iso.org/files/live/sites/isoorg/files/news/News_archive/2021/10/Ref2737/Survey_IAF_ILAC_ISO_2021

Poll Question no. 4

ComplianceQuest should contact me for an initial level of discussion on how digitization, EQMS and Automation can help our organization

A. Yes

B. No

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“A picture is worth a thousand words”

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Concluding remarks!

> **Cost is more important than quality, but quality is the best way to reduce cost.**

Genichi Taguchi

Taguchi, was an engineer and statistician from Japan.

1950s onwards, he developed a methodology for applying statistics to improve the quality of manufactured goods – Taguchi methods

About ComplianceQuest

About ComplianceQuest

Transform to a fully connected business with a next-generation AI-Powered Product Lifecycle, Quality and Safety management platform, built on Salesforce.

300,000+
Users

1000+
Customer Sites

100M+
Active Records being Managed

1000+
Man years Domain Expertise

Award Winning
Solution

Worldwide
Direct and Partner locations

Financially Strong

INSIGHT PARTNERS

Quality & Compliance begins at home and with Salesforce

CERTIFIED ISO 9001:2015 COMPANY

AICPA SOC 2 Formerly SAS 70 Reports

International Organization for Standardization ISO 27001

FedRAMP

Recognized

Gartner 2022 QMS Market Guide

Frost & Sullivan 2019 Best Practices Award – North American Cloud-Based Enterprise Quality Management System Customer Value Leadership Award

Customer Success

salesforce appexchange

Salesforce Appy

Capterra 5 STAR USER REVIEWS

featured customers

SPRING 2022
TOP PERFORMER
Quality Management Software

SUMMER 2022
TOP PERFORMER
EHS Management Software

2020 Inc. 5000 LIST 2019-2022

Time Tested and Proven

Janssen Pharmaceutical Companies of Johnson & Johnson

Lifescan

Canon Canon Medical

3M

oneblood

TILRAY

TELADOC

Walmart

Continental CONTITECH

flex

Tupperware

John Crane a smiths company

salesforce

CDC

GRIFFIN

FINNING CAT

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Achieve your Quest for Digital Operations

CQ intelligently automates operations from product innovation to customer success

INTEGRATIONS

- CRM
- ERP
- HRMS
- LIMS
- LMS
- MES
- MOM
- PLM
- RIMS
- Others

ENGINEERING	CUSTOMER	QUALITY	SUPPLY CHAIN	RISK	DOCUMENT AND KNOWLEDGE MANAGEMENT	SAFETY	ENVIRONMENT
PRODUCT LIFECYCLE MANAGEMENT (PLM)	CUSTOMER QUALITY, COMPLAINTS AND POST MARKET SURVEILLANCE	QUALITY MANAGEMENT AND CONTROL (QMS)	SUPPLIER QUALITY AND RELATIONSHIP MANAGEMENT	RISK AND COMPLIANCE MANAGEMENT	DOCUMENT MANAGEMENT, TRAINING AND CHANGE CONTROL	HEALTH AND SAFETY MANAGEMENT	ENVIRONMENTAL AND SUSTAINABILITY MANAGEMENT

MANAGEMENT REVIEW

CONNECTIVITY

salesforce, CLOUDBYZ, rootstock software, SERVICEMAX, TAVANT, Microsoft, Google, box, MuleSoft, tableau

- Embedded & Advanced Analytics
- Collaboration (Chatter, MS Teams)
- 2-Way Portal
- Alerts and Notification
- Forms Designer/ Runner
- Mobile
- Pre-Validated
- Ratings
- CQ.AI
- MyCQ for casual users

PLATFORM POWERED BY salesforce

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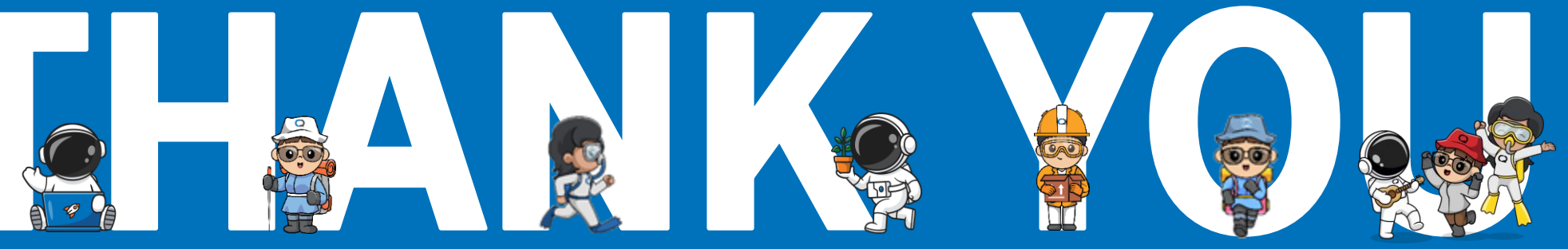
THANK YOU



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