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"Identify, Investigate, and Implement - The CAPA Practices”

Presented by | Sundeep Agarwal

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Speaker Introduction

SUNDEEP AGARWAL

Trainer, Speaker & 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, SaMD, 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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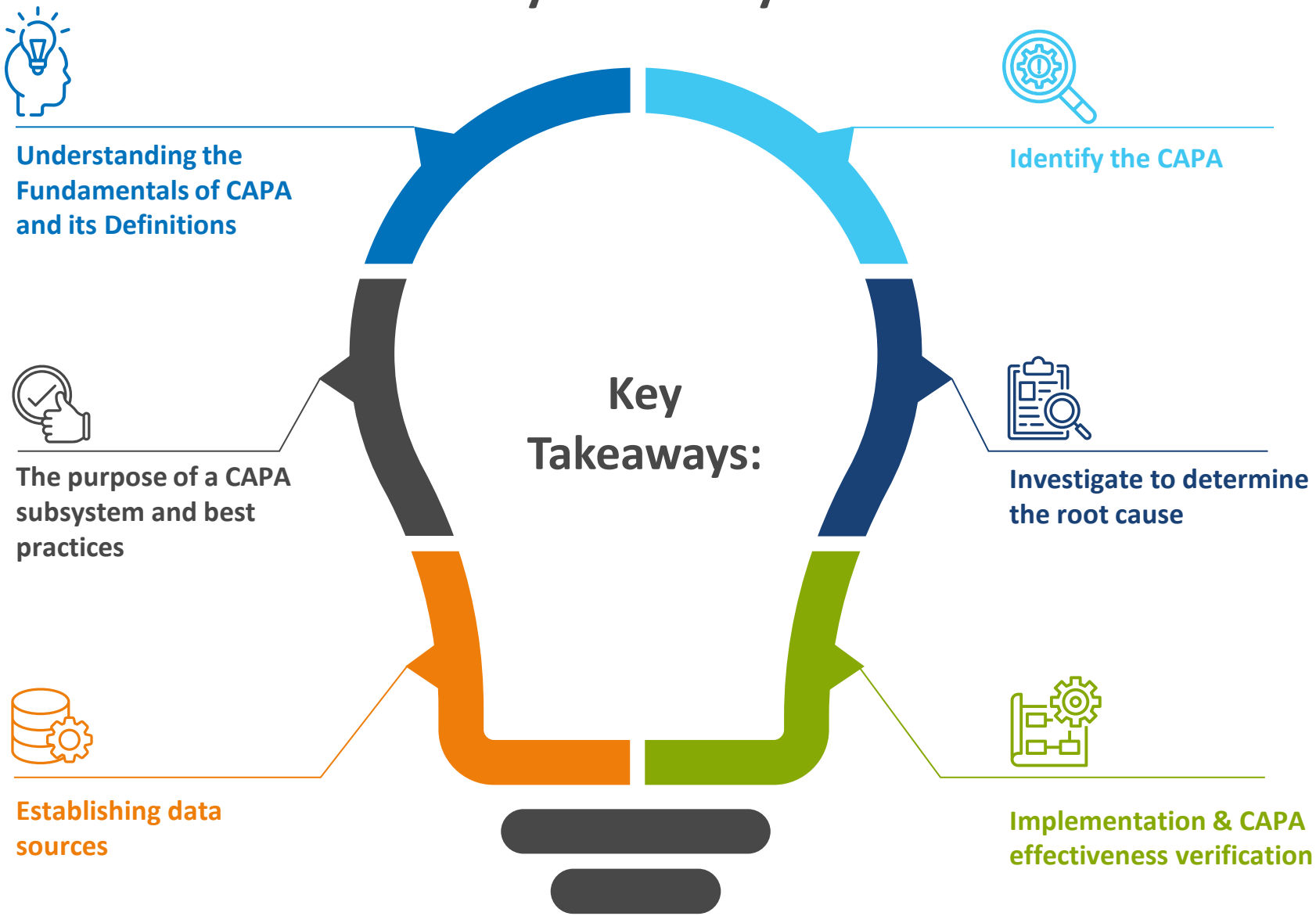
Poll Question no. 1

"As an organization, currently we do face a lot of problem investigating and handling CAPA"

A. Yes

B. No

Key Takeaways:



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Definitions:

Correction
"Correction "action to eliminate **detected nonconformity**.

1. A correction can be made in conjunction with a corrective action.
2. A correction can be, for example, rework or regrade.

"Corrective action" action to eliminate the cause of a **detected non-conformity** or other undesirable situation.

1. There can be more than one cause for a nonconformity.
2. Corrective action is taken to prevent recurrence.
3. There is a difference between correction and corrective action.

"Preventive action" action to eliminate the cause of a **potential non-conformity** or other undesirable situation

1. There can be more than one cause for a potential. nonconformity.
2. Preventive action is taken to prevent occurrence.

Source: FDA presentation on CAPA dtd. Nov 14th, 2014.

What is CAPA (Corrective and Preventive Action)?

CAPA or Corrective and Preventive Action is

1) A methodological strategy for mitigating risks and improving processes,
2) Identifying the sources of actual or potential issues and their root causes,
3) Planning solutions for those problems, and
4) Documenting the solution so that similar issues don't occur in the future.
5) A way to improve the company's processes by taking a series of actions that eliminate the recurring events and causes of non-conformities.

The major intent of a CAPA system is to focus on the root causes of particular problems and risks so that there won't be a need for either corrective action or preventive action in the future.

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

Poll Question no. 2

I agree that including data or quantifiable inputs would result in an effective CAPA?

A. Yes

B. No

Corrective and Preventive Action (CAPA) Process

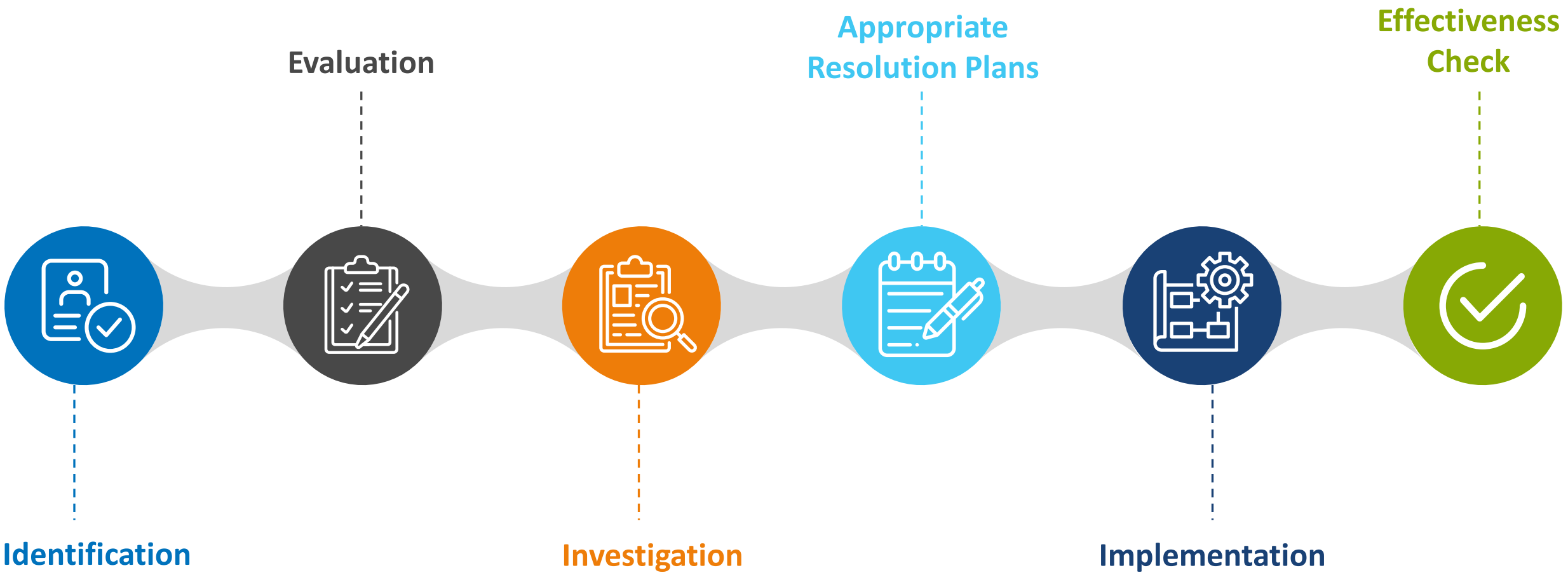

Image Source: https://www.compliancequest.com/capa-corrective-and-preventive-action/

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Identification

What are practical sources that triggers CAPA?

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

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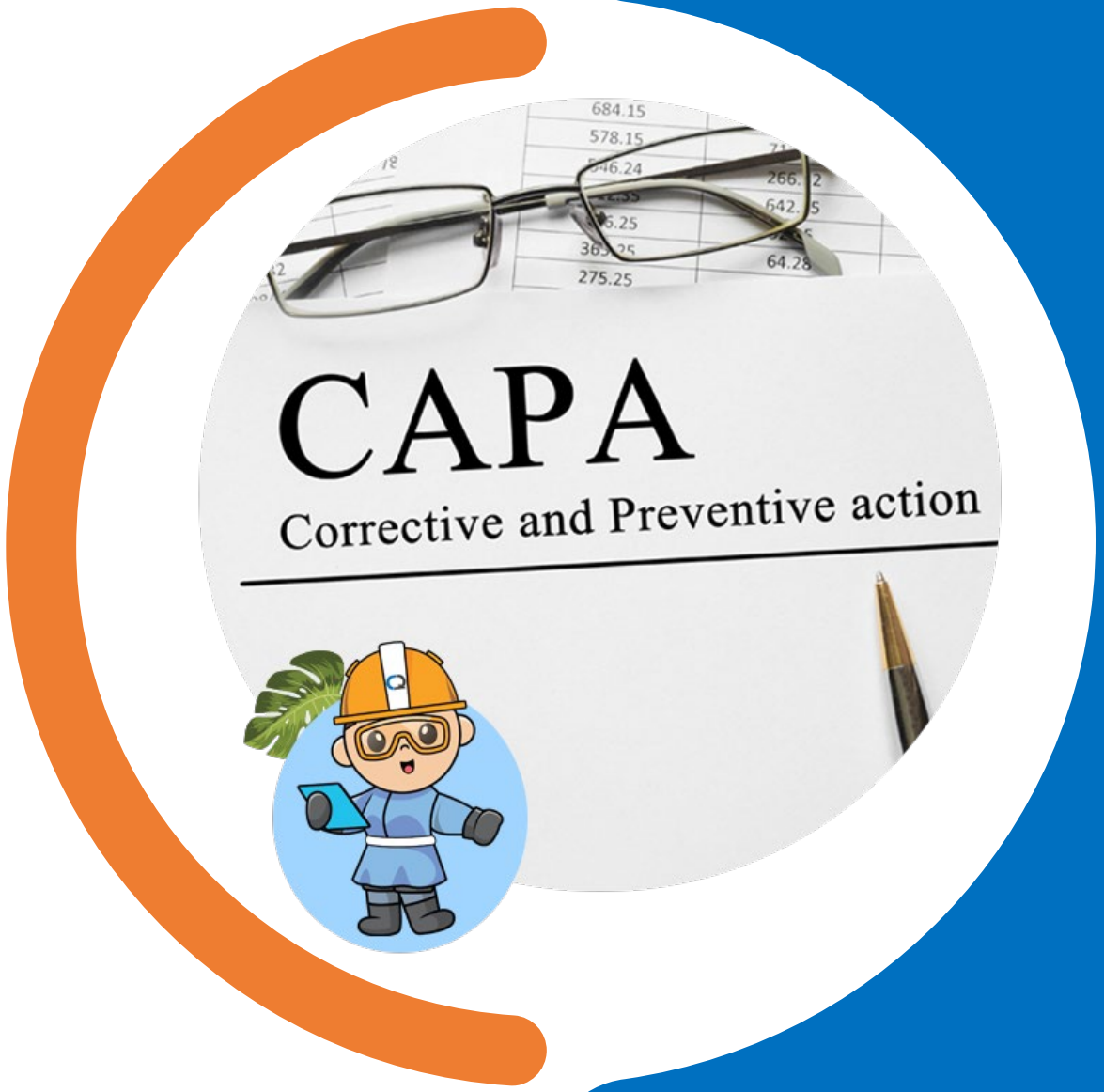
Investigation & Root cause



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.

Methods of RCA:

1. Five Whys
2. Fishbone Diagram
3. Flowchart
4. Pareto Chart
5. Scatter Diagram
6. Other Statistical Tool

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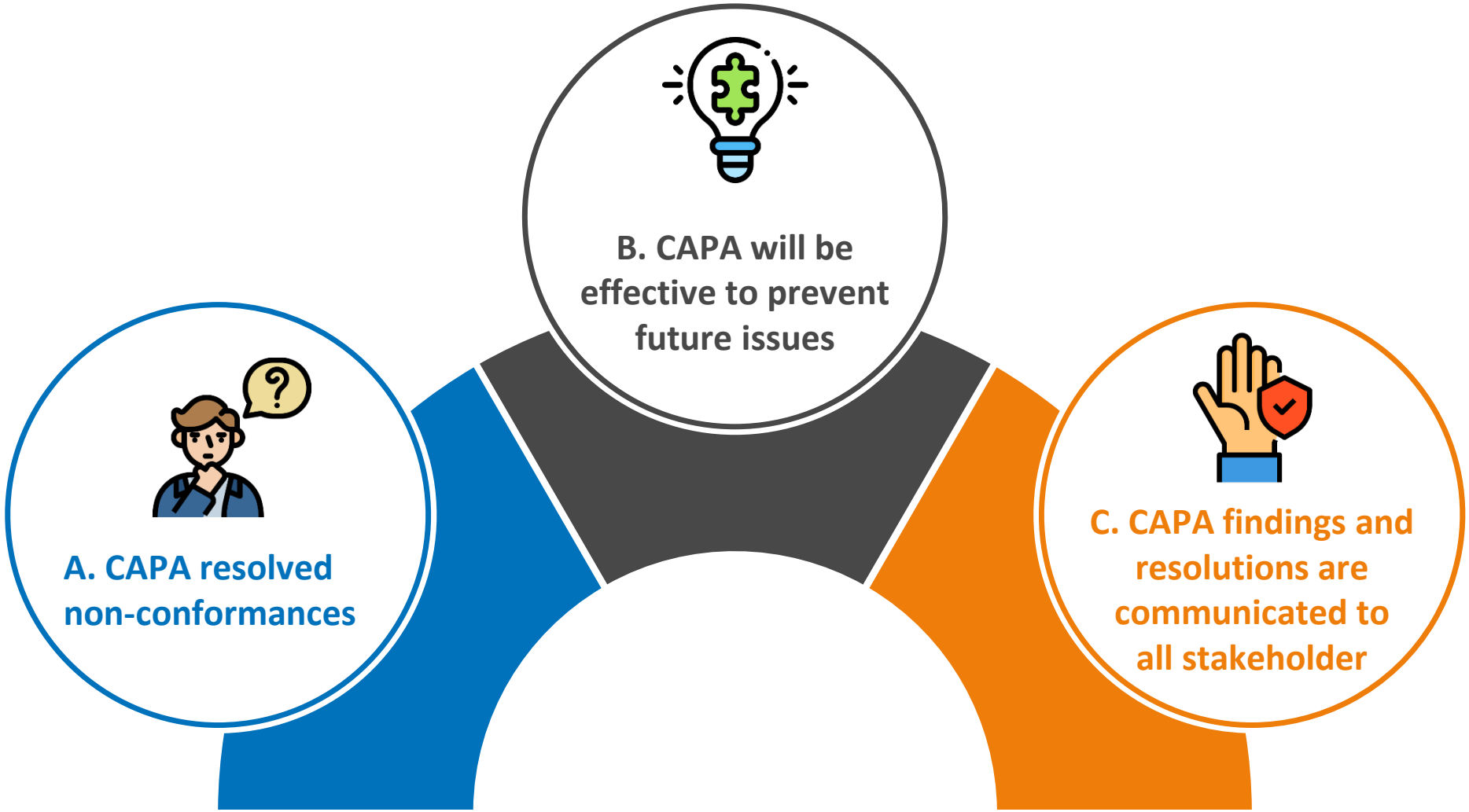
Implementation & Verification

Objective of Verification:



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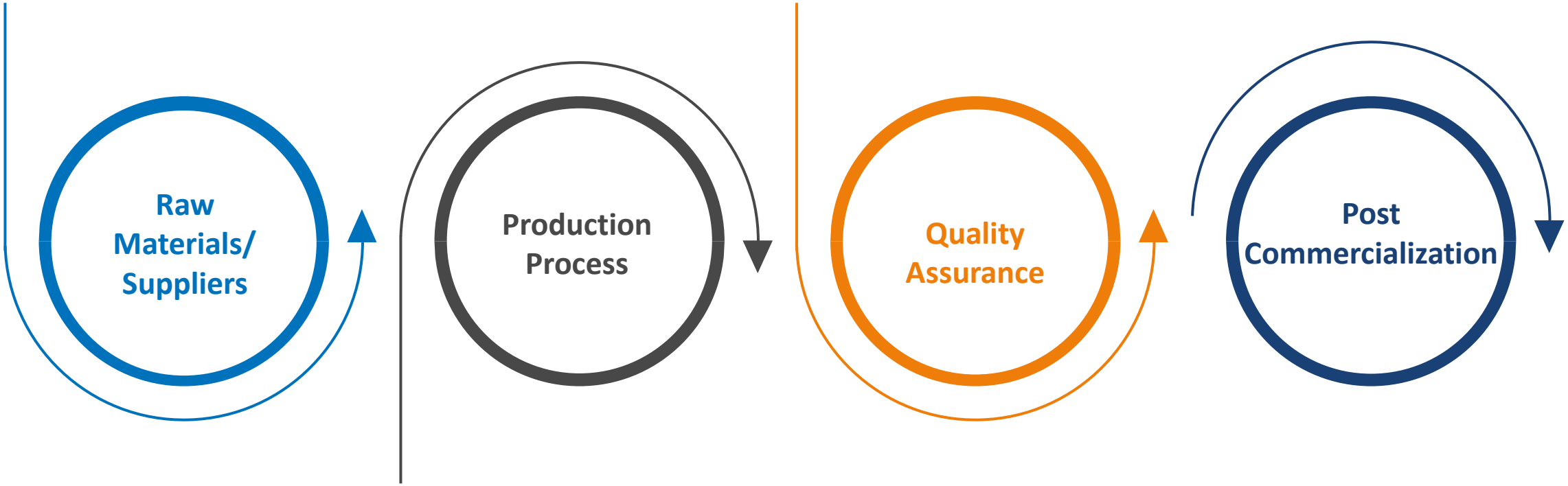
Core area that should be integral part of CAPA:



- A. Components
- B. Non- conformity(s) reports
- C. Supplier Audits/ Findings

- A. Verification and Validation
- B. Manufacturing
- C. Shop floor practical issues

- A. Quality Inspection
- B. Find out the root cause analysis
- C. Prevent reoccurrence

- A. Customer Complaints/ Feedbacks
- B. Distribution, Shipping, Transport, and Packaging

Poll Question no. 3

"Digitalized CAPA handling is preferred and is the way forward for an effective QMS"

A. Yes

B. No

Conclusion

CAPA can be implemented with multiple methodologies, irrespective of the industry, prevent hazards and save millions. Don’t be left behind. Digitalize your methodology as much as possible. Unless CAPA is fully documented, its not done.

And Don’t forget to refer the Free Resource from CQ Website. Download CAPA Checklist at https://www.compliancequest.com/capa-corrective-and-preventive-action/

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About ComplianceQuest

AI-powered cloud platform for Clinical, Quality and Safety management solutions

Clinical | EQMS | EHS

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

CONNECTIVITY

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

MANAGEMENT REVIEW

Analytics | Dashboards, Reports | Collaboration | Community | Communication | Mobile | Validation | Artificial Intelligence

PLATFORM POWERED BY salesforce

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Poll Question no. 4

ComplianceQuest should contact me for an initial level of discussion on how digitalization, EQMS and automation can help our organisation

A. Yes

B. No

On a scale of 1 to 5, with 1 being poor and 5 being excellent, how would you rate this webinar by ComplianceQuest?

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THANK YOU

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