Corrective and Preventive Actions in QMS: Choosing the Right Tool for the Job

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Agenda

- Corrective & Preventive Actions: An Overview
- The CAPA Process: Key Steps
- Overview of CAPA Tools
  - Root Cause Analysis Tools
  - Risk Evaluation Tools
  - Effectiveness Verification Tools
  - Supportive Tools
- Selecting the Right Tools: General Guidelines
- Case Studies: Effective Use of CAPA Tools
- Q&A

Hello! I'm Stephanie!

- **St. Louis University**
  - B.S. in Chemistry
- **15+ years of Quality Management Experience**
  - Biotech, Pharma, Medical Device, Food & Beverage, General Manufacturing
- **ASQ Certified Quality Auditor**
- **ISO 13485 Lead Auditor**
- **Lean Six Sigma Green Belt**

Poll Time!

Where do you find the most gaps in your current CAPA process?

- Root Cause Analysis
- Risk Evaluation
- Corrective/Preventive Action Planning
- Effectiveness Verification
- Documentation and Closure
- Something else
- We don’t have a formal CAPA process

Corrective and Preventive Actions: An Overview

Corrective And Preventive Actions

Corrective Actions:

Actions taken to resolve a non-conformance or defect that has already occurred

Preventive Actions:

Steps taken to prevent potential non-conformances from occurring in the first place

Why CAPA Matters in Your QMS

Mitigates Risk:

- Ensures that past mistakes are corrected and potential risks are addressed

Supports Continuous Improvement:

- Regular CAPA reviews allow companies to refine processes, reduce waste, and enhance product quality

Compliance and Regulatory Significance:

- CAPA processes are required by regulatory agencies in many industries

The CAPA Process: Key Steps

Customer Complaints

Internal Audits

Non-Conformance Reports

Uncovering the underlying reason for the issue

Establishing actionable steps to address the immediate issue and any problems leading to the non-conformance

Execution of the defined corrective and preventive measures

Assessment of effectiveness of executed actions

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Overview of CAPA Tools

Root Cause Analysis	Risk Evaluation
5 Why Analysis Fishbone Diagram Fault Tree Analysis	FMEA Bowtie Analysis Decision Trees
Effectiveness Verification	**Supportive**
Internal Audits KPIs Trend Analysis	Process Flow Diagrams SIPOC Diagrams eQMS

Root Cause Analysis Tools

Root Cause Analysis
5 Why Analysis Fishbone Diagram Fault Tree Analysis

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RCA Tool #1: 5 Why Analysis

What is 5 Why Analysis?

- A **simple** RCA tool used to explore the underlying cause of a problem by asking “Why?” repeatedly
- Best suited **for straightforward, isolated problems** where cause and effect is somewhat linear
- Helps uncover **deeper process or system issues**
- **Quick, low-resource** method requiring minimal training
- Often used in **lean, Six Sigma, and Kaizen** problem solving

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RCA Tool #1: 5 Why Analysis

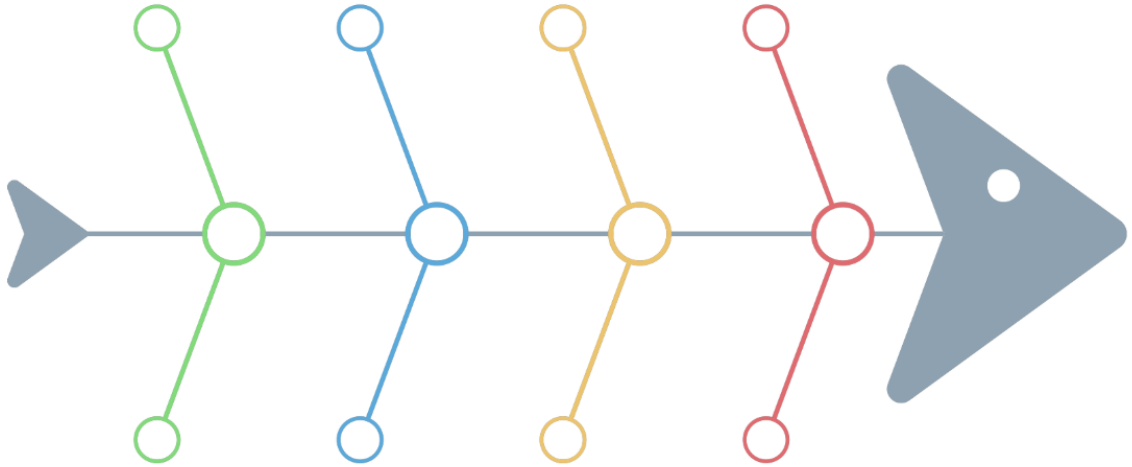
Key Elements of 5 Why Analysis

- **Problem Statement –** Clearly defined issue you're trying to resolve
- **"Why" Chain –** Iterative questioning technique
- **Logical Progression –** Each "Why" must be based on the answer to the previous one
- **Root Cause Identification –** Final answer that reflects a process/system flaw
- **Actionable Outcome –** Enables CAPA team to implement targeted and effective corrective and preventive actions

RCA Tool #2: Fishbone Diagram

What is a Fishbone Diagram?

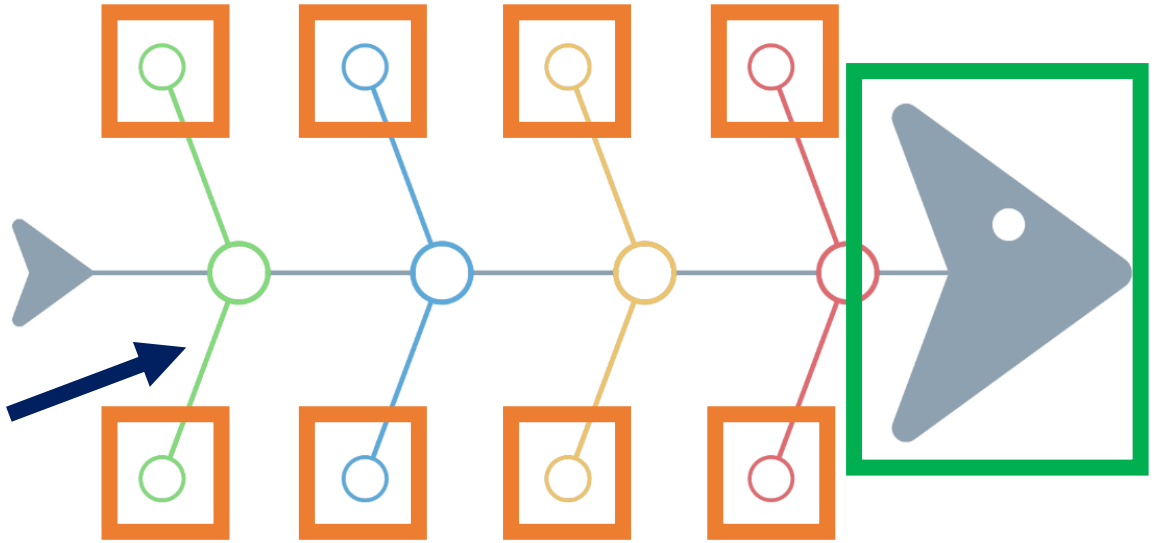
- Also known as **Ishikawa** or **Cause-and-Effect** Diagram
- A **structured brainstorming tool** that categorizes potential causes of a problem
- Visually displays **contributing factors** in major categories
- Ideal for problems with **multiple potential causes** across people, process, equipment, etc.



RCA Tool #2: Fishbone Diagram

Key Elements of a Fishbone Diagram:

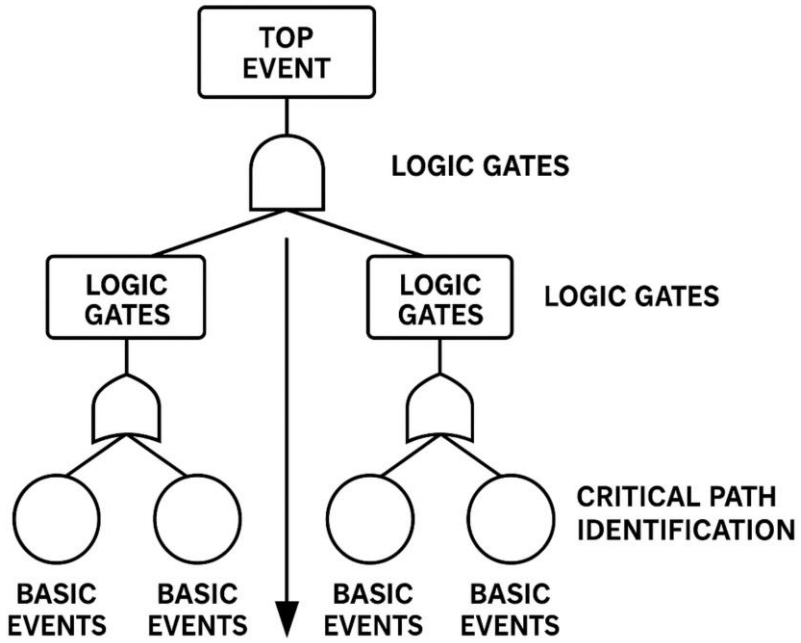
- **Problem Statement –** Clearly written at the head of the “fish”
- **Primary Categories –** Commonly Manpower, Process, Equipment, Materials, Measurement, Environment
- **Sub-Causes –** Specific potential contributors under each main category
- **Visual Structure –** Cause-and-effect relationship is mapped for clarity
- **Team-Based Brainstorming –** Draws input from multiple perspectives



RCA Tool #3: Fault Tree Analysis (FTA)

What is Fault Tree Analysis?

- A **deductive, logic-based** root cause analysis method
- Starts with a **top-level undesirable event** (failure) and works downward to identify all possible contributing causes
- Ideal for **complex, systemic, or interrelated failures**



Key Components of Fault Tree Analysis:

- **Top Event –** The failure or undesirable outcome being analyzed
- **Basic Events –** Underlying causes feeding into the top event
- **Logic Gates –** Show how events interact
- **Branching Tree Structure –** Visualizes complex interdependencies
- **Critical Path Identification –** Highlights most probable failure points

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Root Cause Analysis Tool Comparison

Tool	Ideal Use Cases	Strengths	Limitations
5 Why Analysis	Simple, linear issues with clear symptom to cause relationships	Quick, easy to teach, requires no special tools	Can oversimplify; not suitable for complex or multi factor issues
Fishbone Diagram	Problems with multiple possible root causes across departments	Structured, visual brainstorming; promotes team engagement	May require facilitation; doesn't rank or validate causes
Fault Tree Analysis	High risk failures with interrelated causes	Rigorous, logical, suitable for regulatory scrutiny	Complex to build; time/resource intensive

Poll Time!

Which tool do you or your team use most often during Root Cause Analysis?

- 5 Why Analysis
- Fishbone Diagram
- Fault Tree Analysis
- Brainstorming/Team Discussions
- We don’t use a consistent method
- Not sure

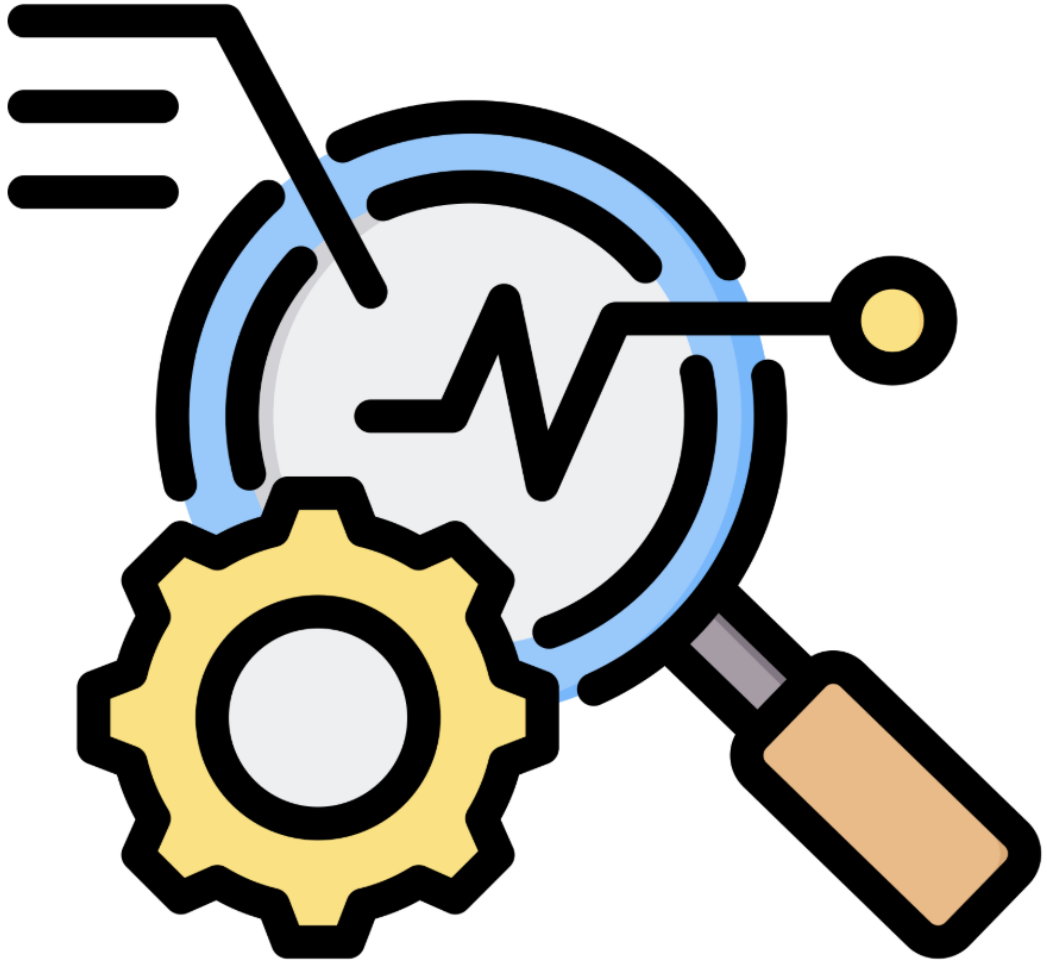
Risk Evaluation Tools

Risk Evaluation
FMEA Bowtie Analysis Decision Trees

Risk Evaluation Tool #1: FMEA

What is Failure Modes & Effects Analysis (FMEA)?

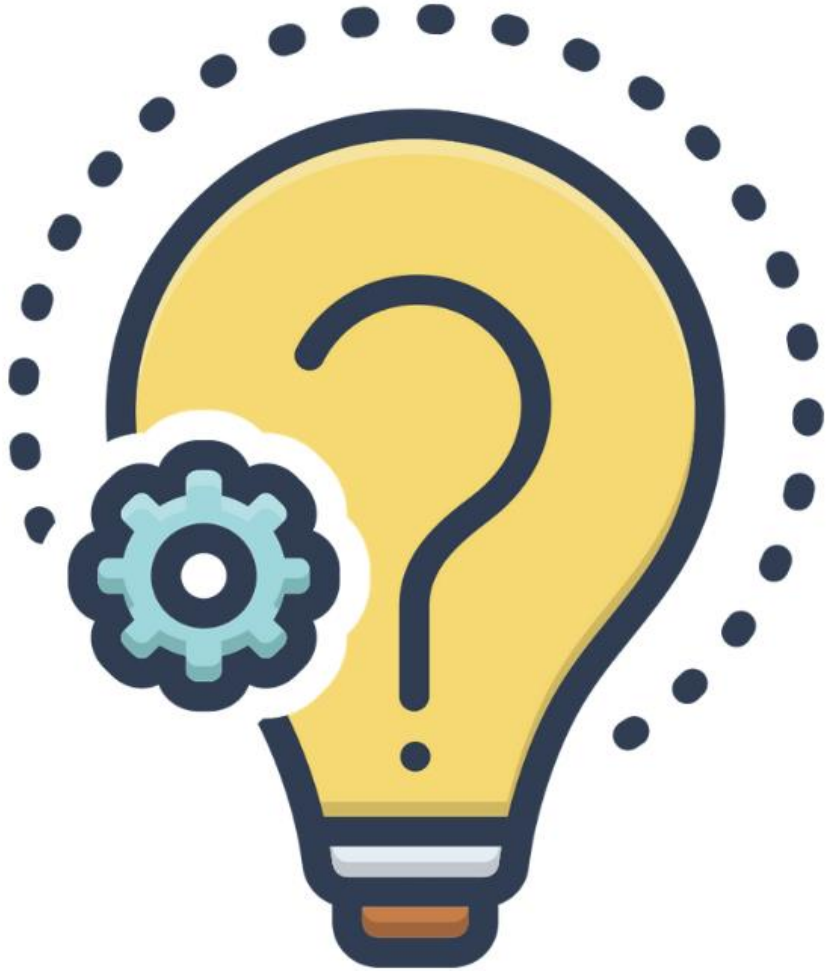
- Used across industries to **prevent failures before they happen**
- A **structured, proactive approach** to identifying potential failure modes and their impact
- Assign a **Risk Priority Number (RPN)** to each failure mode
- Helps teams **prioritize risks** based on **severity, occurrence, and detectability**



Risk Evaluation Tool #1: FMEA

Key Elements of FMEA

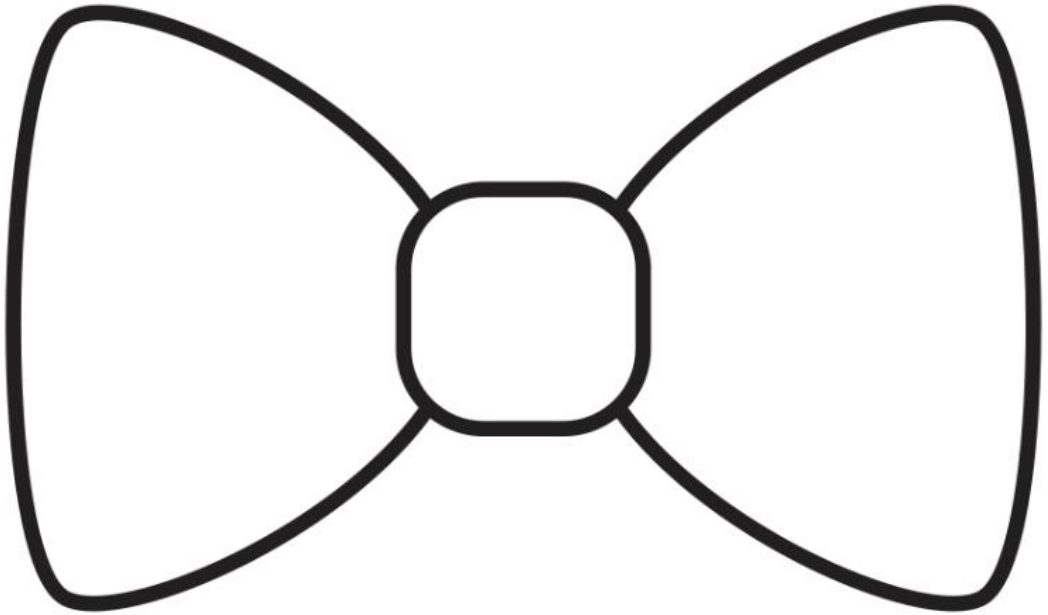
- **Failure Modes –** Ways a process, product, or system can fail
- **Effects –** Consequences of each failure mode on quality, safety, or performance
- **Causes –** The underlying reasons for failures
- **Severity, Occurrence, and Detection Ratings –** Scoring system to prioritize risks
- **Risk Priority Number (RPN) Calculation –** Numeric value that determines which risks require action



Risk Evaluation Tool #2: Bowtie Analysis

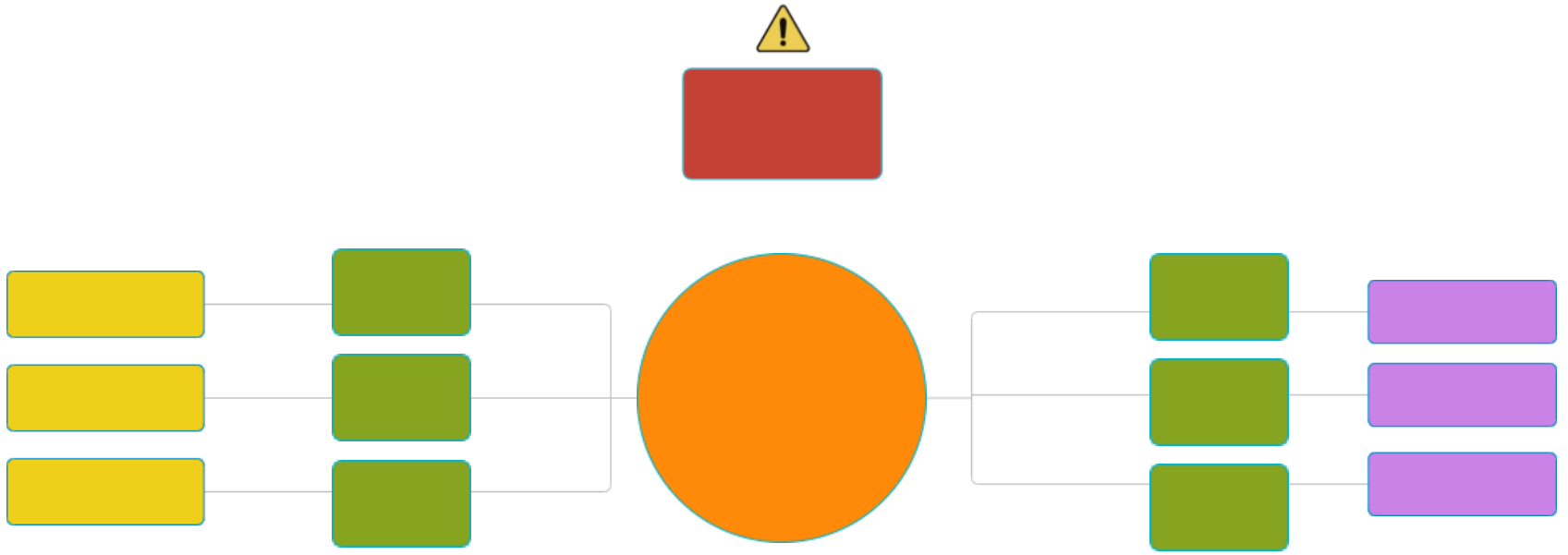
What is a Bowtie Analysis?

- A **visual tool** to map out risk causes and consequences
- Provides a clear **cause and effect structure,** making it easy to understand risk pathways



Risk Evaluation Tool #2: Bowtie Analysis

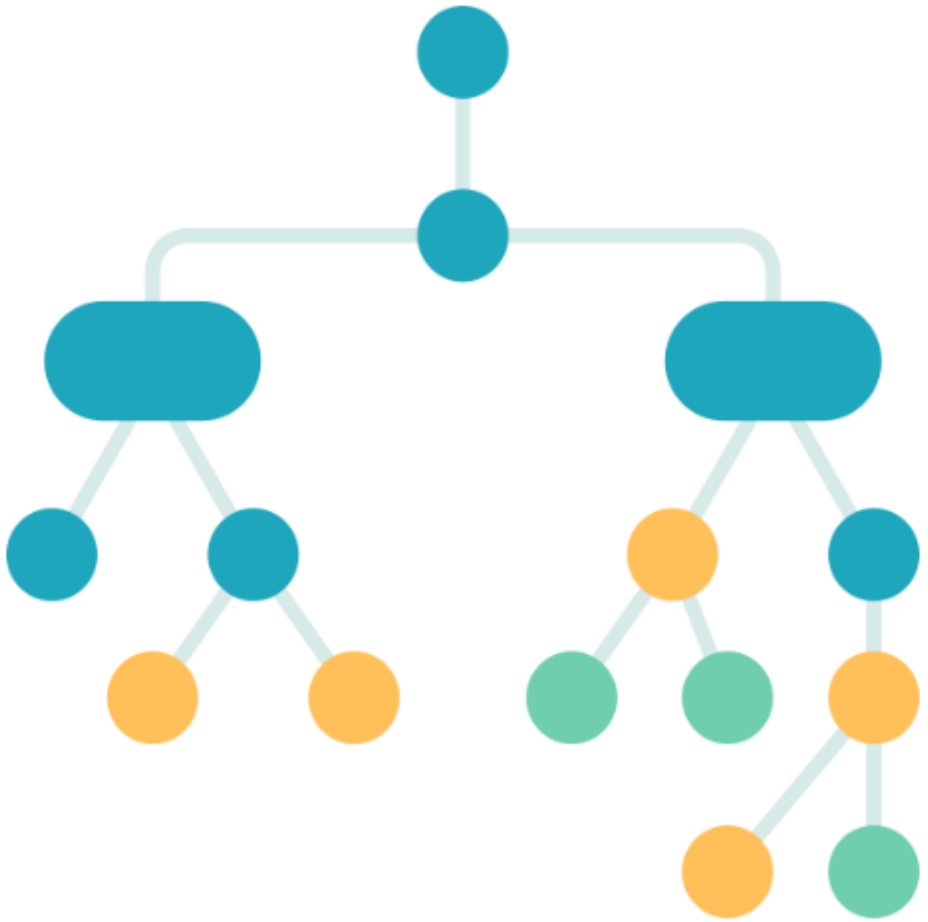
- **Hazard** → Source of potential harm
- **Top Event** → Point where control is lost
- **Threats** → Events leading to the top event
- **Consequences** → Events occurring due to the top event
- **Preventive Controls** → Actions to reduce likelihood of occurrence
- **Mitigative Controls** → Actions to minimize the severity (if the event does occur)



Risk Evaluation Tool #3: Decision Trees

What are Decision Trees?

- A **structured, step-by-step** decision making tool
- Provides a **visual framework** for analyzing choices
- Helps assess **multiple risk factors** and **potential outcomes**



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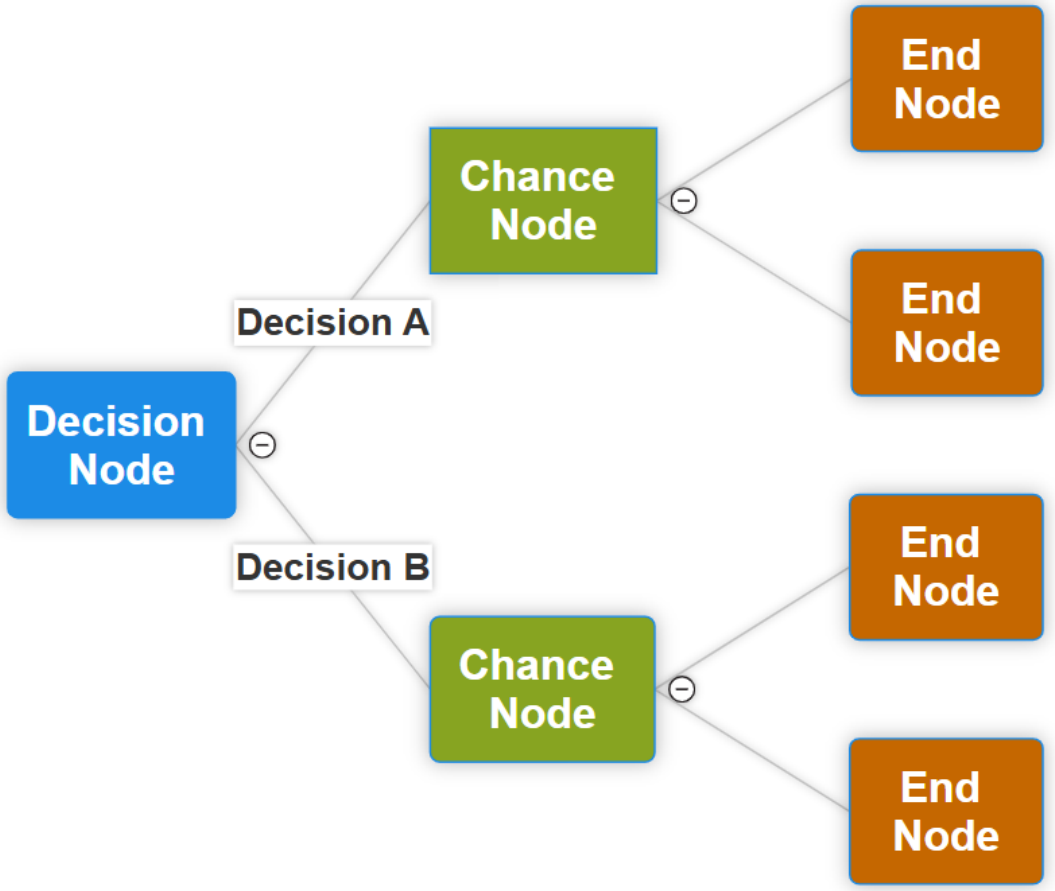
Risk Evaluation Tool #3: Decision Trees

Key Parts of a Decision Tree:

- **Decision Nodes -** Used to represent choices
- **Chance Nodes -** Used to show probability or uncertainty
- **End Nodes -** Represents an outcome or final decision



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Risk Evaluation Tool Comparison

Tool	Ideal Use Cases	Strengths	Limitations
FMEA	Proactively identifying risks in design or process before they cause failures	Quantifies risk (RPN), prioritizes actions, proactive	Requires team training and/or a trained facilitator
Bowtie Analysis	Communicating how threats lead to consequences and what controls exist	Holistic view; maps both preventive and mitigative barriers	Less detailed on root causes
Decision Tree	Guiding escalation decisions/CAPA pathways based on risk and impact criteria	Ensures consistency, helps triage effectively	Can be rigid if not maintained; doesn't uncover root cause

Effectiveness Verification Tools

Effectiveness Verification

Internal Audits
KPIs
Trend Analysis

Effectiveness Verification Tool #1: Internal Audits

What are Internal Audits?

- **Evaluations** of processes, products, or systems against **defined criteria**
- **Validate compliance** with procedures, regulations, and standards
- Often used as an **effectiveness check** for closed CAPAs
- Provide great insights into **recurring gaps** and **implementation effectiveness**

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Effectiveness Verification Tool #1: Internal Audits

Key Elements of Internal Audits:

- **Audit Scope & Criteria –** Defines what's being evaluated and against which standards
- **Audit Plan –** Specifies timing, sampling methods, and responsibilities
- **Audit Checklist –** Guides consistent and objective evaluation
- **Findings & Observations –** Recorded deviations or concerns
- **Follow-Up Actions –** Verification that actions are effective and sustainable

Effectiveness Verification Tool #2: KPIs

What are Key Performance Indicators (KPIs) in CAPA?

- **Quantitative** metrics used to **monitor the performance and effectiveness** of CAPA
- Can help ensure CAPAs are resolved within **target timelines** and **prevent recurrence**
- **Enable visibility** to leadership and quality teams

Examples of CAPA KPIs:

- **Timeliness Metrics –** Days open, cycle time to closure
- **Recurrence Rate –** Number of repeat issues post-CAPA
- **CAPA Aging –** Number of overdue or extended CAPAs
- **Trends Over Time –** Long-term monitoring for systemic issues

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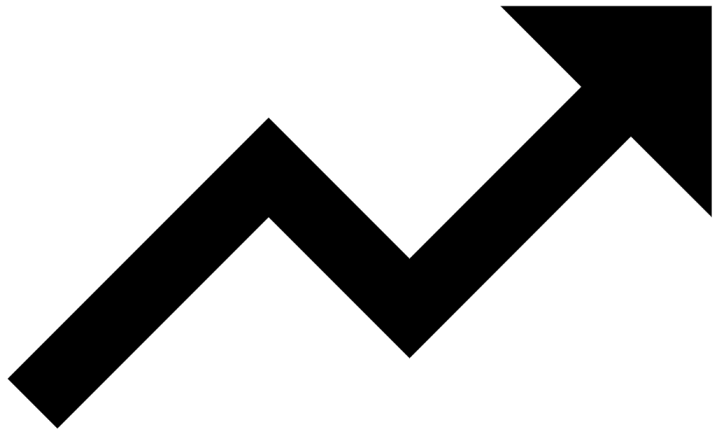
Effectiveness Verification Tool #3: Trend Analysis

What is Trend Analysis?

- The use of historical and current data to identify patterns and recurring issues
- Can reveal problems that may not be obvious from a single event
- Helps detect early signals of failure
- Often used in effectiveness verification

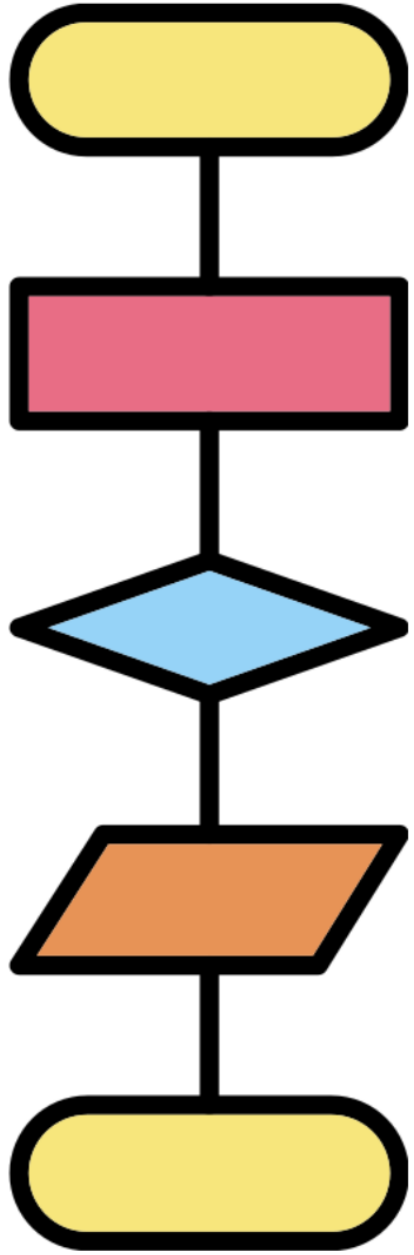


Effectiveness Verification Tool Comparison

Tool	Ideal Use Cases	Strengths	Limitations
Internal Audit	Verifying effectiveness of CAPAs, identifying systemic gaps	Objective review; supports continuous improvement	Relies on well designed audit criteria
Key Performance Indicators	Monitoring CAPA health, performance, and recurrence over time	Quantitative; drives accountability	Can become vanity metrics if not meaningful
Trend Analysis	Detecting recurring issues or systemic failures	Data driven; supports early detection and escalation	Requires robust, well classified data

Supportive Tools

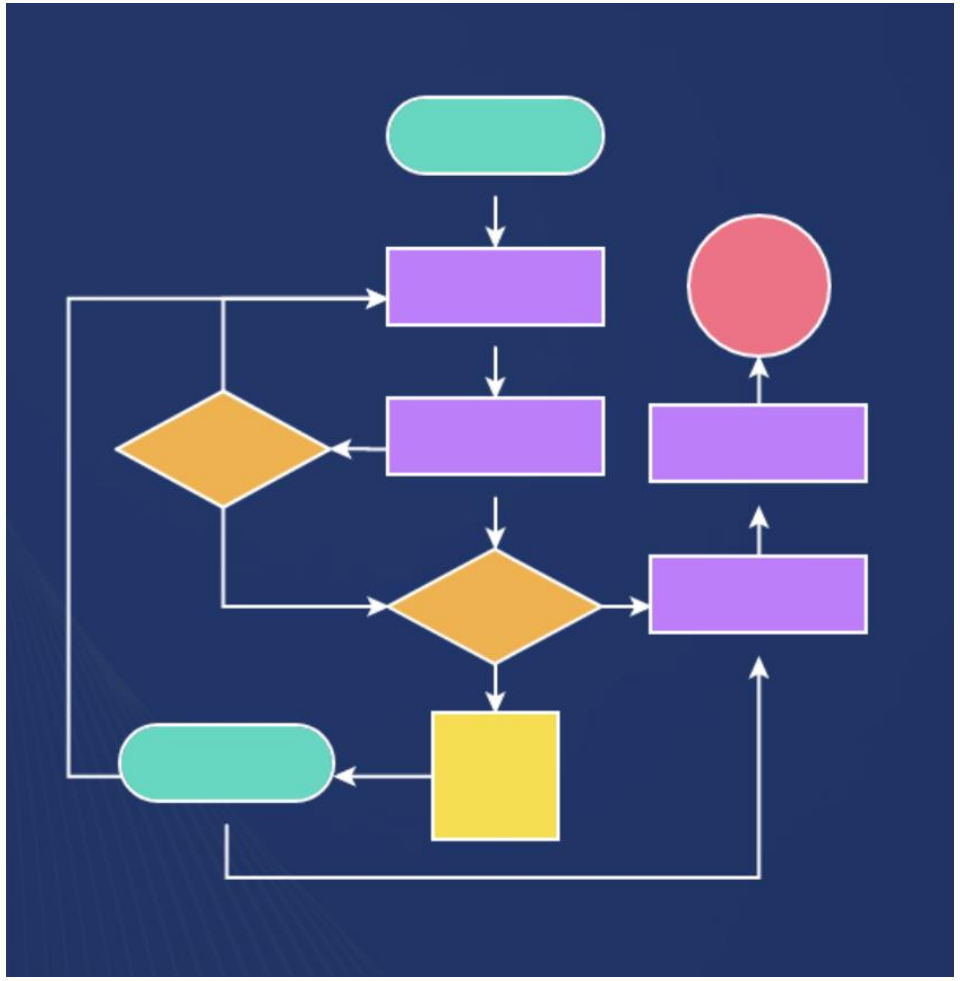
Supportive
Process Flow Diagrams SIPOC Diagrams eQMS



Supportive Tool #1: Process Flow Diagrams

What is a Process Flow Diagram?

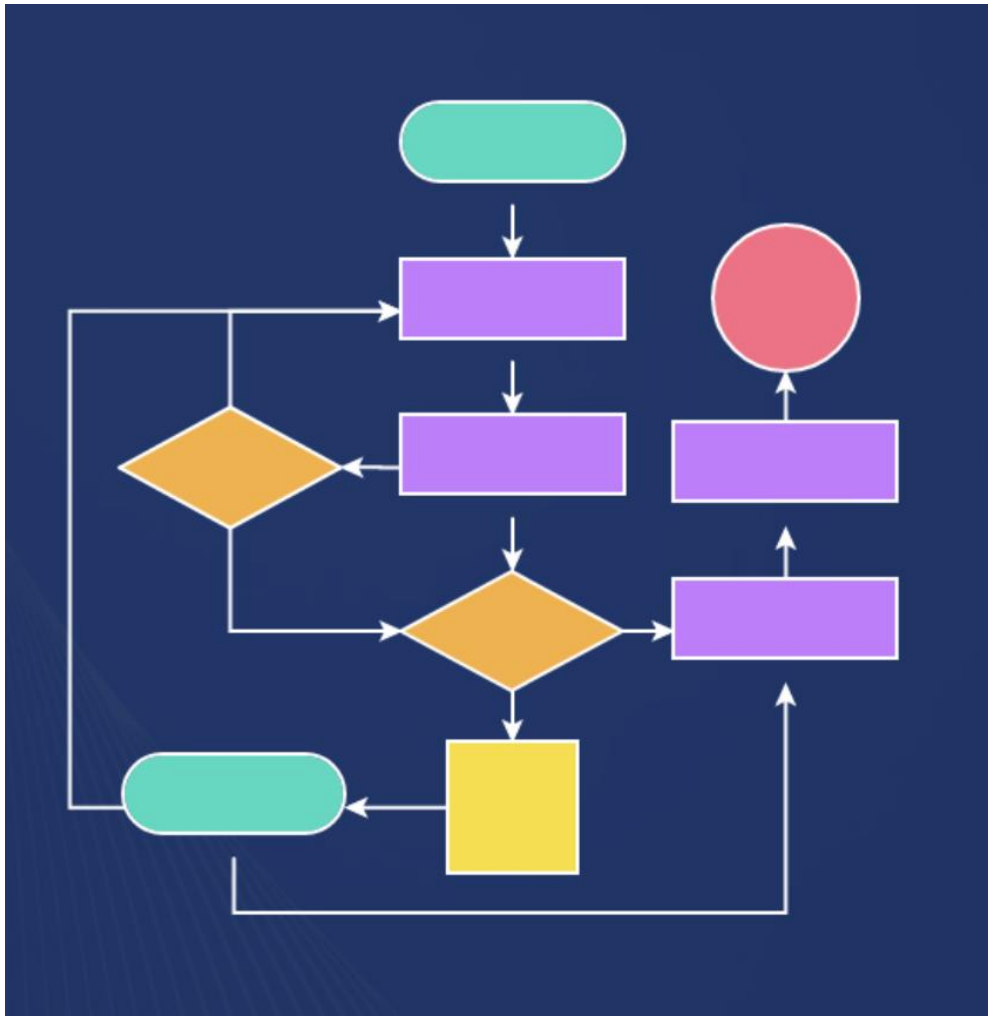
- A **visual representation** of a process or workflow
- Used to identify where a **failure** or **deviation** occurred
- **Clarifies relationships** between steps, decision points, and handoffs



Supportive Tool #1: Process Flow Diagrams

Key Elements of Process Flow Diagrams:

- **Start/End Points –** Clearly defined start and finish of process
- **Steps and Tasks –** All sequential and parallel activities
- **Decision Points –** Where process branches based on conditions
- **Inputs and Outputs –** Materials, data, approvals required at each step
- ***Optional:*** **Failure Points –** Highlighted areas of deviation or inefficiency



Supportive Tool #2: SIPOC Diagrams

What is a SIPOC Diagram?

- Stands for **Suppliers, Inputs, Process, Outputs, Customers**
- A **process mapping tool** used to define and visualize a process from end to end
- Provides a **structured view** of process boundaries, key elements, and stakeholder relationships
- Helps teams align on the current state of a process and who's involved
- Useful when a process spans multiple departments or has unclear ownership

Suppliers	Inputs	Process	Outputs	Customers

Supportive Tool #2: SIPOC Diagrams

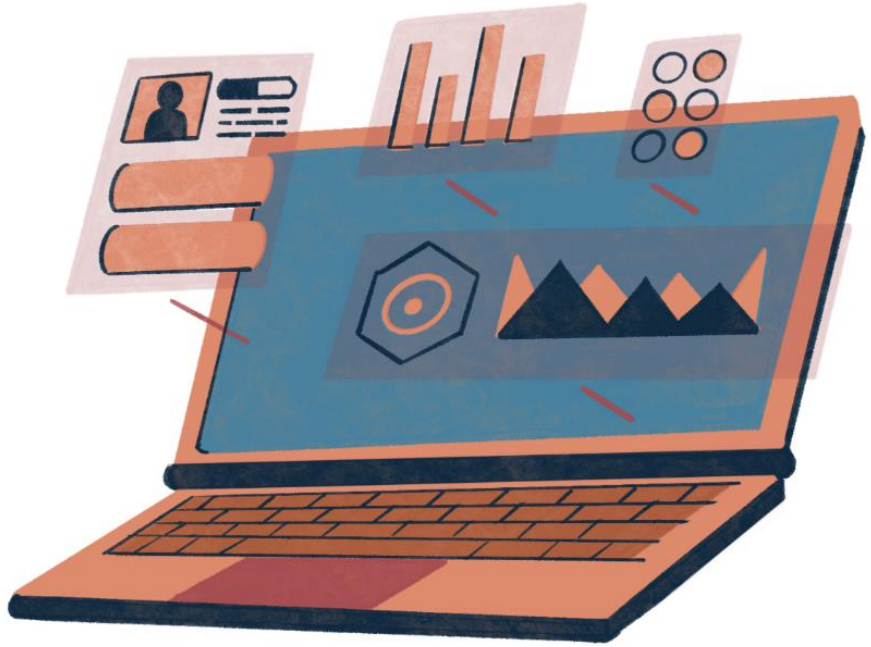
Key Elements of SIPOC Diagrams:

- **Suppliers –** Entities (internal or external) that provide inputs to the process
- **Inputs –** Materials, information, or triggers required to execute the process
- **Process –** Sequence of steps that transform inputs to outputs
- **Outputs –** The product, service, or result produced by the process
- **Customers –** Recipients (or stakeholders!) who receive the outputs

Supportive Tool #3: QMS Software

What is Quality Management System Software?

- Helps companies **streamline** and **automate** their quality management processes
- Serves as a centralized repository for managing quality-related data, documentation, and workflows



Key Features of an eQMS:

- Document Management
- Change Management
- Training Management
- CAPA
- Non-Conformance Management
- Audit Management
- Risk Management
- Supplier Management
- Reporting & Analytics
- Reminders, Alerts, Notifications

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Supportive Tool #3: QMS Software

Key Roles an eQMS Plays in Supporting CAPA:

- Centralizes Documentation
  - Store investigation records, RCA outputs, impact assessments, action plans, verifications in a controlled environment
- Automates Workflow Management
  - Ensures timely handoffs, escalations, and approvals
- Drives Accountability
  - Assigns and tracks tasks with ownership and deadlines
- Supports Effectiveness Checks
  - Tracks due dates and ensures required verifications are completed
- Enables Reporting & Trending
  - Provides dashboards and analytics to detect systemic risks or process drift
- Facilitates Cross-Functional Collaboration
  - Allows users across departments and sites to access and contribute to CAPA records

Supportive Tool Comparison

Tool	Ideal Use Cases	Strengths	Limitations
Process Flow Diagram	Understanding current state process flow	Helps identify failure points or missing controls	Doesn't analyze root cause or risk on its own
SIPOC Diagram	Scoping investigations, especially in cross functional processes	High level overview; aligns teams on process inputs and outputs	Requires training and facilitation
eQMS	Managing CAPA workflows, traceability, effectiveness checks, documentation	Centralizes data, automates alerts and escalations; full audit trail	Requires thoughtful configuration

Poll Time!

What's your biggest barrier to selecting the *right* CAPA tool for each situation?

- Lack of training or knowledge
- Time constraints
- Pressure to close issues quickly
- Limited availability of tools in our system
- Leadership doesn't emphasize root cause depth
- We usually just stick to one method for everything

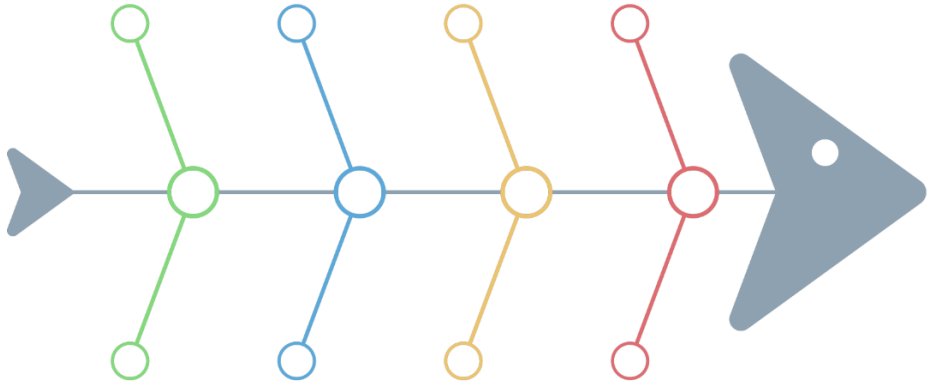
Selecting the Right Tool for the Job

Scenario	Suggested Tool(s)
Low risk, isolated issue	5 Whys, Process Flow Diagram
Moderate risk, cross functional process issue	Fishbone, SIPOC, Trend Analysis
High risk, complex systemic failure	FTA, Bowtie, FMEA
Unclear/poorly defined process	SIPOC, Process Flow Diagram, Fishbone
High visibility/Regulatory scrutiny	FMEA, Bowtie, eQMS, Internal Audit
Recurring issues	Trend Analysis, KPIs, Internal Audits, Decision Trees
Need to prioritize or escalate	Decision Trees, FMEA, KPIs
Verification/Effectiveness Checks	Internal Audits, KPIs, Trend Analysis, eQMS

Case Study #1: Using Fishbone to Solve a Recurring Packaging Defect

The Problem:

- Customers reported recurring packaging seal failures
- Initial fixes did not resolve the issue
- Complaint trend triggered a CAPA investigation



Why Fishbone Was Selected:

- Problem appeared **multi-factorial** (spanning process, people, and equipment)
- Needed a **collaborative** and visual method to identify and structure potential causes

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Step-by-Step Process: Creating a Fishbone Diagram

Step 1: Define the Problem Clearly

- **Problem Statement:** Seal failures found in final packaging

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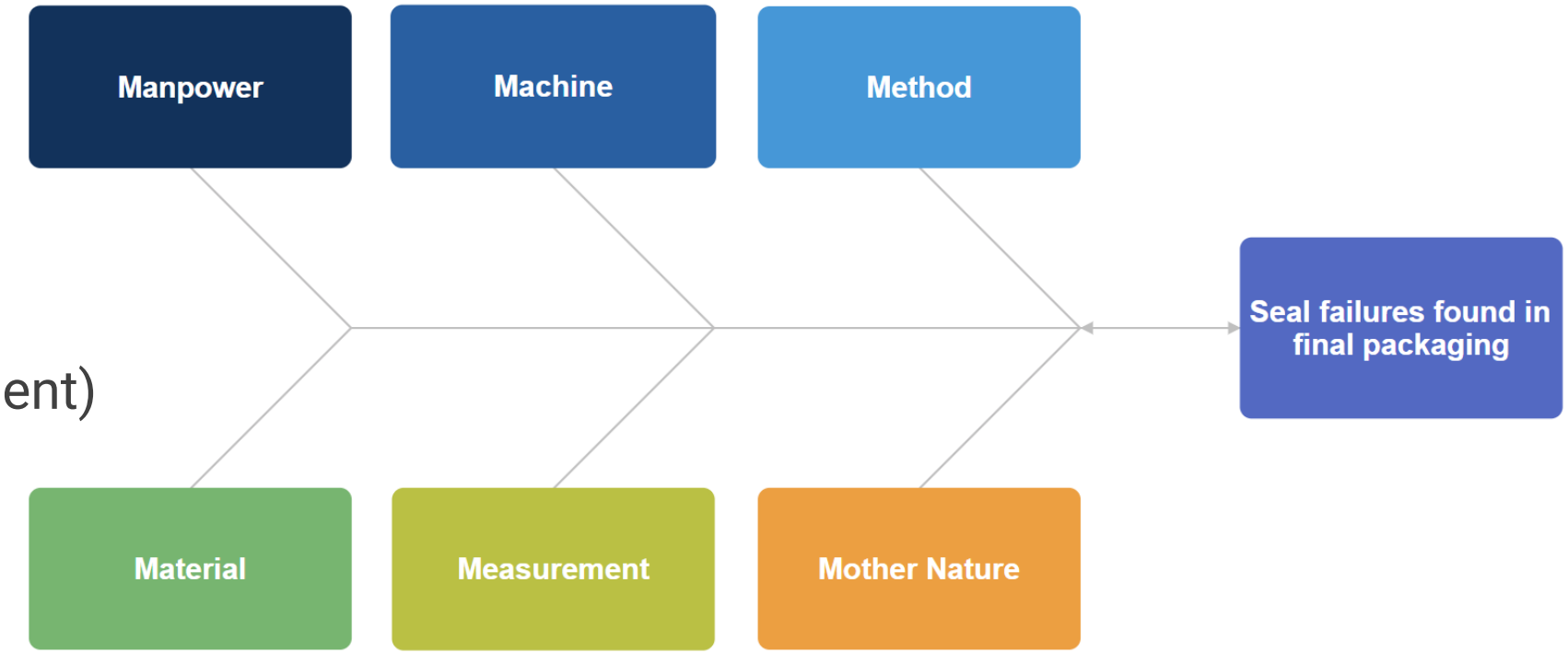
Step-by-Step Process: Creating a Fishbone Diagram

Step 2: Determine Major Cause Categories

- Manpower (People)
- Machine (Equipment)
- Method (Process)
- Material (Supplies/Input)
- Measurement
- Mother Nature (Environment)



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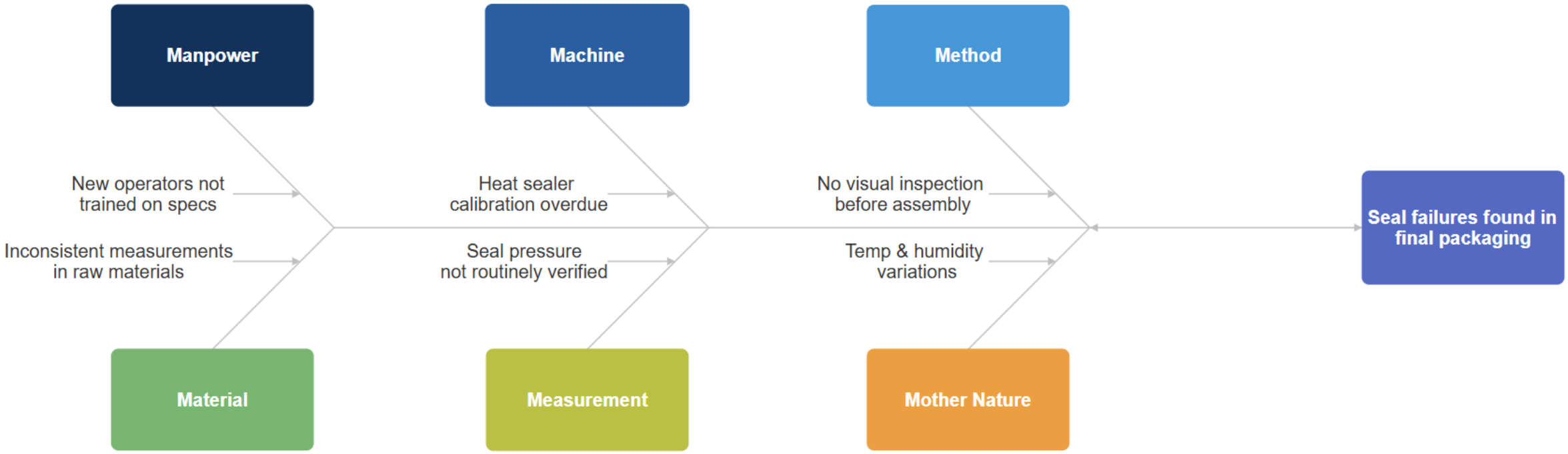
Step-by-Step Process: Creating a Fishbone Diagram

Step 3: Brainstorm Possible Causes

- Manpower (People)
  - New operators on 2nd shift not trained on sealing specs
- Machine (Equipment)
  - Heat sealer calibration overdue
- Method (Process)
  - No visual inspection before assembly
- Material (Supplies/Input)
  - New lot of raw materials had inconsistent measurements
- Measurement
  - Seal pressure not routinely verified
- Mother Nature (Environment)
  - Temperature and humidity variations during 2nd shift

Step-by-Step Process: Creating a Fishbone Diagram



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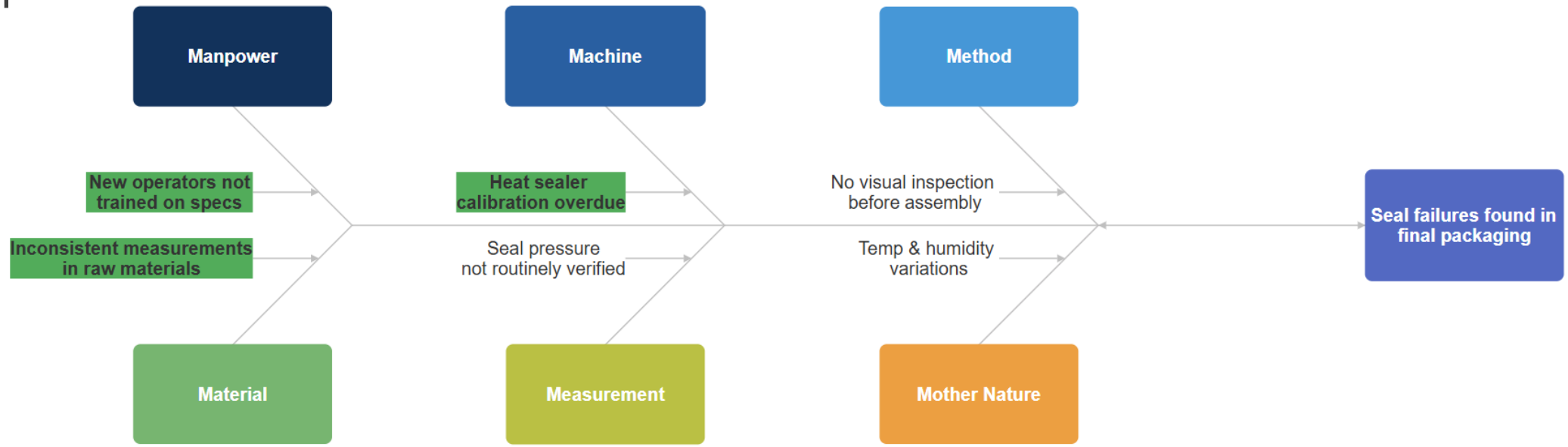
Step-by-Step Process: Creating a Fishbone Diagram

Step 4: Analyze & Prioritize Likely Root Causes

- Inconsistent material width
- Uncalibrated sealer temperature
- Inadequate operator training on seal verification



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Step-by-Step Process: Creating a Fishbone Diagram

Step 5: Validate Root Cause(s) & Take Action

- **Validation Activities:**
  - Ran material width tests → material out of tolerance
  - Confirmed calibration issue with heat sealer → off by 10 degrees
  - Internal Audit finding → 2nd shift training records incomplete
- **Next Steps:**
  - Issued SCAR to material supplier
  - Calibrated and added alarm to heat sealer
  - Updated WI and retrained all operators
  - Updated CAPA record with Fishbone Diagram as evidence

Case Study #2: Using SIPOC to Scope a Cross-Functional CAPA

The Problem:

- A series of lot release delays occurred due to incomplete batch records
- Impacted on-time delivery to distributors
- Triggered an internal CAPA escalation

Why SIPOC Was Selected:

- The CAPA involved multiple departments and lacked clarity around process handoffs
- Needed to define current-state process and establish boundaries
- Necessary to align all stakeholders before deeper analysis

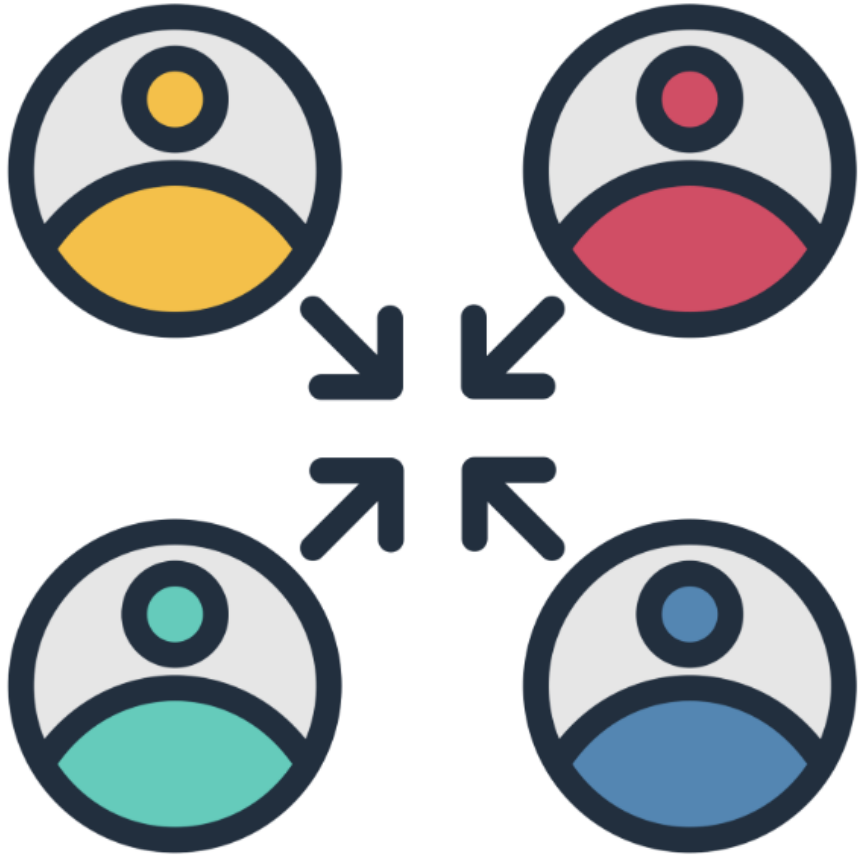
Step-by-Step Process: Creating a SIPOC Diagram

Step 1: Identify the Process to be Mapped

- **Process:** Batch Record Review & Release Process
- **Scope:** Production Completion → Final Lot Release
  - Excluded manufacturing and distribution activities

Step 2: Engage the Right Stakeholders

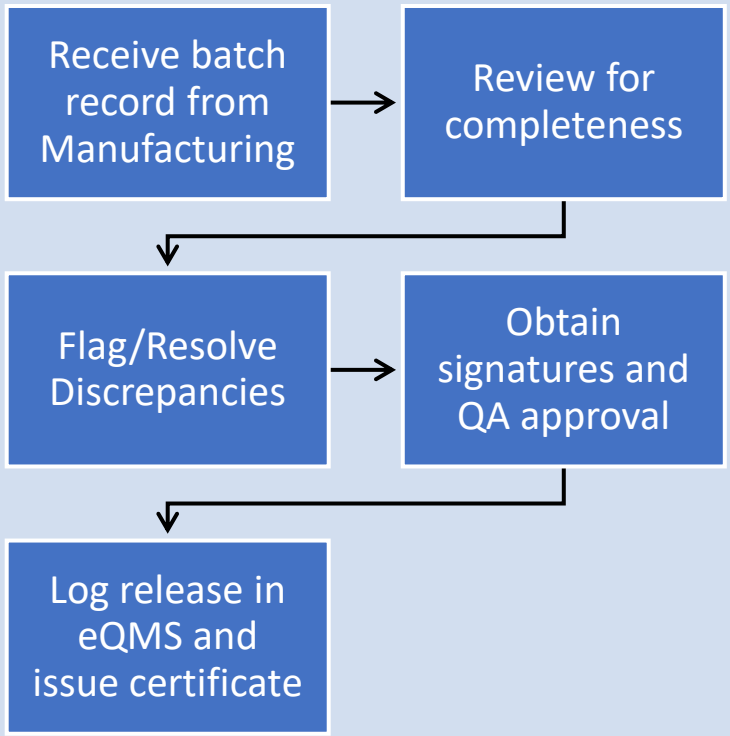
- **Assembled a cross-functional team:**
  - Manufacturing Lead
  - Packaging Supervisor
  - Quality Manager
  - QC Reviewer
  - IT Support



Step-by-Step Process: Creating a SIPOC Diagram

Step 3: Populate the SIPOC Diagram

- Populated the categories of **Suppliers, Inputs, Process Steps, Outputs,** and **Customers**

Suppliers	Inputs	Process	Output	Customer
Manufacturing	Completed Batch Record		Released Lot	Warehouse
Packaging	Label Reconciliation Sheet		Release Certificate	Supply Chain
Document Control	System Access		Signed Batch Record	Regulatory
eQMS System	Production & Testing Data		Updated Production Log	Quality Manager

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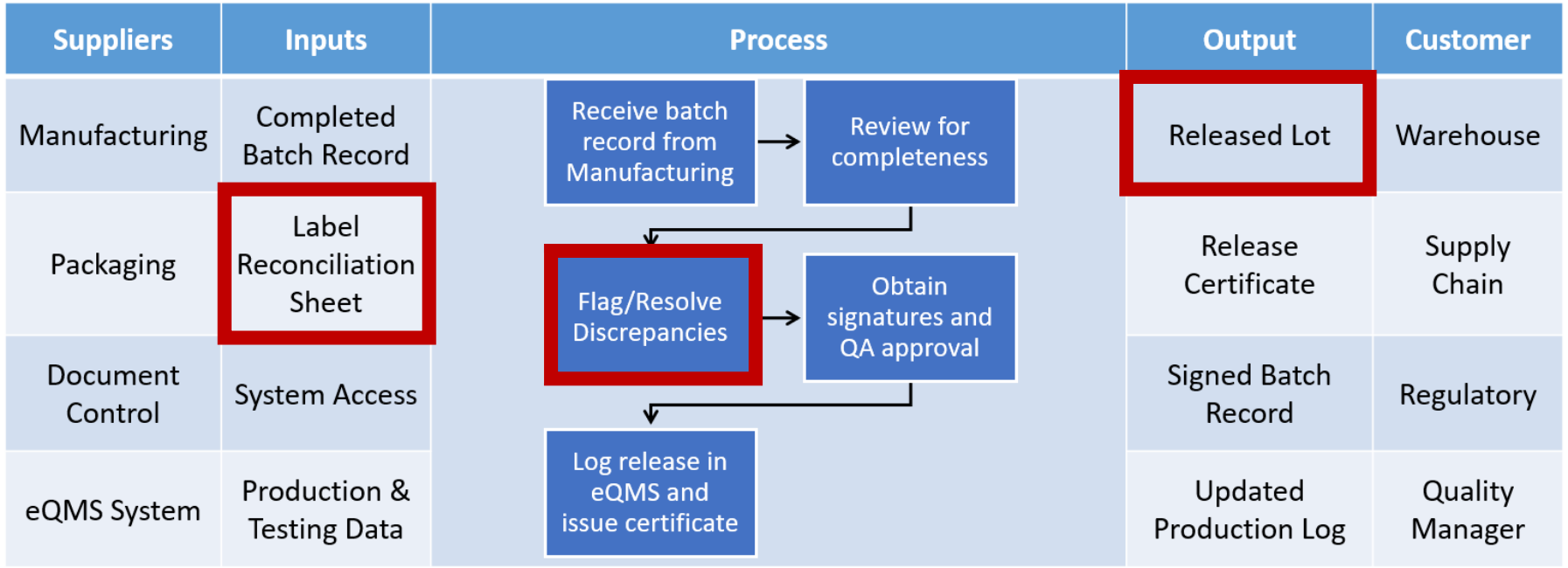
Step-by-Step Process: Creating a SIPOC Diagram

Step 4: Use SIPOC to Identify Gaps

- **Key Issues Identified:**
  - Missing label reconciliation sheet from packaging
  - No clear owner for discrepancy resolution
  - Document control team unaware of issues affecting timelines



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Step-by-Step Process: Creating a SIPOC Diagram

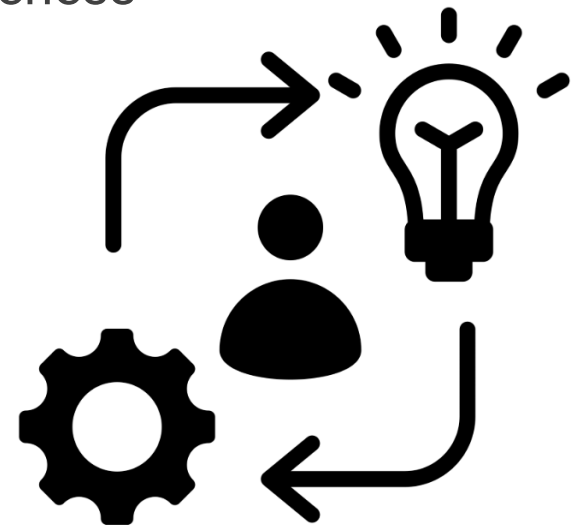
Step 5: Use SIPOC to Guide Next Steps

- **Action Items:**
  - Assign clear responsibility for discrepancy resolution
  - Update document checklist to include all required batch components
  - Establish system alerts when records are submitted late

Case Study #3: Using an Internal Audit to Verify CAPA Effectiveness

The Problem:

- External audit findings cited overdue calibrations and documentation gaps
- CAPA was launched to update the calibration SOP and retrain operators
- QA initiated an internal audit to verify implementation and long-term effectiveness



Why Internal Audit Was Selected:

- Provided a **structured** method to validate whether SOP updates and training were working as intended
- Allowed teams to **monitor performance** and **identify gaps**
- Offered **evidence of a completed CAPA process** for future regulatory inspections

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Step-by-Step Process: Using Internal Audits

Step 1: Develop the Audit Plan

- **Objective:** Verify effectiveness of CAPA related to calibration process failures
- **Scope:**
  - Calibration process adherence
  - Training completion and retention
  - System tracking of calibration due dates
- **Criteria:**
  - Revised calibration SOP
  - Completed training records
  - Calibration system reports

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Step-by-Step Process: Using Internal Audits

Step 2: Build the Audit Questionnaire

- Created audit questions mapped directly to the CAPA actions and SOP changes

Scope	Question	Criteria	Suggested Evidence
QA & Maintenance Teams	Are all calibration events documented in the eQMS?	Calibration SOP	Calibration logs, timestamped system records
Manufacturing Floor	Are overdue gauges prevented from being used in production?	Calibration and Risk Control SOPs	Gauge logs, floor observation
Operators using calibrated tools	Were all applicable operators retrained on the revised SOP?	Training Policy	Training records, employee sign off sheets
Manufacturing Team	Do operators understand the new escalation process for overdue gauges?	Calibration Work Instructions	Operator interviews, quiz results

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Step-by-Step Process: Using Internal Audits

Step 3: Conduct the Audit

- Scheduled site visits and document reviews
- Used interviews, record sampling, and process walk-throughs to gather evidence
- Observed processes on the manufacturing floor during gauge use
- Documented objective evidence for each checklist item
- Captured findings and OFIs

Step-by-Step Process: Using Internal Audits

Step 4: Analyze Findings and Determine Effectiveness

- **Findings:**
  - 95% of calibration events tracked properly
  - 100% of overdue gauges quarantined per SOP
  - Training records 100% complete
- **Conclusion:** Corrective & Preventive Actions were implemented and effective!

Step 5: Document and Report

- Created an Internal Audit Report with all audit details, summary, and follow-ups
- *Bonus Step – Upload completed report to your CAPA record in your eQMS!*

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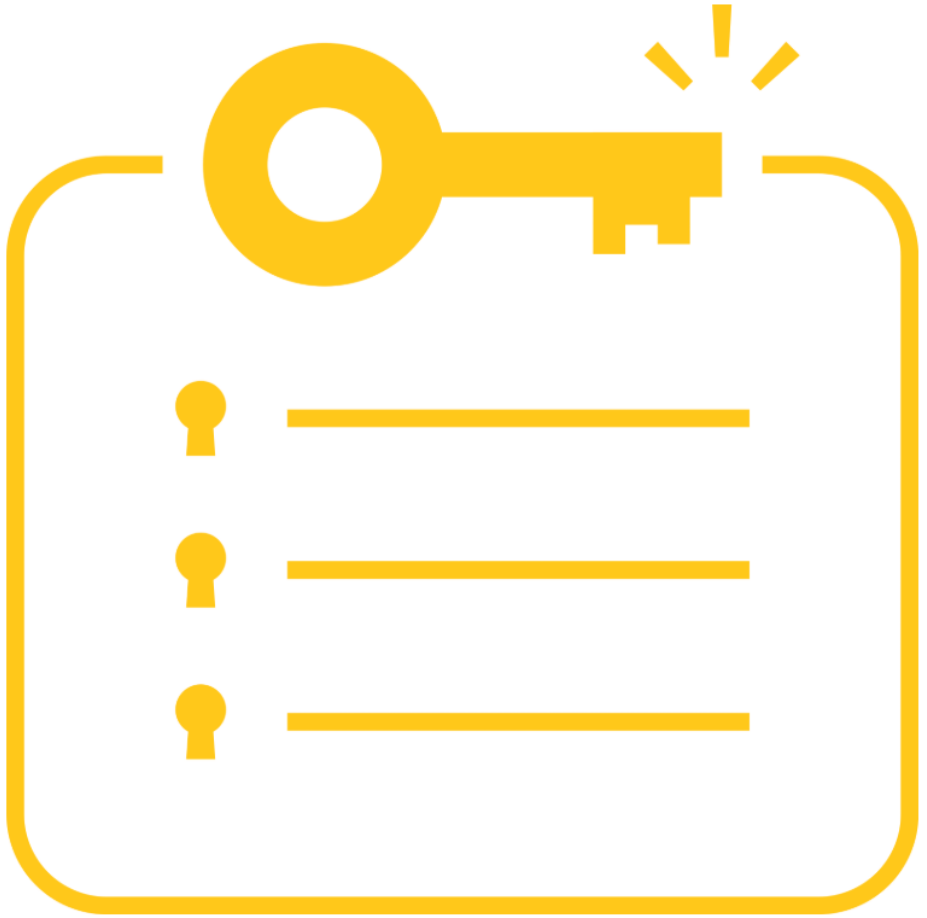
Key Takeaways

Effective CAPA drives compliance and improvement

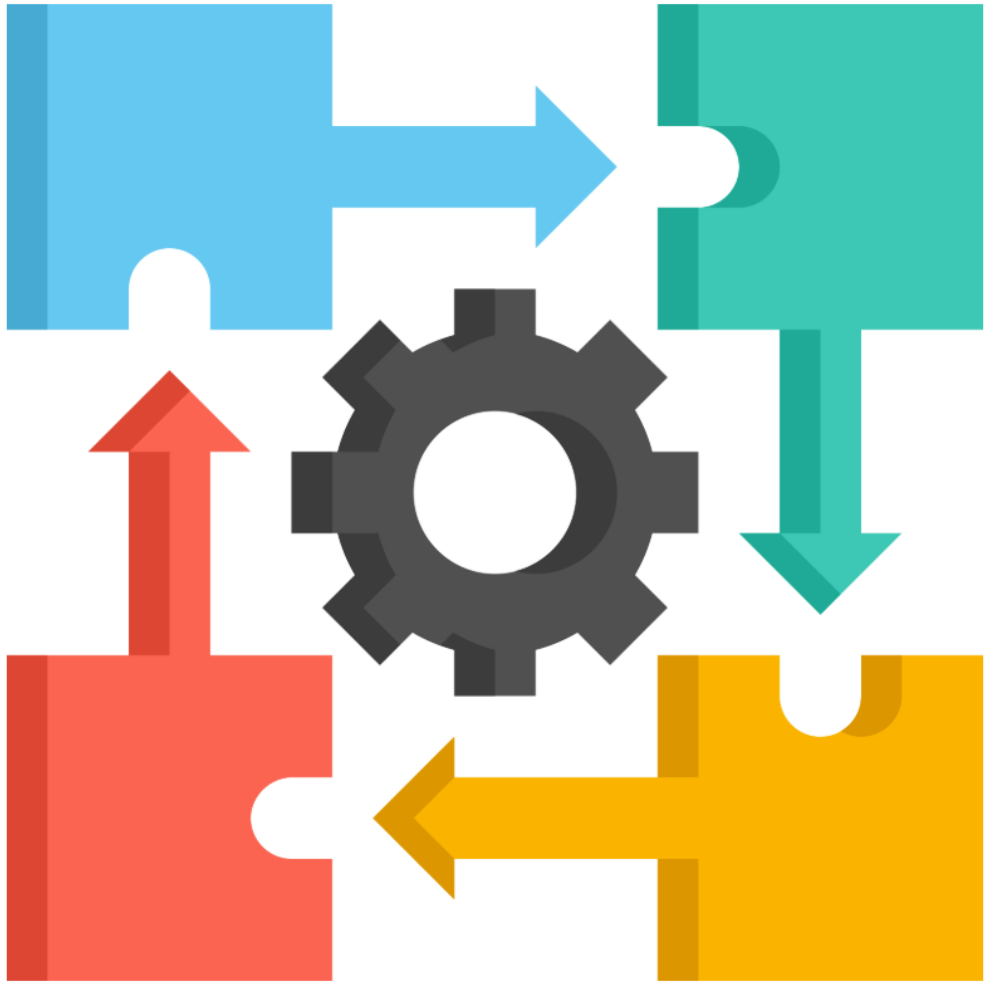
- Root Cause Analysis tools help resolve problems at the source
- Risk-aligned CAPA tool selection ensures appropriate response to issues
- Clear documentation and effectiveness checks support audit readiness and sustainability



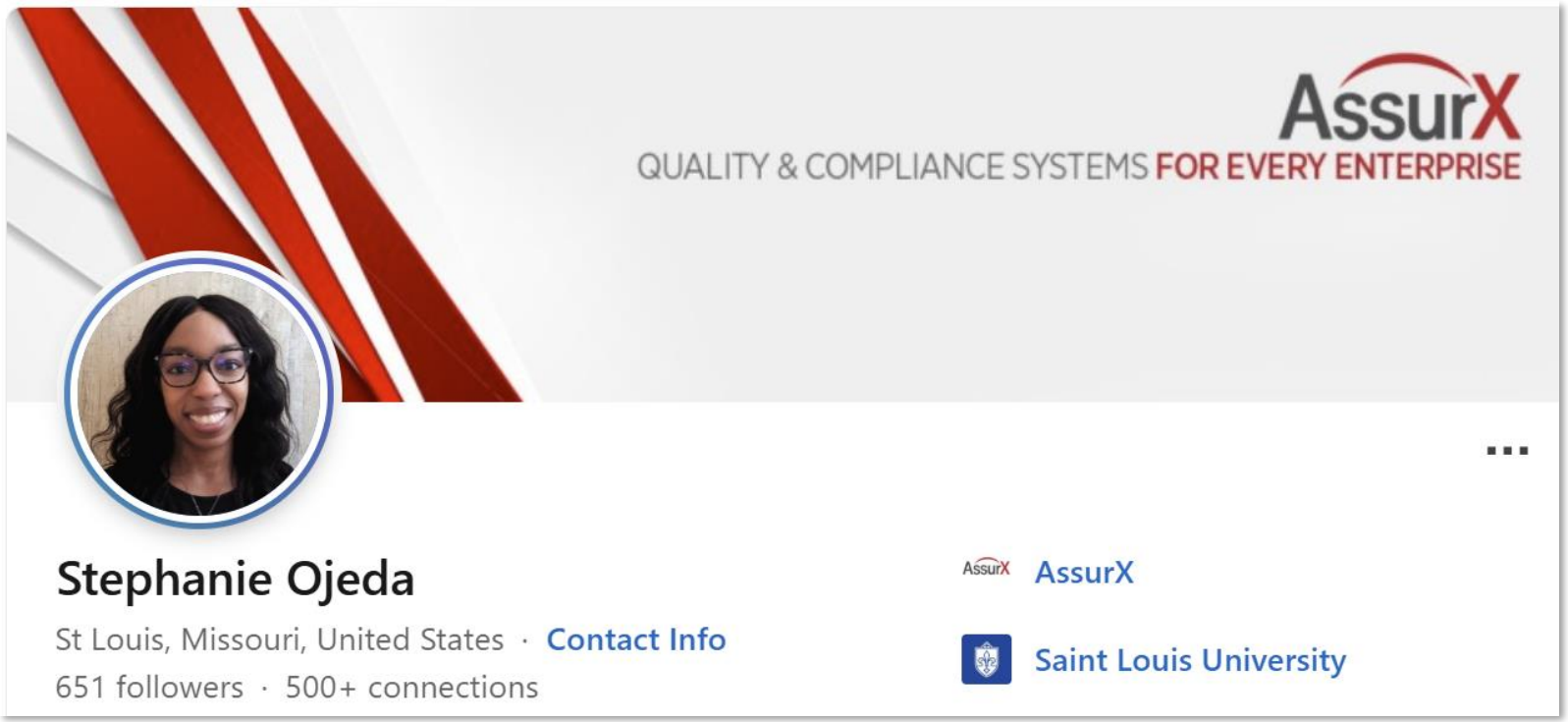
Key Takeaways

Choosing the right CAPA tool depends on the issue type and process complexity

- **5 Why Analysis, Process Flow Diagrams:** Best for simple, linear problems with a clear path to root cause
- **Fishbone Diagram, SIPOC:** Ideal for visualizing and brainstorming multi-factor issues
- **Fault Tree Analysis:** Supports complex, logic-driven root cause investigations
- **FMEA, Decision Trees, & Bowtie:** Useful for risk evaluation and prevention planning
- **Trend Analysis, KPI Monitoring, Internal Audits:** Great for monitoring CAPA effectiveness
- **eQMS:** Enables traceability, automation, and accountability



Let’s Connect!



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Questions & Answers