Risk-Based Decision Making in QMS: Choosing the Right Tool for the Job

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Agenda

- Why Risk-Based Decision Making Matters in QMS
- Overview of Risk Management Tools
  - Failure Modes and Effects Analysis (FMEA)
  - Hazard Analysis & Critical Control Points (HACCP)
  - Bowtie Analysis
  - Risk Registers
  - Decision Trees
- Integrating Risk-Based Decision Making into QMS Workflows
- Case Studies: Effective Use of Risk Management 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**
- **Certified HACCP Manager**

Poll Time!

What is the biggest challenge you face in risk management today?

- Lack of standardized processes or tools
- Difficulty getting cross-functional teams engaged
- Siloed or incomplete risk data
- Resistance to change from leadership or teams
- We’re doing well, but always looking to improve
- Something else

Why Risk-Based Decision Making Matters in QMS

Risk Management is the Foundation of Quality and Compliance

- Ensures consistent product quality and safety
- Reduces variability and improves process control
- Supports a proactive approach

Regulatory Frameworks Emphasize Risk-Based Thinking

- ISO 9001
- ISO 13485
- ISO 14971
- FDA QMSR

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Why Risk-Based Decision Making Matters in QMS

The Impact of Poor Risk Management

- Product recalls – companies failing to identify risks before launch
- Regulatory fines – non-compliance due to inadequate risk controls
- Reputational damage – loss of customer trust, market share, financial losses, etc.

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Overview of Risk Management Tools

Failure Modes & Effects Analysis (FMEA)

Identifies potential failure modes, prioritizes risks, helps prevent failures before occurrence

Hazard Analysis & Critical Control Points (HACCP)

Systematic approach for identifying, evaluating, and controlling hazards

Risk Registers

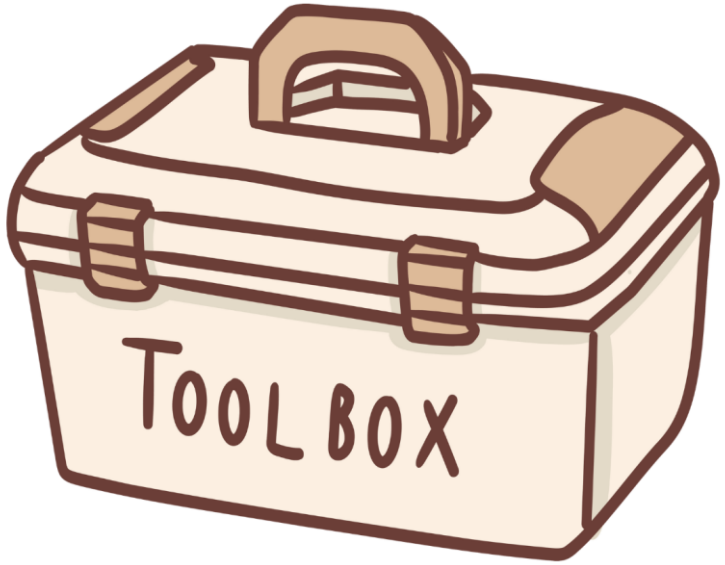
Centralized system to track, assess, and monitor risks across an organization

Bowtie Analysis

A visual tool that maps out cause and effect relationships, showing how risks develop & how to prevent them

Decision Trees

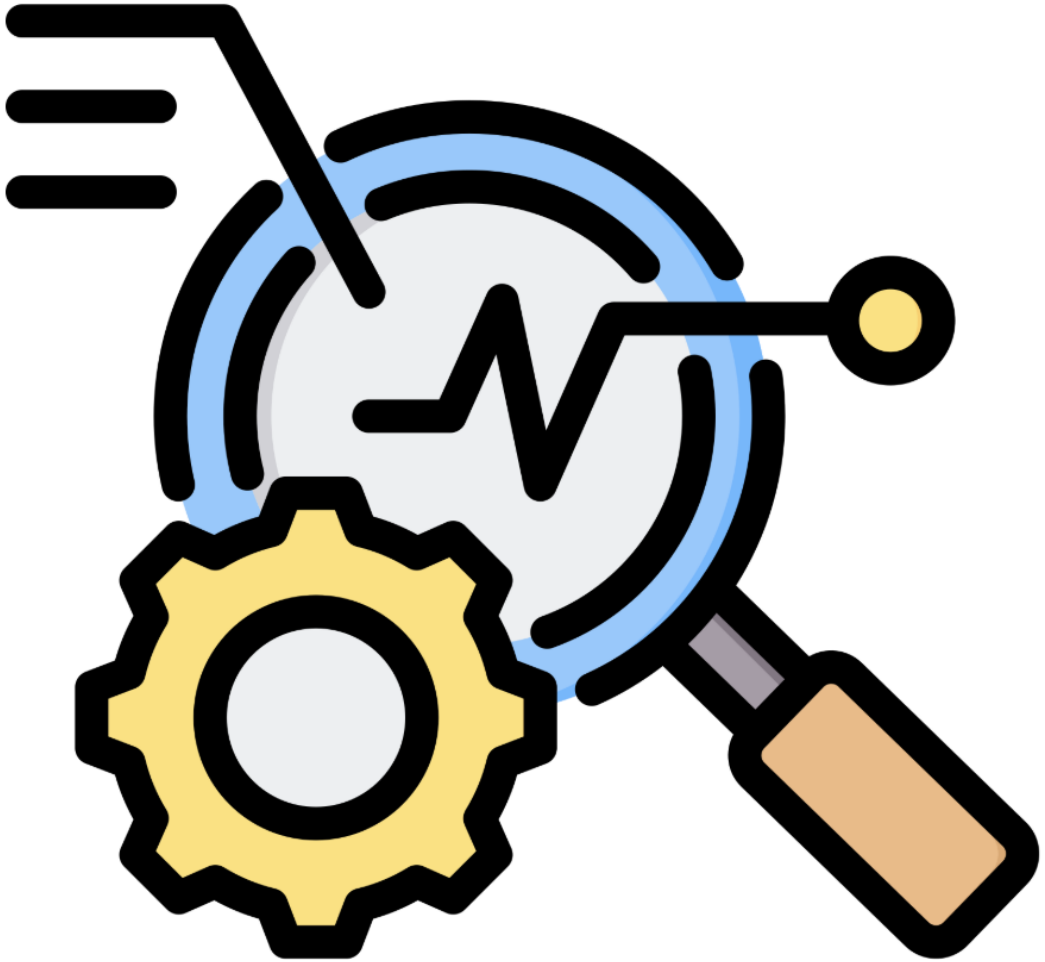
Structured decision making tool that helps evaluate different risk scenarios and their outcomes



Failure Modes and Effects Analysis (FMEA)

What is FMEA?

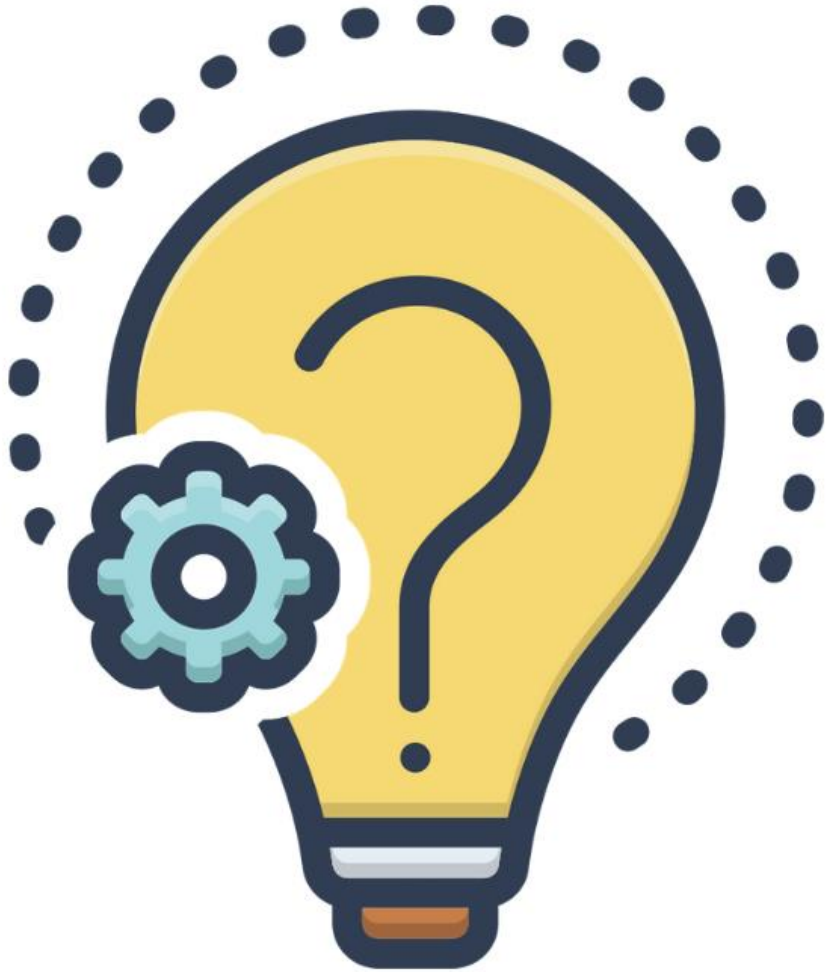
- Used across industries to **prevent failures before they happen**
- A **structured, proactive approach** to identifying potential failure modes and their impact
- Assign a **Risk Priority Number (RPN)** to each failure mode
- Helps teams **prioritize risks** based on **severity, occurrence, and detectability**



Failure Modes and Effects Analysis (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



Hazard Analysis & Critical Control Points (HACCP)

What is HACCP?

- Required for **regulatory compliance** in food, pharma, and other industries
- A **proactive, science-based system** to identify and control biological, chemical, and physical hazards
- Used to **prevent contamination** in industries where safety is critical

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Hazard Analysis & Critical Control Points (HACCP)

The 7 Principles of HACCP:

- **Conduct a Hazard Analysis**: Identify potential risks in a process
- **Determine Critical Control Points (CCPs):** pinpoint steps where controls should be applied
- **Establish Critical Limits:** Define acceptable thresholds for each control point
- **Implement Monitoring Procedures:** Track CCPs to ensure they stay within critical limits
- **Define Corrective Actions:** Outline steps to take when a deviation occurs
- **Verify System Effectiveness:** Conduct audits, testing, and validation to confirm
- **Maintain Detailed Records:** Keep documentation to prove compliance and track trends

Risk Registers

What is a Risk Register?

- A **centralized tool** for tracking and managing risks across an organization
- Helps teams **document, assess, and mitigate** risks systematically
- Provides a **structured approach** to risk management in quality systems

Key Components of a Risk Register:

- **Risk Description –** What is the identified risk?
- **Likelihood & Impact Assessment –** How probable is it, and what is the potential effect?
- **Risk Owner –** Who is responsible for managing and mitigating the risk?
- **Mitigation Actions –** Steps to reduce or eliminate the risk

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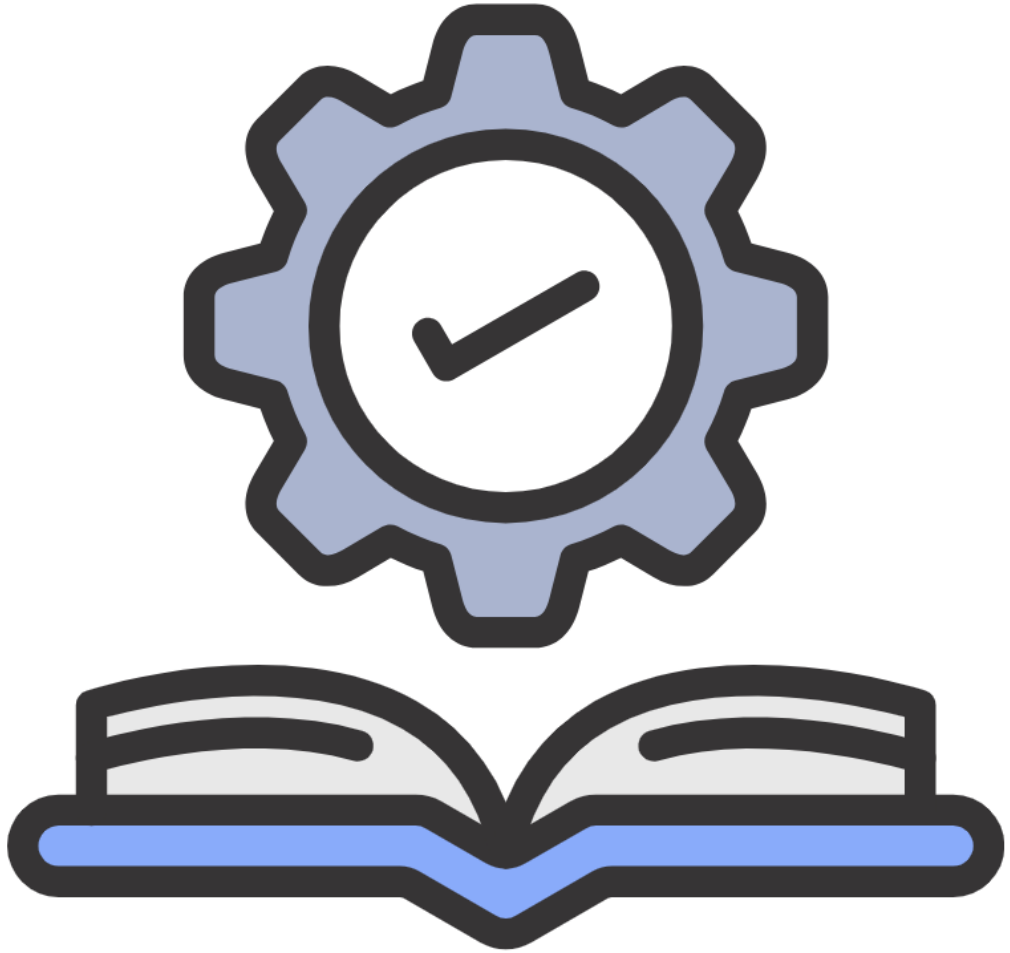
Risk Registers

Best Practices for Using Risk Registers:

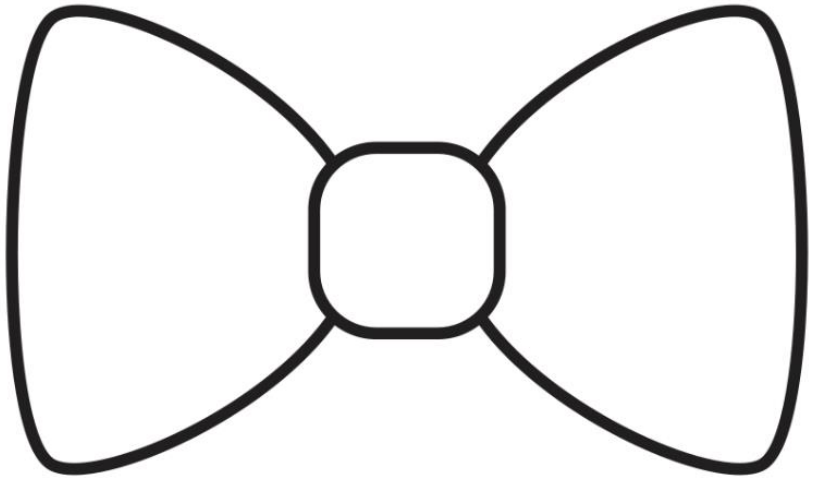
- Keep it updated regularly
- Assign clear ownership
- Integrate with other QMS processes



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

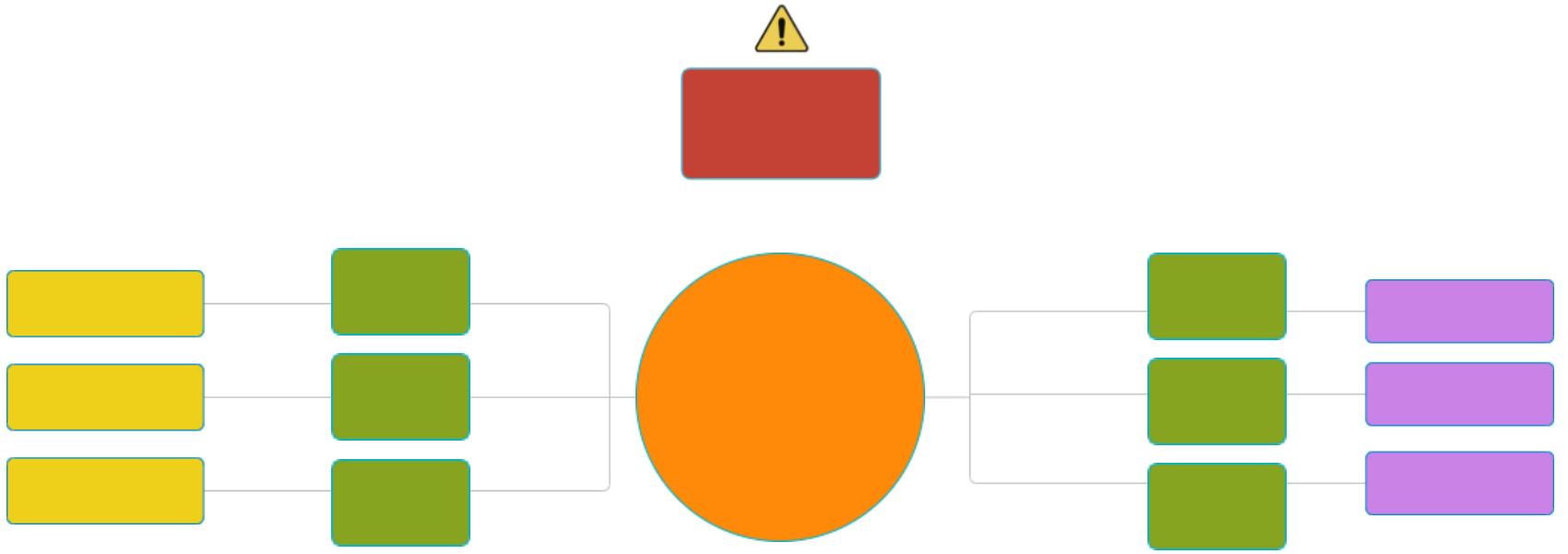


Why Use Bowtie Analysis?

- **Clarifies risk relationships –** shows connections between causes, events, and consequences
- **Identifies control measures –** makes it easier to develop prevention and mitigation strategies
- **Enhances risk communication –** easy to interpret for stakeholders across different departments

Bowtie Analysis – Key Elements

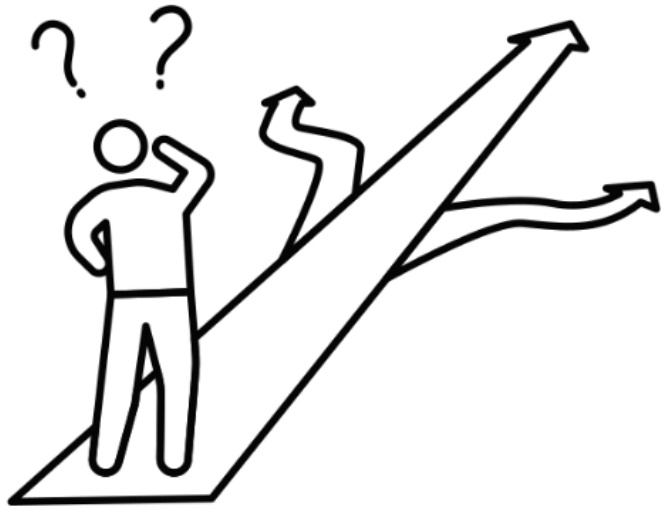
- **Hazard** → Source of potential harm
- **Top Event** → Point where control is lost
- **Threats** → Events leading to the top event
- **Consequences** → Events occurring due to the top event
- **Preventive Controls** → Actions to reduce likelihood of occurrence
- **Mitigative Controls** → Actions to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

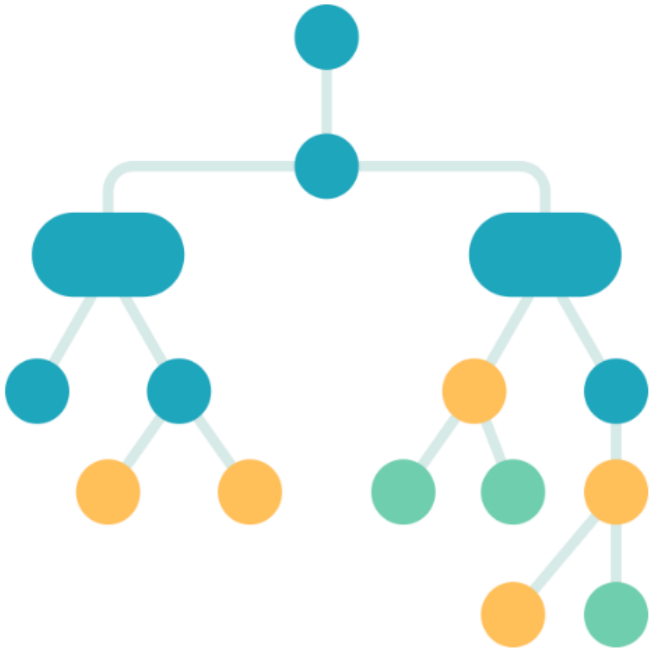


Decision Trees

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**





Why Use Decision Trees in Risk Management?

- **Supports complex decision making** via evaluation of different risk pathways
- **Quantifies and compares risk levels** for different options
- **Reduces bias** by ensuring structured evaluation rather than gut feelings

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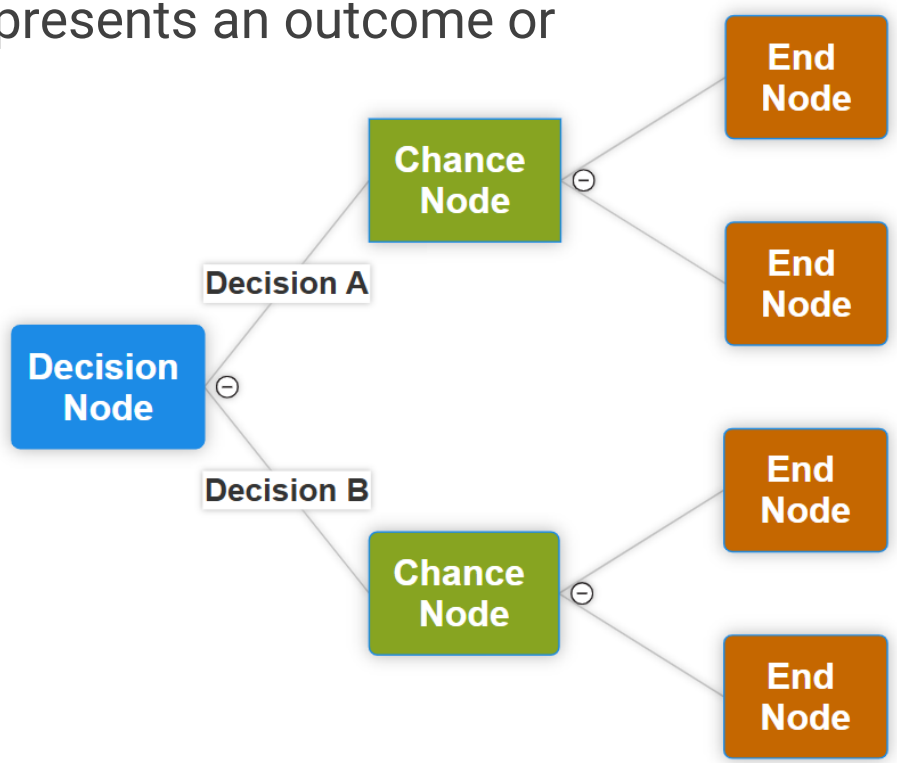
Decision Trees

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



Best Practices for Decision Trees:

- Clearly define the decision you need to make
- Use real data whenever possible
- Revisit your decision tree over time

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Selecting the Right Tool for the Job

Key Considerations When Selecting a Risk Management Tool

- Complexity of the process or product
- Regulatory requirements
- Data availability

Integrating Risk-Based Decision Making into QMS Workflows

Where Risk Management Fits in QMS:

- **Design & Development:** Risk-based design controls to prevent product failures
- **Supplier Management:** Selecting suppliers based on risk criteria
- **Change Management:** Assessing risk before implementing process changes
- **CAPA (Corrective & Preventive Actions):** Ensuring corrective actions are proportionate to risk level

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Integrating Risk-Based Decision Making into QMS Workflows

Best Practices for Integration:

- **Establish clear criteria** for selecting risk tools
- **Train teams** on risk assessment methodologies to improve adoption
- **Use automation and QMS software** to streamline workflows and centralize risk data

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Poll Time!

Which Risk Management tool would have the biggest impact in your organization?

- FMEA
- Bowtie Analysis
- Risk Registers
- Decision Trees
- Something else (add it to the chat!)
- Not sure yet

Case Study – Using FMEA to Improve Product Quality

Company Background & Challenge:

Industry: Medical Device

Problem: High failure rates reported in post-market surveillance

Root Cause: Design flaws leading to component failures and regulatory compliance risks

How they used FMEA:

Applied FMEA during Design & Development to proactively address potential failures

Step-by-Step Process: Applying FMEA

Step 1: Identify Potential Failure Modes

- Assembled a cross-functional team
- Mapped out all possible failure points within the product design
- Key failures identified:
  - Battery casing too weak → risk of overheating and leakage
  - Sensor calibration issues → inconsistent readings
  - Material defects → increased wear & tear

Step 2: Assess the Risks (RPN Calculation)

- Assigned Risk Priority Numbers (RPNs) using:
  - Severity: How bad is the failure?
  - Occurrence: How often does it happen?
  - Detection: How easy is it to catch before reaching customers?
- Ranked failure modes by highest RPN scores

Failure Mode	Severity	Occurrence	Detection	RPN
Battery casing too weak	9	4	8	288
Sensor calibration issues	8	2	5	80
Material defects	7	5	2	70

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Case Study – Bowtie Analysis in Manufacturing

Company Background & Challenge:

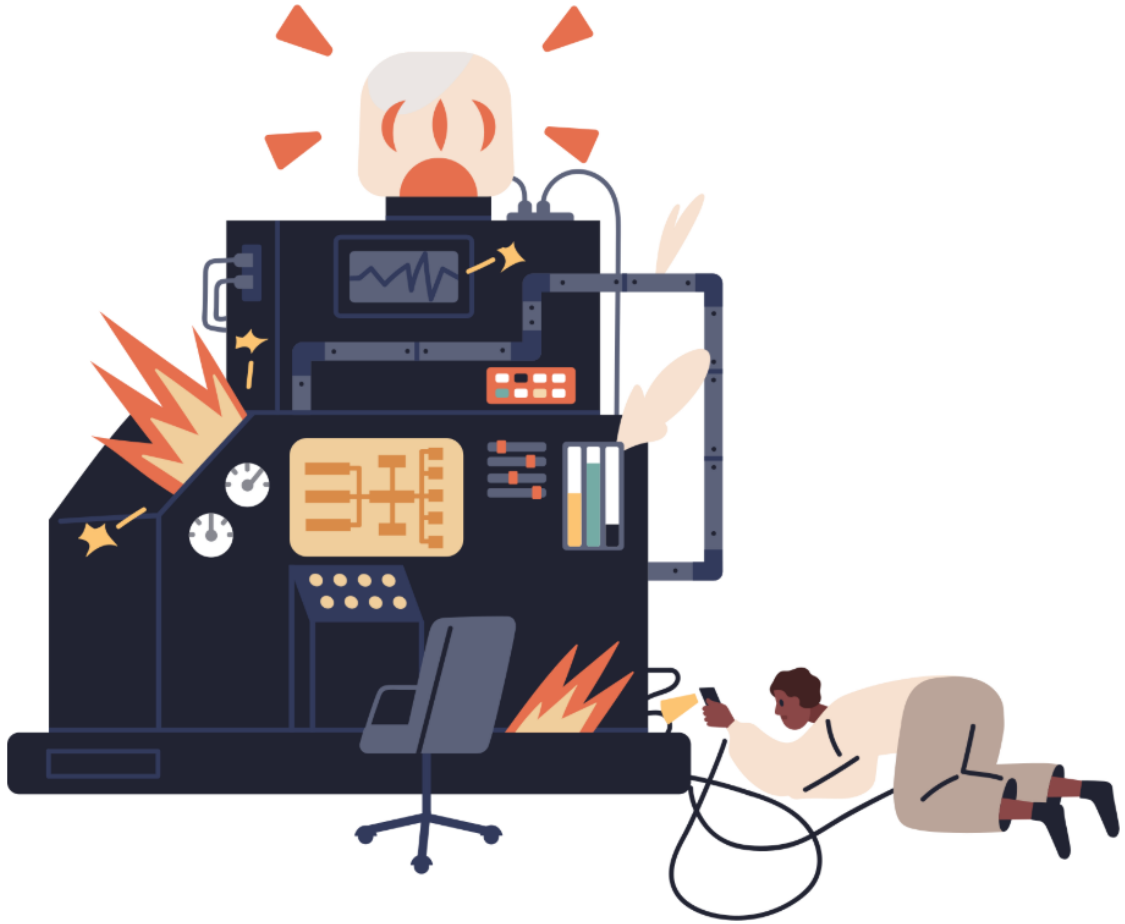
Industry: Manufacturing

Problem: Frequent equipment breakdowns causing unplanned downtime and missed orders

Root Cause: Poor preventive maintenance and inconsistent operator training

How they used Bowtie Analysis:

Mapped risks to visualize causes, consequences, and control measures



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Step-by-Step Process: Applying Bowtie Analysis

Step 1: Identify the Hazard

- Defined the main hazard: Machine failures leading to production downtime

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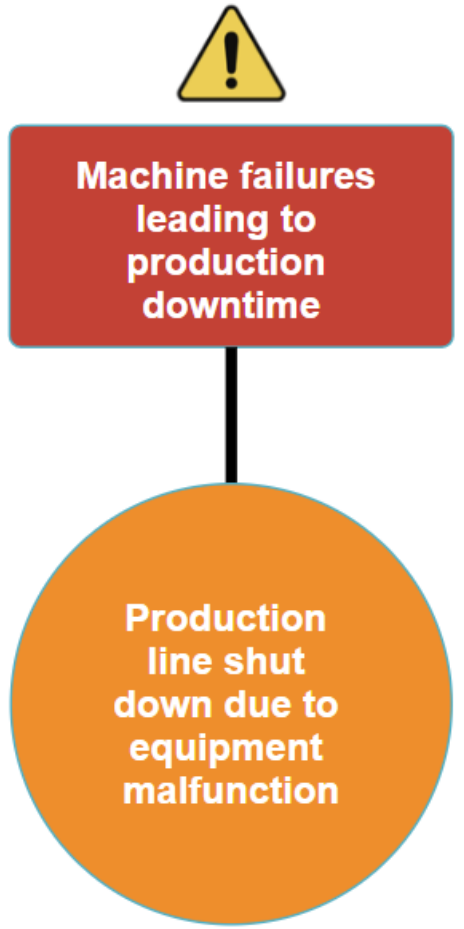
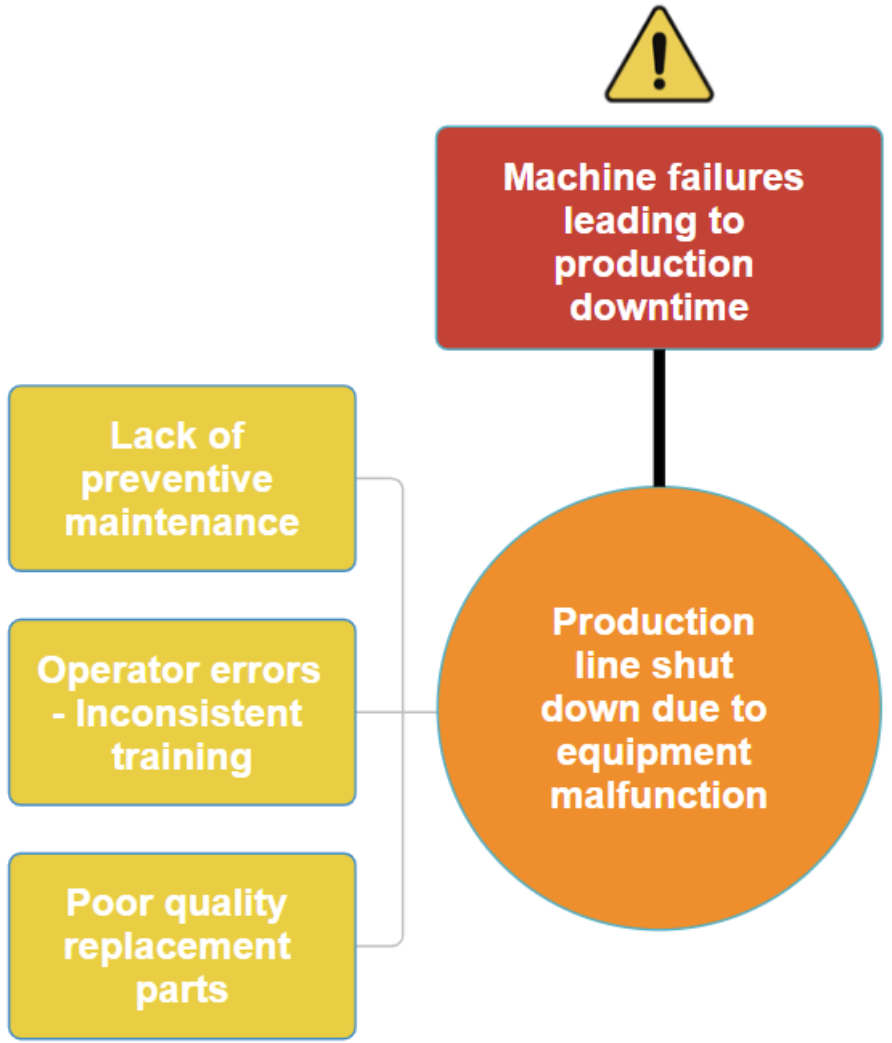
Step-by-Step Process: Applying Bowtie Analysis



Step 2: Define the Top Event

- Critical failure event: Production line shut down due to equipment malfunction

Step-by-Step Process: Applying Bowtie Analysis



Step 3: Identify Threats (Causes of the Top Event)

- Lack of preventive maintenance
- Operator errors due to inconsistent training
- Poor quality replacement parts

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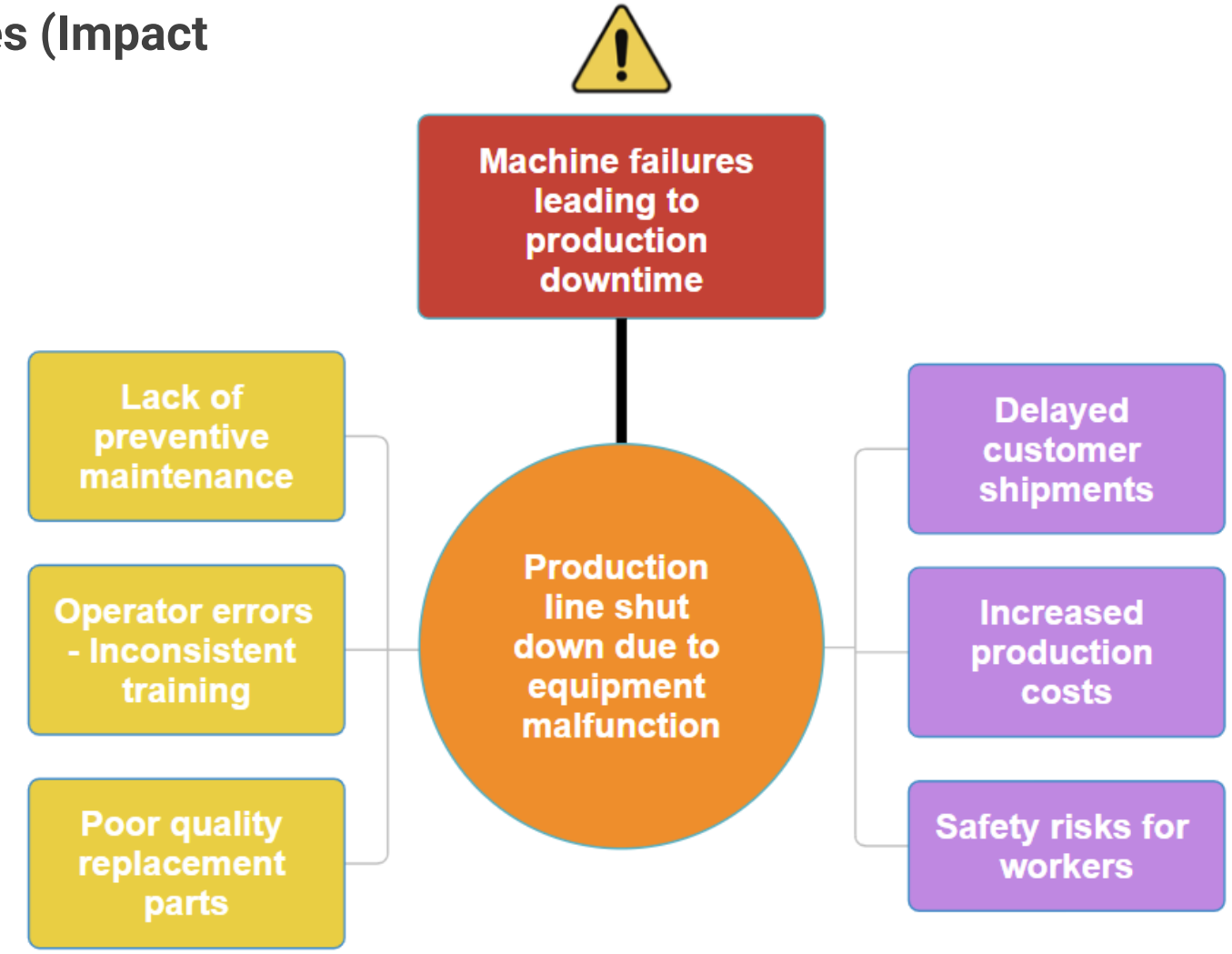
Step-by-Step Process: Applying Bowtie Analysis

Step 4: Identify Consequences (Impact of the Breakdown)

- Delayed customer shipments
- Increased production costs
- Safety risks for workers



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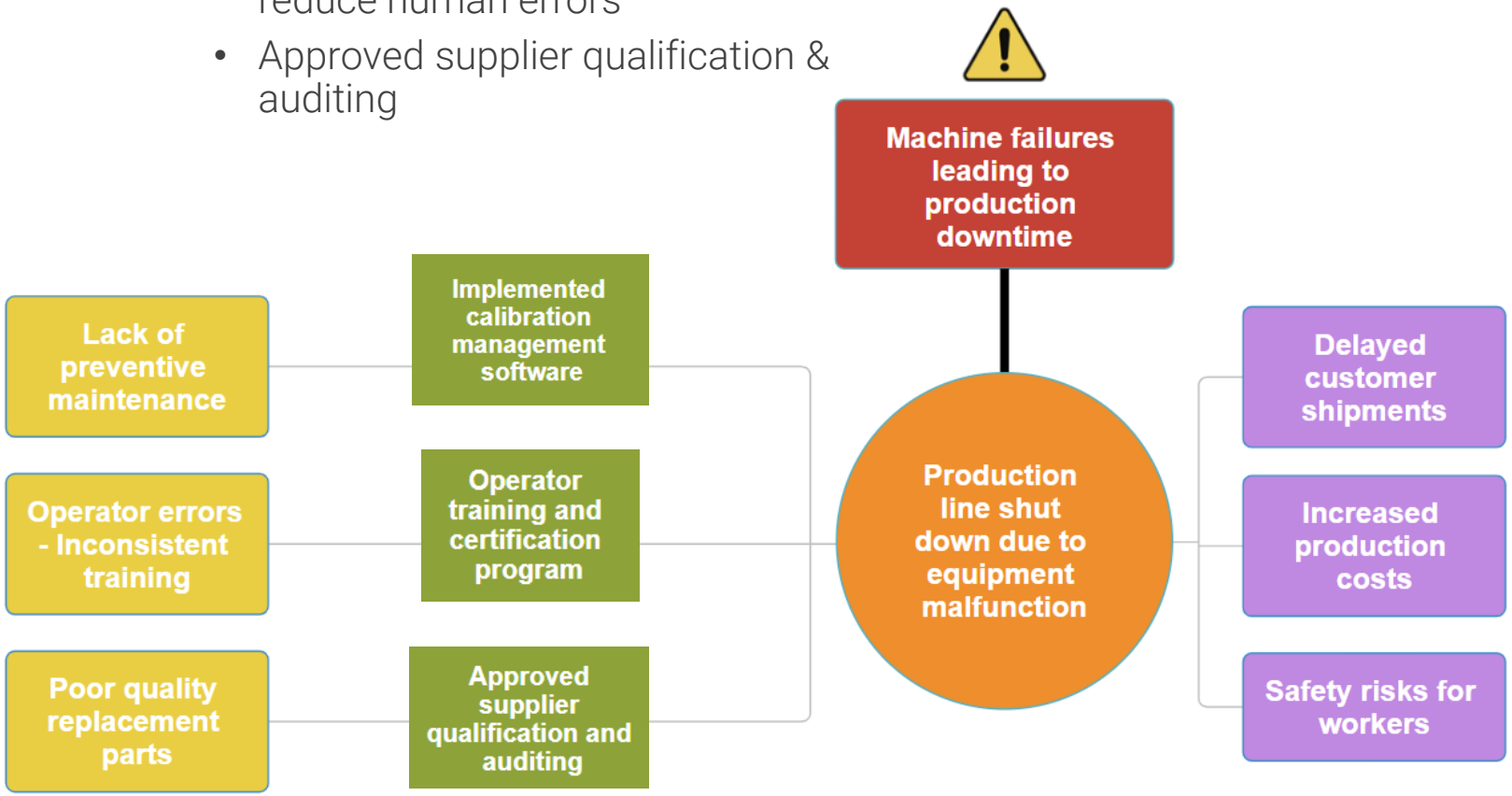
Step-by-Step Process: Applying Bowtie Analysis

Step 5: Implement Preventive & Mitigative Controls/Barriers

- Preventive Controls/Barriers:
  - Implemented calibration management software
  - Standardized operator training to reduce human errors
  - Approved supplier qualification & auditing



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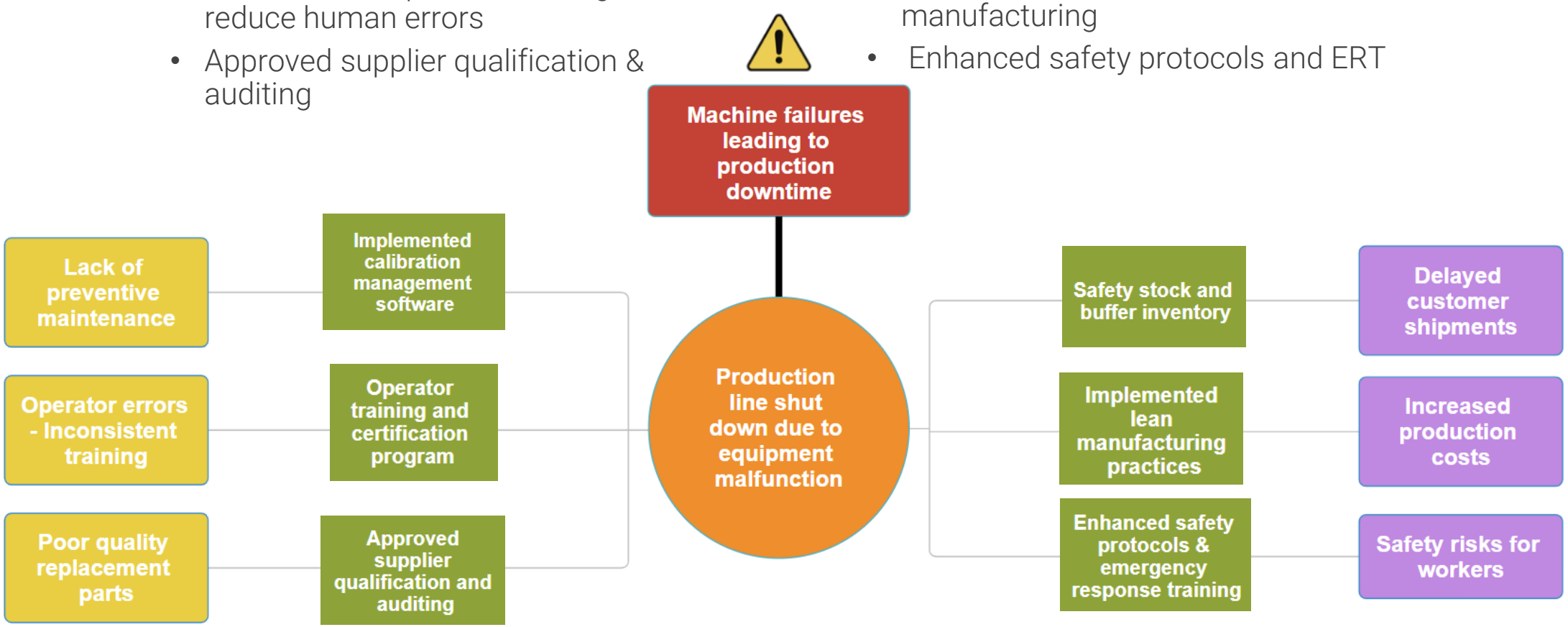
Step-by-Step Process: Applying Bowtie Analysis

Step 5: Implement Preventive & Mitigative Controls/Barriers

- Preventive Controls/Barriers:
  - Implemented calibration management software
  - Standardized operator training to reduce human errors
  - Approved supplier qualification & auditing
- Mitigative Controls/Barriers:
  - Initiated a safety stock & inventory program
  - Optimized resource allocation & lean manufacturing
  - Enhanced safety protocols and ERT



Case Study – Risk Registers in Supplier Management

Company Background & Challenge:

Industry: Pharmaceutical

Problem: Frequent supplier non-conformances, leading to regulatory compliance risks

Root Cause: Lack of visibility into supplier risk levels & inconsistent risk tracking

How they used Risk Registers:

- *Implemented a Risk Register to track, assess, and mitigate supplier risks*
- *Categorized risks by likelihood, impact, and mitigation plans*

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Step-by-Step Process: Creating Risk Registers

Step 1: Identify Supplier Risks

- Reviewed historical supplier performance data
- Conducted on-site audits and document reviews
- Risks identified:
  - Material quality inconsistencies
  - Late deliveries affecting production schedules
  - Regulatory non-compliance (missing certifications, poor documentation)

Step-by-Step Process: Creating Risk Registers

Step 2: Document Risks in a Risk Register

- Created a Risk Register Table:
  - Risk Description
  - Likelihood (Low, Medium, High)
  - Impact (Low, Medium, High)
  - Risk Owner
  - Mitigation Actions
  - Review Frequency

Risk Description	Likelihood	Impact	Owner
Inconsistencies in material quality	Medium	Low	Supply Chain Manager
Late deliveries affecting production schedules	High	High	Procurement Lead
Regulatory non-compliance	Low	High	Quality Director

Step-by-Step Process: Creating Risk Registers

Step 3: Implement Mitigation Actions

- Be proactive, not just reactive
- Address the root cause
- Make actions measurable and specific
- Assign clear ownership & accountability

Risk Description	Likelihood	Impact	Owner	Mitigation Actions
Inconsistencies in material quality	Medium	Low	Supply Chain Manager	• Establish strict supplier quality agreements • Conduct routine raw material testing
Late deliveries affecting production schedules	High	High	Procurement Lead	• Develop backup supplier relationships • Implement inventory buffer stock
Regulatory non-compliance	Low	High	Quality Director	• Perform regular internal audits • Maintain comprehensive documentation and training

Key Takeaways

Risk-based decision making enhances compliance, efficiency, and product quality

- Proactive risk assessment **prevents costly issues before they occur**
- Ensures **regulatory compliance** and reduces audit findings
- Leads to **faster, more confident decision making** across teams

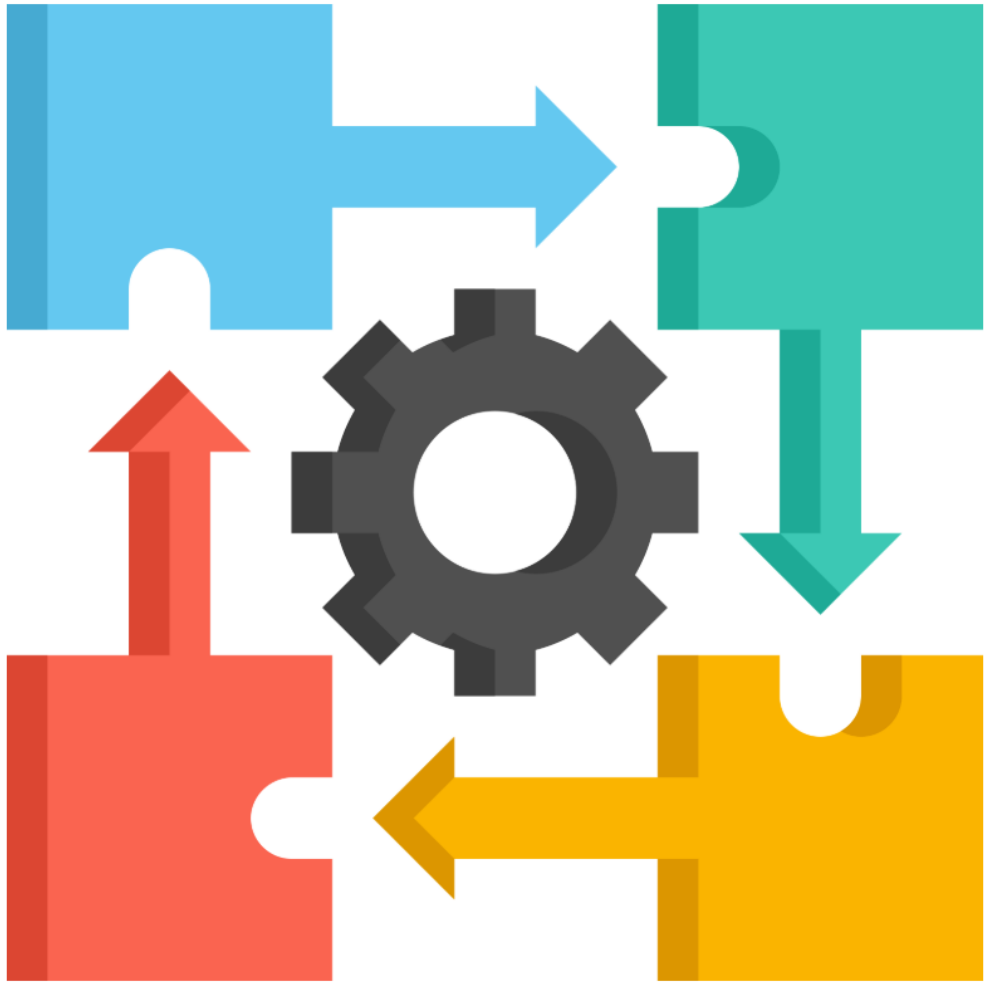
Choosing the right risk tool depends on the scenario and industry needs

- **FMEA**: Best for product design and process risks
- **Bowtie Analysis**: Great for visualizing complex cause and effect relationships
- **Risk Registers**: Ideal for tracking and managing ongoing risks
- **Decision Trees**: Helps with structured, data-driven risk-based decisions

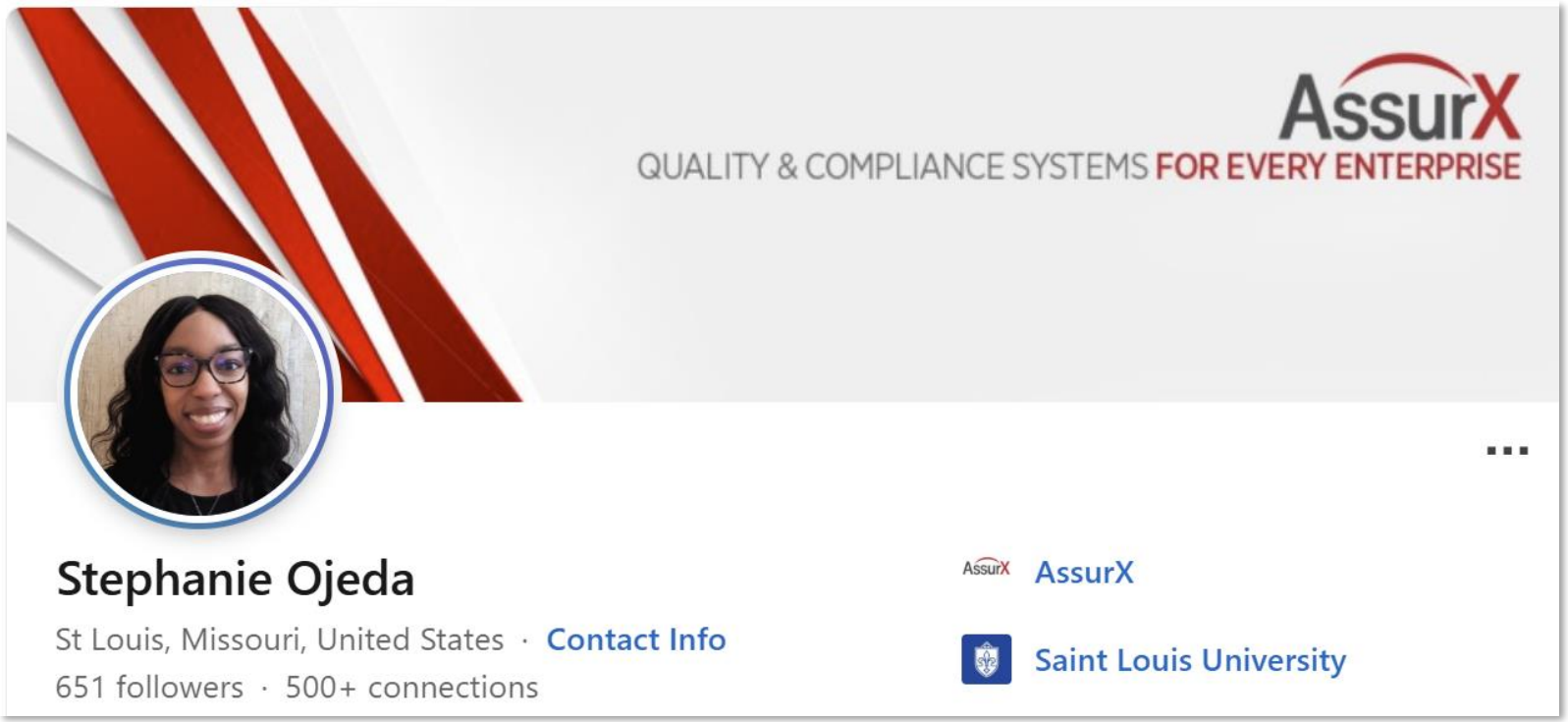
Key Takeaways

Integration with your QMS is essential for long-term success!

- Risk tools should be embedded in existing workflows (CAPA, Supplier Management)
- Cross-functional collaboration makes risk management a shared responsibility
- Automation ensures consistency and real-time visibility into risk assessments



Let’s Connect!



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Questions & Answers