INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

DAVID UMAHI FEDERAL UNIVERSITY OF HEALTH SCIENCES UBURU, EBONYI STATE.

Process Improvement & Risk Management in Laboratory Quality Management Systems

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Week 5

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Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Learning Objectives

- By the end of this session, participants should be able to:
  - Understand the principles of Lean and Six Sigma in laboratory QMS
  - Implement process improvement strategies for enhanced efficiency
  - Conduct effective Root Cause Analysis (RCA) and implement Corrective and Preventive Actions (CAPA)
  - Develop proactive risk management strategies for laboratory quality enhancement
  - Enhance laboratory compliance and quality through continuous process improvement

Question 1

- **Which of the following best describes the role of Lean methodology in laboratory process improvement?**

a. Increasing the number of laboratory procedures to maximize productivity

b. Eliminating waste and improving workflow efficiency

c. Reducing quality control checks to save time

d. Replacing ISO 15189 requirements with internal policies

Question 2

- **How can a laboratory address slow turnaround times while promoting continuous improvement?**

a. Implement an advocacy campaign to raise awareness about laboratory processes.

b. Introduce digital reporting systems to streamline communication with stakeholders.

c. Focus solely on training laboratory staff to handle complaints more efficiently.

d. Increase the number of laboratory personnel to reduce workload.

Question 3

- **To implement proactive risk management strategies, which of the following is the best approach?**

  a. Conducting risk assessments only after a serious incident occurs

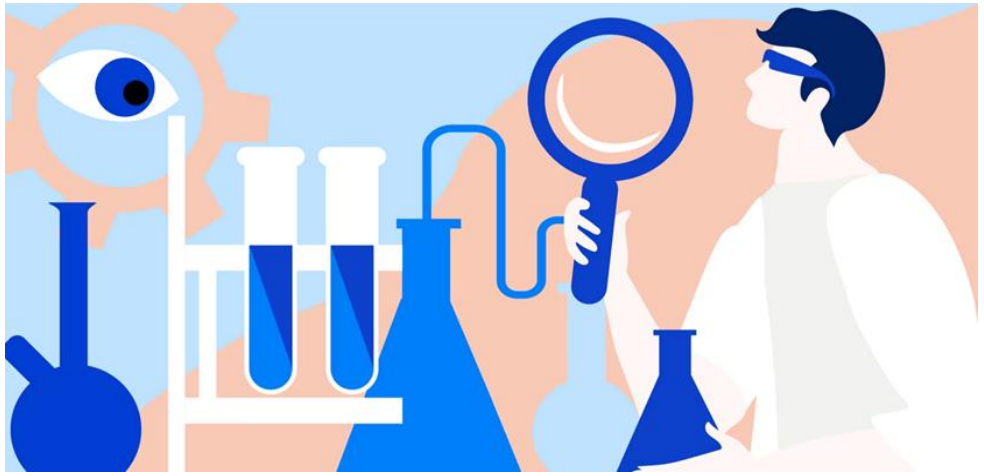
  b. Implementing preventive measures before issues arise

  c. Focusing risk assessments only on tests with known high error rates

  d. Reducing staff involvement in risk management to avoid unnecessary workload

Introduction

- Laboratories play a critical role in healthcare, and require efficiency, accuracy, and reliability.
- QMS ensure standardization, compliance, and continuous improvement.
- Two key pillars driving laboratory excellence are **Process Improvement**, and **Risk Management**.
- Both help laboratories achieve better patient outcomes, reduced errors, and accreditation readiness.



Importance:

Process Improvement:

- Reduces turnaround time (TAT) and improves workflow efficiency.
- Minimizes waste, errors, and unnecessary resource utilization.
- Aligns laboratory operations with accreditation standards; ISO 15189:2022, CAP, WHO AFRO SLIPTA, etc.

Risk Management:

- Helps identify, assess, and mitigate risks before they impact patient care.
- Ensures compliance with regulatory requirements and enhances patient safety.
- Moves laboratories from reactive problem-solving to proactive risk prevention.

Interrelationship between the key elements for optimizing laboratory performance:

Process improvement:

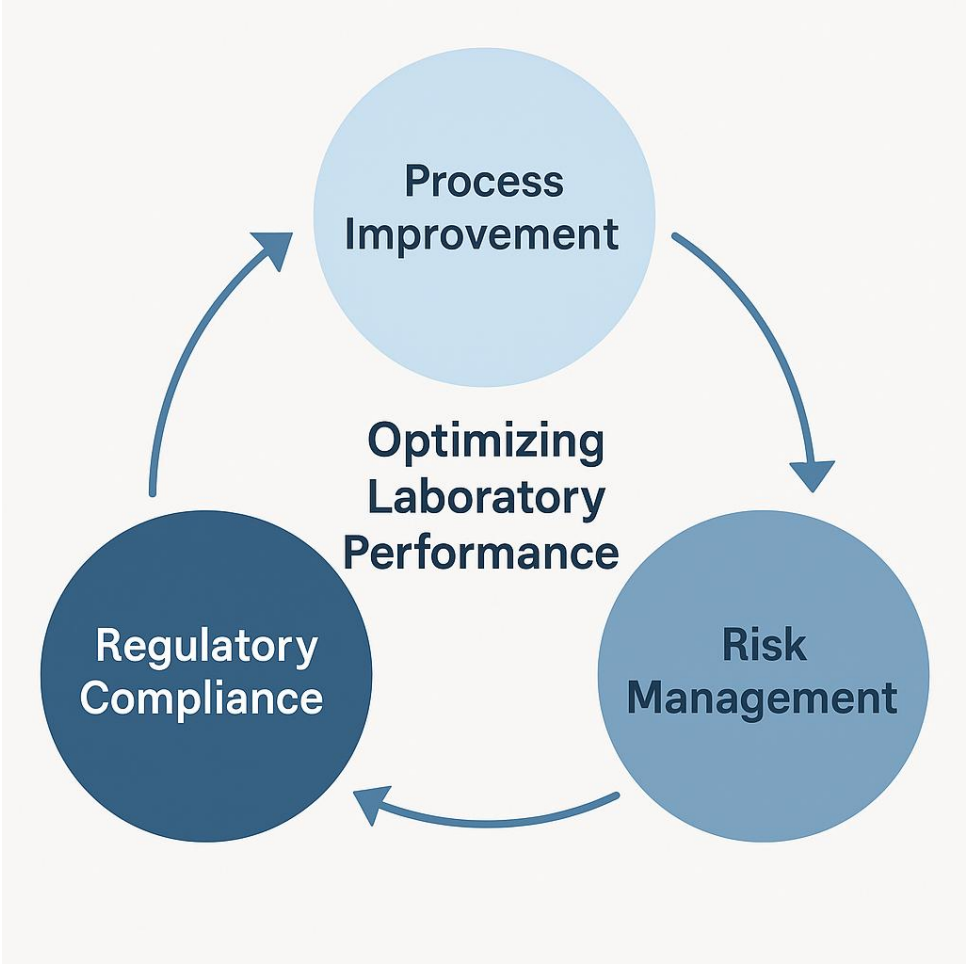
- enhances efficiency and reduces errors

Risk management:

- mitigates potential risks to ensure patient safety

Regulatory compliance:

- ensures adherence to industry standards



Risk Management in Laboratory Quality Improvement:

- Focuses on identifying and mitigating risks before they impact patient care and compliance.
- Common risks include: *sample mislabeling*, *equipment failure*, *reporting errors*, and *biosafety hazards*, which require proactive detection strategies like RCA.
- **Proactive risk management strategies** prevents errors through assessments, training, and quality indicators, while **reactive strategies** address errors after they occur using CAPA and audits.
- Importance of risk assessment:
  - identify areas for improvement, and
  - guide continuous quality enhancement.

A strong risk management culture improves laboratory safety, regulatory compliance, and overall service quality.

Implementing Lean and Six Sigma for Process Optimization

Lean

- Focuses on **eliminating waste**, improving flow, and creating value.
- Waste includes unnecessary motions, delays, overproduction, and underutilized resources.
- Origin: Toyota Production System

Six Sigma

- Focuses on **minimizing errors**, improving quality, and ensuring data-driven decision-making.
- It targets near-perfect performance with fewer than 3.4 defects per million opportunities
- Origin: Motorola

A Combination of Lean and Six Sigma ensures optimal efficiency and high-quality results.

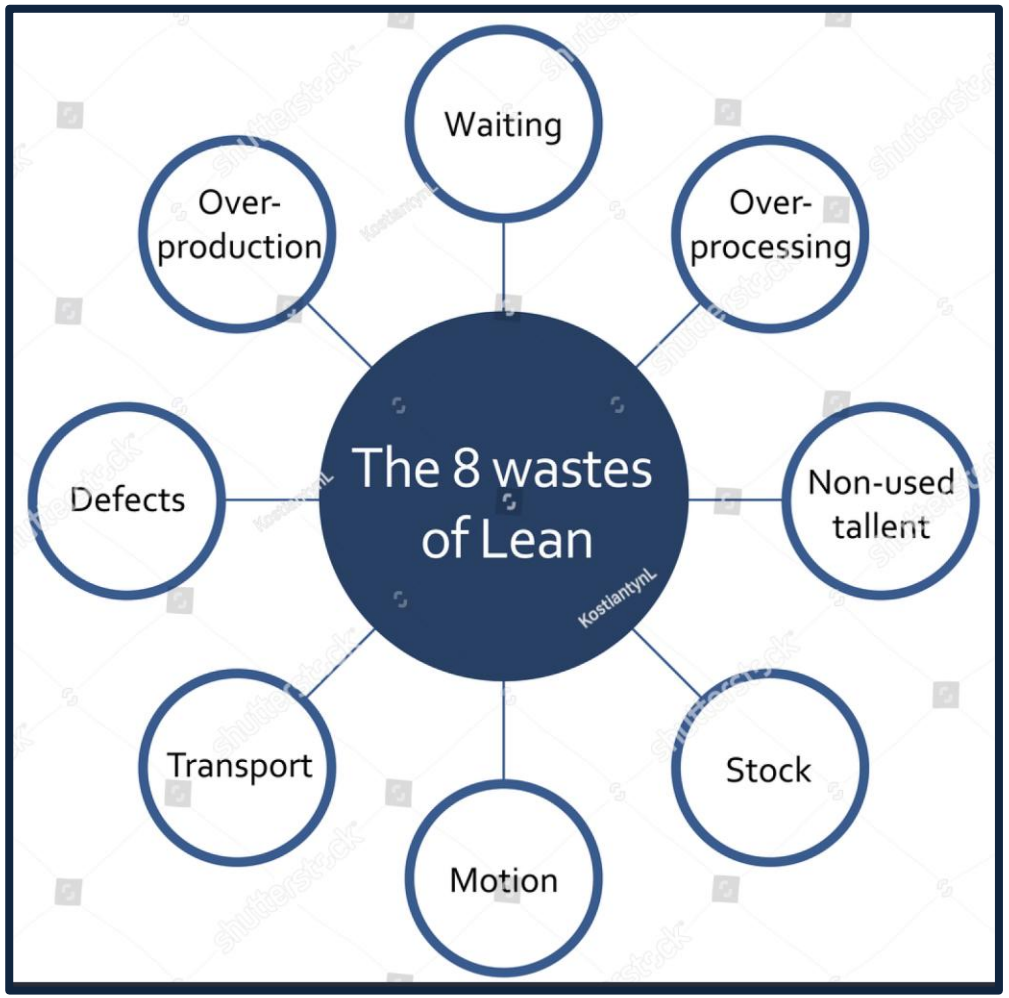
Lean Methodology in Laboratory QMS:

The eight wastes in Lean, often remembered by the acronym DOWNTIME, represent inefficiencies that hinder productivity and quality.

These include unnecessary movement of people or materials, excessive inventory that ties up resources, overproduction leading to wasted effort, defects requiring rework, and waiting time that slows down processes.

Additionally, underutilization of talent means not leveraging employees' full potential, extra processing involves redundant steps, and transportation waste occurs when samples or supplies are moved inefficiently.

Reducing these wastes optimizes workflow, enhances efficiency, and improves overall laboratory quality.



DOWNTIME

EXCESS PROCESSING
Unnecessary effort (production or communication) which adds no value to a product or service.

DEFECTS
Mistakes that require additional time, resources, and money to fix. In the manufacturing process, a the defect might involve a defective part that has to be remade, or office paperwork that needs to be redone.

NON-UTILISED/UNDERUTILISED TALENT
Companies fail to recognise or utilise people's talents, skills or special knowledge, not only are they missing the benefit of these resources, the underutilised are likely to become dissatisfied and may begin to perform poorly, or leave. This waste of talent happens when management is not responsive, does not assign tasks appropriately or does not train properly.

TRANSPORTATION
Waste caused by moving things around. This is less of a problem in a business office than in a the manufacturing plant, since most of what office workers "transport" can be sent by email these days.

MOTION
Simply having to move around too much can slow you down significantly. Poor workstation design or layout as well as processes that require doubling back rather than streamlined and efficient flow.

OVERPRODUCTION
In some organisations, workers just blindly keep producing, even when those who receive their output either aren't ready for it or don't need it. What, what you end up with is too much stuff, too early, that the customer doesn't necessarily want.

WAITING
When work stops for reasons such as needing approval, not having adequate materials or a technical issue like failed equipment or a power outage, causing idleness for those workers affected.

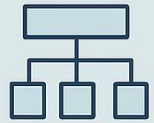
INVENTORY
A surplus of materials has waste associated with the money spent, the time involved in handling, and space/storage requirements. In the service industry this can also include over staffing due to unrealistic customer demand projections.

Implementing Lean Principles in the Laboratory:

- Applying Lean principles in the laboratory helps streamline operations, reduce waste, and enhance efficiency.
- One key approach is **Value Stream Mapping**, which visualizes the entire workflow to pinpoint bottlenecks and inefficiencies, allowing for targeted improvements. Another - Kaizen Events.
- **Standardizing workflows** through well-defined Standard Operating Procedures (SOPs) ensures consistency, reduces variability, and improves compliance with quality standards.
- The **5S methodology**—Sort, Set in Order, Shine, Standardize, and Sustain—creates a well-organized workspace, improving productivity and minimizing errors.
- Additionally, **automation and digital solutions** help reduce manual processes, enhance accuracy, and accelerate turnaround time, ultimately optimizing laboratory performance and patient outcomes.

Appliyng Lean in the Laboratory

Value Stream Mapping



Identifying bottlene-cks and inefficiencies

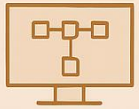
Standardizing Workflows

Developing Standard Operating Procedures

5S Methodology

Organizing the work-space for efficiency

Automation and Digital Solutions



Minimizing manual processes and errors

Implementing Lean Principles in the Laboratory – Identifying and eliminating waste:

Value Stream Mapping (VSM):

- A Lean tool that maps out every step in a laboratory workflow to distinguish between value-adding and non-value-adding activities.
- **Purpose**: Identifies delays, redundancies, and inefficiencies in processes.
- **Benefits**: Highlights bottlenecks, optimizes resource utilization, and improves turnaround time.
- **Implementation**:
  - Document the current workflow with a cross-functional team.
  - Categorize steps as “value-adding” or “non-value-adding.”
  - Develop an optimized process map to eliminate inefficiencies.

Kaizen Events:

- Short-term, focused initiatives aimed at rapidly improving specific laboratory processes.
- **How It Works:**
  - Teams collaborate to solve targeted challenges, such as reducing sample processing delays.
  - Solutions are tested and implemented within days, with immediate feedback.
- **Key Benefits:**
  - Encourages teamwork and staff engagement.
  - Delivers quick, measurable improvements.
  - Fosters a culture of continuous improvement.

Implementing Lean Principles in the Laboratory – The 5s lean laboratory Methodology: Step-by-Step Guide.

- The 5s lean laboratory methodology is a cornerstone of Lean, providing a systematic approach to organizing and maintaining a clean, efficient workspace.
- Here's a breakdown of its five steps and how they apply to laboratories:

Sort

- ✅ Eliminate expired reagents, redundant tools, and outdated equipment.
- ✅ Frees up space, reduces clutter, and enhances workflow efficiency.

Set in Order

- ✅ Arrange frequently used items within reach and use labeled storage.
- ✅ Minimizes search time and improves productivity.

Shine

- ✅ Establish daily cleaning routines for workbenches and equipment.
- ✅ Prevents contamination, extends equipment lifespan, and ensures accuracy.

Standardize

- ✅ Implement SOPs for reagent storage, equipment maintenance, and waste disposal.
- ✅ Ensures consistency, reduces errors, and enhances compliance.

Sustain

- ✅ Conduct regular audits and training sessions, recognizing compliance.
- ✅ Maintains long-term efficiency and prevents lapses into disorganization.

Six Sigma Approach in Laboratory QMS:

- **Sigma (σ)** represents the standard deviation of a process, which measures variability.
- **Six Sigma** means that the process operates within ±6 standard deviations from the mean (process average) before reaching specification limits.
- In a normally distributed process, Six Sigma quality results in a defect rate of ***3.4 defects per million opportunities*** (DPMO).

For a process with a mean (μ) and standard deviation (σ), the upper and lower specification limits (USL and LSL) define acceptable performance. Six Sigma ensures:

$$USL - \mu = 6\sigma$$
$$\mu - LSL = 6\sigma$$

This means **99.99966%** of all outcomes fall within acceptable limits, minimizing defects and improving reliability.

Six Sigma Approach in Laboratory QMS - DMAIC methodology:

The **DMAIC methodology** is a structured Six Sigma approach used to enhance laboratory performance and minimize errors.

- **Define:** Identify key problem areas such as high turnaround time (TAT) or frequent testing errors.
- **Measure:** Collect and evaluate key performance indicators (KPIs) and quality metrics to assess current efficiency.
- **Analyze:** Determine root causes of inefficiencies, such as issues with specimen handling or workflow bottlenecks.
- **Improve:** Implement targeted solutions like workflow optimization, staff training, or equipment upgrades.
- **Control:** Maintain improvements by conducting periodic audits, monitoring performance, and ensuring adherence to best practices.

Practical Applications of Six Sigma in Laboratories:

- Reducing analytical errors and increasing test accuracy
- Optimizing reagent usage and reducing waste
- Standardizing testing processes to minimize variability

Root Cause Analysis (RCA) and Corrective and Preventive Actions (CAPA) Frameworks

RCA

Root Cause Analysis

- Investigate underlying issues
- Identify root causes

↓

CAPA

Corrective and Preventive Actions Framework

- Address root causes
- Implement corrective actions
- Implement preventive actions

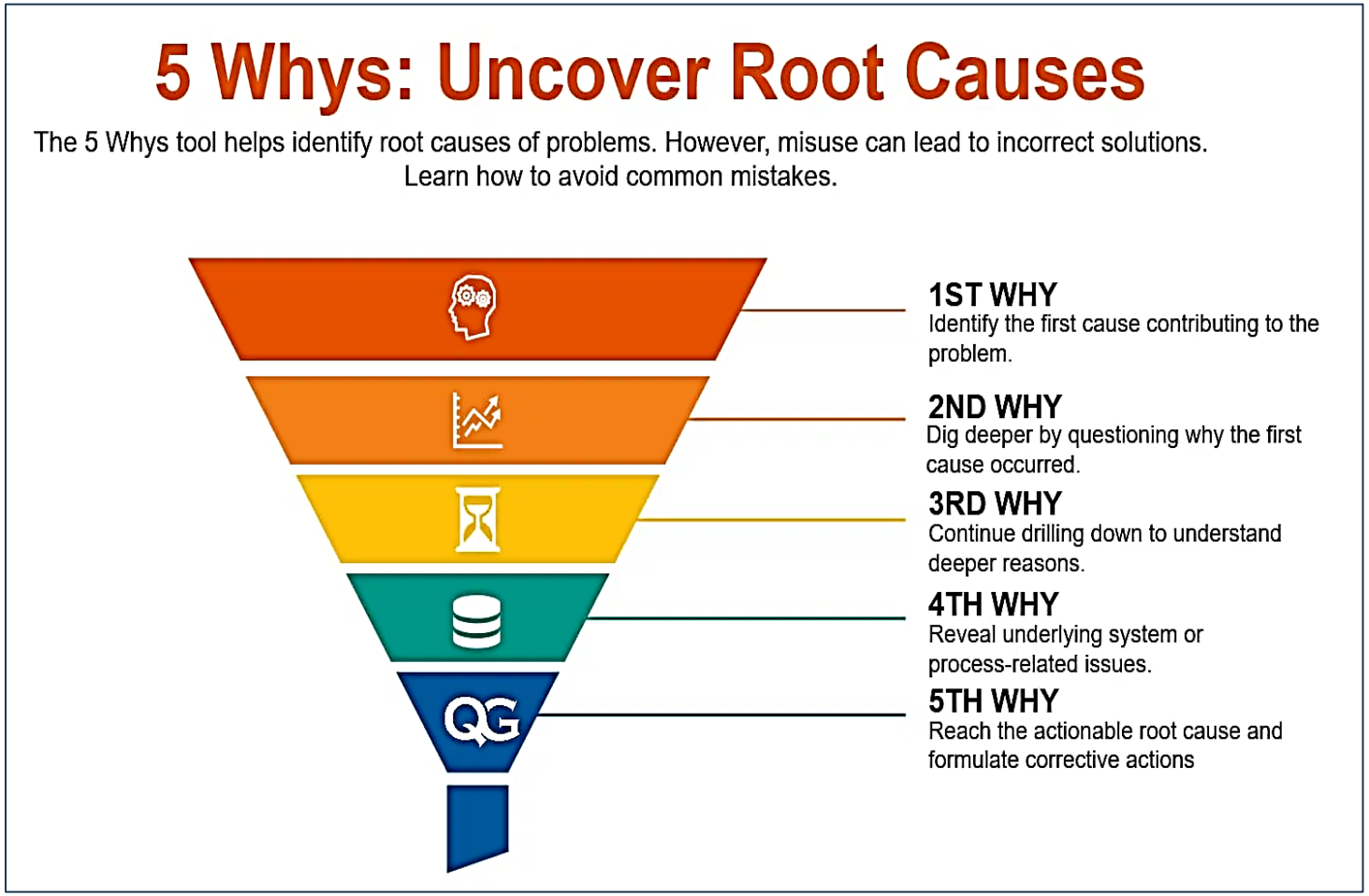
Root Cause Analysis (RCA):

- **Definition of RCA**: A systematic approach to identifying the root cause of errors
- It reduces recurrence, improves patient safety, and ensures compliance with ISO 15189.
- **Why RCA is Essential in Laboratory QMS**
  - Reduces recurrence of errors
  - Improves patient safety and test reliability
  - Ensures compliance with ISO 15189 requirements

Common RCA Techniques:

- **5 Whys Analysis** – Asking "why" five times to reach the root cause.
- **Fishbone Diagram (Ishikawa)** – Identifying different contributing factors (People, Process, Equipment, Materials, Environment).
- **Failure Mode and Effects Analysis (FMEA)** – Risk assessment tool ranking failure risks based on severity, occurrence, and detection.

RCA – 5 Whys Analysis:



Common mistakes in 5 Whys Analysis:

- Stopping at symptoms instead of root causes
- Jumping to conclusions
- Failing to involve the right team
- Using vague or generic answers
- Not verifying causes with data
- Neglecting systemic factors
- Lack of follow-up on corrective actions

RCA – Fishbone Diagram (Ishikawa):

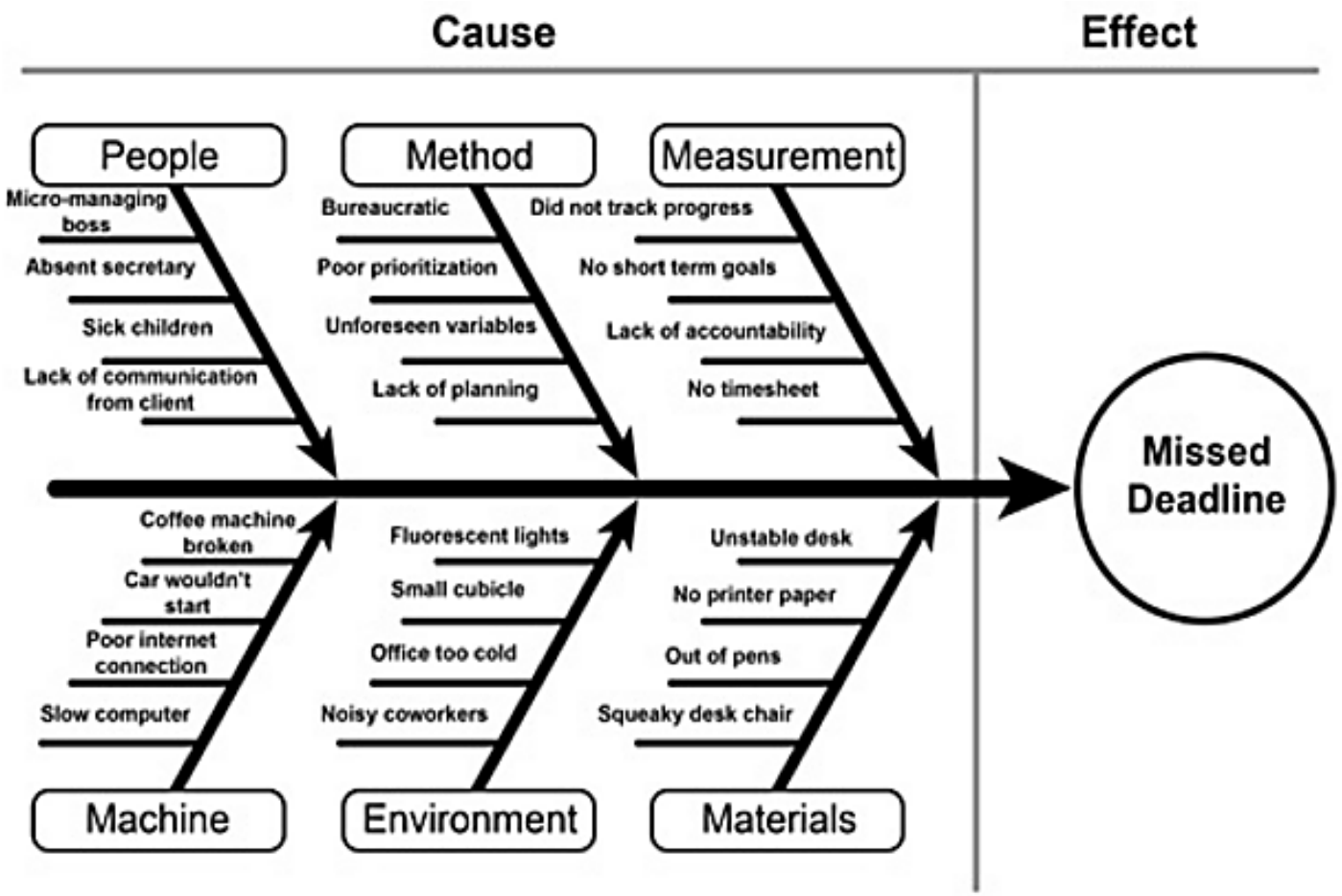
The Fishbone Diagram – tool used to identify and visualize the various factors that contribute to a problem or effect.

It helps teams systematically explore potential causes across different categories.

Key Elements of the Fishbone Diagram:

- **People:** Factors related to human resources, including staff training, performance, and communication.
- **Process:** Issues in the workflow, procedures, or methods used that could contribute to the problem.
- **Equipment:** Failures or inadequacies in the tools, machines, or technology used in the process.
- **Materials:** Problems related to raw materials, chemicals, or consumables, such as quality or availability issues.
- **Environment:** External conditions like temperature, humidity, or workspace setup that may impact the process or results.

RCA – Fishbone Diagram (Ishikawa) – contd:



The Fishbone Diagram helps in organizing thoughts, uncovering hidden causes, and fostering teamwork in problem-solving efforts.

RCA - Failure Mode and Effects Analysis (FMEA):

Failure Mode and Effects Analysis (FMEA) is a structured risk assessment tool used to identify potential failure points in a process, product, or system, and evaluate their risks based on three key factors:

- **Severity (S)**: The seriousness of the consequences if a failure occurs. Higher severity means a greater impact on safety, quality, or performance.
- **Occurrence (O)**: The likelihood that a failure will happen. A higher occurrence rating indicates a higher probability of failure.
- **Detection (D)**: The ability to detect the failure before it impacts the process or customer. Lower detection scores indicate a higher risk of undetected failure.

FMEA assigns a Risk Priority Number (RPN), which is calculated by multiplying the ratings for severity, occurrence, and detection.

RPN = S × O × D)

The higher the RPN, the higher the priority for addressing the failure risk.

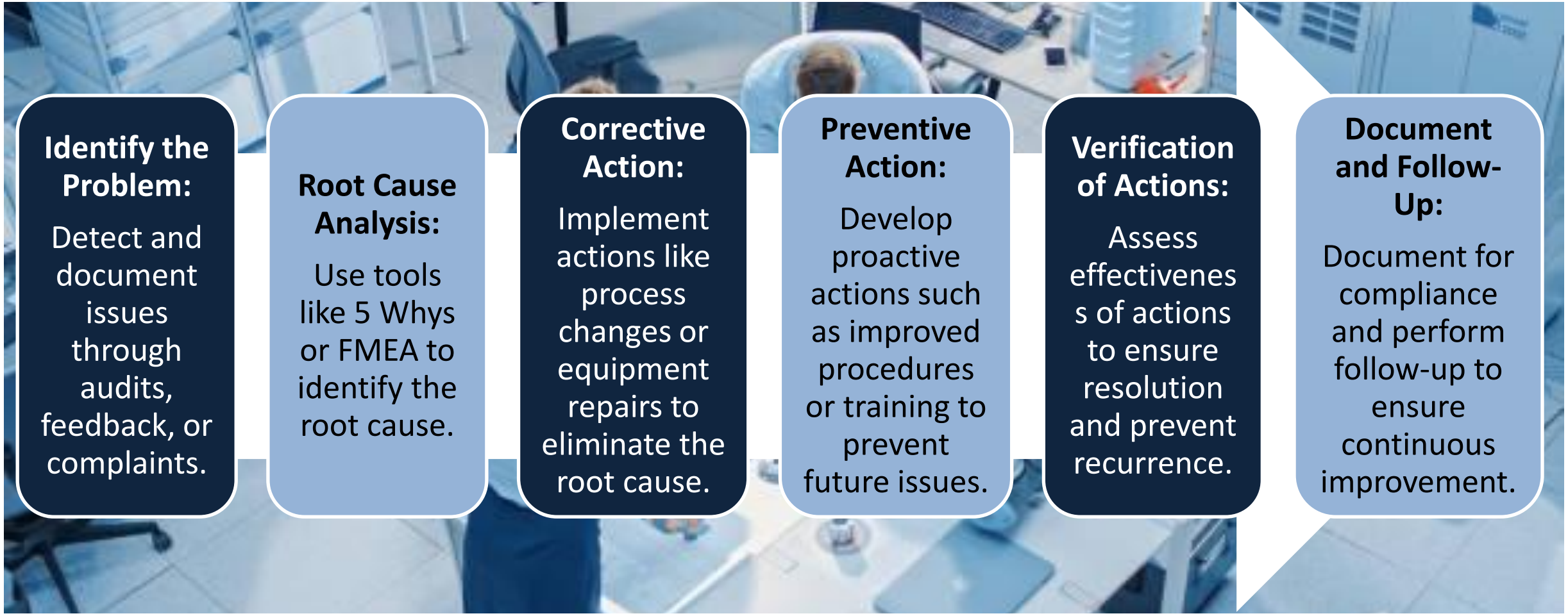
This tool helps prioritize actions to mitigate risks by identifying critical failure modes and guiding corrective measures.

Corrective and Preventive Actions (CAPA) Framework:

The Corrective and Preventive Actions (CAPA) framework is a systematic approach used to identify, correct, and prevent issues within processes, systems, or products to ensure continuous quality improvement and safety:

- **Corrective Action:**
  - ***Purpose****: To address and eliminate the root cause of a problem or non-conformance that has already occurred.*
  - ***Goal****: Prevent the issue from recurring in the future.*
- **Preventive Action:**
  - ***Purpose****: To identify and eliminate potential causes of future problems before they occur.*
  - ***Goal****: Preventive actions are proactive and focus on reducing the likelihood of issues arising in the first place.*

CAPA – Steps for Implementing CAPA in Laboratories:



Identify the Problem:
Detect and document issues through audits, feedback, or complaints.

Root Cause Analysis:
Use tools like 5 Whys or FMEA to identify the root cause.

Corrective Action:
Implement actions like process changes or equipment repairs to eliminate the root cause.

Preventive Action:
Develop proactive actions such as improved procedures or training to prevent future issues.

Verification of Actions:
Assess effectiveness of actions to ensure resolution and prevent recurrence.

Document and Follow-Up:
Document for compliance and perform follow-up to ensure continuous improvement.

Importance of CAPA:

- **Enhances Quality**: helps maintain and improve the quality of processes, products, or services.
- **Reduces Risks**: addresses risks to quality, safety, or compliance by eliminating the root cause of issues and preventing their recurrence.
- **Improves Compliance**: a critical component for ISO 15189 compliance, ensuring that laboratories meet quality standards.
- **Continuous Improvement**: supports a culture of continuous improvement, encouraging organizations to always look for ways to enhance their processes and prevent potential failures.

Case Scenario for Discussion

- **Background:**

  A hospital laboratory has experienced a consistent issue with inaccurate blood test results, leading to delayed diagnoses and potential patient safety concerns. The laboratory conducts tests for a variety of departments, including hematology, clinical chemistry, and microbiology.

  Recently, there has been a noticeable increase in the rejection rate of samples due to incorrect labeling and mislabeled test results. The laboratory's ISO 15189 accreditation is under review, and the laboratory manager has initiated an internal audit to assess the causes and determine appropriate actions.

- **Key Findings:**
  - **Problem**: inaccurate blood test results compromising patient care.
  - **Root Cause**: Breakdown in communication between phlebotomists and laboratory staff due to unclear labeling procedures.
  - **Possible Contributing Factors**: Lack of training, poor supervision, and absence of a double-check system.
  - **Action**: initiation of an internal audit.

Case Scenario for Discussion – Questions:

- 1 What immediate corrective actions should the laboratory take?
- 2 What preventive action can be taken thereafter?
- 3 What role do digital tools play in reducing human errors?
- 4 How can risk-based thinking and process improvement prevent future issues?

Case Scenario for Discussion – Answers:

1 Immediate Corrective Actions:

- Retrain staff on labelling.
- Implement double-checks for labelling.
- Conduct an audit to correct mislabelling.

2 Preventive Actions:

- Train new staff regularly.
- Use barcode scanners for sample IDs.
- Monitor labelling consistently.

3 Role of Digital Tools in Reducing Errors:

- Barcode scanners reduce ID errors.
- Automation tracks samples, minimizing mistakes.
- Digital checklists ensure procedure adherence.

4 Risk-Based Thinking & Process Improvement:

- Identifies potential failures early.
- Continuous improvements prevent recurring issues.

Proactive Risk Management Strategies for Lab Quality Improvement

Effective risk management in laboratory QMS ensures:

- **patient safety,**
- **regulatory compliance, and**
- **operational efficiency.**

Instead of merely responding to issues as they arise, proactive risk management focuses on anticipating and mitigating risks before they impact laboratory operations.

Risk-Based Thinking in LQMS – *ISO 15189:2022 Risk Management:*

*ISO 15189:2022 r*equires labs to systematically identify and control potential risks across all stages of the testing process.

Identifying Risks at Each Stage:

- Every phase of the laboratory workflow (from sample collection to result reporting) presents unique risks that must be managed.
- By analyzing potential failure points, laboratories can prevent disruptions and errors.

Shifting from Reactive to Proactive Error Prevention:

- Traditional quality management often focuses on fixing errors ***after*** they occur.
- A proactive approach ***prevents*** errors by implementing safeguards and process improvements in advance.

Risk Identification in Laboratory Processes:

Pre-analytical Risks

- Sample Misidentification
- Poor Sample Transport Conditions
- Incorrect Test Requests

Analytical Risks

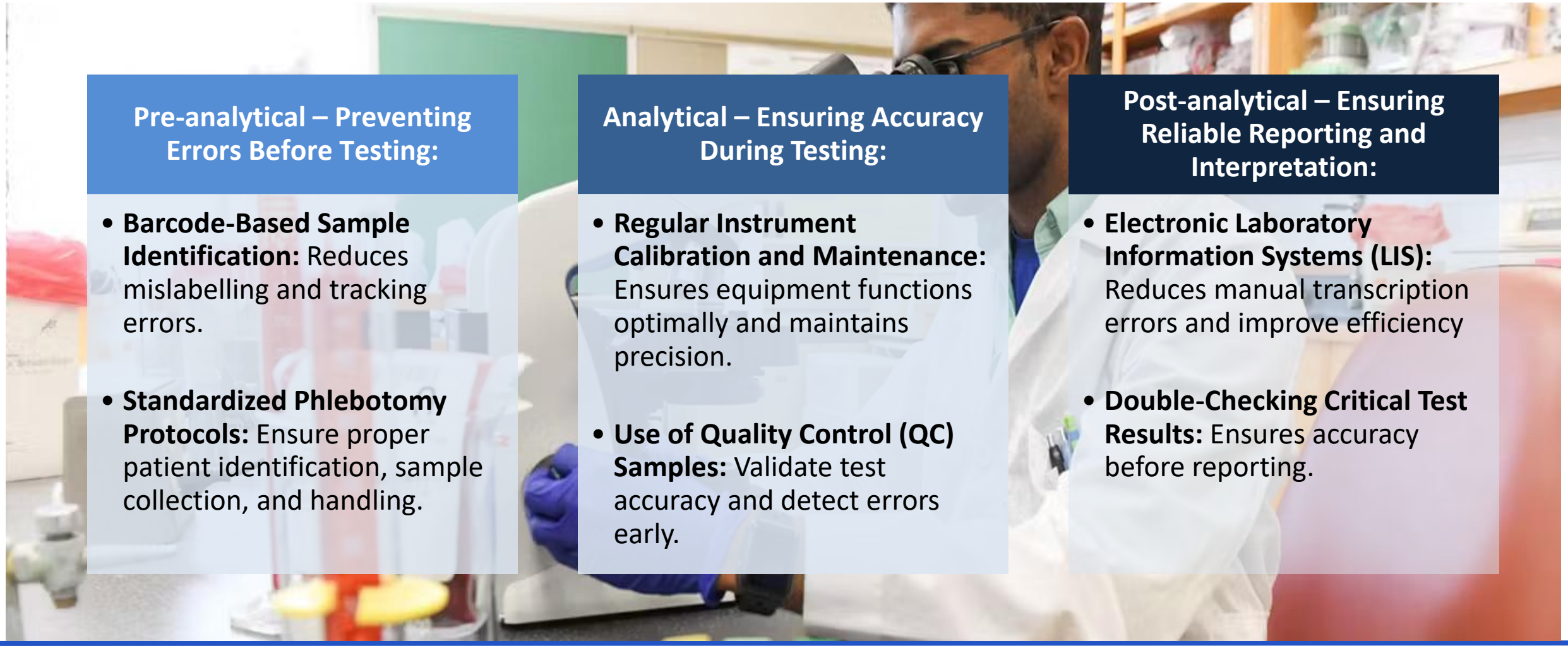
- Equipment Calibration Errors
- Reagent Contamination
- Technician-Related Errors

Post-analytical Risks

- Data Transcription Errors
- Delayed Result Reporting
- Misinterpretation of Test Results

Each phase has its own set of potential risks that can compromise test quality and patient outcomes

Risk Mitigation Strategies:



Pre-analytical – Preventing Errors Before Testing:

- **Barcode-Based Sample Identification:** Reduces mislabelling and tracking errors.
- **Standardized Phlebotomy Protocols:** Ensure proper patient identification, sample collection, and handling.

Analytical – Ensuring Accuracy During Testing:

- **Regular Instrument Calibration and Maintenance:** Ensures equipment functions optimally and maintains precision.
- **Use of Quality Control (QC) Samples:** Validate test accuracy and detect errors early.

Post-analytical – Ensuring Reliable Reporting and Interpretation:

- **Electronic Laboratory Information Systems (LIS):** Reduces manual transcription errors and improve efficiency
- **Double-Checking Critical Test Results:** Ensures accuracy before reporting.

Case Scenario – Question?

- **Background:**

  A busy anatomical pathology lab processes over 100 biopsy specimens daily. Recently, a near-miss incident occurred where **two patient specimens were almost switched** during grossing due to similar names and container labeling errors. Fortunately, the error was caught before slide preparation. The laboratory corrected the error and instituted a proactive risk management strategies.

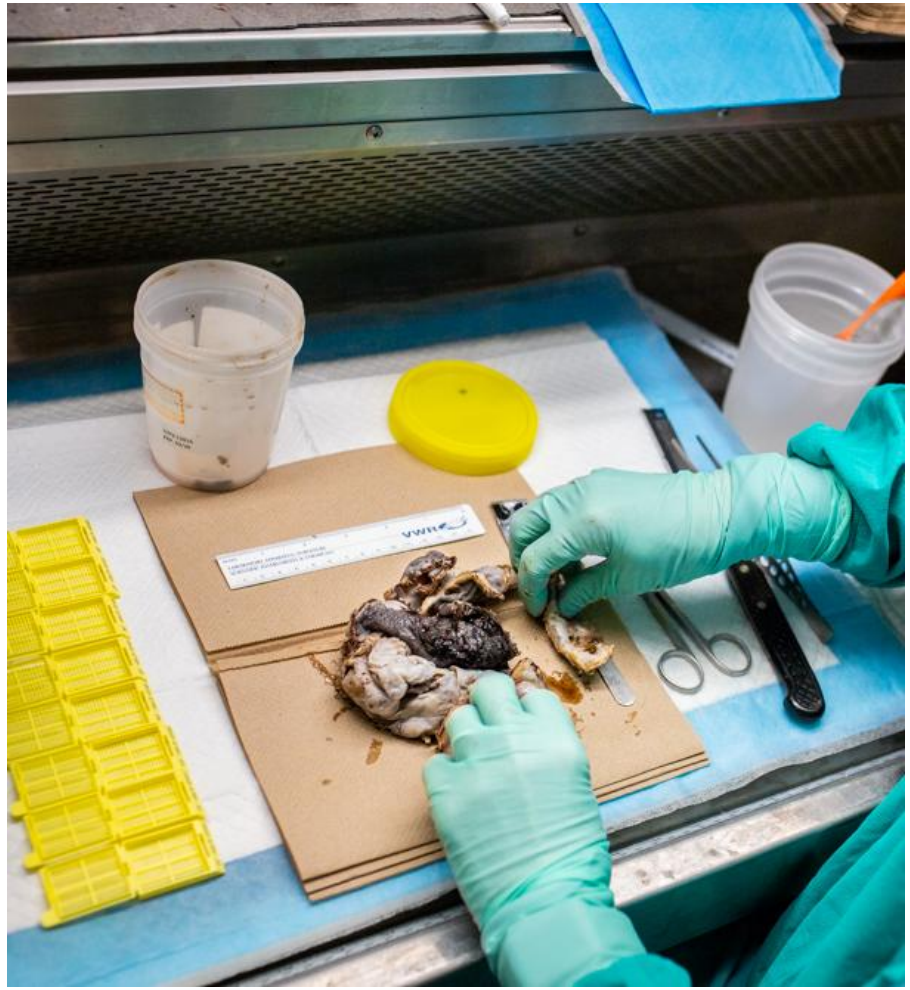
- **Identified Risk**:

  High likelihood of specimen misidentification during peak workflow periods, especially in the absence of a standardized verification process.

What Proactive Risk Management Strategies can be Implemented in the situation?

Case Scenario – Answers?

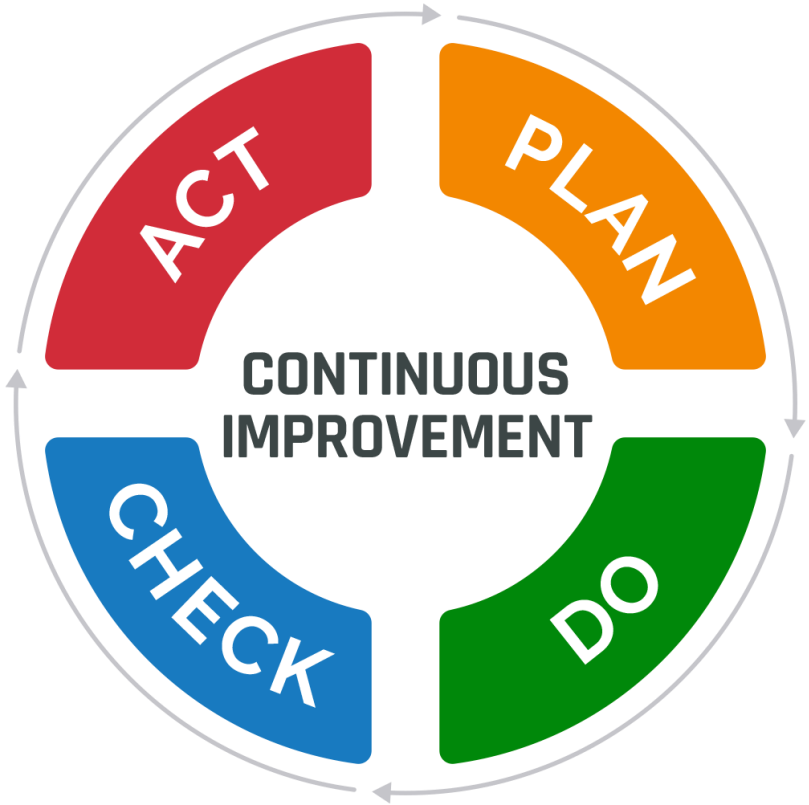
- **Failure Mode and Effects Analysis (FMEA):**
  - Risk mapping performed on the entire specimen handling workflow to identify vulnerable steps (e.g., receipt, labeling, grossing).
- **Colour-Coded Labeling System:**
  - Specimen containers and requisition forms can be colour-coded by tissue type and urgency to reduce confusion.
- **Two-Person Verification Rule:**
  - Can be introduced at the accessioning and grossing stages to ensure specimen-patient identity match.
- **Barcoded Tracking System:**
  - Barcoded labels can be scanned at every processing point to ensure traceability and minimize manual errors.
- **Staff Training & Simulation Drills:**
  - On handling high-risk scenarios (e.g., duplicate names, unclear labeling) can be conducted to improve response and alertness.



Continuous Quality Improvement (CQI) in Risk Management:

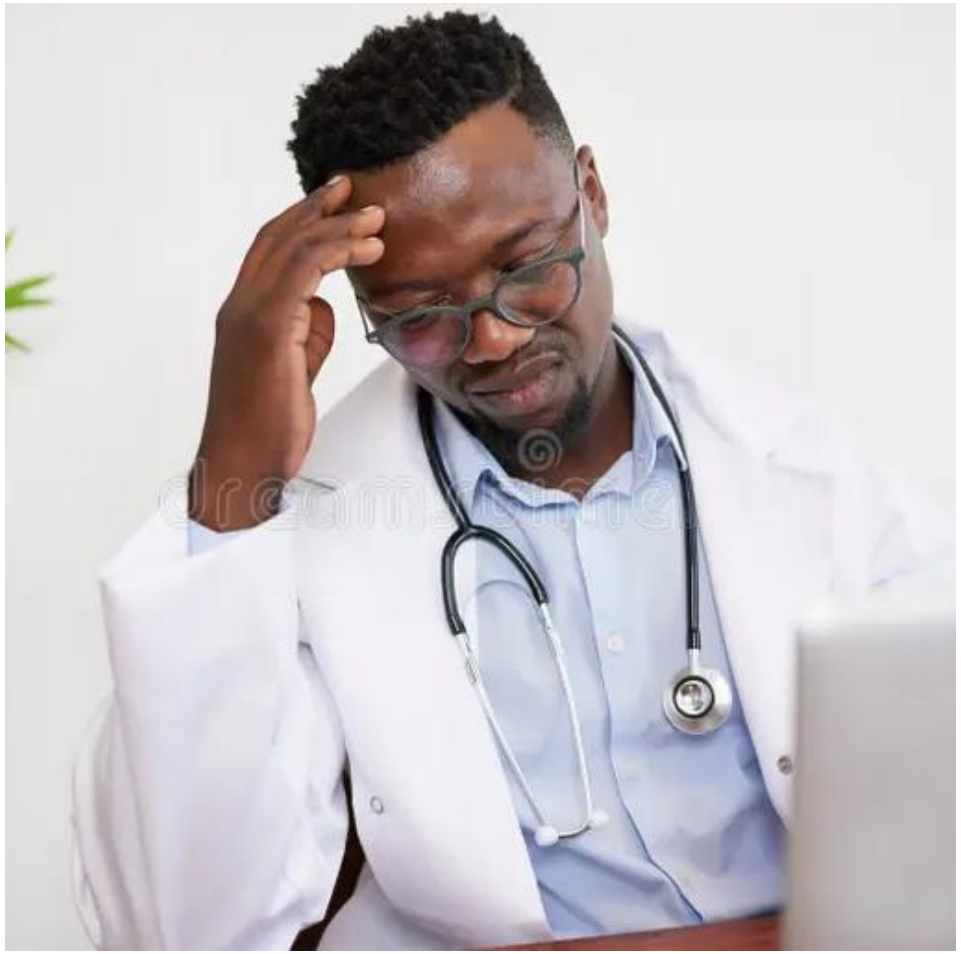
ISO15189:2022 update extends the concept of continuous improvement in LQMS to Risk Management.

Risk management is not a one-time process – it requires ongoing monitoring and improvement through CQI strategies.



CQI in Risk Management – Tracking Key Performance Indicators (KPIs):

- KPIs help laboratories measure risk and performance trends over time.
- Common KPIs include:
  - **Sample rejection rates** – indicates the frequency of pre-analytical errors.
  - **TAT for urgent tests** – evaluate efficiency in critical test reporting.
  - **Error rate in laboratory reports** – tracks transcription and analytical errors for improvement.
  - **Reagent stockout frequency** – highlights supply chain or inventory management issues that can delay testing.
  - **Equipment downtime** – measures the reliability and maintenance effectiveness of analytical instruments.
  - **Customer complaint trends** – Provides insights into service gaps and stakeholder satisfaction.



CQI in Risk Management – Conducting Internal Audits and EQAs:

- **Periodic internal audits** – help drive targeted improvements and strengthen the overall QMS.
- **Participation in EQA programs** – enables laboratories to compare their performance with peer institutions, recognize deviations in test accuracy or precision, and implement corrective actions.
- **Benchmarking against best practices from audit findings and EQA feedback** – helps laboratories adopt evidence-based improvements, align with national and international quality expectations, and foster a culture of accountability and learning.

CQI in Risk Management – Developing a Risk Management Culture:

- **Leadership Commitment:** must take an active and visible role in promoting risk management by:
  - Setting clear quality objectives
  - Allocating adequate resources
  - Reinforcing the importance of safety, accuracy, and compliance
- **Encouraging Frontline Staff Participation:** should be empowered and encouraged to report risks, near-misses, and process inefficiencies without fear of blame. Their involvement in identifying hazards and co-developing solutions promotes:
  - Ownership and responsibility
  - Team trust and collaboration
  - Shared commitment to continuous improvement across the lab.

Conclusion – Key Takeaways:

- **Lean and Six Sigma** are powerful tools for improving laboratory efficiency by eliminating waste, reducing variability, and standardizing processes.
- **Root Cause Analysis (RCA)** helps identify the true source of errors, enabling effective **Corrective and Preventive Actions (CAPA)** to avoid recurrence.
- **Proactive Risk Management** (as emphasized in ISO 15189:2022) shifts the focus from reacting to failures to anticipating and mitigating risks before they impact quality.
- **Continuous quality improvement** depends on a culture of continuous learning, team involvement, and data-driven decision-making.
- Finally, integrating these approaches strengthens patient safety, regulatory compliance, and laboratory credibility.

💡 Final Thought! 💡

🔬 *Quality in the laboratory is not an act, but a habit* — built through

🔁 **consistent improvement**,

⚠️ **vigilant risk management**, and

🌟 **a commitment to excellence**.

🧪 Let quality guide every process, not just the outcome.

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Thank You

NEXT WEEK (14th April 2025):

Enhancing Customer Service, Communication & Stakeholder Engagement – Dr. Mba I.N (MBBS, FMCPath., IFCAP)

- Strategies to improve patient and clinician interactions in laboratory services
- Digital reporting systems and turnaround time optimization
- Effective management of complaints, feedback, and service improvement initiatives

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