INTERNATIONAL INSTITUTE FOR PATHOLOGY AND FORENSIC SCIENCE RESEARCH

COLLEGE of AMERICAN PATHOLOGISTS FOUNDATION

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

Optimizing Supply Chain, Inventory, and Procurement in the Laboratory Quality Management System

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Advancing Laboratory Quality Management Systems for Better Patient Outcomes

Learning Objectives

- By the end of this session, participants will be able to:
  - Understand common causes of reagent shortages and how to manage supply chain disruptions.
  - Learn how digital inventory systems improve resource tracking and reduce waste.
  - Identify sustainable procurement practices that enhance laboratory cost-effectiveness.
  - Recognize how inventory and procurement align with ISO 15189:2022 requirements.

Question 1

- **Why is supplier diversification important in laboratory procurement?**

  a. It reduces the number of invoices generated

  b. It increases dependence on global markets

  c. It minimizes the impact of disruptions from a single supplier

  d. It lowers the quality of laboratory materials.

Question 2

- **Which of the following is NOT a common root cause of reagent shortages in laboratory settings?**

a. Overreliance on a single supplier

b. Effective inventory forecasting

c. Importation delays and customs issues

d. Global supply chain bottlenecks

Question 3

- **Which strategy is MOST appropriate for mitigating the risk of critical reagent stockouts?**

a. Placing bulk orders annually regardless of usage trends

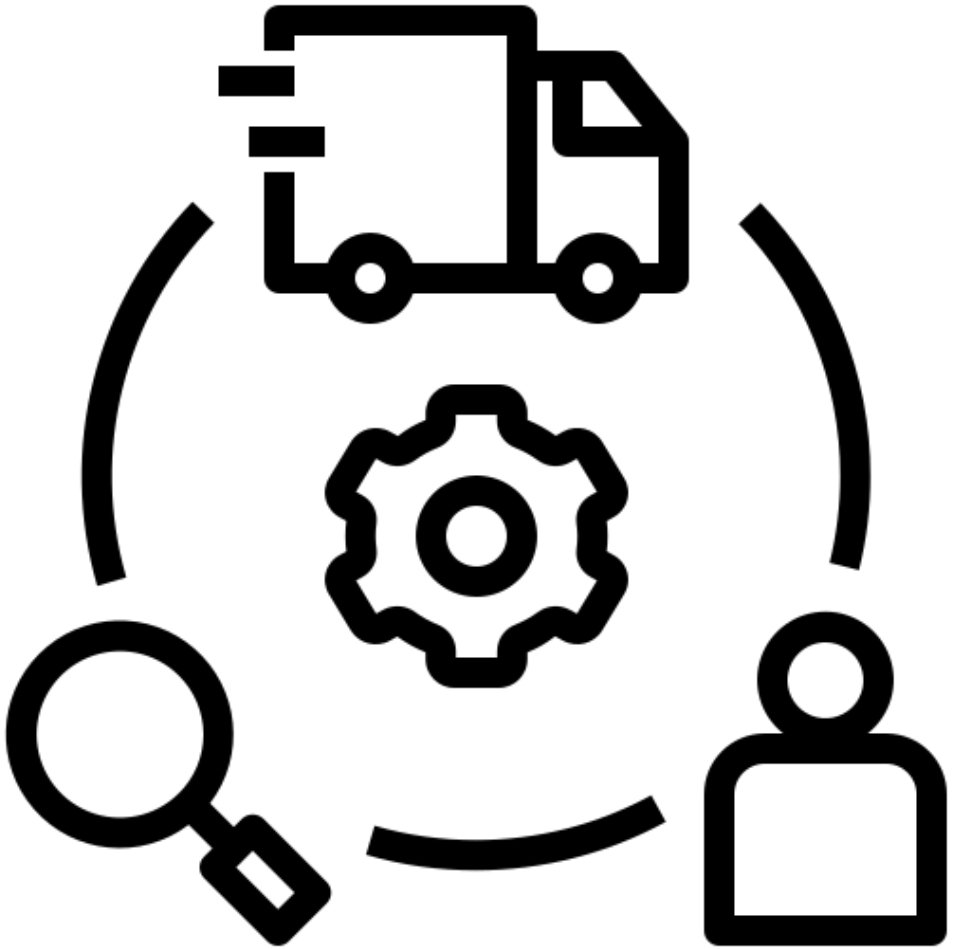
b. Engaging in pooled procurement schemes with other laboratories

c. Limiting communication with suppliers to reduce pressure

d. Depending solely on emergency requisitions during shortages

Introduction

- Efficient supply chain, inventory, and procurement management form the backbone of reliable and responsive laboratory operations.
- The importance of procurement and inventory control is reinforced by international standards such as ISO 15189:2022 and the WHO Laboratory Quality Management System (LQMS).
- These frameworks emphasize integrating supply chain processes into the overall QMS and adopting a risk-based approach to supply management.



Why Optimize Supply Chain, Inventory & Procurement?

- ISO 15189:2022 strengthens requirements for supplier evaluation, procurement documentation, contingency plans, and traceability.
- Poor supply chain management leads to stockouts, expired reagents, and financial loss.
- These issues affect test quality, delay diagnoses, and risk patient safety.
- Optimization is a strategic necessity for reliable, compliant, and sustainable laboratory operations.

Interrelationship between the key elements:

Procurement:

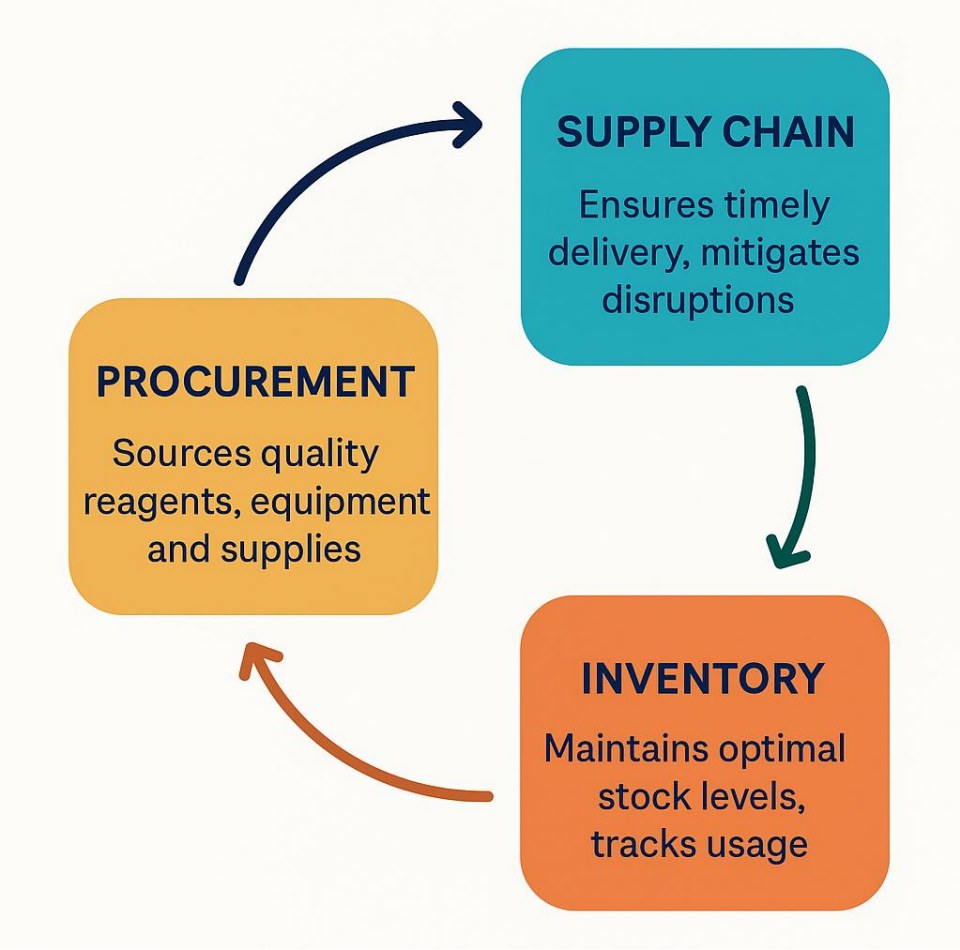
- initiates the cycle by sourcing quality reagents, equipment, and supplies through vetted suppliers—ensuring cost-effectiveness, compliance, and reliability.

Inventory control:

- maintains optimal stock levels, tracks usage, prevents wastage, and supports uninterrupted testing.

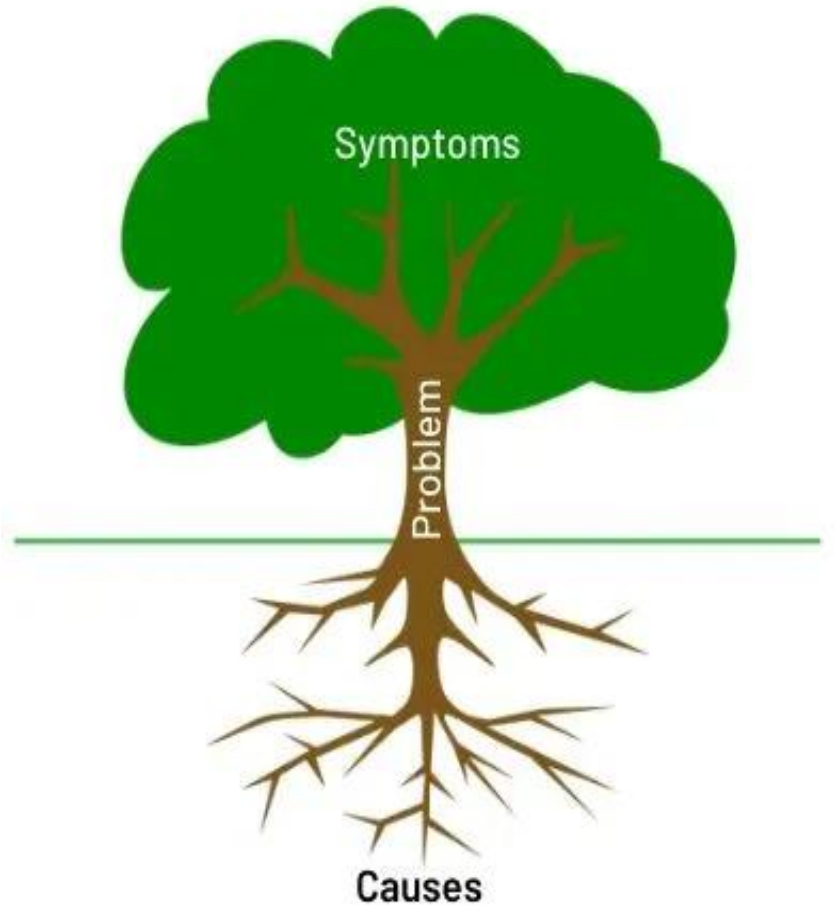
Supply chain management:

- ensures timely delivery, mitigates disruptions, and maintains traceability of materials from supplier to lab bench



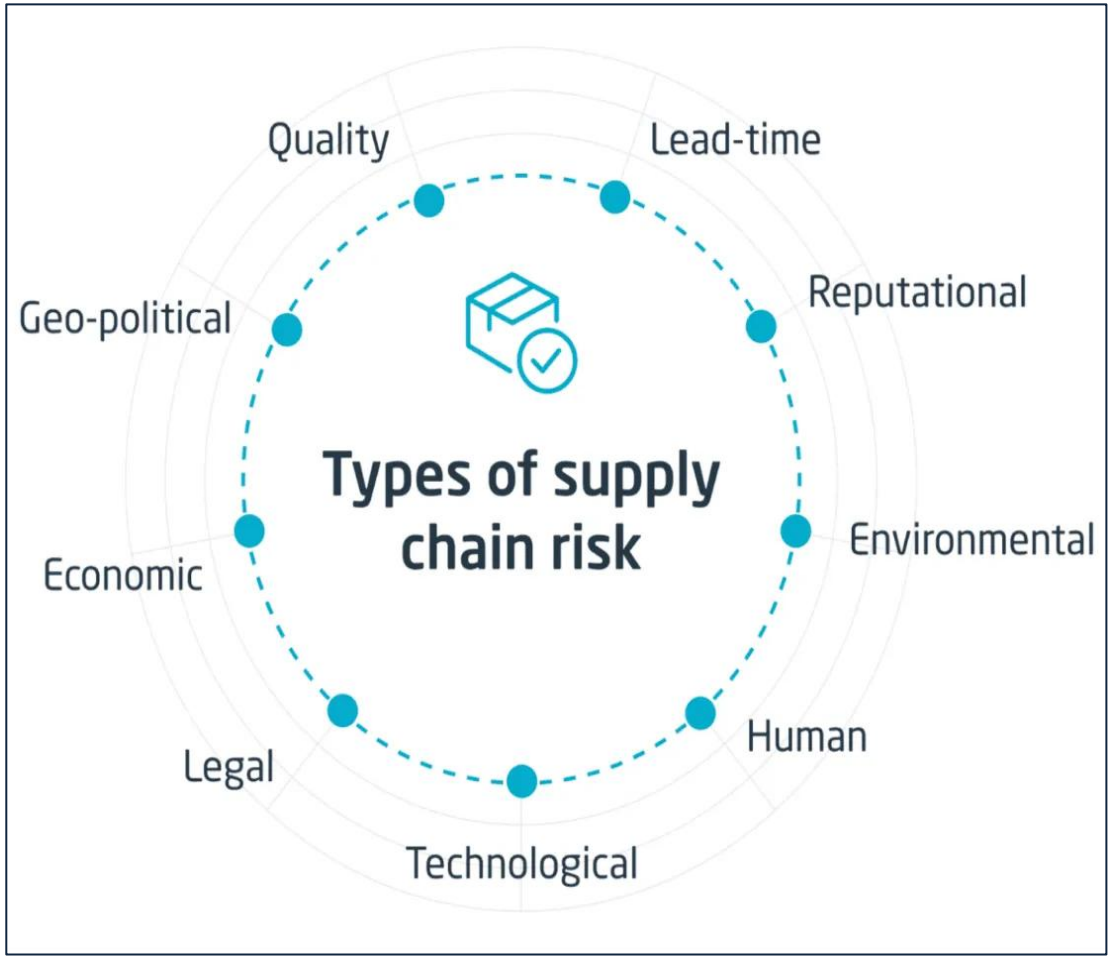
Managing Reagent Shortages and Mitigating Supply Chain Disruptions

- Reagent shortages can severely disrupt laboratory operations and compromise patient care.
- To effectively address this challenge, it is essential to first understand the underlying causes.
- Root Causes of Reagent Shortages are:
  - Global and local supply chain bottle necks
  - Over-reliance on single suppliers or geographic regions
  - Importation delays, customs issues, and regulatory barriers
  - Poor forecasting and inventory control



Risk-Based Supply Chain Mapping and Analysis

- A structured, risk-based approach to supply chain management allows laboratories to anticipate potential disruptions and develop strategies for resilience.
- Strategies for risk-based supply chain mapping and analysis are:
  - categorizing supplies based on criticality to laboratory functions
  - mapping supply chain vulnerabilities and development of alternative pathways.
  - Building Risk registers and Mitigation Plans.



Implementing Risk-Based Supply Chain Mapping and Analysis: Step-by-Step Guide.

- **Define Objectives and Scope**
  - Identify the goal (e.g., improving reagent availability, compliance with ISO 15189).
  - Determine which supplies, services, or processes will be mapped.
- **Identify Key Supplies and Suppliers**
  - List all critical reagents, consumables, and equipment.
  - Document associated suppliers, including intermediaries and alternate vendors.
- **Map the Supply Chain**
  - Create a visual flow diagram showing each stage from sourcing to point-of-use.
  - Include supplier locations, transport routes, warehousing, and internal distribution.
- **Assess Risks at Each Node**
  - Evaluate risks such as supplier reliability, transport delays, single-source dependencies, quality failures, etc.
  - Use tools like FMEA or a risk matrix.
- **Categorize and Prioritize Risks**
  - Classify risks by likelihood and impact (e.g., low/medium/high).
  - Highlight critical points where disruption would severely affect operations.
- **Develop Mitigation Strategies**
  - Establish contingency plans (e.g., buffer stocks, dual sourcing, emergency procurement protocols).
  - Strengthen supplier agreements and include performance expectations.
- **Monitor and Review**
  - Implement key performance indicators (KPIs) to monitor supply reliability and risk.
  - Review and update the risk map regularly or after disruptions.

Mitigation Strategies

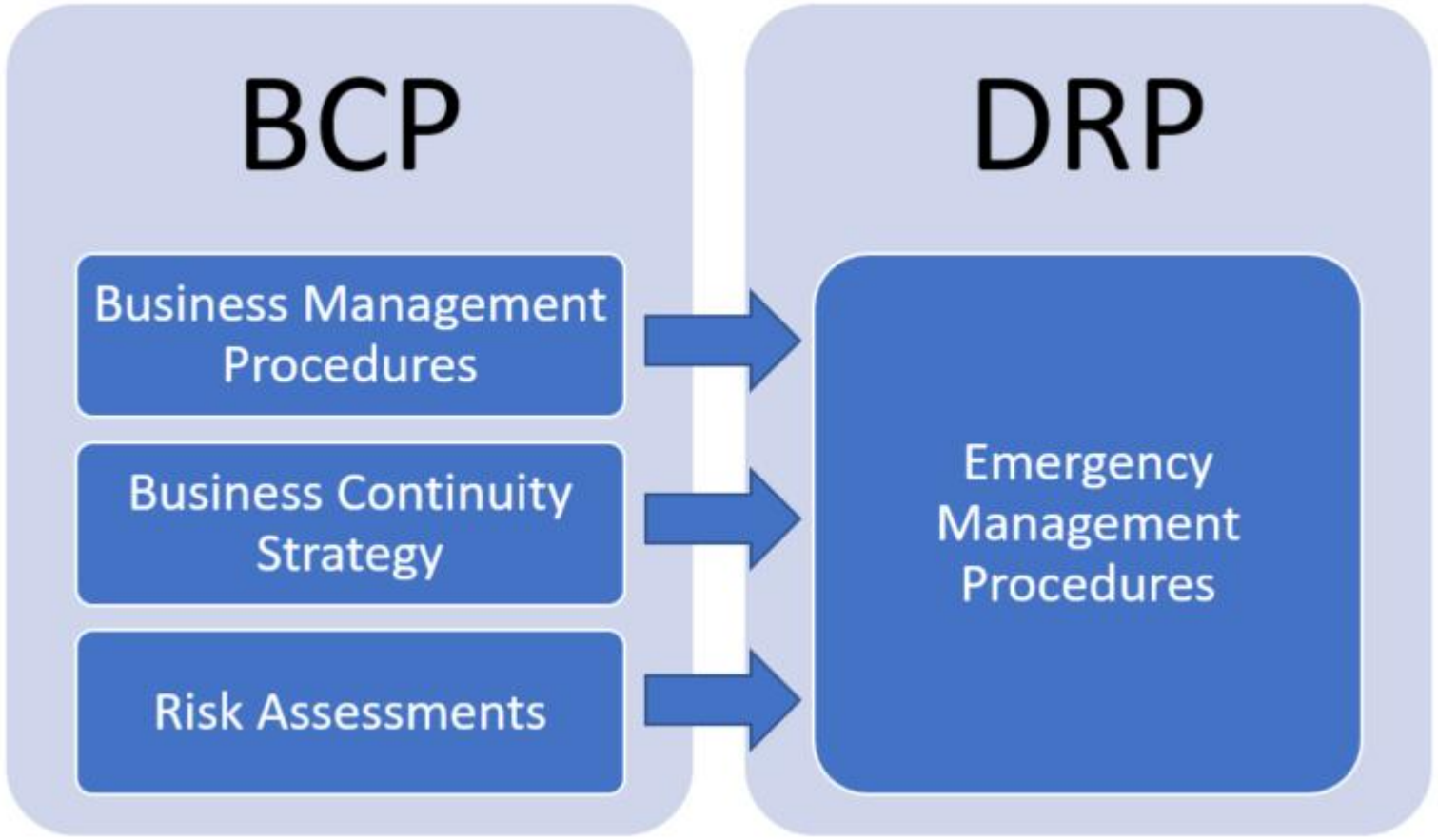
Once risks are identified, laboratories can adopt practical strategies to build resilience and reduce the likelihood of shortages. Such Risk mitigation strategies are:

- Framework contracts and buffer stock policies
- Regional or pooled procurement schemes
- Proactive communication with suppliers
- Demand forecasting tools and historical data analytics
- Diversifying suppliers and sourcing locally when feasible

Emergency Preparedness and Business Continuity Planning

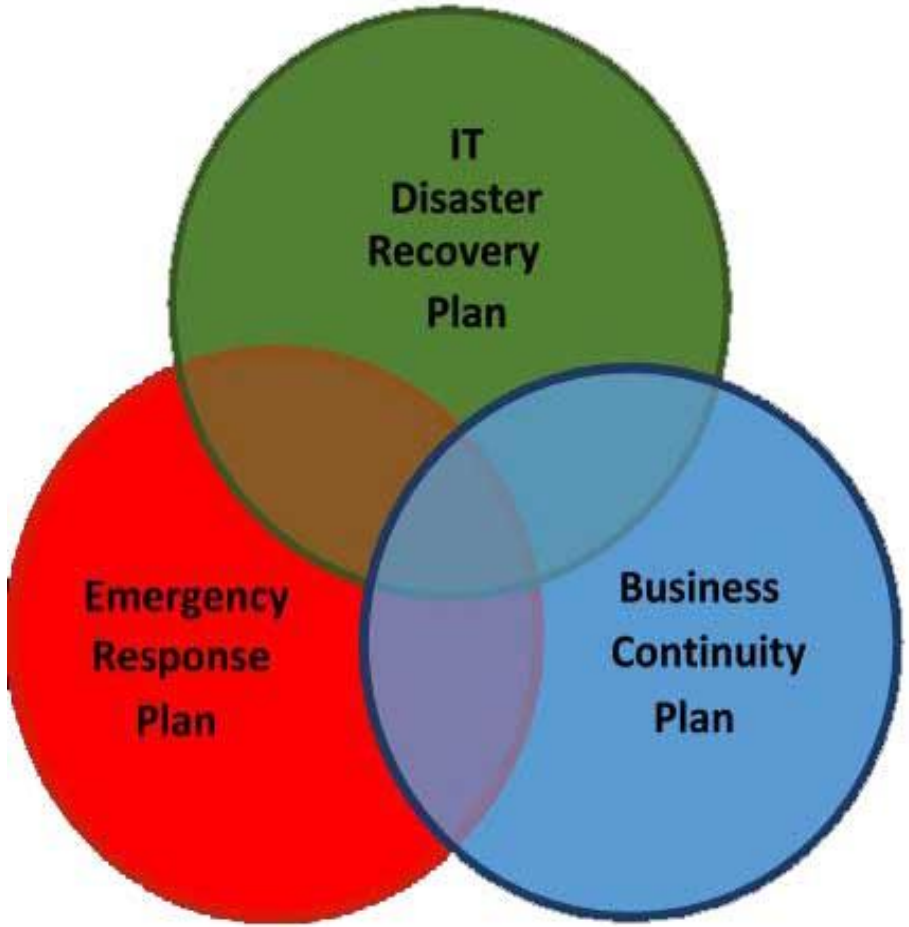
- In line with risk-based thinking, laboratories must establish formal plans to manage unexpected supply disruptions. Such Plans are:
  - –Creating contingency plans for essential reagents and consumables.
  - –Stock rotation and inventory cycling to prevent expiration.
  - –Setting up internal SOPs for emergency requisitions and substitutions

Business Continuity Plans and Disaster Recovery Plan



ISO 15189:2022 Emphasis:

- The ISO 15189:2022 standard explicitly reinforces the need for a robust and risk-based approach to supply chain and inventory management
- It requires laboratories to identify risks that could compromise quality or continuity of service and to establish documented contingency plans for critical supplies and services. This includes both routine and emergency procurement procedures.
- The standard also emphasizes engaging with competent suppliers—those who demonstrate adherence to quality systems (e.g., ISO 13485 or ISO 9001) and have a proven track record of reliability.
- Through these requirements, ISO 15189:2022 aims to ensure that laboratories maintain uninterrupted services and uphold patient safety, even in the face of supply chain challenges.



A case study on management of Reagent Shortages and Mitigation of Supply Chain Disruptions

Scenario:

- A tertiary hospital laboratory experienced a week-long delay in diagnosing tuberculosis due to a shortage of GeneXpert cartridges.
- The delay led to treatment deferrals and increased risk of community transmission.

Questions:

- What proactive steps could have averted this?
- What steps can be taken to avoid a recurrence?

A case study on management of Reagent Shortages and Mitigation of Supply Chain Disruptions –contd:

Discussion:

- If the laboratory had conducted a risk-based supply chain analysis, GeneXpert cartridges would have been identified as critical.
- A buffer stock policy and a contingency plan such as alternate procurement through a pooled procurement group or emergency allocation from another lab could have averted the disruption.
- Regular engagement with the supplier and integration of digital inventory tracking would also have flagged the impending shortage earlier, allowing timely intervention.

Implementing Digital Inventory Tracking for Efficient Resource Utilization – Transitioning from Manual to Digital Systems:

Challenges with Paper-Based Inventory:

- Prone to human errors (e.g., incorrect stock counts, missed entries).
- Delayed updates and lack of real-time visibility, leading to poor decision-making.
- Limited traceability, making audits and investigations more difficult.
- Inconsistent record-keeping can cause stockouts, overstocking, and expired items.

Benefits of Digital Inventory Management:

- Real-time tracking of stock levels, expiry dates, and usage patterns.
- Enhances transparency and accountability across departments.
- Automated alerts for reordering, low stock, or approaching expiries.
- Facilitates data-driven forecasting for procurement and budgeting.
- Improves compliance with ISO 15189:2022, particularly in traceability and documentation.

Impact of Digital Systems:

Digital inventory systems enhance laboratory accountability and resource optimization by empowering laboratories to implement effective mechanisms such as:

- **User Roles and Access Controls:** Assigning user-specific permissions ensures accountability and prevents unauthorized inventory actions.
- **Tracking Waste and Usage Patterns:** Digital logs help identify wastage, monitor usage trends, and support corrective actions.
- **Linking Inventory to Operational Outputs:** Connecting stock data to test volumes enables efficient resource planning and justification.

ISO 15189:2022 Emphasis

Traceability and Real-Time Tracking:

- ISO 15189:2022 requires laboratories to maintain full traceability of reagents and materials from acquisition to disposal, ensuring accountability and quality control.

Stock Management Procedures:

- The standard mandates defined procedures for stock monitoring and replenishment to prevent shortages and maintain uninterrupted testing.

Digital Tools for Accuracy and Efficiency:

- It supports the adoption of digital systems to reduce manual errors, streamline inventory workflows, and enhance overall operational reliability.

Case Scenario – Inventory Waste Due to Overstocking:

Scenario:

- A diagnostic laboratory frequently overorders reagents, resulting in excessive stock that often expires before use.
- This leads to financial losses, inefficient use of storage space, and increased biohazard disposal costs.

Key Problem:

- Lack of real-time inventory data and usage tracking prevents informed procurement decisions.

Guiding Question:

- How can a digital inventory system help prevent overordering and reduce wastage?

Discussion – How Digital Inventory Systems Solve the Problem:

Automated Alerts:

- Notifies users when stock is nearing expiry or when levels exceed defined limits, helping avoid unnecessary reordering.

Consumption Analytics:

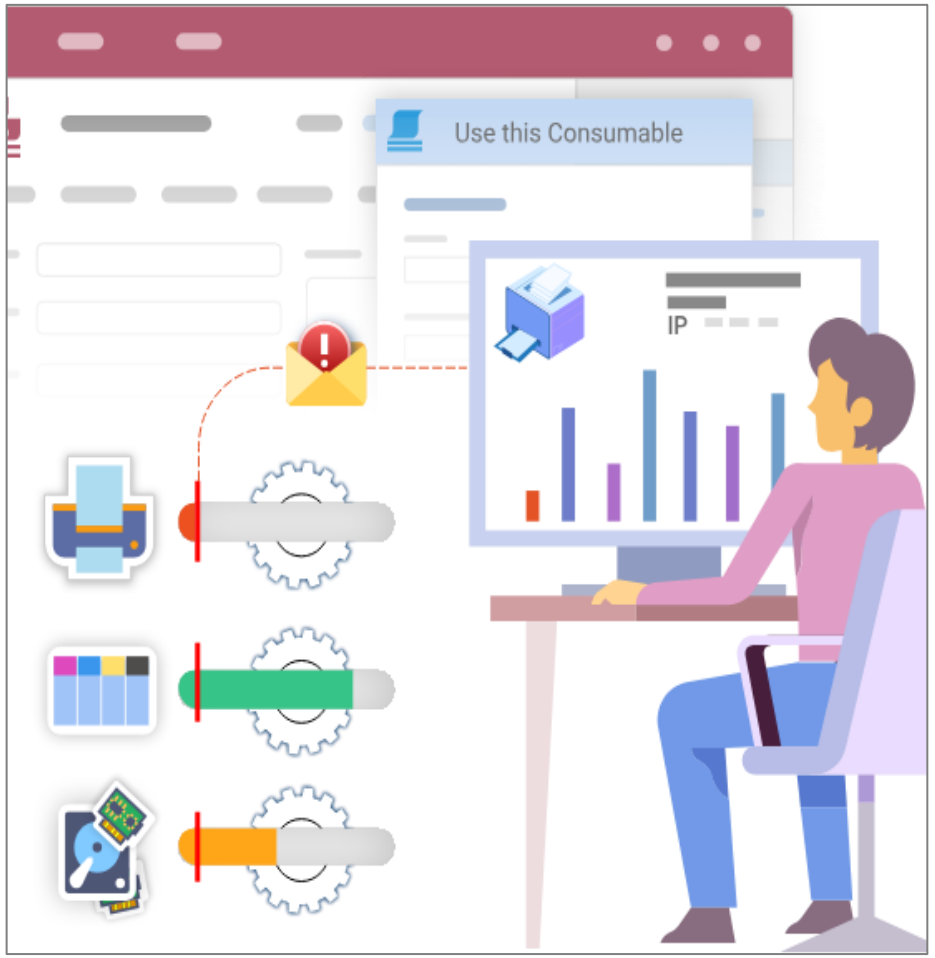
- Tracks usage trends over time, allowing data-driven forecasting and more accurate procurement planning.

Reorder Thresholds:

- System-defined minimum and maximum levels trigger orders only when needed, preventing both under- and overstocking.

Audit Trails:

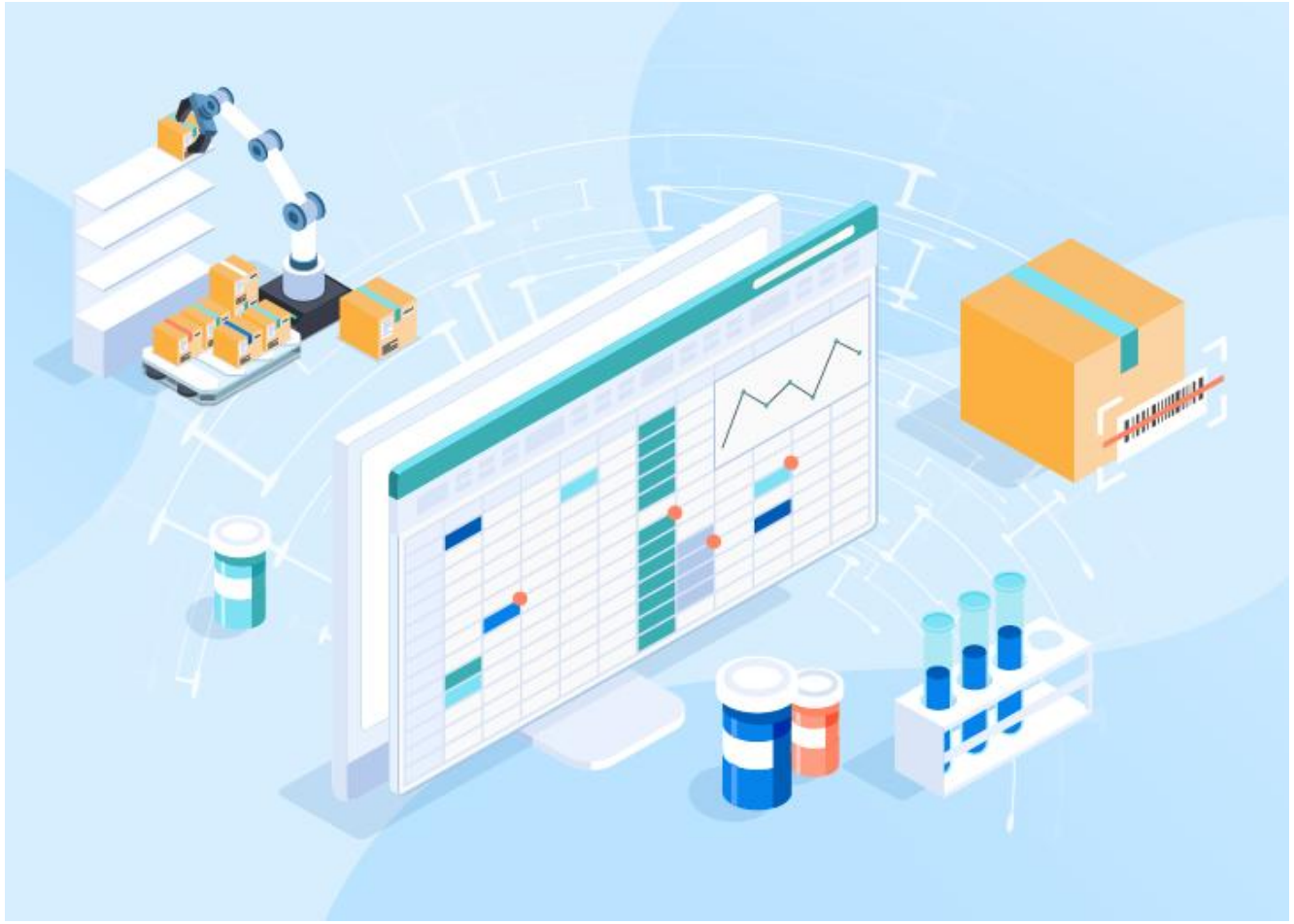
- Maintains a log of all inventory actions (e.g., additions, removals, adjustments) to ensure accountability and identify misuse or mismanagement.



Sustainable Procurement Strategies for Laboratory Cost-Effectiveness and Reliability:

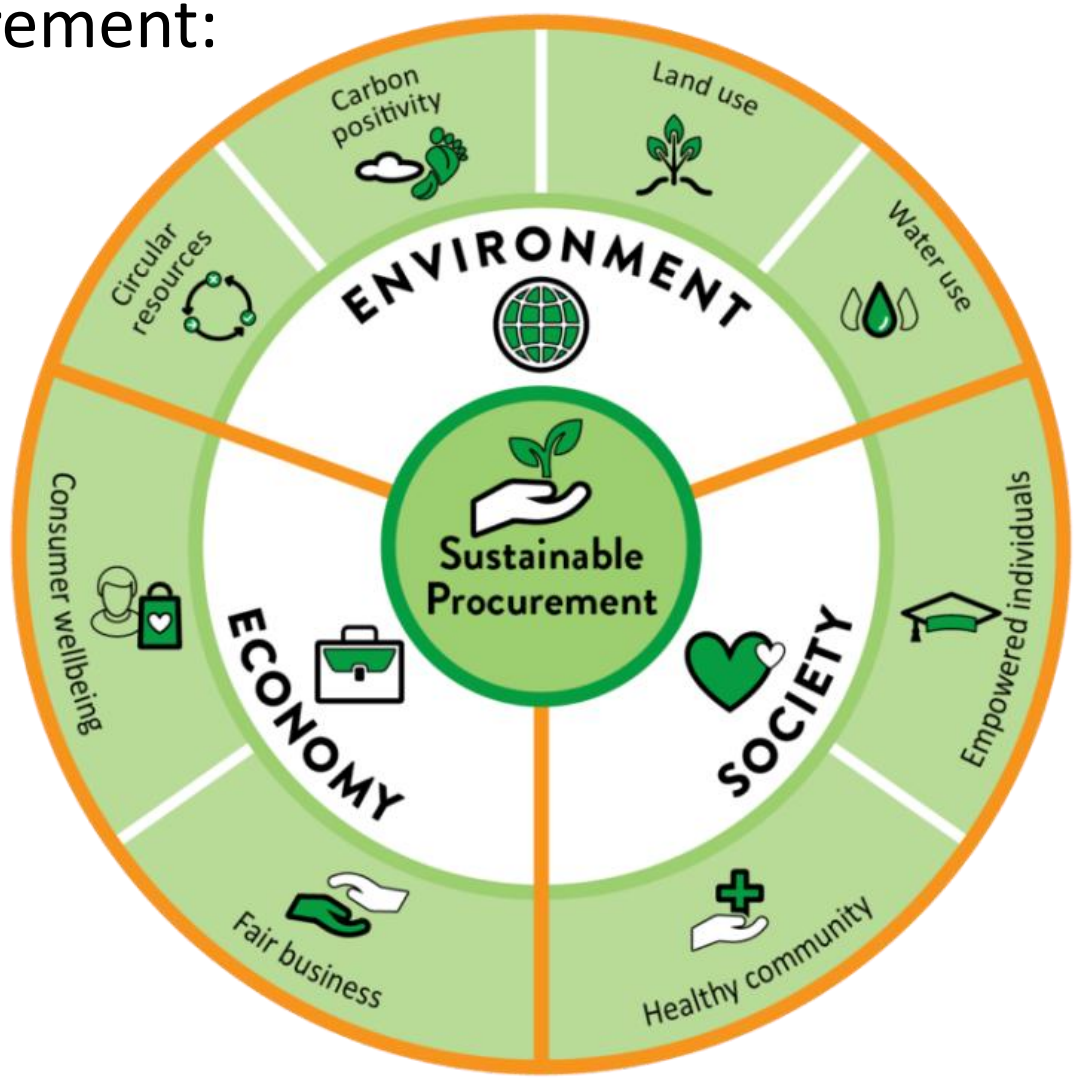
In modern laboratory management, the procurement process is not just a logistical function but a strategic tool for achieving both operational excellence and environmental responsibility

With rising costs, stricter regulations, and global commitments to sustainability, laboratories must evolve their procurement approaches to support long-term viability, reliability, and compliance.



Principles of Green and Sustainable Procurement:

- **Green and sustainable procurement involves making purchasing decisions that consider not just cost and quality, but also environmental, social, and ethical impacts.**
- **This requires laboratories to shift from traditional short-term purchasing to a more holistic, lifecycle-based approach by:**
  - **Prioritizing Environmentally Responsible Suppliers**
  - **Considering Lifecycle Costs**
  - **Reducing Packaging and Promoting Re-usables**

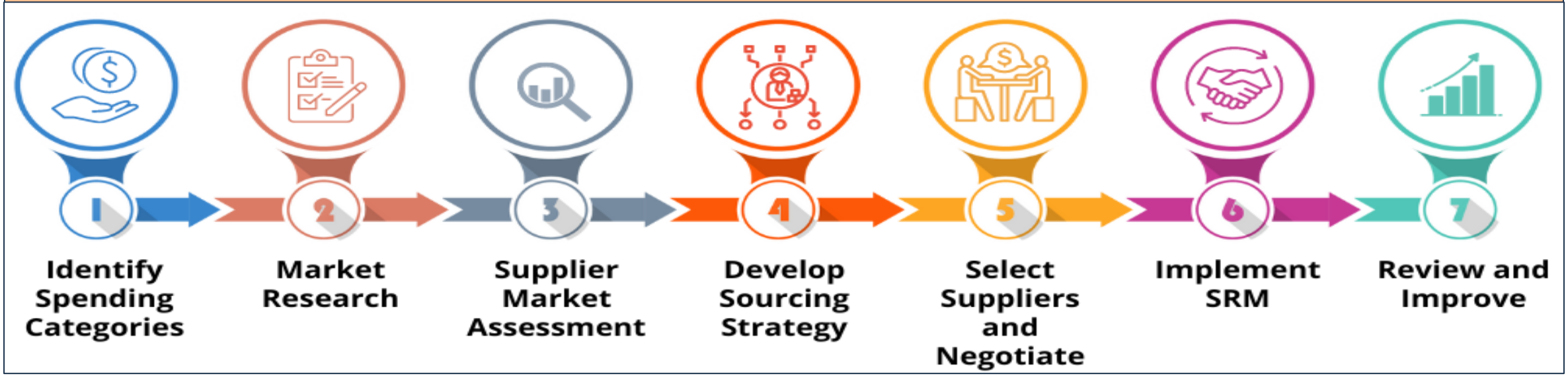


Strategic Sourcing and Vendor Management:

- **Strategic sourcing is the process of planning and managing procurement to ensure long-term supply reliability, quality assurance, and cost control.**
- **Vendor management plays a critical role in achieving consistent service levels and fostering supplier accountability.**
- **This can be achieved through**
  - **Approved Vendor Lists with Performance Monitoring**
  - **Incorporating Quality and Delivery Benchmarks in Contracts**
  - **Supplier Partnerships for Innovation and Value-Added Services**

Strategic Sourcing – 7 steps:

Strategic sourcing is a structured approach to procurement that focuses on optimizing supplier performance, reducing costs, and aligning purchasing decisions with the laboratory's long-term goals. It goes beyond just buying products by emphasizing data-driven decision-making, supplier evaluation, and value creation. The following seven steps outline a systematic process that helps laboratories secure reliable, cost-effective, and high-quality supplies while managing risk and ensuring compliance.



Cost-Effective Procurement Practices:

Cost containment is a priority for laboratories, particularly in settings with limited budgets.

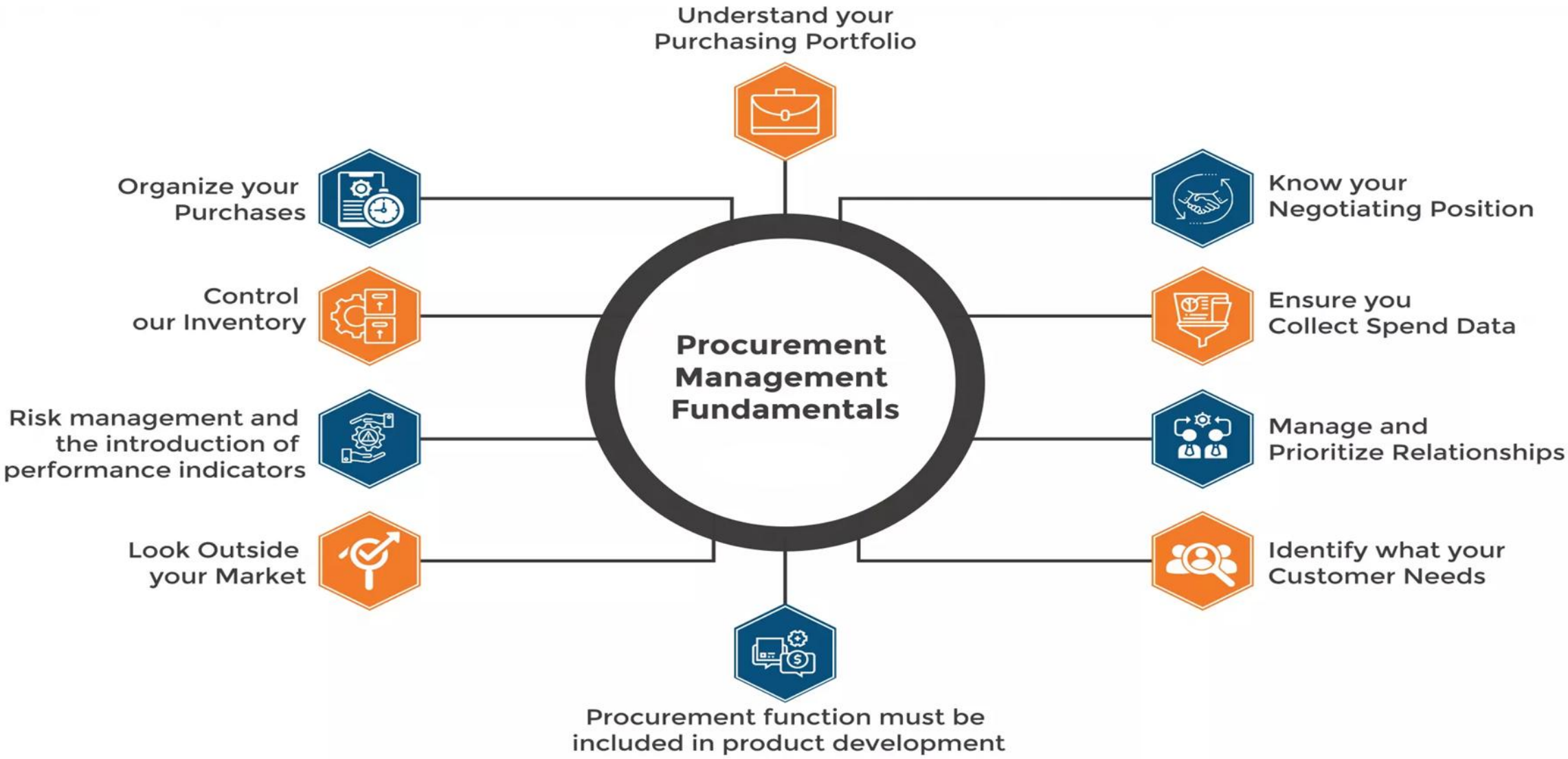
Sustainable procurement does not mean higher expenses—in fact, it can lead to significant cost savings when executed strategically.

Such cost-effective practices include:

- Bulk Purchasing and Framework Agreements
- Centralized Procurement for Multi-Laboratory Networks
- Use of E-Procurement Platforms and Reverse Auctions

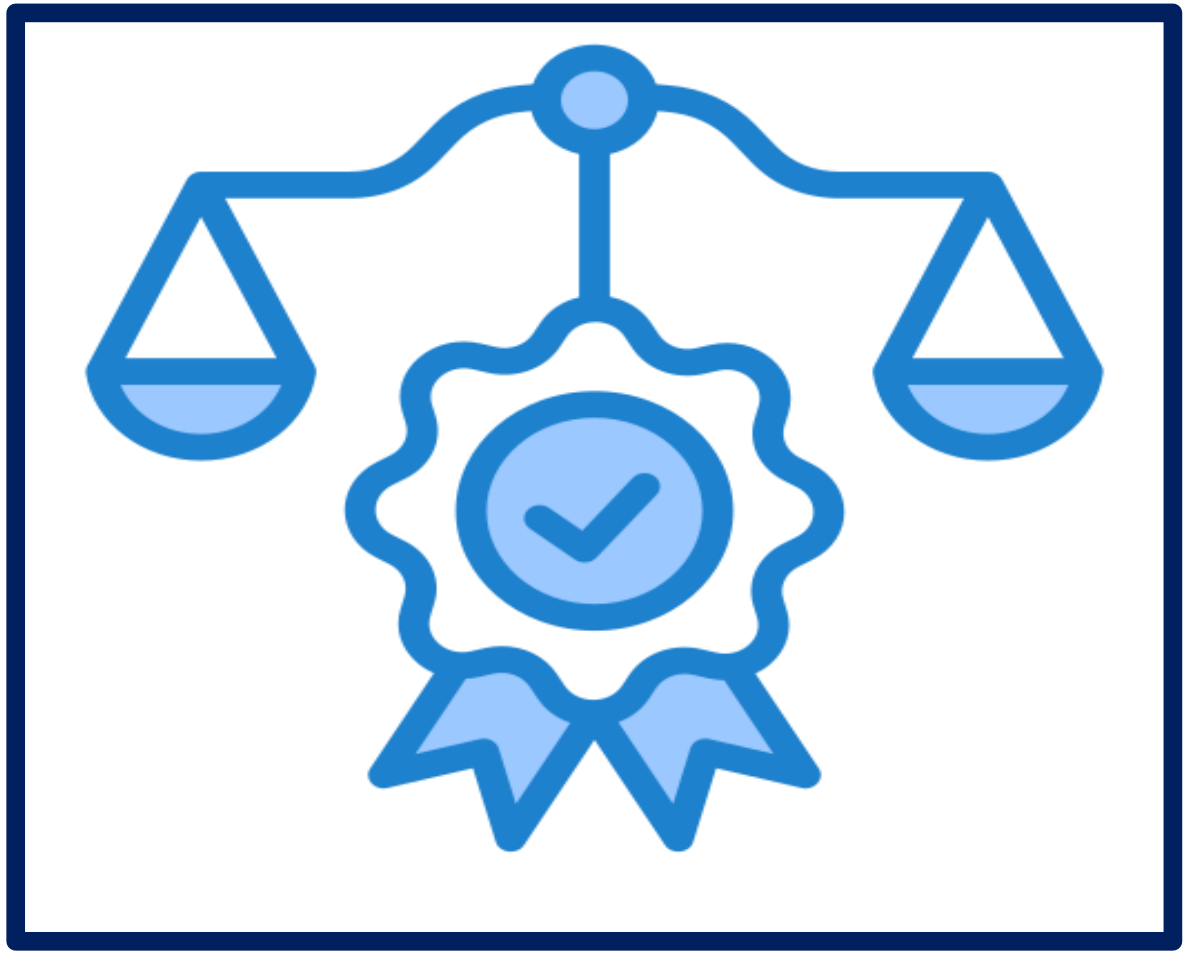
12 Cost Reduction Strategies in Procurement for 2025

1. Supplier Negotiations
2. Sourcing Value
3. Demand Forecasting
4. Savings Analysis
5. E-procurement Solutions
6. Lean Management
7. Value Analysis
8. Supplier Relationship Management
9. Risk Management
10. Optimizing Contracts
11. Green Procurement
12. Continuous Improvement


Understand your Purchasing Portfolio
Organize your Purchases
Control our Inventory
Risk management and the introduction of performance indicators
Look Outside your Market
Procurement Management Fundamentals
Know your Negotiating Position
Ensure you Collect Spend Data
Manage and Prioritize Relationships
Identify what your Customer Needs
Procurement function must be included in product development

Regulatory and Quality Compliance:

- **Procurement must align with international and local standards to ensure safety, traceability, and quality of all materials and equipment entering the laboratory workflow.**
- **This can be achieved by:**
  - **Adherence to Standards (ISO 13485, ISO 9001, GMP)**
  - **Supply Chain Traceability.**
  - **Verification of Ethical Sourcing and Supplier Certifications.**



ISO 15189:2022 Emphasis:

The updated ISO 15189:2022 standard, which sets requirements for quality and competence in medical laboratories, includes several new provisions that align with sustainable procurement principles such as

- Stronger Requirements for Supplier Evaluation and Monitoring
- Encouragement of Environmental Sustainability in Procurement
- Continuous Procurement Performance Review

Case Scenario for Discussion

Scenario:

- Your lab wants to reduce its environmental footprint while cutting costs.
- Discuss how sustainable procurement could meet both goals.

Case Scenario – Discussion:

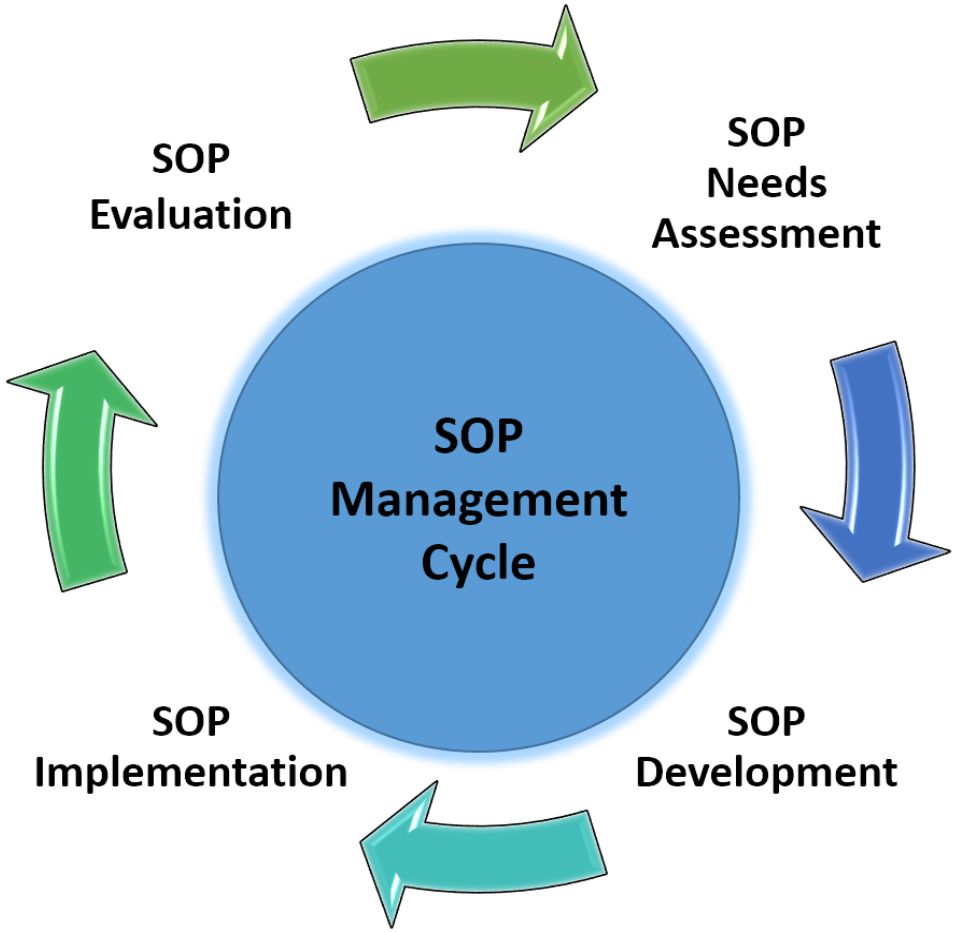
- Sustainable procurement enables laboratories to achieve dual objectives—**cost efficiency** and **environmental responsibility**—without compromising service quality. For example:
- Instead of purchasing single-use plastics, the lab can switch to **refillable buffer solutions**, reducing both waste and repeated purchase costs.
- Implementing **bulk purchasing** agreements for gloves and pipette tips reduces cost per unit and shipping-related emissions.
- By selecting vendors who provide **local delivery options**, the lab can reduce transportation emissions and delivery delays.
- Transitioning to equipment with **energy-saving features** may have a higher upfront cost but will result in long-term savings on electricity bills.
- Using a **digital procurement platform** minimizes paperwork and allows for easier comparison of suppliers based on both cost and environmental attributes.
- Moreover, by tracking procurement KPIs, the lab can quantify the financial and environmental benefits of these changes—such as percentage reduction in waste, annual cost savings, and improved vendor performance.

Integrating Supply Chain Management into the Laboratory Quality Management System (QMS):

- An efficient and resilient laboratory system is supported by a well-structured supply chain integrated into the QMS.
- Integrating supply chain management ensures that lab supplies are available, traceable, and appropriately managed, contributing to patient safety, operational efficiency, and regulatory compliance.
- ISO 15189:2022 and related standards now place significant emphasis on structured procurement, inventory control, and supplier management as essential components of laboratory quality.

Policy Development and Standard Operating Procedures (SOPs):

- **Establishing clear policies and procedures is the first step in institutionalizing supply chain processes within the laboratory QMS.**
- **These documents define how supplies are sourced, managed, and utilized, ensuring consistency, accountability, and compliance with quality and ethical standards.**
- **Such policies and SOPs are:**
  - **Procurement Policy**
  - **Inventory Control SOPs**
  - **Emergency Procurement and Incident Response**



Staff Training and Competence:

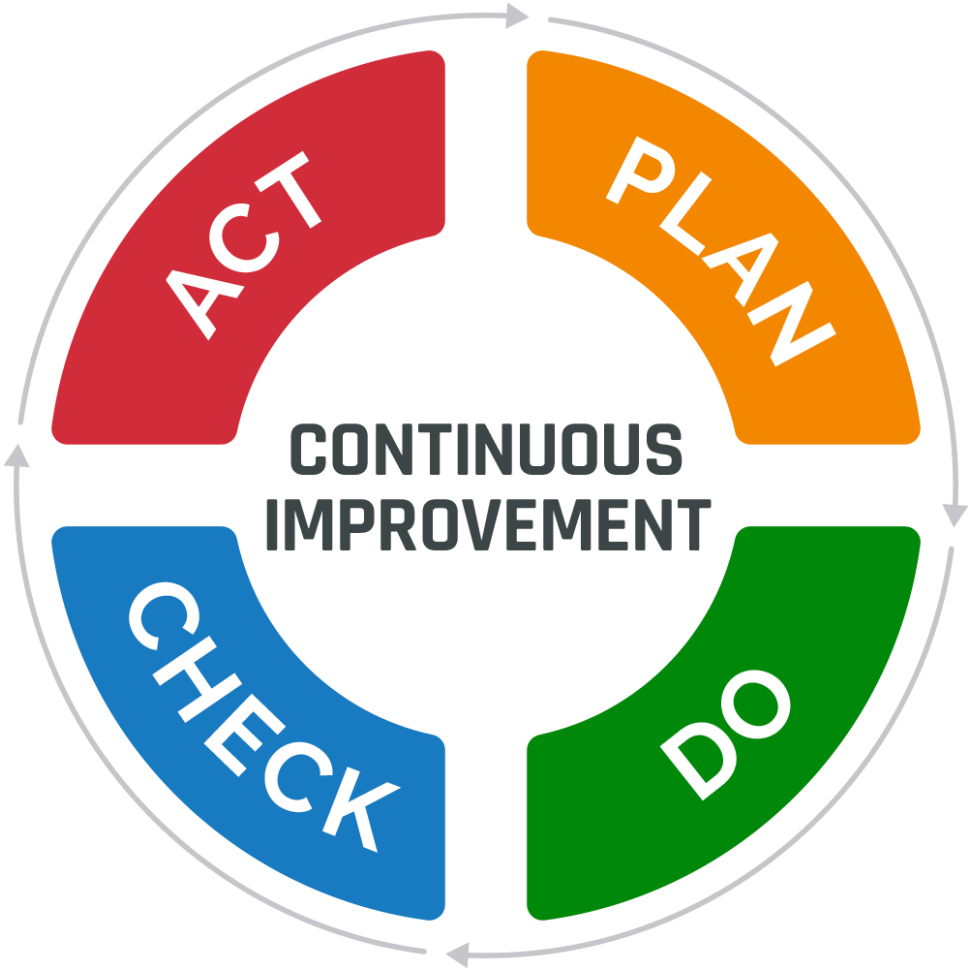
- **Competent staff are critical to maintaining a functional laboratory supply chain.**
- **Training and clearly defined roles ensure that processes are implemented accurately and consistently.**
- **This involves:**
  - **Training on Inventory Systems and SOPs**
  - **Designating Roles and Responsibilities**
    - **Inventory Officers**
    - **Storekeepers**
    - **Procurement Focal Points**
  - **Competence Assessments**

Performance Monitoring and Continuous Improvement:

- **Embedding supply chain performance into the QMS allows for data-driven decision-making and continuous process optimization.**
- **Routine monitoring ensures that bottlenecks are identified and corrected promptly.**
- **Key Performance Indicators (KPIs):**
  - **Stock-out Rates: Frequency of critical items being unavailable when needed.**
  - **Order Turnaround Time: Time from requisition to delivery of supplies.**
  - **Expiry Rates: Percentage of items expired before use—indicative of poor forecasting or overordering.**
  - **Vendor Compliance: Measurement of vendor performance based on delivery time, product quality, and contract adherence.**

Performance Monitoring and Continuous Improvement – contd:

- **Internal Audits and Corrective Actions**
  - Regular audits must include inventory management and procurement practices.
  - Any non-conformities—such as delayed deliveries, inconsistent documentation, or poor storage—must be logged, investigated, and corrected.
  - Audit results should feed into periodic management review meetings.
- **Feedback Loops from End-Users**
  - Clinicians, lab scientists, and quality officers should be encouraged to provide feedback on supply adequacy, product usability, and service responsiveness.
  - This information is valuable for refining vendor selection, procurement schedules, and inventory management practices.



Case Scenario:

Scenario:

- **A regional laboratory network reports frequent delays in testing due to stock-outs of essential reagents.**
- **Internal audits reveal inconsistent procurement timelines and poor coordination between central and satellite labs.**

Question:

- **How can integrating supply chain management into the laboratory's QMS help improve the situation?**

Case Discussion:

- By integrating supply chain management into the laboratory's QMS, several improvements can be introduced:
  - **Policy Standardization:** Develop harmonized SOPs for forecasting, ordering, and inventory tracking across all sites.
  - **Staff Training:** Train focal staff at each location on a unified inventory platform and reinforce adherence to SOPs.
  - **Performance Monitoring:** Introduce monthly KPIs such as stock-out frequency and delivery timelines. Review these metrics at regular quality meetings.
  - **Communication Channels:** Establish real-time communication and feedback loops between central procurement units and satellite labs for proactive issue resolution.

Challenges in Inventory Management in LMIC Laboratories:

- Inadequate or outdated inventory tools (manual or non-integrated systems)
- Lack of trained personnel for inventory control
- Unreliable supply chains and erratic delivery schedules
- Poor forecasting leading to frequent stockouts or wastage
- Limited storage capacity or substandard storage conditions
- Weak linkage between inventory and procurement units

Strategies for Strengthening Inventory Management:

- **Capacity building** of laboratory and logistics personnel on inventory best practices.
- Implementation of **digital inventory systems** (e.g., OpenLMIS, GxP-compliant tools).
- Development of **standard operating procedures (SOPs)** for all inventory activities.
- Regular **inventory audits** and feedback mechanisms for continuous improvement.
- Use of **mobile inventory apps** in remote or decentralized labs.

Conclusion – Key Takeaways:

- Robust supply chain, inventory, and procurement management is vital for laboratory quality, resilience, and sustainability.
- Digital tools, strategic planning, and sustainable procurement must be integrated into QMS for optimal outcomes.
- Continuous review and improvement will support laboratory readiness, cost control, and quality service delivery.

💡 Final Thought! 💡

🔬 ***An optimized supply chain, inventory, and procurement system is not just a logistical function. It is a cornerstone of laboratory quality and resilience.***

By proactively managing shortages, leveraging digital tools, and adopting sustainable sourcing practices, laboratories can ensure uninterrupted service, regulatory compliance, and better patient outcomes, even in the face of uncertainty.

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Thank You

NEXT WEEK (26th May 2025):

Leadership, Governance & Documentation for Effective Laboratory QMS – Dr. Ojo E. (BMLS, MPH, Ph.D, AMLSCN)

- Strengthening leadership and governance to drive quality in laboratory settings
- Best practices for regulatory documentation, compliance, and workflow optimization
- Strategies to streamline document control and ensure adherence to quality standards

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