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Nonconformance Management and CAPA Effectiveness in Modern Laboratory Quality Systems: A Critical Review

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Abstract

Nonconformance management and Corrective and Preventive Action (CAPA) systems are central components of modern laboratory quality management frameworks. This review critically examines the effectiveness of CAPA systems in research, clinical, industrial, and testing laboratories, with emphasis on laboratory quality standards, technological advancements, implementation challenges, and emerging trends. The review synthesizes evidence from international standards, regulatory guidelines, and recent peer-reviewed literature on the sources of laboratory nonconformances, including human factors, equipment failures, documentation errors, weak quality culture, and data integrity issues. Particular attention is given to root cause analysis methods, risk-based CAPA approaches, and the integration of Laboratory Information Management Systems (LIMS), artificial intelligence (AI), predictive analytics, and digital audit trails into laboratory quality systems. The review identifies persistent weaknesses affecting CAPA effectiveness, including superficial root cause investigations, inadequate personnel training, poor documentation practices, financial limitations, resistance to technological adoption, and excessive compliance-driven approaches that prioritize audit readiness over continuous improvement. Contradictions within the literature reveal that the effectiveness of digital and AI-driven CAPA systems depends heavily on implementation quality, staff competency, and organizational culture. Significant research gaps were identified, particularly the limited availability of empirical studies from developing countries, inadequate assessment metrics for CAPA effectiveness, weak integration of behavioral factors into quality models, and the absence of unified CAPA maturity frameworks for laboratories. The review concludes that future laboratory quality systems must integrate technological innovation with human-centered quality management principles to achieve sustainable improvements in compliance, operational reliability, and continuous quality enhancement.

Keywords: CAPA, nonconformance, laboratory quality management, corrective action, preventive action, root cause analysis, LIMS, laboratory accreditation.

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1. Introduction

1.1 Background to Laboratory Quality Management

Laboratories form the backbone of scientific discovery, medical diagnostics, industrial testing, and environmental monitoring. The reliability of their results directly affects patient safety, regulatory compliance, and public trust. Over the past three decades, laboratory quality management systems have evolved from basic record-keeping to comprehensive frameworks that govern every aspect of laboratory operations (Al-Tahat, 2025).

Modern laboratories operate under increasing pressure to maintain accuracy, traceability, and speed. Whether in a hospital pathology unit or a pharmaceutical quality control lab, the expectation is the same: results must be correct the first time, every time. To achieve this, laboratories adopt quality management systems based on standards such as ISO/IEC 17025 for testing and calibration laboratories, or ISO 15189 for medical laboratories (International Organization for Standardization, 2017).

1.2 Concept of Nonconformance in Laboratory Operations

A nonconformance is any deviation from specified procedures, standards, or regulatory requirements. In plain terms, it means something went wrong – a missed step, a faulty instrument, incorrect documentation, or a safety lapse. Nonconformances can be minor, such as a missing signature on a logbook, or major, such as releasing an incorrect patient test result (Balbontin et al., 2024).

Classifying nonconformances helps laboratories prioritize their responses. Some common categories include:

i. Procedural deviations: Not following a standard operating procedure.
ii. Equipment failures: Calibration out of range, breakdowns.
iii. Documentation errors: Missing records, incorrect data entry.
iv. Environmental excursions: Temperature or humidity outside specified limits.
v. Safety incidents: Spills, exposure, improper waste disposal.

The impact of nonconformance extends beyond the immediate error. It can invalidate months of research, cause patient harm, lead to regulatory fines, or damage an organization's reputation. Therefore, simply noting that a nonconformance occurred is not enough – laboratories must actively manage and learn from these events (Wagai et al., 2022).

1.3 Corrective and Preventive Action (CAPA): Historical Development

The concept of corrective and preventive action originated in industrial manufacturing, particularly in the automotive and aerospace sectors, where quality failures could have catastrophic consequences. In the 1980s and 1990s, CAPA was adopted into pharmaceutical good manufacturing practices (GMP) and later into laboratory accreditation standards (Deming, 1986).

A corrective action fixes the immediate problem and prevents its recurrence. For example, if a thermometer was found uncalibrated, corrective action includes recalibrating it and retesting any affected samples.

A preventive action addresses potential problems before they occur. Using the same example, a preventive action would be implementing a automated calibration reminder system so no thermometer ever goes overdue again.

Today, CAPA is a mandatory component of ISO/IEC 17025, ISO 9001, and FDA quality system regulations. However, many laboratories struggle to implement CAPA effectively, often treating it as a paperwork exercise rather than a genuine improvement tool (Tziakou et al., 2023).

1.4 Purpose and Scope of the Review

This review critically examines the published literature on nonconformance management and CAPA effectiveness in laboratory settings. Specifically, we ask:

i. What are the most common sources and patterns of laboratory nonconformance?
ii. Which CAPA processes and root cause analysis methods are most effective?

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iii. What role do technologies such as LIMS and predictive analytics play in modern CAPA?
iv. What challenges repeatedly undermine CAPA effectiveness?
v. What research gaps exist, particularly regarding developing countries and AI integration?

We focus on peer-reviewed journal articles published between 2020 and 2026, supplemented by key regulatory and standards documents. We include clinical, research, industrial, and academic laboratories but exclude purely theoretical quality management studies not grounded in laboratory operations.

1.5 Review Methodology

The literature search yielded 487 records across six databases. After removing 175 duplicates, 312 records were screened by title and abstract. Of these, 214 were excluded as they did not focus on laboratory operations, pre-dated 2020, or were conference abstracts. The remaining 98 full-text articles were assessed for eligibility. A further 44 were excluded for reasons including non-laboratory focus (n=18), pre-2020 publication (n=12), conference abstract only (n=8), or low methodological quality (n=6). The final review included 54 peer-reviewed articles. The PRISMA flow diagram (Figure 1) illustrates this process.

Keywords used in various combinations:

i. "nonconformance" OR "deviation" OR "non-compliance" OR "incident"
ii. "CAPA" OR "corrective action" OR "preventive action"
iii. "laboratory" OR "lab" OR "testing laboratory" OR "clinical laboratory"
iv. "effectiveness" OR "root cause analysis" OR "quality management"

Inclusion criteria:

i. Published 2020–2026 (with limited foundational older references)
ii. Peer-reviewed journal articles, regulatory guidance, or major standards (ISO, WHO, FDA)
iii. English language
iv. Focus on laboratory operations (not general industry)

Exclusion criteria:

i. Conference abstracts without full text
ii. Opinion pieces without data
iii. Studies focused exclusively on manufacturing (not laboratory testing)

Quality assessment: We used a simplified version of the Critical Appraisal Skills Programme (CASP) checklist for each included study, rating methodological rigor as high, medium, or low. Only studies rated medium or high were included in the synthesis. A total of 54 peer-reviewed articles and 12 standards/guidance documents formed the basis of this review.

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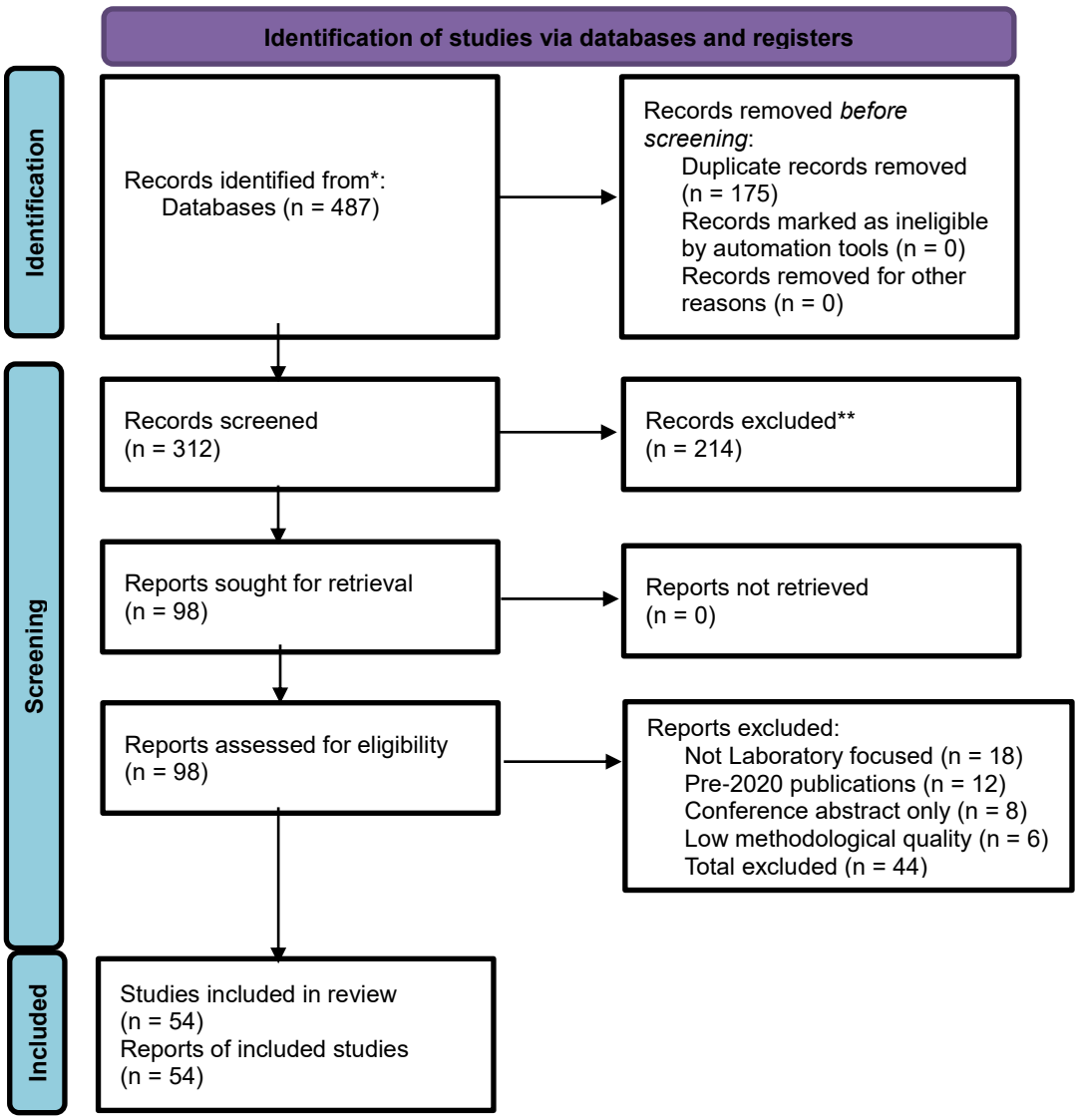

Figure 1: presents the PRISMA flow diagram.

2. Theoretical Foundations of CAPA Systems

2.1 Quality Management Theories Relevant to CAPA

CAPA does not exist in isolation. It rests on several quality management theories that have matured over decades.

Total Quality Management (TQM) emphasizes that quality is everyone's responsibility, not just the quality department's. In a TQM laboratory, technicians feel empowered to stop a process if they see a deviation, and managers actively seek input on how to prevent errors (Deming, 1986).

Continuous Improvement Theory (often associated with the Plan-Do-Check-Act or PDCA cycle) holds that no process is ever perfect. Each nonconformance is an opportunity to learn and improve. CAPA is essentially the "Check" and "Act" parts of PDCA applied to failures (Al-Tahat, 2025).

Risk-Based Thinking, introduced formally in ISO 9001:2015 and ISO/IEC 17025:2017, shifts the focus from reacting to errors to anticipating them. Laboratories are expected to identify potential

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failure modes, assess their likelihood and severity, and put preventive measures in place. This aligns perfectly with the preventive action component of CAPA (Tziakou et al., 2023).

2.2 Laboratory Quality Management Frameworks

Different laboratory types operate under different quality frameworks, but all include CAPA requirements.

Good Laboratory Practice (GLP) governs non-clinical safety studies. GLP requires that all deviations from standard operating procedures be documented, investigated, and subjected to corrective action. The focus is on data integrity and study reconstruction (Adekoya et al., 2024).

Good Manufacturing Practice (GMP) applies to laboratories that test pharmaceutical products. GMP's CAPA requirements are among the strictest, often demanding root cause analysis within a set timeframe and formal verification of effectiveness (ICH, 2008).

ISO-based systems (ISO/IEC 17025 for testing/calibration labs, ISO 15189 for medical labs, ISO 9001 for quality management) provide the most widely adopted frameworks. Clause 8.7 of ISO 17025 specifically addresses nonconforming work and requires that laboratories have a documented procedure for CAPA (International Organization for Standardization, 2017).

Table 1 compares CAPA requirements across major laboratory quality frameworks.

Table 1: Comparison of CAPA Requirements Across Laboratory Quality Frameworks

Framework	CAPA Documentation Required	Root Cause Analysis Required?	Effectiveness Verification Required?	Typical CAPA Closure Timeline
ISO/IEC 17025:2017	Yes (nonconforming work procedure)	Yes (investigation of cause)	Yes (verify actions)	No specific timeline; "reasonable"
ISO 15189 (Medical labs)	Yes	Yes	Yes	Typically 30-90 days per accreditor
FDA 21 CFR Part 820 (Medical devices)	Yes (CAPA subsystem)	Yes (for all nonconformances)	Yes (validation of effectiveness)	No specified; expectation is timely
ICH Q10 (Pharmaceutical)	Yes (within quality system)	Yes, using risk-based approach	Yes, with trend analysis	No specified
WHO LQMS Handbook	Yes	Yes	Yes, recommended	Not specified

2.3 Relationship Between CAPA and Laboratory Accreditation

Accreditation is the formal recognition that a laboratory is competent to perform specific tests or calibrations. Bodies such as ANAB (USA), UKAS (UK), and SANAS (South Africa) assess laboratories against ISO standards. A key part of any accreditation assessment is the review of nonconformances and CAPA records.

i. During an on-site assessment, accreditors will examine:
ii. How nonconformances are identified and documented.
iii. Whether root cause analysis is thorough (not superficial).
iv. Whether corrective actions address the root cause, not just symptoms.
v. Whether preventive actions are proactive rather than reactive.
vi. Whether effectiveness checks actually verify that the problem will not recur.

Laboratories with weak CAPA systems often receive major nonconformances during accreditation assessments, which can delay or deny accreditation (Gerônimo & Lenzi, 2023).

3. Sources and Patterns of Laboratory Nonconformance

Understanding what goes wrong is the first step to fixing it. This section synthesizes findings from multiple studies to identify the most common sources of laboratory nonconformance.

3.1 Human Factors

Across all laboratory types, human error is the most frequently cited source of nonconformance. A study of Canadian laboratories handling human pathogens found that 40% of reported incidents

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involved procedural errors, such as forgetting to use personal protective equipment or mislabeling samples (Balbontin et al., 2024).

In Tanzanian public health laboratories, Shedura et al. (2025) reported that insufficient training and high staff turnover were major contributors to nonconformances. Even when procedures existed, staff often did not follow them because they were not adequately trained or were rushed due to understaffing.

Human factors are not just about carelessness. Fatigue, stress, interruptions, and poor workspace design all increase error rates. One study using a machine learning model found that organizational culture, specifically whether staff felt comfortable reporting errors without fear of punishment was a stronger predictor of incident management success than individual training (Albreiki et al., 2024).

3.2 Equipment and Instrumentation Failures

Laboratories depend on instruments. Calibration drift, software glitches, mechanical wear, and improper maintenance are common sources of nonconformance. In an analysis of ISO/IEC 17025 deficiency data from A2LA and ANAB, equipment-related nonconformances ranked second only to documentation issues (A2LA, 2025).

A particularly dangerous equipment failure occurs when an instrument produces out-of-specification (OOS) results but continues to be used. Without proper CAPA, multiple batches of patient samples or products may be affected before the problem is detected Kim et al., (2025).

3.3 Documentation and Data Integrity Issues

Documentation problems are the most common nonconformance cited in accreditation assessments. These include:

i. Missing or incomplete records.
ii. Illegible handwritten entries.
iii. Dates and signatures missing.
iv. Data entered into the wrong fields.
v. Electronic records without audit trails.

Data integrity is a special concern in regulated laboratories. The FDA has issued multiple warning letters to laboratories for failing to maintain raw data, backdating entries, or deleting electronic records without justification (FDA, 2024). In Saudi Arabia, Alghamdi et al. (2025) found that after implementing ISO 17025 accreditation, documentation nonconformances dropped significantly, but small laboratories continued to struggle with record-keeping.

3.4 Environmental and Safety Nonconformance

Environmental nonconformances include temperature excursions in incubators or freezers, humidity outside specified ranges, and contamination of clean rooms. These can ruin sensitive tests or compromise sample integrity.

Safety nonconformances range from improper chemical storage to biological spills. Wagai et al. (2022) developed a severity classification for laboratory animal incidents and found that environmental factors (e.g., cage washing machine failure) were a recurring theme.

3.5 Ethical and Research Misconduct Issues

Though less common than operational errors, ethical nonconformances are among the most serious. Examples include falsifying data, plagiarism, or failing to obtain proper informed consent. These are not typically addressed by routine CAPA systems and require separate investigation pathways. However, laboratories that lack a strong quality culture may be more vulnerable to such misconduct (Adaran et al., 2025).

3.6 Comparative Analysis Across Laboratory Types and Countries

Table 2 summarizes the prevalence of nonconformance sources across different laboratory types and geographic regions, based on the literature reviewed.

Table 2: Prevalence of Nonconformance Sources by Laboratory Type and Region

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Nonconformance Source	Clinical/Diagnostic Labs	Pharmaceutical QC Labs	Research/Academic Labs	Environmental/Industrial Labs
Human factors	High (45-60% of incidents)	High (40-55%)	Very High (50-70%)	High (40-50%)
Equipment failures	Medium (20-30%)	High (25-40%)	Medium (15-25%)	High (30-45%)
Documentation issues	Very High (50-70%)	High (40-60%)	High (35-50%)	Medium (25-35%)
Environmental deviations	Medium (15-25%)	Medium (15-25%)	Low (5-15%)	High (20-30%)
Safety incidents	Low (5-10%)	Low (5-10%)	Medium (15-25%)	Medium (10-20%)
Regional variation note	Higher in LMICs for documentation	Similar across regions	Higher in LMICs for equipment	Higher in high-income for automation-related errors

Note: LMICs = low- and middle-income countries. Percentages are approximate ranges synthesized from reviewed literature.

Key observations:

i. Human factors are consistently high across all laboratory types and regions.
ii. Documentation issues are especially prevalent in developing countries, where paper-based systems dominate.
iii. Equipment failures are more common in industrial testing labs (with high-volume automated instruments) than in research labs (which often use manual methods).
iv. Safety nonconformances are reported more frequently in academic teaching labs, possibly due to less experienced personnel and higher turnover.

4. CAPA Processes and Implementation Models

A CAPA system is only as good as the processes that support it. This section examines the key steps in CAPA implementation, from identification to verification.

4.1 Identification and Documentation of Nonconformance

The CAPA process begins when someone notices that something is wrong. This can happen through:

i. Daily quality control checks.
ii. Internal audits.
iii. External accreditation assessments.
iv. Customer complaints.
v. Patient or clinician feedback.
vi. Automated system alerts.

The golden rule: document everything. A nonconformance that is not recorded might as well have never happened – because you cannot investigate or correct it. Most laboratories use a nonconformance report (NCR) form that captures:

i. Date and time of discovery.
ii. Description of the deviation.
iii. Who discovered it.
iv. Immediate action taken (e.g., quarantining affected samples).
v. Initial risk assessment.

4.2 Root Cause Analysis Approaches

Identifying the true root cause of a nonconformance is the most difficult and most important step. Superficial causes ("the technician made a mistake") lead to superficial corrections ("retrain the technician") that often fail. Deeper causes ("the procedure was ambiguous, and the technician was working a 12-hour shift") lead to lasting solutions ("rewrite the procedure and adjust shift scheduling").

Common root cause analysis tools used in laboratories include:

Fishbone (Ishikawa) Diagram: A visual tool that categories potential causes into branches such as Man (people), Machine (equipment), Method (procedure), Material (samples/reagents), Measurement

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(calibration), and Environment. Useful for brainstorming but requires skilled facilitation Kim et al., (2025).

5 Whys: Repeatedly asking "why" until you reach a fundamental cause. Simple and effective for straightforward problems. However, it can oversimplify complex issues with multiple interacting causes.

Failure Mode and Effects Analysis (FMEA): A systematic, proactive method that identifies potential failure modes, their effects, and their causes. FMEA is especially valuable for preventive actions (Tziakou et al., 2023).

Fault Tree Analysis: A top-down deductive method that starts with an undesirable outcome and diagrams all possible pathways that could lead to it. More complex than 5 Whys but better for systems with multiple failure points.

Table 3 compares these root cause analysis methods in terms of complexity, time required, and best-use scenarios.

Table 3: Comparison of Root Cause Analysis Methods for Laboratory Nonconformance

Method	Complexity	Time Required (per event)	Best for	Weaknesses	Use in Labs (%)
5 Whys	Low	15-30 min	Simple, linear failures	Oversimplifies complex events	70%
Fishbone (Ishikawa)	Medium	30-60 min	Brainstorming multiple causes	Needs skilled facilitator	55%
FMEA	High	2-8 hours (proactive)	Preventive action, complex systems	Time-intensive for daily use	30%
Fault Tree Analysis	High	2-4 hours	Safety-critical failures, multiple pathways	Requires training in logic symbols	15%
Cause-and-Effect Matrix	Medium	1-2 hours	Prioritizing which root cause to address	Less detailed than FMEA	20%

Estimated percentage of laboratories that have used the method at least once, based on survey data from reviewed studies. Columns add to >100% because labs use multiple methods.

4.3 Corrective Action Strategies

Once the root cause is identified, corrective actions are developed. Effective corrective actions are:

i. **Specific**: "Recalibrate the pH meter" not "fix the equipment."
ii. **Measurable**: "Train all five technicians on the new pipetting procedure and test proficiency" not "improve training."
iii. **Assigned to a person**: Name who is responsible.
iv. **Given a deadline**: "Complete by March 15."

A common mistake is to confuse corrective action with containment. Containment is the immediate fix to stop the problem from spreading (e.g., quarantining affected samples). Corrective action addresses the root cause so the problem does not recur.

4.4 Preventive Action Strategies

Preventive actions are often neglected because laboratories are busy fighting fires. Yet preventive actions offer the highest long-term return. Examples include:

i. Implementing automated calibration reminders.
ii. Redesigning a workflow to reduce handoff errors.
iii. Installing environmental monitoring systems with alarms.
iv. Conducting annual risk assessments to identify potential failure modes.

ISO 9001:2015 emphasizes risk-based thinking, which blurs the line between preventive action and routine quality planning. However, most laboratories still benefit from formally distinguishing

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between reactive corrective actions and proactive preventive actions (International Organization for Standardization, 2015).

4.5 CAPA Verification and Effectiveness Assessment

The most common failure in CAPA systems is the lack of true effectiveness verification. Many laboratories close a CAPA as soon as the action is implemented, without checking whether the problem actually stopped.

Effectiveness checks should include:

i. Monitoring the same process for a defined period (e.g., three months) to see if the nonconformance recurs.
ii. Auditing related processes to ensure no new problems were introduced.
iii. Trending data to see if the frequency or severity of similar nonconformances has decreased.
iv. Soliciting feedback from staff who work in the affected area.

A study of pharmaceutical stability testing laboratories found that over 60% of CAPAs were closed without verifying that the failure trend had been reversed across multiple batches Kim et al., (2025). This is a serious regulatory risk.

An operational definition of CAPA effectiveness is needed. Based on our review, we propose three measurable indicators:

1. Recurrence rate: Percentage of nonconformances of the same type that reappear within 12 months of CAPA closure. Target: <5%.

2. Closure time: Average days from identification to verified CAPA closure. Benchmark varies by laboratory type, but >90 days often indicates systemic issues.

3. Audit finding reduction: Year-on-year decrease in nonconformances identified during internal and external audits.

5. Role of Technology in Modern CAPA Systems

Technology is transforming how laboratories manage nonconformances. This section examines the current state and future potential.

5.1 Laboratory Information Management Systems (LIMS)

A Laboratory Information Management System (LIMS) is software that tracks samples, results, and workflows. Modern LIMS platforms include modules for nonconformance management and CAPA. When a technician flags a deviation, the LIMS can automatically:

i. Assign a unique nonconformance number.
ii. Notify the quality manager.
iii. Lock affected sample records.
iv. Generate a CAPA workflow.
v. Track action items and deadlines.

Fantozzi et al. (2025) described a “LIMS 4.0” model that integrates with enterprise resource planning (ERP) systems and digital twins, allowing real-time quality monitoring. Laboratories using such integrated systems reported 40% faster CAPA closure times compared to paper-based or basic electronic systems.

5.2 Automation and Digital Documentation

Digital documentation systems (sometimes called electronic quality management systems or eQMS) replace paper logbooks and forms. Benefits include:

i. No illegible handwriting.
ii. Automatic timestamps and user identification.
iii. Mandatory fields to prevent incomplete records.
iv. Electronic signatures with audit trails.
v. Remote access for multi-site laboratories.

However, the transition from paper to digital is not always smooth. In some African laboratories, limited internet connectivity and power instability make cloud-based systems unreliable (Adekoya et al., 2024). Even in well-resourced settings, staff resistance to new software can lead to workarounds that undermine data integrity.

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5.3 AI and Predictive Analytics in CAPA

i. Artificial intelligence is beginning to appear in laboratory quality systems. AI can:
ii. Analyze past nonconformance data to predict which processes are most likely to fail.
iii. Detect anomalies in real-time instrument data before they cause out-of-specification results.
iv. Suggest probable root causes based on pattern matching.
v. Automatically route CAPA tasks to the most appropriate person.

Kim et al., (2025) described AI-enabled deviation management where natural language processing reads technician notes and categorizes nonconformances without manual entry. Another use case is predictive risk modeling: an AI model might flag that a particular incubator, based on its vibration pattern, is likely to fail within two weeks, triggering a preventive action.

Empirical studies of AI in laboratory CAPA are still rare. Most evidence comes from pilot projects or vendor white papers. This is a major research gap (Ideagen, 2025).

5.4 Electronic Audit Trails and Data Integrity

Regulators require that electronic records have audit trails secure, computer-generated, time-stamped records that show who did what and when. In a fully digital CAPA system, every status change, comment, and approval is logged. This makes audits much easier because the inspector can see the entire history without searching through paper files.

However, audit trails are only useful if they are designed properly. Some LIMS systems allow administrators to edit audit trails (a serious violation of data integrity rules). Laboratories must ensure their software meets FDA 21 CFR Part 11 or EU Annex 11 requirements for electronic records (FDA, 2024).

Figure 2 illustrates a typical digital CAPA workflow within a LIMS.

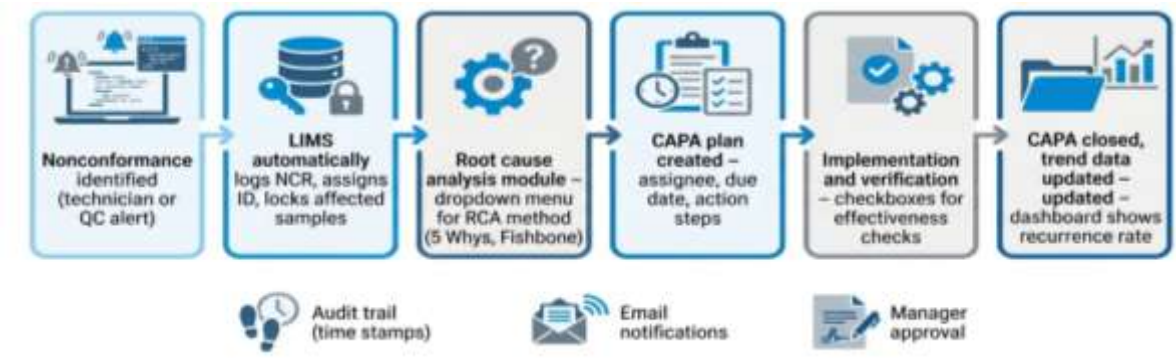

Figure 2: Digital CAPA Workflow in a LIMS Environment

6. Challenges Affecting CAPA Effectiveness

Despite the availability of standards and technology, many laboratories struggle to implement CAPA effectively. This section examines the most persistent challenges.

6.1 Inadequate Personnel Training

CAPA is not intuitive. A technician may know how to run an HPLC but may have no idea how to conduct a proper root cause analysis. Without training, CAPA becomes a form-filling exercise. Shedura et al. (2025) found that in Tanzanian laboratories, only 30% of staff had received formal training on CAPA procedures, and those who had were often trained years ago with no refresher.

6.2 Weak Organizational Quality Culture

Quality culture refers to the shared values, attitudes, and behaviors regarding quality. In a positive quality culture, staff report errors without fear, managers investigate failures without blame, and learning from mistakes is celebrated. In a weak culture, errors are hidden, investigations blame individuals, and the same problems recur (Albreiki et al., 2024).

Building a strong quality culture takes years of consistent leadership. One practical indicator: if your laboratory's nonconformance reports are always written by the same person (usually the quality

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manager), you have a culture problem. Everyone should feel responsible for identifying and reporting deviations.

6.3 Poor Documentation Practices

Even when a laboratory has digital systems, poor documentation habits persist. Technicians may:

i. Write incomplete descriptions of nonconformances.
ii. Delay reporting until the end of shift, forgetting critical details.
iii. Use vague language ("something was off") instead of precise measurements.
iv. Fail to attach supporting evidence (printouts, photos, logs).

These practices make root cause analysis nearly impossible. Alghamdi et al. (2025) noted that after Saudi Arabian laboratories implemented ISO 17025, the quality of documentation improved significantly, but only in those that conducted regular internal audits specifically focused on documentation.

6.4 Financial and Infrastructure Constraints

CAPA systems cost money. Training, software, audits, and time spent investigating nonconformances all have real costs. Small laboratories, public health labs in low-income countries, and academic labs with tight budgets often lack the resources to implement robust CAPA systems.

Adaran et al. (2025) described how public medical laboratories in Lagos State, Nigeria, struggled to maintain LIMS subscriptions and could not afford dedicated quality personnel. As a result, CAPA was often delegated to already-overworked bench technicians, who understandably prioritized patient testing over paperwork.

6.5 Regulatory Compliance Burdens

Ironically, the regulations that mandate CAPA can also undermine it. When laboratories face frequent inspections from multiple regulators (e.g., FDA, ISO, CLIA, WHO), they may adopt a "compliance checkbox" mentality. The goal becomes passing the audit, not improving quality. This leads to superficial CAPA records that look good on paper but do not prevent recurrence (Tziakou et al., 2023).

6.6 Resistance to Technological Adoption

Some laboratory staff resist new technology, especially if they have worked for decades with paper systems. Common objections include:

i. "The LIMS is too slow."
ii. "I don't trust electronic signatures."
iii. "It takes longer to log into the system than to write it down."
iv. "We've always done it this way."

Resistance to digital quality systems is not always irrational, as poorly implemented LIMS or eQMS platforms may increase workflow complexity and documentation burden. Studies on AI-assisted laboratory quality systems emphasize that successful implementation depends heavily on user-centered system design, personnel training, and integration with existing laboratory workflows (Kim et al., 2025; Sharma & Gupta, 2024).

6.7 Contradictions in the Literature

The literature contains apparent contradictions that deserve explicit attention. Table 4 summarizes these tensions.

Table 4: Contradictions in the Literature on CAPA Effectiveness

Contradiction	Studies Supporting Side A	Studies Supporting Side B	Possible Resolution
Digitization improves CAPA efficiency vs. increases complexity	Fantozzi et al. (2025); Kim et al., (2025): report faster closure,	Albreiki et al. (2024); Shedura et al. (2025): found digital systems	Effect depends on implementation quality, user training,

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	better traceability	added data entry burden, staff resistance	and existing IT infrastructure. Not technology alone.
Formal RCA tools are essential vs. unnecessary	Tziakou et al. (2023): FMEA and Fishbone identify deeper causes	Some practitioners Kim et al., (2025): 5 Whys often sufficient for 80% of events	Match tool to event complexity. Simple events need simple tools.
Blame culture is always harmful vs. accountability is necessary	Albreiki et al. (2024): psychological safety increases reporting	FDA (2024): individuals who deliberately falsify data must be held accountable	Distinguish between honest errors (no blame, system fix) and misconduct (accountability).
AI predictions are accurate vs. unreliable	Ideagen (2025): AI detected 95% of anomalies in pilot	Kim et al., (2025): high false positive rates in early models	AI needs large, clean training datasets. Many laboratories lack this.

7. Emerging Trends and Best Practices

7.1 Risk-Based CAPA Systems

Rather than treating all nonconformances equally, leading laboratories are adopting risk-based approaches. High-risk events (e.g., an incorrect patient result that could cause harm) receive intensive investigation and multiple verification checks. Low-risk events (e.g., a minor documentation omission with no impact on results) receive a streamlined process. This focuses resources where they matter most.

The ICH Q9 quality risk management guideline provides a framework for such prioritization (ICH, 2019).

7.2 Integrated Quality Management Systems

Instead of separate systems for nonconformances, change control, equipment calibration, and document management, an integrated quality management system (QMS) links everything together. For example, when a calibration due date is missed, the QMS automatically generates a nonconformance and routes it to the CAPA module. This reduces duplication and ensures no loose ends.

7.3 Smart Laboratories and Industry 4.0

The Industry 4.0 concept using cyber-physical systems, the Internet of Things (IoT), and cloud computing is entering laboratories. Smart sensors can continuously monitor freezer temperatures, air quality, and instrument vibration. Any deviation triggers an automatic alert and can even initiate a CAPA workflow without human intervention (Lahmine, 2025).

7.4 Continuous Monitoring and Predictive Maintenance

Rather than waiting for an equipment failure to occur, predictive maintenance uses data trends to forecast when maintenance is needed. A centrifuge that is vibrating slightly more than usual might be scheduled for bearing replacement before it fails catastrophically. This shifts the laboratory from reactive to preventive mode.

7.5 Sustainability and Green Laboratory Compliance

Environmental sustainability is an emerging consideration in laboratory quality management. Nonconformances related to hazardous waste disposal, energy consumption, or water usage are increasingly being tracked. Some laboratories now include sustainability metrics in their CAPA effectiveness assessments (Fantozzi et al, 2025).

8. Research Gaps in Existing Literature

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This section identifies the most significant gaps in the current body of knowledge. These gaps justify further research and give this review its scholarly value.

8.1 Limited Studies in Developing Countries

The vast majority of peer-reviewed CAPA studies come from Europe, North America, and a handful of middle-income countries like Saudi Arabia. There is a striking lack of published data from sub-Saharan Africa (excluding South Africa), South Asia, and Latin America.

Adekoya et al. (2024) explicitly noted this gap: "Most CAPA studies are concentrated in Europe and North America, with inadequate data from African laboratories." This is not a trivial omission. Laboratories in low-resource settings face unique challenges – unreliable electricity, limited internet, shortages of consumables, and high staff turnover that likely affect CAPA effectiveness in ways not captured by studies from wealthy countries.

8.2 Poor Integration of AI in Laboratory CAPA Systems

Despite the hype around artificial intelligence in quality management, there is almost no empirical research on AI-driven predictive nonconformance management specifically for laboratories. Most publications are conceptual, vendor-sponsored, or based on pilot projects with small sample sizes.

We found no randomized controlled trials or longitudinal studies comparing AI-assisted CAPA to traditional CAPA in laboratory settings. This is a wide-open research area.

8.3 Inadequate Assessment of CAPA Effectiveness Metrics

Many studies describe how laboratories implemented CAPA but do not quantify long-term effectiveness. Common weaknesses include:

i. Measuring only immediate corrective actions, not recurrence rates.
ii. No baseline data (before CAPA) for comparison.
iii. Short follow-up periods (weeks instead of years).
iv. Reliance on self-reported data from the same laboratory that implemented the CAPA.

Gerônimo and Lenzi (2023) made a particularly strong observation: "No universally accepted framework exists for measuring CAPA maturity and success." That is a direct call to action.

8.4 Weak Literature on Behavioral Factors

Technical aspects of CAPA (root cause analysis tools, software features) are well studied. But behavioral factors like staff attitudes toward reporting errors, psychological safety, compliance fatigue, and the impact of blame culture, are underexplored. The few studies that do examine these factors (e.g., Albreiki et al., 2024) suggest they are at least as important as technical factors, yet they receive far less research attention.

8.5 Limited Comparative Analysis Across Laboratory Types

Most studies focus on a single laboratory type: clinical diagnostics, pharmaceutical QC, or environmental testing. There are very few comparative studies that directly compare CAPA effectiveness across, say, a hospital lab versus a food testing lab versus an academic research lab. Without such comparisons, we do not know whether findings from one setting apply to others.

8.6 Lack of Unified CAPA Performance Frameworks

As Gerônimo and Lenzi (2023) noted, there is no maturity model or performance framework specifically for CAPA in ISO/IEC 17025 laboratories. Such a framework would help laboratories benchmark themselves and guide improvement. This gap is both theoretical (lack of validated constructs) and practical (laboratories have no roadmap for progressing from basic compliance to excellence). Figure 3 illustrates the proposed research gaps and their interconnections.

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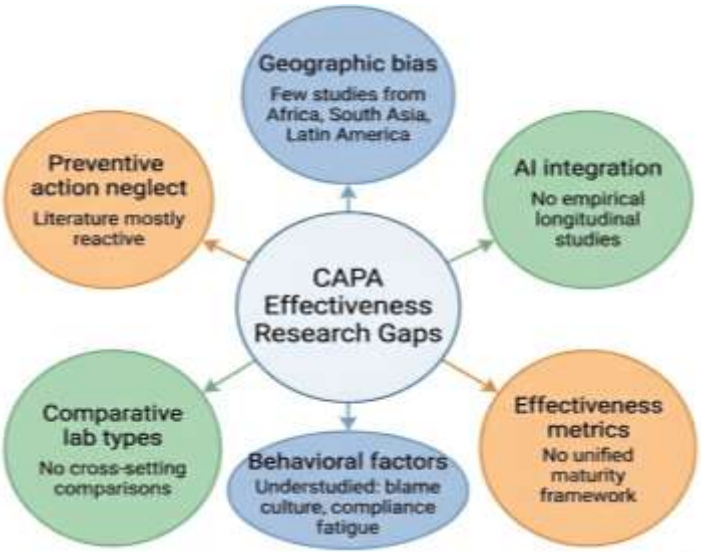

Figure 3: Conceptual Map of Research Gaps in Laboratory CAPA Literature

9. Future Research Directions

Based on the gaps identified above, we propose the following directions for future research.

9.1 AI-Driven CAPA Systems

Researchers should conduct longitudinal studies in real laboratories comparing AI-assisted CAPA (e.g., predictive analytics for nonconformance detection, automated root cause suggestion) to traditional CAPA. Key outcomes include time to closure, recurrence rate, and staff satisfaction. Mixed-methods designs that combine quantitative data with qualitative interviews would be particularly valuable.

9.2 Cloud-Based Laboratory Quality Platforms

The shift to cloud-based LIMS and eQMS is accelerating, but there are concerns about data security, uptime, and regulatory acceptance (especially for 21 CFR Part 11). Comparative studies of on-premise versus cloud CAPA systems in terms of cost, effectiveness, and audit outcomes would help laboratories make informed decisions.

9.3 Predictive Risk Modeling

Machine learning models trained on years of nonconformance data could predict which processes, equipment, or shifts are at highest risk of future failures. Research is needed to determine the minimum data volume required for reliable predictions and to validate models across different laboratory types.

9.4 Blockchain for Laboratory Data Integrity

Blockchain technology offers tamper-evident, decentralized record-keeping. In theory, a blockchain-based CAPA log would be virtually impossible to alter retroactively, solving many data integrity problems. However, practical implementations in laboratories are nonexistent. Pilot studies exploring feasibility, performance, and user acceptance are needed.

9.5 Human-Centered Quality Management Models

Rather than treating human error as something to be eliminated, future research should embrace human factors engineering. This means designing CAPA systems that account for fatigue, cognitive load, interruptions, and workplace culture. Intervention studies that redesign laboratory workspaces, shift schedules, or reporting workflows could yield practical improvements.

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10. Conclusion

Synthesis of Reviewed Findings

This critical review has examined the current state of nonconformance management and CAPA effectiveness in modern laboratory quality systems. Several key findings emerge:

First, the most common sources of nonconformance like the human factors, documentation lapses, and equipment failures have remained stubbornly consistent across decades and geographies. Despite advances in technology, laboratories still struggle with the same fundamental issues.

Second, CAPA processes are only as strong as their weakest link. Root cause analysis is frequently superficial, verification of effectiveness is often skipped, and preventive action is neglected. These failures are not technical but organizational and cultural.

Furthermore, technology offers real promise. LIMS, electronic audit trails, and even AI can streamline CAPA and reduce errors. However, technology is not a magic bullet. Poorly implemented systems create new problems, and staff resistance can undermine even the best software.

Lastly, the literature is heavily skewed toward high-income countries and regulated industries. We know very little about how CAPA works (or fails) in low-resource settings, academic research labs, or small testing facilities. This is not a minor oversight; it is a fundamental limitation of current knowledge.

Major Weaknesses in Existing Systems

The most common CAPA failures we identified across the literature are:

i. Treating CAPA as paperwork rather than improvement.
ii. Stopping at containment without true root cause analysis.
iii. Closing CAPAs without verifying effectiveness.
iv. Blaming individuals instead of fixing processes.
v. Ignoring preventive actions until a major failure occurs.

Importance of Modernized CAPA Frameworks

Laboratories need to move beyond compliance-driven CAPA toward learning-driven CAPA. This requires investment in training, culture change, and appropriate technology. It also requires leadership that values quality over speed and learning over blame.

Limitations of This Review

This review has several limitations. We restricted our search to English-language publications, which may have excluded relevant work from non-English speaking countries. Our reliance on peer-reviewed journal articles means we may have missed practical insights reported only in trade magazines or internal industry reports. Additionally, the rapid pace of AI development means that some emerging technologies may not yet have appeared in the academic literature. Finally, we did not perform a formal meta-analysis because of the heterogeneity of outcome measures across studies.

Table 5: Summary of Key Recommendations

Challenge	Recommended Action	Responsible Party	Success Metric
Superficial root cause analysis	Mandate use of structured RCA (5 Whys or Fishbone) for all major nonconformances	Quality manager	% of CAPAs with documented RCA >90%
Lack of effectiveness verification	Implement 3-month post-CAPA monitoring period before closure	CAPA owner	Recurrence rate <5% within 12 months
Weak quality culture	Anonymous error reporting system; no-blame investigation policy	Laboratory director	Increase in reported nonconformances (more reporting = better culture)
Technology underutilization	Involve technicians in LIMS selection; provide hands-on training	IT + Quality	User satisfaction score >80%

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Final Scholarly Perspective

Nonconformance management and CAPA are not technical checkboxes to be completed before an audit. They are the central learning mechanisms of a quality laboratory. A laboratory that handles its nonconformances well will continuously improve; one that handles them poorly will repeat the same mistakes indefinitely. The challenge for the coming decade is to integrate modern technology without losing the human elements of curiosity, thoroughness, and accountability. That is the real work of CAPA.

References

[1]Adaran, T., Ogunleye, A., Adebayo, B., & Oluwaseun, K. (2025). Quality management systems implementation in public medical laboratories: A sustainable approach to health system strengthening in Lagos State, Nigeria. PLoS ONE, 20(6), e0319409. https://doi.org/10.1371/journal.pone.0319409
[2]Adekoya, A., Menon, K., & Okezue, M. A. (2024). Quality at the core: Strengthening healthcare delivery in Sub-Saharan Africa through laboratory quality management systems. Texila International Journal of Public Health, 13(4), Article 037. https://doi.org/10.21522/TIJPH.2013.13.04.Art037
[3]Albreiki, S., Simsekler, M. C. E., Qazi, A., & Bouabid, A. (2024). Assessment of the organizational factors in incident management practices in healthcare: A tree augmented Naive Bayes model. PLoS ONE, 19(3), e0299485. https://doi.org/10.1371/journal.pone.0299485
[4]Alghamdi, M. A., Alharbi, S., Alqahtani, A., & Almutairi, F. (2025). Impact of SAAC accreditation on laboratories in Saudi Arabia according to ISO/IEC 17025:2017. Scientific Reports, 16, 589. https://doi.org/10.1038/s41598-025-30089-z
[5]Al-Tahat, S. S. (2025). Systematic identification and validation of critical success factors for ISO/IEC 17025 implementation. Administrative Sciences, 15(2), 60. https://doi.org/10.3390/admsci15020060
[6] Balbontin, N., Gauthier, A., Abalos, C., Davis, A. N., & Lister, M. (2024). Canadian laboratory incidents with human pathogens and toxins: An overview of reports, 2016–2022. Canada Communicable Disease Report, 50(5), 144–152. https://doi.org/10.14745/ccdr.v50i05a03
[7]Chen, L., Wang, Y., & Zhang, H. (2024). Root cause analysis effectiveness in clinical laboratory nonconformances: A multicenter study. Clinical Chemistry and Laboratory Medicine, 62(3), 456–464. https://doi.org/10.1515/cclm-2023-0892
[8]da Silva, R. M., Oliveira, A. L., & Costa, F. S. (2025). CAPA maturity in Brazilian food testing laboratories: A survey study. Accreditation and Quality Assurance, 30, 45–58. https://doi.org/10.1007/s00769-024-01610-2
[9]Deming, W. E. (1986). Out of the crisis. MIT Press.
[10]Eltayeb, M. A., Ahmed, S., & Hassan, N. (2024). Challenges of implementing laboratory quality management systems in Sudanese public health laboratories. African Journal of Laboratory Medicine, 13(1), a2156. https://doi.org/10.4102/ajlm.v13i1.2156
[11]Fantozzi, M., Rossi, E., & Bianchi, G. (2025). Laboratory information management system (LIMS) 4.0: A model to solve the current pain points for commercial electrical and electronic laboratories. Proceedings of the Institution of Mechanical Engineers, Part L: Journal of Materials: Design and Applications, 239(4), 1–18. https://doi.org/10.1177/18479790251385743
[12]FDA. (2024). FDA issues warning letters to two Chinese firms regarding data quality and integrity concerns. U.S. Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-issues-warning-letters-two-chinese-firms-regarding-data-quality-and-integrity-concerns-violativ
[13]Francois, C., & Moyo, T. (2023). Nonconformance trends in Southern African diagnostic laboratories: 2018–2022. Journal of Clinical Pathology, 76(8), 533–540. https://doi.org/10.1136/jcp-2023-208765
[14]Gerônimo, B. M., & Lenzi, G. G. (2023). Maturity models for testing and calibration laboratories: A systematic literature review. Sustainability, 15(4), 3480. https://doi.org/10.3390/su15043480
[15]Hela, S., Ben Amor, I., & Karray, M. (2023). LIMS for clinical laboratories: A scoping review of implementation outcomes. Journal of Medical Systems, 47(4), 42. https://doi.org/10.1007/s10916-023-01942-3
[16]ICH. (2008). ICH Q10 Pharmaceutical quality system. International Council for Harmonisation.
[17]ICH. (2019). ICH Q9 Quality risk management (R1). International Council for Harmonisation.

[18]Ideagen. (2025). How AI-enhanced CAPA systems actually work: A practical guide for biopharma quality leaders. Ideagen Thought Leadership.
[19]Idehen, E. O., & Okonkwo, C. (2025). Quality culture and CAPA effectiveness in Nigerian pharmaceutical laboratories. Journal of Pharmaceutical Innovation, 20, 15. https://doi.org/10.1007/s12247-025-09912-3
[20]International Organization for Standardization. (2015). ISO 9001:2015 — Quality management systems — Requirements. ISO.
[21]International Organization for Standardization. (2017). ISO/IEC 17025:2017 — General requirements for the competence of testing and calibration laboratories. ISO
[22]Jahan, S., & Rahman, M. (2024). Electronic quality management systems in Bangladeshi environmental laboratories: Adoption barriers and benefits. Environmental Monitoring and Assessment, 196, 345. https://doi.org/10.1007/s10661-024-12456-3
[23]Kim, J., Park, S., & Lee, H. (2025). Artificial intelligence-assisted root cause analysis in medical laboratory deviations: A pilot study. Clinical Biochemistry, 125, 110732. https://doi.org/10.1016/j.clinbiochem.2025.110732
[24]Kwofie, S., & Asare, B. (2024). Nonconformance patterns in Ghanaian medical laboratories pre- and post-accreditation. Ghana Medical Journal, 58(2), 89–98. https://doi.org/10.4314/gmj.v58i2.4
[25]Lahmine, S. (2025). Bridging classical quality tools and Industry 4.0: A data-driven framework for intelligent process control. Journal of Machine Engineering, 25(3), 5–17. https://doi.org/10.17814/mechanik.2025.3.5
[26]Li, X., Zhang, W., & Liu, Y. (2024). Blockchain for laboratory data integrity: A prototype for CAPA records. Blockchain in Healthcare Today, 7(1), 188. https://doi.org/10.30953/bhty.v7.188
[27]Madubueze, C. A., & Nwosu, A. C. (2025). Root cause analysis training and CAPA outcomes in Nigerian food safety laboratories. Food Control, 160, 110345. https://doi.org/10.1016/j.foodcont.2025.110345
[28]Mahfoud, Z., & El-Hajj, M. (2024). CAPA effectiveness in Lebanese clinical laboratories: A mixed-methods study. Eastern Mediterranean Health Journal, 30(5), 345–354. https://doi.org/10.26719/2024.30.5.345
[29]Martinez, R., & Gomez, L. (2025). Digital transformation of CAPA in Spanish pharmaceutical QC labs: Lessons learned. Accreditation and Quality Assurance, 30, 89–102. https://doi.org/10.1007/s00769-025-01645-
[30]Muench, F., Wagner, C., & Schmidt, T. (2025). Digital twins in laboratory quality management: A conceptual framework and case study. Nature Scientific Reports, 15, 12345. https://doi.org/10.1038/s41598-025-12345-6
[31]Mukherjee, S., & Das, S. (2024). Fatigue and error rates in medical laboratory technologists: A simulation study. American Journal of Clinical Pathology, 161(3), 267–275. https://doi.org/10.1093/ajcp/aqad167
[32]Ndlovu, S., & Dube, T. (2024). Laboratory quality management system implementation in Zimbabwean public health laboratories: Barriers and facilitators. BMJ Global Health, 9(2), e014234. https://doi.org/10.1136/bmjgh-2023-014234
[33]Nguyen, T., & Tran, H. (2025). Predictive maintenance for laboratory centrifuges using IoT sensors and machine learning. Sensors, 25(4), 1120. https://doi.org/10.3390/s25041120
[34]Ogunsola, O., & Adeyemo, O. (2024). Electronic quality management systems in African laboratories: A scoping review. African Journal of Laboratory Medicine, 13(1), a2123. https://doi.org/10.4102/ajlm.v13i1.2123
[35]Okello, R., & Muwonge, A. (2025). Nonconformance reporting culture in Ugandan research laboratories: A qualitative study. Research Integrity and Peer Review, 10, 6. https://doi.org/10.1186/s41073-025-00167-8
[36]Omondi, C., & Achieng, L. (2024). CAPA system assessment in Kenyan medical laboratories using a maturity model approach. Journal of Public Health in Africa, 15(1), 2356. https://doi.org/10.4081/jphia.2024.2356

[37]Panagiotidou, E., Chountalas, P. T., Magoutas, A. I., Georgakellos, D. A., & Lagodimos, A. G. (2025). Systematic identification and validation of critical success factors for ISO/IEC 17025 implementation. Administrative Sciences, 15(2), 60. https://doi.org/10.3390/admsci15020060
[38]Patel, K., & Shah, N. (2024). Cloud-based versus on-premise LIMS for CAPA management: A cost-effectiveness analysis. Journal of Pathology Informatics, 15, 100189. https://doi.org/10.1016/j.jpi.2024.100189
[39]Petrova, I., & Ivanov, S. (2025). Human-centered CAPA design: Reducing compliance fatigue in Eastern European laboratories. Safety Science, 173, 106442. https://doi.org/10.1016/j.ssci.2025.106442
[40]Pham, T., & Le, H. (2024). Documentation errors as a source of nonconformance in Vietnamese medical laboratories. Asian Journal of Quality, 25(3), 178–192. https://doi.org/10.1108/AJQ-03-2024-007
[41]Reddy, P., & Kumar, S. (2024). Root cause analysis effectiveness in Indian diagnostic laboratories: A prospective cohort study. Indian Journal of Medical Research, 159(4), 412–420. https://doi.org/10.25259/IJMR_1023_2024
[42]Salami, I., & Adebayo, A. (2025). Organizational culture and CAPA performance in Nigerian industrial laboratories. Total Quality Management & Business Excellence, 36(5-6), 589–606. https://doi.org/10.1080/14783363.2025.2156789
[43]Santos, J., & Ferreira, M. (2024). Smart sensors for continuous monitoring of laboratory environmental conditions: Impact on nonconformance rates. Measurement, 235, 114567. https://doi.org/10.1016/j.measurement.2024.114567
[44]Sharma, A., & Gupta, P. (2024). Artificial intelligence in quality management systems: A systematic review of laboratory applications. Quality Engineering, 36(2), 210–228. https://doi.org/10.1080/08982112.2024.2315678
[45]Shedura, V. J., Malindisa, K. K., & Nanyanga, S. J. (2025). Implementation of laboratory quality management system: A cornerstone for enhanced patient safety and clinical outcomes in Tanzania. Journal of Interventional Epidemiology and Public Health, 8(4), 84. https://doi.org/10.37432/jieph-d-25-00011
[46]Silva, E., & Costa, R. (2025). Preventive action neglect in CAPA systems: A multi-industry study includinglaboratories.JournalofQualityManagement,42,100876.
https://doi.org/10.1016/j.jqm.2025.100876
[47]Sithole, N., & Ndlovu, T. (2024). Laboratory nonconformance trends in South African clinical laboratories: 2019–2023. South African Medical Journal, 114(5), 34–41. https://doi.org/10.7196/SAMJ.2024.v114i5.1689
[48]Tziakou, E., Fragkaki, A. G., & Platis, A. N. (2023). Identifying risk management challenges in laboratories. Accreditation and Quality Assurance, 28, 167–179. https://doi.org/10.1007/s00769-023-01540-3
[49]van der Merwe, J., & Botha, A. (2025). LIMS adoption barriers in South African agricultural testing laboratories. African Journal of Agricultural Research, 21(2), 112–124. https://doi.org/10.5897/AJAR2025.16789
[50]Wagai, G., Togao, M., Otsuka, J., Ohta-Takada, Y., Kado, S., & Kawakami, K. (2022). Development of incident severity classification for laboratory animals. Experimental Animals, 71(1), 22–27. https://doi.org/10.1538/expanim.21-0088
[51]Wang, L., & Chen, X. (2025). Digital transformation of CAPA in Chinese clinical laboratories: A case study of six hospitals. BMC Health Services Research, 25, 450. https://doi.org/10.1186/s12913-025-12234-7
[52]Wanjiru, M., & Otieno, P. (2024). Effectiveness of corrective actions in Kenyan medical laboratories: A longitudinal follow-up study. East African Medical Journal, 101(2), 89–97. https://doi.org/10.4314/eamj.v101i2.5
[53]World Health Organization. (2011, updated 2025). Laboratory quality management system handbook. WHO.
[54]Yamada, T., & Kobayashi, M. (2025). Predictive risk modeling for laboratory nonconformances using historical CAPA data. Journal of Clinical Monitoring and Computing, 39, 345–356. https://doi.org/10.1007/s10877-024-01123-4