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From informatics to AI: Building intelligent laboratory quality systems

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Clinical laboratories have always been quality-driven organizations, but the way quality is achieved is changing quickly. For much of the twentieth century, the center of gravity for quality management was the analytical phase: accuracy, precision, and reproducibility demonstrated through quality control materials, calibration verification, proficiency testing, and routine instrument maintenance. This approach established the laboratory's reputation as a scientific environment where performance could be measured, controlled, and improved.

Over the past two decades, however, the definition of quality has expanded well beyond analytic performance. The modern quality management system (QMS) must encompass the entire total testing process, from ordering and specimen collection through accessioning, analysis, verification, reporting, and clinician response. In practice, many of today's quality failures originate outside the analytical phase—in specimen labeling, transport delays, interface mapping errors, or communication breakdowns. Informatics has therefore become a core discipline of quality management, designing workflows that prevent errors, standardizing decisions, reducing variability, and capturing evidence automatically.

The next step in that evolution is the potential introduction of artificial intelligence (AI) and machine learning (ML) into laboratory quality management. While fully AI-driven quality systems are still emerging in most clinical laboratories, informatics-driven workflows are already transforming how laboratories monitor quality and manage risk.

AI is not a replacement for scientific judgment, nor is it a shortcut to quality. Its real value lies in its potential to make quality systems more proactive by helping detect patterns that humans may not easily see in real time. Used thoughtfully, AI can help laboratories transition from a reactive "inspect-and-correct" model to a proactive, data-driven "predict-and-prevent" approach.

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LEARNING OBJECTIVES

Upon completion of this article,the reader will be able to:

1. Differentiate between analytical, pre-analytical, and post-analytical phases of laboratory testing.
2. Describe the evolution of laboratory quality management systems by explaining the shift from reactive, QC-focused models to proactive models.
3. Discuss concepts of digital and informatics-driven quality management through examples of standardized, auditable workflows.
4. Discuss the importance of the role of artificial intelligence and real-time quality indicators in modern laboratory practice by including predictive analytics, data readiness, and team involvement.

From paper logs to smart data systems: The quiet revolution in laboratory quality

A useful way to understand the present moment is to look at how dramatically laboratory quality work has already changed. In the not-so-distant past, quality programs relied heavily on paper logs, manual temperature recordings, phone calls for critical values, handwritten corrective action notes, and retrospective audits to confirm compliance. The quality manager's quality tools were often a collection of binders—QC records, maintenance logs, reagent inventories, competency checklists, and incident reports.

Today, middleware rules enforce autoverification thresholds, delta checks, specimen integrity flags, and instrument-specific quality hard stops. Digital traceability can capture time-stamped events from collection through reporting.

When a critical value is resulted, the preferred pathway is no longer a manual phone call with variable documentation; it is an integrated, closed-loop communication workflow that documents notification automatically. These systems reduce transcription risk, improve documentation reliability, and generate structured data that laboratories can analyze to identify improvement opportunities.

Informatics is the bridge between regulatory mandates and future quality systems, making the measurement of laboratory quality truly continuous. This shift—from paper to digital workflow—represents the real foundation on which future AI capabilities will build. For modern laboratory quality management terms, see **Figure 1**.

Term	What it means in the clinical lab	Why it matters for quality
Informatics	Integration of analyzers, middleware, LIS, and EHR so data flows reliably across the total testing process	Creates continuous visibility into specimen flow, turnaround time, and quality events
Intelligent Workflow	Rule-based processes that route specimens, trigger reflex testing, flag exceptions, and document events automatically	Reduces variability, prevents errors, and creates auditable quality evidence
Artificial Intelligence (AI)	Tools that can assist with pattern recognition and predictive analytics using large data sets	May help identify emerging risks earlier and support proactive quality management
Machine Learning (ML)	Algorithms that learn from historical lab data to improve predictions over time	Can support anomaly detection in QC trends, workflow bottlenecks, and instrument performance
Closed-Loop Communication	Automated systems that document when critical values are sent, received, and acknowledged	Improves compliance, patient safety, and documentation reliability
Real-Time Quality Monitoring	Dashboards showing TAT, backlog, recollections, analyzer uptime, and notification performance	Allows intervention before patient impact occurs
Predict-and-Prevent Quality	Moving from retrospective audits to proactive detection of risk patterns	Aligns with modern QMS goals of continuous improvement

Figure 1. The new language of laboratory quality.

A practical example of informatics-enabled quality improvement: Epic Secure Messaging and critical value closed-loop communication

The benefits of informatics become clearest when viewed through a real quality problem. Critical value reporting has historically been one of the most labor-intensive and failure-prone post-analytic processes. Phone calls can be delayed by busy clinical units, unavailable clinicians, and inconsistent documentation. Implementing Epic Secure Messaging can help laboratories transition from manual communication to a closed-loop process that documents when a message is sent, opened, and acknowledged. This approach improves compliance, reduces transcription risk, and creates reliable data that can be analyzed for continuous quality improvement.

A laboratory's implementation of Epic Secure Messaging illustrates what intelligent quality looks like in practice. Instead of relying on manual call chains, the system routes the result directly to the responsible provider, captures the exact time and user acknowledgment, and places the documentation automatically into the medical record. The workflow becomes standardized, auditable, and measurable transforming a historically inconsistent process into a controlled quality system.

Closed-loop communication reduces documentation gaps and produces structured data that laboratories can

QSE area	How AI & informatics help
Organization & Supervision	Real-time dashboards reveal risk trends, support workload forecasting, and help leaders detect conditions that increase error risk.
Personnel	Workflow analytics identify where errors cluster, enabling targeted, individualized training instead of generic annual refreshers.
Equipment	Predictive maintenance detects drift and performance changes early, reducing downtime and preventing workarounds.
Purchasing & Inventory	Forecasting tools predict reagent needs, prevent stockouts, and identify unusual consumption patterns.
Documents & Records	Automated documentation, version control, and audit trails reduce missing records and strengthen compliance.
Process Control	Patient-based data and anomaly detection complement QC charts and identify problems earlier.
Information Management	AI depends on clean data—standardized identifiers, reliable interfaces, and structured fields become critical quality priorities.
Occurrence Management	Pattern recognition identifies trends in mislabels, recollections, specimen integrity issues, and workflow delays.
Assessment	Continuous monitoring replaces "audit panic," allowing audits to focus on real risk areas.
Customer Service	Closed-loop communication tools (e.g., Epic Secure Messaging) improve clinician experience and patient safety.
Process Improvement	Faster measurement and trend detection accelerate Plan-Do-Study-Act cycles.
Facilities & Safety	Environmental monitoring and safety analytics support proactive safety management.

Figure 2. How AI and informatics impact quality system essentials and reshape the entire QMS.

analyze by unit, service line, or time of day to identify trends and improvement opportunities. The benefits are not only faster notification, and better notification, but improved patient safety.

Real-world examples of emerging AI applications in laboratory quality

A common myth to be dispelled is that AI will replace laboratorians. In the clinical laboratory, AI can be a tool that supports—not replaces—professional judgement. It refers to tools that assist with pattern recognition, anomaly detection, and predictive analytics. Machine learning models can be trained on historical data to identify emerging trends in instrument performance, specimen integrity, or workflow bottlenecks. Informatics integrates systems so that data flows reliably between analyzers, middleware, LIS, and EHR environments. Intelligent workflows combine these capabilities into rule-based or analytics-supported processes that route specimens, flag exceptions, and document key quality events automatically.

Several legitimate AI-supported use cases are already emerging in laboratory medicine. Patient-based, real-time quality control approaches use statistical and machine learning methods to detect subtle analytical drift. Digital pathology tools use image recognition to support diagnostic consistency and workload triage. Hematology image-analysis systems assist with abnormal cell detection. Predictive maintenance analytics are being explored to identify patterns that precede analyzer downtime. Natural language processing tools can analyze incident reports to identify recurring quality risks.

These applications are not yet universal, but they illustrate how AI may build upon existing informatics-driven quality systems. See **Figure 2** for how AI impacts quality system essentials (QSE).

Real-time data as the new quality indicator

In the traditional model, quality indicators were often reviewed monthly or quarterly. That cadence can still be useful, but it is insufficient for an environment where specimen flow and analyzer demand can change hour by hour.

Modern laboratories increasingly depend on real-time visibility: turnaround time distributions, specimen queue backlogs, analyzer uptime, pending lists, incident trends, etc. This visibility changes quality culture. Instead of discovering problems in a retrospective audit, teams can intervene during the shift. The goal is to make corrections before patient impact occurs. When this is done well, it creates operational excellence. Staff see the system's behavior, understand where bottlenecks arise, and actively intervene to prevent impact.

This mirrors how high-performing industries outside healthcare operate. Consumer technology organizations continuously measure engagement and performance to optimize systems. The laboratory equivalent is not "engagement"—it is patient safety, timeliness, and reliability. The goal is the same: use data as a feedback engine to optimize outcomes.

What must be in place before AI improves laboratory quality

The most common barrier to AI-enabled quality improvement is not the model itself. It is the laboratory's readiness in informatics fundamentals. If LIS-to-EHR interoperability is inconsistent, if specimen identifiers are not unified across systems, or if workflow steps are not captured as discrete events, AI has little stable ground to stand on. Laboratories must first modernize data capture and interface integrity before AI can deliver meaningful quality gains.

Another common barrier is metric overload. The QMS must prioritize indicators that are actionable and tied to improvement responsibilities. ISO-aligned thinking helps here: quality indicators should systematically monitor and evaluate contributions to patient care, not become an endless list of numbers.

Finally, culture matters. Building a data-driven culture is not about surveillance, it is about transparency and creating a learning environment. Quality improves when staff can see how the system works, trust the fairness of measurement, and are trained to interpret AI/informatics tools alongside their professional judgment. When teams understand how the tools work—and how to question them appropriately—they solve problems more effectively and make decisions with greater confidence.

Conclusion: The future of laboratory quality is intelligent

Clinical laboratory quality has always been about discipline: controlling processes, documenting performance, and improving continuously. What changes in the AI era is the laboratory's ability to sense its own operation in real time, detect risk earlier, and optimize faster.

Informatics and intelligent workflows are already transforming quality management by automating data capture, standardizing decisions, and creating closed-loop evidence of compliance. AI will build upon that transformation by adding predictive surveillance, pattern detection across the total testing process, and operational optimization that reduces variability and error risk.

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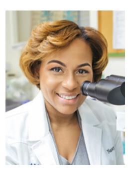
The laboratory of the future is not simply automated—it is intelligent, continuously learning from its own data and monitoring its systems, where technology strengthens rather than replaces professional judgment. In that environment, quality management becomes what it has always aspired to be: proactive, adaptive, continuous, and built into the workflow by design.



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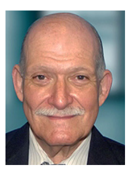

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