

MediaLab

by vastian



WHITE PAPER

SUPPORTING ISO 15189 ACCREDITATION WITH MEDIALAB BY VASTIAN

A PRACTICAL FRAMEWORK FOR MEDICAL LABORATORIES SEEKING
EXCELLENCE IN QUALITY AND COMPETENCE

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WHITE PAPER

SUPPORTING ISO 15189:2022 ACCREDITATION WITH MEDIALAB BY VASTIAN: A MODERN SOLUTION FOR MEETING GLOBAL STANDARDS IN LABORATORY MEDICINE

Executive Summary

ISO 15189:2022 sets the global standard for medical laboratory quality and competence. Accreditation to this standard demonstrates a lab's commitment to delivering reliable results, maintaining rigorous quality management, and prioritizing patient safety. As laboratories navigate the complexities of ISO 15189, MediaLab by Vastian offers an integrated suite of cloud-based Quality and compliance software that maps directly to the standard's core clauses. With over 30 years of experience and innovation in the laboratory quality arena, MediaLab empowers laboratories to systematize quality, automate compliance while maintaining full traceability, and sustain year-round audit readiness.

ISO 15189:2022 – More Than Compliance

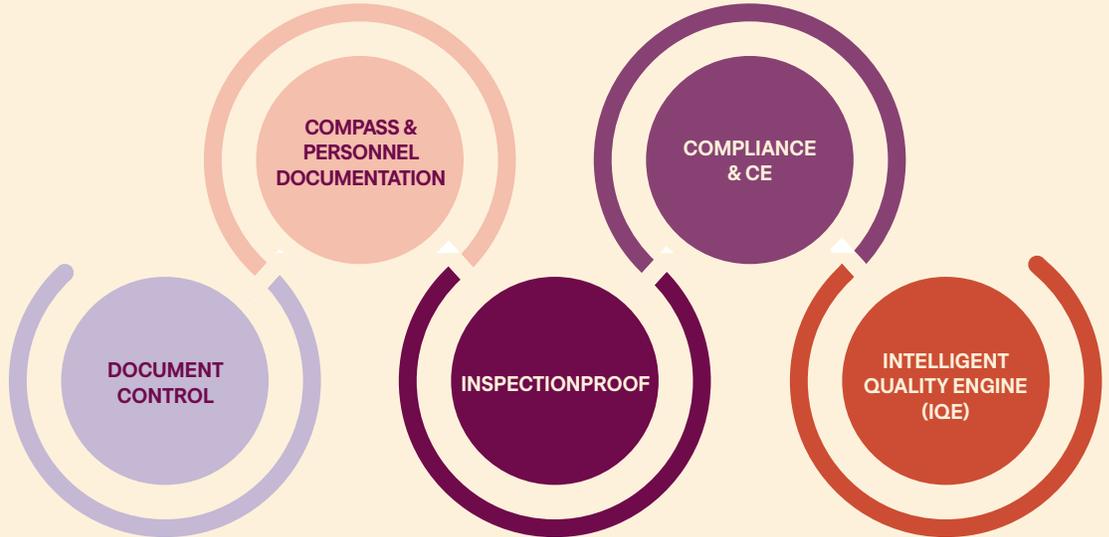
Accreditation under ISO 15189:2022 sends a powerful message to patients, partners, and regulatory bodies — that your laboratory is committed to excellence, accountability, and internationally recognized best practices. It establishes a framework for consistent, evidence-based decision making that can be applied across all areas of laboratory departments and operations. Beyond meeting requirements, the standard encourages laboratories to identify opportunities for innovation and proactive improvement while positioning themselves as leaders in both clinical excellence and operational integrity. The emphasis on competence, training, and continuous learning aims to foster a more engaged and capable laboratory workforce as well. Ultimately, ISO 15189 helps transform compliance into a strategic advantage — strengthening trust, reducing errors, and supporting better patient outcomes.

ISO 15189 accreditation is increasingly sought by laboratories that:

- Seek formal recognition of their technical competence on an international level
- Aim to go beyond CLIA and other foundational regulatory requirements
- Prioritize the development of sustainable, efficient, and resilient quality systems

MEDIA LAB BY VASTIAN'S ALIGNMENT WITH ISO 15189:2022 CLAUSES

MediaLab's applications support key ISO 15189 requirements across the following major clauses:



DOCUMENT CONTROL

Supports Clauses 7.3.6, 8.2, 8.3 – Control of Documents

- Documenting and providing access to examination procedures, working instructions, management system objectives, and policies
- Role-based approval workflows, employee access controls, and robust audit logs
- Unique document IDs, periodic reviews, full version control, and version history archive



Focus:

Ensures prevention of unauthorized access; document version control; approvals and periodic reviews; all while supporting personnel access at the point of use.

COMPASS & PERSONNEL DOCUMENTATION

Supports Clauses 5.2.3, 6.2 – Personnel Competence & Records

- Role-specific competency scheduling, including checklists, direct observation, and problem-solving quizzes
- Manage personnel files/records including position descriptions, education requirements, qualifications, training, and competency assessment over time
- Document authorizations for laboratory systems access and delegation of duties



Focus:

Managing delegation of duties, maintaining complete and accurate personnel records, and ensuring documented competence of all personnel.

INSPECTIONPROOF

Supports Clause 8.8.3 – Internal Audits

- Self-assessment internal audit mapped directly to ISO 15189 clauses
- Year-round inspection preparation and tracking with real-time progress dashboards, full traceability, and reports
- Central repository for both on-site and self-assessment evidence and outcomes



Focus:

Conducting internal audits at planned intervals and maintaining a compliant audit program with retention of audit records.

COMPLIANCE & CE

Supports Clause 6.2.4 – Ongoing Education and Improvement

- Assign CE activities from MediaLab's vast library by user role or department
- Upload and track external CE activities in addition to MediaLab CE courses
- Review education history and employee CE transcripts
- Create custom education to accompany procedural changes



Focus:

A continuing education program must be available to all personnel to support their participation in CE and professional development activities.

INTELLIGENT QUALITY ENGINE (IQE)

Supports Clause 5.6 – Risk Management

- Complete Failure Modes and Effects Analysis (FMEA) and include risk matrices (likelihood vs. severity), root cause analysis (for known events), and more in customized IQE forms
- Risk analysis tied to patient care and impact level
- Monitor, evaluate, and improve risk controls and assessments
- Use quality indicators (see Section 8.8.2) to track and monitor performance



Focus:

Integrating risk-based thinking and documented risk management practices into laboratory operations.

INTELLIGENT QUALITY ENGINE (IQE), CONT.

Supports Clauses 6.4.6, 6.4.7 – Equipment Incidents & Records

- Document, investigate, and report incidents and accidents related to equipment
- Document and act on manufacturer recalls or other notices
- Use vendor/supplier (delete spaces before and after the slash), asset management, and instrument maintenance data log forms to maintain equipment records



Focus:

Investigating and reporting equipment-related incidents, responding to manufacturer notices, and maintaining complete, traceable records for each item of equipment.

Supports Clauses 7.3.7.4 – Comparability of Examination Results

- Complete and evaluate comparability studies
- Set comparability studies schedule with automated reminders
- Retain documentation with full traceability

Supports Clauses 7.5, 7.7 – Nonconforming Work & Complaints

- Identify and manage any nonconforming work on NCE forms
- Document all incidents, actions taken, and effectiveness of corrections
- Maintain a formal complaint handling process with complaint form
- Track trends in complaints and maintain records of all complaints and actions taken



Focus:

Systematically detecting, managing, and documenting nonconforming work and complaints and resolving issues.

Supports Clauses 8.5, 8.6, 8.7, 8.8.2 – Opportunities for Improvement

- Log and manage improvement opportunities from staff suggestions, audit results, and incident reports
- Integration of Corrective & Preventive Action (CAPA) phases on IQE forms
- Export NCE and CAPA data in Excel and PPT for quality improvement meetings
- Define, monitor, and evaluate quality indicators across pre-examination, examination, and post-examination processes



Focus:

Proactively managing risks, correcting issues, driving improvements, and monitoring quality through defined indicators.



OPERATIONAL INTEGRATION & EASE OF USE

MediaLab is built to work with your existing lab infrastructure, offering:



A cloud-hosted platform with secure role-based access



APIs for integration with HR systems and SSO providers



Audit-ready exports in multiple formats



Simple user setup with tiered permissions and training tools

Even with complex requirements, MediaLab makes compliance manageable and measurable.

CONCLUSION: ACHIEVE AND SUSTAIN ISO 15189 EXCELLENCE WITH MEDIALAB BY VASTIAN

ISO 15189:2022 is not just a regulatory hurdle — it's a strategic opportunity to elevate laboratory performance and reputation. MediaLab helps you build a living, breathing QMS that grows with your lab, meets audit demands confidently, and puts your team in control of quality, not scrambling to prove it.

With unmatched focus, user-centered tools, and a track record of lab success, MediaLab is your partner for real-time, long-term ISO 15189 compliance.

Let's Talk Quality:

[BOOK A DEMO](#)

