Advanced Laboratory Testing and Quality Management Course

16 – 27 November 2026
Tokyo

AGILE LEADERS
Training Center

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Ref: 1497_210530 **Date:** 16 – 27 November 2026 **Location:** Tokyo **Fees:** 15000 Euro

Overview

Advanced Laboratory Testing and Quality Management Course is a two-week course for laboratory leaders and technical personnel, who leave with a Laboratory Testing and Quality Management Pack. The course connects ISO 15189:2022, quality system essentials, test methods, specimens, equipment, reagents, quality control, results, information, nonconforming work, risk, assessment, and improvement. Agile Leaders Training Center presents laboratory testing and quality management as one controlled operational system.

Who Should Attend

- Teams responsible for laboratory governance and service performance
- Personnel responsible for test-method selection, verification, and technical oversight
- Functions responsible for quality systems, documents, records, and audits
- Teams responsible for specimens, equipment, reagents, results, and information
- Personnel responsible for competence, risk, nonconforming work, and improvement

The course assumes participants already work with laboratory processes and leaves out beginner bench techniques, accreditation guarantees, and jurisdiction-specific regulatory advice.

Departments and Industries

The course supports departments that manage testing quality across healthcare, public health, research, environmental, and product-testing laboratories.

- Medical and diagnostic laboratory services
- Public health and reference laboratories
- Clinical research and biotechnology laboratories
- Environmental, food, and product-testing laboratories
- Quality, safety, information, and healthcare operations functions

Learning Objectives

By the end of this course, participants will be able to:

- Apply ISO 15189:2022 and quality system essentials to laboratory governance
- Analyze pre-examination, examination, and post-examination process risks
- Build method, equipment, reagent, specimen, and competence controls
- Evaluate quality control, external assessment, and result-release evidence
- Diagnose nonconforming work and prioritize corrective action

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- Design indicators, audits, management reviews, and improvement plans

Course Agenda

Day 1: Laboratory Quality System Architecture

- ISO 15189:2022 Quality and Competence Map
- Laboratory Quality System Essentials Framework
- Service Scope and Process Interaction Map
- Quality Policy and Objective Deployment Matrix
- Laboratory Governance and Responsibility Chart

Day 2: Documents, Records, and Competence

- Quality Manual Architecture
- Standard Operating Procedure Lifecycle
- Document Approval and Change-Control Register
- Training and Competency Assessment Matrix
- Personnel Authorization and Scope Record

Day 3: Suppliers, Inventory, and Equipment

- Supplier Qualification and Monitoring Scorecard
- Reagent Receipt, Lot, and Expiry Control Log
- Inventory Level and Stock-Risk Model
- Equipment Qualification and Maintenance Plan
- Calibration and Metrological Traceability Record

Day 4: Methods and Examination Control

- Test Method Selection Decision Matrix
- Method Verification and Validation Plan
- Measurement Uncertainty Evaluation Record
- Analytical Interference and Limitation Register
- Examination Procedure Performance Review

Day 5: Specimen and Pre-Examination Workflow

- Request and Patient Preparation Checklist
- Sampling and Specimen Identification Standard
- Specimen Transport and Stability Control Map
- Acceptance, Rejection, and Exception Criteria
- Pre-Examination Quality Indicator Dashboard

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Day 6: Quality Control and External Assessment

- Internal Quality Control Planning Model
- Control Chart Interpretation and Response Rules
- External Quality Assessment Participation Plan
- Proficiency Testing Investigation Record
- Quality Control Trend and Shift Analysis

Day 7: Results and Information Management

- Technical Result Review and Authorization Checklist
- Critical Result Notification and Escalation Pathway
- Amended Report and Correction Control Log
- Laboratory Information Access and Integrity Matrix
- Post-Examination Turnaround and Release Dashboard

Day 8: Nonconformity and Risk Control

- Nonconforming Work Containment Decision Tree
- Occurrence Investigation and Root-Cause Record
- Corrective Action Effectiveness Review
- Laboratory Risk and Opportunity Register
- Complaint and Customer Feedback Resolution Map

Day 9: Assessment and Improvement

- Internal Audit Program and Evidence Plan
- Laboratory Quality Indicator Portfolio
- Management Review Input and Decision Pack
- Continual Improvement Prioritization Matrix
- Improvement Action Ownership and Follow-Up Board

Day 10: Laboratory Management Practice

- Suggested Exercise: Testing Process Risk Review
- Suggested Exercise: Method and Equipment Evidence Check
- Suggested Exercise: Quality Control and Result Decision
- Suggested Exercise: Nonconformity and Improvement Response
- Capstone Exercise: Laboratory Testing and Quality Management Pack

Practical Exercises

The course uses suggested activities with fictional medical, public-health, research, and environmental laboratory scenarios.

- Suggested activity: map testing processes, responsibilities, documents, competence, and resource controls.
- Suggested activity: evaluate method, equipment, reagent, specimen, and quality-control evidence.
- Suggested activity: review results, critical notifications, information integrity, and post-examination indicators.
- Suggested activity: investigate nonconforming work and build an audit, review, and improvement response.

FAQs

Who suits laboratory testing and quality management training, and what does it assume?

Laboratory managers, supervisors, quality personnel, technical leads, scientists, and operations staff suit the course; it assumes experience with laboratory processes and records.

How does laboratory testing and quality management differ from basic quality control training?

Laboratory testing and quality management integrates governance, competence, resources, methods, the total testing pathway, information, assessment, risk, and improvement rather than concentrating only on analytical control results.

What does ISO 15189:2022 address in laboratory management?

ISO 15189:2022 addresses quality and competence requirements for medical laboratories, connecting management-system controls with technical processes and laboratory services.

How should nonconforming laboratory work be managed?

Nonconforming laboratory work requires identification, containment, impact evaluation, decision authority, investigation, correction, communication, corrective action, effectiveness review, and retained evidence.

Which laboratory quality indicators support management review?

Useful laboratory quality indicators cover specimens, method and equipment performance, quality control, external assessment, result release, critical reporting, turnaround, nonconformities, complaints, competence, audits, and improvement actions.

Conclusion

Participants leave with a Laboratory Testing and Quality Management Pack containing governance, method, specimen, resource, control, result, information, risk, assessment, and improvement tools. The pack links technical evidence to management decisions across the testing pathway. It helps laboratories operate, monitor, review, and improve controlled testing services.