



# Laboratory Quality Manager and Laboratory Assessor



## OVERVIEW

The European Organization for Quality (EOQ) training course is designed to teach laboratory personnel and future laboratory assessors how to install, maintain, improve and assess a Laboratory Quality Management System that meets the requirements of ISO/IEC 17025, ISO 15189 Standard and OECD GLP, and is applicable for laboratories of any size and any activities related to calibration and testing.

The training covers valuable topics for accredited or to-be accredited laboratories such as uncertainty estimation, method validation, proficiency testing, calibration and risk management, as well as audit methods and tools. During the course the participants obtain knowledge about the process oriented approach to QMS, based on the latest version of the Standard ISO 9001.

## STRUCTURE OF THE COURSE

LQMAT

LQMATP

## PREREQUISITES

- Either university degree or equivalent in chemistry, physics, engineering or relevant fields or
- secondary education plus two years experience in a testing or calibration laboratory

## TARGET GROUP

- Laboratory and Quality Managers
- Laboratory staff dealing with quality of analysis and/or calibration
- Laboratory Assessors

## CONTENT

### Workshop 1 (WS1): ISO/IEC 17025, ISO 15189 Management System

- Brief overview of modern QMS principles based on ISO 9001
- International regulations related to the quality of measurements, calibration and accreditation
- Structure and the requirements of the standards ISO 17025 and ISO 15189

### WS2: Quality Assurance and Quality Documentation

- Process based management approach for laboratories
- Document Management structure
- Quality Manual, SOPs, quality records
- IT solutions for quality documentation

### WS3: Basic statistical tools for Laboratories

- Errors in quantitative testing, error propagation
- Characteristics of data population
- Data distributions, tolerance and confidence intervals
- Significance tests

### WS4: Internal Quality Control for Laboratories, Method Validation

- Steps for implementing Method Validation
- Validation requirements and parameters
- Method Validation characteristics and protocol
- Method Validation practices: 'Single-laboratory' or 'In-house'





**WS5: Quantifying Uncertainty in Analytical Measurements**

- Uncertainty sources and components
- Uncertainty estimation: „Top-down“ and „Bottom-up“ approaches
- Reporting uncertainty

**WS6: Traceability of Measurements**

- International system of quantities and units (SI)
- Traceability of measuring standards
- Certified reference materials (CRM) and reference materials (RM)
- Traceability of equipment

**WS7: Inter-laboratory Quality Control Measures**

- Proficiency testing schemes, inter-comparison and collaborative studies
- Operation principle of proficiency testing schemes
- Data processing in proficiency testing schemes

**WS8: Risk Management**

- Risks and opportunities in the context of laboratory management
- Process and methods to manage risks and opportunities

**WS9: Laboratory Audit**

- Accreditation standards and guidance documents: Requirements of ISO 19011 standard
- Audit process activities: planning, preparation, review, monitoring, reporting, follow-up and corrective action
- Audit documentation and risk management
- Roles and responsibilities of assessor, auditee and client
- Psychological aspects of audits
- Qualification of Assessor

9 days, 09:00 – 17:00. Working language is English.

**FEE**

10 days (training and examination) € 3.790,- (excl. 20% VAT)

The workshops also can be attended selectively. Daily fee € 477,- (excl. 20% VAT)

**DATES**

Vienna	13 – 23 June 2022
Vienna	07 – 17 November 2022

**EXAMINATION FOR LABORATORY QUALITY MANAGERS AND LABORATORY ASSESSORS**

The purpose of the examination is to assess the applicants knowledge on the following subjects:

- Quality Management System: development, maintenance, improvement
- Specific Quality Assurance and Quality Control Tools for calibration and testing laboratory
- Laboratory Assessment: standards, tools, approaches

**PREREQUISITES**

Attendance of the **qualityaustria/EOQ** training course for Laboratory Quality Managers and Assessors

**FORMAT**

Examination for Laboratory Quality Managers:

- Written multiple choice test
- Group work followed by presentation

Examination for Laboratory Assessor:

- Written multiple choice test

Working language is English.

**DATES**

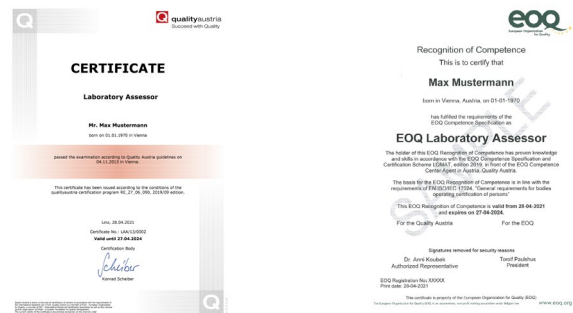
Vienna	24 June 2022
Vienna	18 November 2022

**CERTIFICATE**

Upon successful completion of the examination and submitted practical evidence the participants receive the certificates **Laboratory Quality Manager** and **Laboratory Assessor**.

You are entitled to apply for European Organization for Quality (EOQ) certificates of **EOQ Laboratory Quality Manager** and **EOQ Laboratory Assessor**.

**Note:** If participants do not have the requested practical experience, the certificate Laboratory Quality Manager „Candidate“ or Laboratory Assessor „Candidate“ will be issued.



**VALIDITY OF THE CERTIFICATE**

3 years



## CRITERIA FOR EXTENSION

**For Laboratory Quality Managers:** The competence of a Laboratory Quality Manager shall be reconfirmed using at least two of the below described re-certification methods:

1.) Professional development by task-specific/related training (on-site, videoconferencing or e-learning) of at least one day (8 hours), which may include a knowledge evaluation (covering e.g. new developments on standards and/or relevant laws/new methods and instruments).

2.) Examination: The examination shall be designed to comply with PRU 14: EOQ Harmonized Examination System – Framework. The minimum sum of ERP for the examination shall be 20.

3.) Providing evidence regarding professional practice: Declaration by the employer or by contractor(s) on at least one full year of work-experience in a function that includes tasks related to the “Laboratory Quality Manager” task description in the re-certification period.

**For Laboratory Assessors:** At least three complete system audits with at least 15 audit days either internal, 2<sup>nd</sup> or 3<sup>rd</sup> party audits (9 days of them on site) in the last 3 years, as to be declared by the employer or contractor(s)/customer(s) of the certified person.

Alternatively: Evaluation by a designated peer: 2 days of on-site witnessing, where the candidate is acting as auditor. The audit documentation prepared by the candidate shall be evaluated by the peer.

## REFRESHER COURSE FOR LABORATORY QUALITY MANAGERS AND LABORATORY ASSESSORS

### CONTENT

- New structure and requirements of the ISO 17025 Standard
- Process approach and process requirements of ISO 9001, ISO 17025 and ISO 15189 Standards
- Definition, description and visualization of processes in the laboratory; Efficiency and effectiveness of the processes, KPIs, process optimization and management
- Optimization of document management through a process-based approach and modern IT tools
- Sources of risks and opportunities in the laboratory
- Identification, evaluation, assessment and management of risks

- Development of risk-based quality control procedures
- Risks and opportunities in the context of laboratory management
- Management of risks and opportunities in an audit process in accordance with ISO 9011 Standard requirements

### DATE

online 03 – 04 November 2022

### FEE

2 days training € 1.298,- (excl. 20% VAT)

**Note:** Participation in Refresher Course is one-time mandatory for prolongation of the certificates of Laboratory Quality Managers and Assessors.

### QUALITY AUSTRIA – WHO WE ARE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is the leading Austrian contact for system and product certification, verification and validation, assessments, trainings and certification of persons as well as the Austria Quality Seal. Basis are worldwide applicable accreditations by the Federal Ministry for Digital and Economic Affairs (BMDW). Furthermore, since 1996 the Austrian Excellence Award is presented together with the BMDW. The organization cooperates with some 50 partner and member organizations worldwide and is national representative of IQNET, EOQ and EFQM.

### REGISTRATION

For registration please contact **Dr. Eugenia Soboleva, MBA** or **Ms. Susanne Bader** (susanne.bader@qualityaustria.com).



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