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BEMCON
INSTITUTE OF LAB QUALITY MANAGEMENT



ISO/IEC 17025:2017

GENERAL REQUIREMENTS FOR THE COMPETENCE
OF TESTING AND CALIBRATION LABORATORIES

CQI & IRCA UNITED KINGDOM REGISTERED (ASHBROOKE QUALITY ASSURANCE LTD.
IRCA CERTIFICATE NO. A17020)
5 DAYS ASSESSOR / LEAD ASSESSOR TRAINING & CERTIFICATION PROGRAM



OBJECTIVE

This intensive 5-day course is certified by the Governing Board of the International Register of Certificated Auditors (Ashbrooke Quality Assurance Ltd. IRCA Certificate No. A17020).

On successful completion of this course participants will achieve one of the formal requirements in becoming an IRCA Registered Lead Auditor. This course will allow delegates to develop practical audit skills and apply the newly updated management and technical requirements of ISO/IEC 17025:2017 to the specific processes and needs of the company. Furthermore delegates will be able to assess compliance of an organization's testing and calibration laboratory practices to meet the company's own internal or external (e.g. Accreditation Body) requirements.

This course will show attendees on how to plan, develop and implement an internal and external audit process appropriate to the requirements of ISO/IEC 17025:2017 with confidence. Interactive learning techniques are used to teach delegates how to identify risks and opportunities in an organization and take preventative action against risks. On top of that this course will coach delegates on how to save time and cost through more efficient lab testing procedures and calibration processes.

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COURSE OVERVIEW

Ashbrooke's 5-day ISO/IEC 17025:2017 Assessor/Lead Assessor Training Course is designed to develop the necessary expertise to audit a Laboratory Management System based on the updated ISO/IEC 17025:2017 standard requirements. Participants will cover the full range of assessment techniques, good practices, and assessor responsibilities and gain practical experience of planning, running, and reporting on assessments; after which each successful delegate will have earned his/her training qualification for certification as an IRCA Lab QMS Auditor / Lead Auditor.

This new ISO/IEC 17025:2017 aligns and harmonizes the requirements for a Laboratory Management System with ISO 9001:2015. The five-day course incorporates and explains the amendments to clauses where ISO determined that such changes were necessary. The technical requirements for laboratories who provide testing and calibration services are enhanced by the use of management systems

that incorporate the requirements of ISO 9001:2015.

This is generally followed by understanding:

1. ISO 19011:2018
2. Quality Management principles
3. ISO/IEC 17025:2017 principles

Over 90% of the course is dedicated to syndicate activities designed to examine and explore the disciplines of planning and conducting QMS audits. This course contains 4 Questionnaires, 8 Workshops, plus several additional skills development activities.

Prior Knowledge Expectation...

To ensure detailed and thorough understanding it is advised to:

1. Fill Pre-course form
2. Have basic understanding of ISO/IEC 17025:2017 before attending this course.
3. Basic knowledge of Management System and in particular Quality Management System

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WHAT ARE THE BENEFITS?

On successful completion, the delegate will know the Laboratory Quality Management System (LQMS) which is under the ISO/IEC 17025:2017 and will be:

1. Trained and qualified Auditors or Assessors to perform the auditing for ISO/IEC 17025:2017 of any laboratory.
2. Competent to audit your own organization, subcontractors and suppliers as Auditors or Lead Auditors.
3. Able to prepare and conduct assessments for the purpose of accreditation.
4. Understanding the economic advantages of laboratory Quality Management Systems.
5. Confident in continuing improvement and compliance with ISO/IEC 17025:2017.
6. Saving time and cost through more efficient lab testing and calibration processes.
7. Awareness of quality control and employee engagement.
8. Increasing stakeholder trust and confidence in your testing and calibration data as well as your laboratory quality control system.

WHAT WILL I LEARN?

1. The updated requirements of ISO/IEC 17025:2017 and how to meet them.
2. Understand the laboratory accreditation process.
3. How to plan, conduct and report on a lab audit.
4. The team roles and responsibilities required by ISO/IEC 17025:2017.
5. How to continually improve quality control processes.

COURSE ASSESSMENT

The delegate is assessed based on participation and performance throughout the duration of the course. This includes all exercises, role plays, case studies and all other activities during the course. Please note, full attendance is required during the training course.

There is a 2 hour written examination at the end of the course. The exam is closed book in that a delegate is entitled to use only their copy of the International Standard(s) in question or dictionary if delivery language is not their native language. The minimum pass rate for the examination is 70%.

COURSE CERTIFICATION

Ashbrooke's course is approved by IRCA (IRCA Certification No. A17020) and Chartered Quality Institute (CQI). It meets the training requirements for individuals seeking registration as a Lead Auditor under the IRCA Auditor Registration Scheme.



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SESSION INFO

Teaching Hours		40	Number Of Exercises		10
Total Hours		50	Course Assessment		2.00 Hours Writing Exam
Number Of Days		5 FullDays	Question Type		Descriptive and scenario based
Case Studies		10	Qualification Criteria		70% Exam Score
Number Of Attendees		10-12	Certificate Type		Digital Certificate

4 EASY STEPS REGISTER

1. The registration will be purely based on "FIRST COME - FIRST SERVE"
2. Visit www.ISO17025.Training to register online for the course.
3. Upon receiving your registration details, BEMCON will begin your registration process.
4. Once you receive your registration number that means your enrolment is confirmed.

DISCOUNT POLICY:

1. BEMCONIANS (Existing BEMCON Customers) = 15% Discount
2. Student = 15% Discount
Govt. Official and Staff from Govt. Labs = 10% Discount
3. Multiple participation from same organization = 10%

NOTE:

Students & Govt. Official are required to present official ID to avail the discount.





HAVE A GROUP TO TRAIN?

ASHBROOK approved experienced instructors will come to your site, or train your team through our live virtual online training option. Inquire today to schedule training.

COURSE DELIVERY:

1. IN-PERSON CLASSROOM:

5 days (an additional 6th day option available for client-based courses)

2. VIRTUAL INSTRUCTOR-LED TRAINING (VILT):

40 hours delivered in 6 x 6.6 hour blocks over 6 days

TRAINING OPTIONS:

We offer flexible training options to meet your needs and can build a schedule that works for you and your organization.

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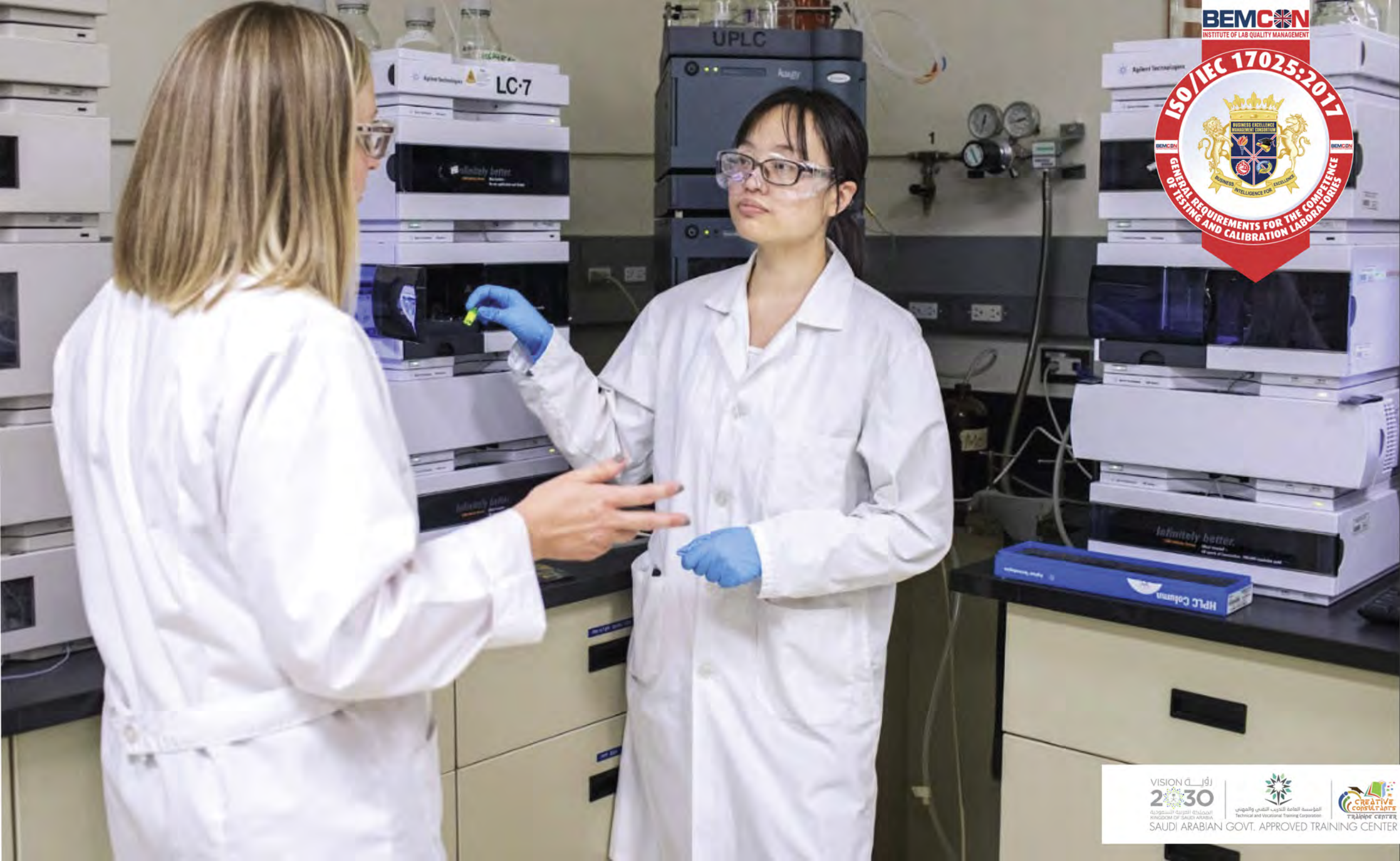
WHO SHOULD ATTEND?

1. This seminar is designed for Lab Management Representatives, ISO/IEC 17025:2017 Implementation Teams, Internal Auditors and others who would like to develop judgment and decision-making in ISO/IEC 17025:2017 and learn the auditing process for first, second, and third party auditors.
2. Anybody that wants to comply with mandatory ISO/IEC 17025:2017, SASO Saudi Arabia, ESMA UAE, DAC Dubai or any other country requirements for training of Quality Managers in laboratories
3. Professionals that want to know the advantages of operating an effective laboratory management system.
4. Anybody that is looking to expand his / her skills in the area of good laboratory practices Anybody involved in preparing an organization for assessment/accreditation by Govt. Agency, any Accreditation Body around the world.
5. Existing ISO 9001:2015 / ISO/TS 16949 auditors who are looking to expand their skills in the area of laboratory practices or who wish to audit laboratory environments.

The below mentioned roles and designation are mostly attending this ISO/IEC 17025:2017 Lead Auditor Courses, but not limited to:

- | | | |
|--|---|---|
| 1. Laboratory Directors and Managers | 1. Laboratory Engineers and Calibration Engineers | 1. Members of the Laboratories seeking ISO/IEC 17025:2017 accreditation |
| 2. Technical Director and Managers | 2. Laboratory Technicians | 2. Auditors wanting to perform audits under ISO/IEC 17025:2017 |
| 3. Laboratory Operation Manager | 3. Medical Laboratory Technician | 3. Project managers or consultants wanting to master the Laboratory Management System audit process |
| 4. Govt. Laboratory Officials | 4. Calibration Technicians | |
| 5. Quarantine and Regulatory Laboratory Inspectors | 5. Laboratory Analysts | |
| | 6. Technical experts wanting to prepare for a laboratory audit function | |

Above mentioned are not only group people to attend this course but if you are associated or interested in improvement of Quality Management systems for lab, you are encouraged to attend this course



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COURSE CONTENTS

8:30 AM - 6:30 PM

DAY 01

1. Introduction
2. Course Requirements
3. Pre-Course Questionnaire review
4. Auditor Code of Conduct
5. Key Vocabulary - Review
6. Principles - Review
7. Decision Rule
8. Audit Cycle
9. Case Study 1 - Examining Documentation to ISO/IEC 17025:2017
10. Audit Trail Challenge

8:30 AM - 6:30 PM

DAY 02

1. Open Review
2. Questionnaire No. 1
3. Auditor's Challenge - Incident
4. Case Study 2 - Preparing a Checklist
5. Audit Trail Challenge
6. Case Study 3 - Preparing an Audit Plan
7. Audit Trail Challenge
8. Case Study 4 - Conducting an Opening Meeting
9. Auditor's Bingo

8:30 AM - 6:30 PM

DAY 03

1. Open Review
2. Questionnaire No. 2
3. Auditor's Challenge - Incident
4. Case Study 5 - Conducting an Interview
5. Auditor's Challenge - Incident
6. Auditor's Bingo

8:30 AM - 6:30 PM

DAY 04

1. Open Review
2. Questionnaire No. 3 Auditor's Challenge - Incident
3. Case Study 6 - Preparing an Audit Report
4. Audit Trail Challenge
5. Case Study 7 - Conducting a Closing Meeting
6. Case Study 8 - Follow-up and Review of Corrective Action
7. Auditor's Bingo

8:30 AM - 6:30 PM

DAY 05

1. Open Review
2. Questionnaire No. 4
3. Audit Trail Challenge
4. Final Instructions and Questions
5. Final Examination
6. Course Close

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LAB QUALITY TRAINING PORTFOLIO

No.	MODULES	DURATION
1.	Uncertainty of Measurement	3 days
2.	Preparation for Laboratory Accreditation	3 days
3.	ISO/IEC 17025: 2017 Transition Preparation	2 days
4.	Practical Measurement Uncertainty - Calibration	2 Days
5.	Combined Laboratory Management	4 Days
6.	Laboratory Management - Role of the Quality Manager	3 Days
7.	Certified Calibration Technician Certification Preparation	5 Days
8.	Risk Management and Analysis for Medical Devices	2 Days
9.	Proficiency Testing ISO/IEC 17043	2 Days
10.	Implementing Design Control Requirements and Best Practices	2 Days
11.	Implementing CAPA Programs for the Medical Device Industry	2 Days
12.	Process Validation Principles and Protocols	2 Days
13.	Calibration Requirements and Equipment Controls for Medical Devices	2 Days
14.	Laboratory Operational Management Certificate Program	5 Days
15.	Assessor Training – Medical Laboratories ISO 15189	3 Days
16.	Statistics for Analytical Scientists	2 Days
17.	Advanced Hands-On Metrology	5 Days
18.	Practical Approaches to Quality Control in the Clinical Laboratory Certificate Program	5 Days
19.	Basic MET/CAL Procedure Writing	5 Days
20.	Patient Safety Essentials for Laboratory Professionals Certificate Program	5 Days
21.	Statistical Methods for Clinical Laboratorians Certificate Program	5 Days
22.	Basic Hands-On Metrology	5 Days
23.	Metrology Applications For Engineers And Scientists	5 Days
24.	Introduction To Measurement And Calibration	5 Days
25.	Advanced MET/CAL Procedure Writing	2 Days





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FURTHER PROGRESSION TO DEVELOP THE LAB STAFF COMPETENCE FOR ORGANIZATIONAL IMPROVEMENT



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DAMMAM

JANUARY 26-30, 2025
SUNDAY - THURSDAY



RIYADH

FEBRUARY 02-06, 2025
SUNDAY - THURSDAY



JEDDAH

FEBRUARY 09-13, 2025
SUNDAY - THURSDAY





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BUSINESS EXCELLENCE & MANAGEMENT CONSORTIUM

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