



**Africa Institute of Healthcare Quality
Safety & Accreditation (AfHQSA)**



**Quality & Accreditation Institute
Centre for Education & Training**

Medical Laboratory Quality Manager Training Course

(in accordance with ISO 15189:2012)

This Training Program is a Collaboration between AfHQSA & QAI

Who should attend?

As per accreditation requirements, it is important for the Quality Manager of a medical lab or any Biomedical Scientist who is interested in a career in healthcare quality and safety to get trained in a course which covers Quality Management Systems (QMS) and Internal Auditing. It is also equally useful for:

1. Biomedical Scientists
2. Pathologists
3. Medical Directors
4. Microbiologists
5. Biochemists
6. Technicians working in Medical laboratories to understand this international standard and sustain the quality and accreditation framework.
7. Healthcare Managers
8. Quality Managers
9. Clinical, industrial and academics with interest in medical laboratory are also invited to attend
10. Other stakeholders in health interested in quality and safety of medical laboratories

Learning outcomes: At the end of successful completion of the course, participants will learn and be exposed to the following:

- Appreciate their role and their ability to advance patient safety through medical diagnostics
- Understand the fundamentals of healthcare quality & safety
- Understanding and interpretation of the requirements of the standards
- Basic quality management systems as per ISO 15189
- Identify documents and records required by ISO 15189
- Understanding of a risk management plan
- Understanding of auditing principles
- Knowledge of internal auditing process including planning
- How to perform an internal audit
- Compose audit findings
- Preparation of audit report, follow-up and closing the loop
- Characteristics of an effective internal auditor



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Concept

Content of the course is aligned to ISO 19011: Guidelines for auditing management systems and it is tailored to be relevant to the assessment of medical laboratories.

Certification Process

All participants will receive a certificate of 'attendance'. However, to be Certified as a Quality Management Systems (QMS) & Internal Auditor (Medical Laboratory Category); participants will be expected to:

1. Score not less than 80% in a one-hour multiple choice exam that will be written on the final day of the course.
2. Pay an additional USD 150 or its cedi equivalent for the certification examination

Participants will therefore be expected to indicate their choice and willingness at the time of registration.

Course Certificates will be issued jointly by the Africa Institute of Healthcare Quality Safety & Accreditation (AfHQSA) and the Quality & Accreditation Institute (QAI) respectively.

Certified QMS & Internal Auditors (Medical Laboratory) will be expected to renew their certifications annually with AfHQSA.



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Course Schedule

Africa Institute of Healthcare Quality Safety & Accreditation (AfIQSA)				
Medical Laboratory Quality Manager Training Course (in accordance with ISO 15189:2012)				
Day 1	Duration	Content	Objectives	Facilitator
0800 - 0830	30 mins	Registration	to equip participants with the requisite knowledge & skills to appreciate their role and their ability to advance patient safety; to understand the fundamentals of healthcare quality & safety; to understand and interpret the requirements of the standards; to institute basic quality management systems as per ISO 15189	Secretariat
0830 - 0900	30 mins	Introduction to the training course		Gilbert
0900 - 0950	50 mins	Fundamentals of healthcare quality & safety		Elom
0950 - 1010	20 mins	Laboratory Accreditation : International Scenario		BK
1010 - 1020	10 mins	Group Photo		All
1020 – 1030	10 mins	Snack Break		All
1030 - 1300	4hrs 30mins	ISO 15189:2012 – Clause 4: Management Requirements		BK
1300 - 1330	30 mins	Lunch Break		All
1330 - 1530	3hrs 20 mins	ISO 15189:2012 – Clause 4: Management Requirements		RF
1530 - 1545	15 mins	Snack Break		All
1545 – 1700	2hrs 35mins	Exercise No. 1: Clause identification (reference clause 4)		Elom
1700 - 1730	30 mins	Outline of Case Study 1: Policy, Procedure, Process, Document & Record		BK



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Day 2	Duration	Content	Objectives	Facilitator
0830 – 0900	30 mins	Review of Day 1	to understand and institute a risk management plan; to identify documents & records required by ISO 15189; to understand & institute a risk management plan; to understand the auditing principles; to know the internal auditing process including planning	Elom
0900 – 1100	3hrs 20 mins	ISO 15189:2012 – Clause 5: Technical Requirements		BK
1100 – 1145	45mins	Snack Break		All
1145 – 1300	2hrs 35mins	ISO 15189:2012 – Clause 5: Technical Requirements		RF
1300 - 1330	30 mins	Lunch Break		All
1330 – 1530	3hrs 20 mins	Exercise No. 2: Clause identification (reference clause 5)		BK
1530 – 1545	15 mins	Snack Break		All
1545 - 1715	2hrs 50mins	Discussion on Case Study 1		Elom
1715 - 1730	15 mins	Outline of Case Study 2: Evaluation of Quality Manual		BK
Day 3	Duration	Content	Objectives	Facilitator
0830 - 0900	30mins	Review of Day 2	To equip participants to perform an internal quality audit; to enable participants prepare an audit report, follow-up & close the loop; to equip participants with the basic competencies & characteristics of an effective internal auditor	Elom
0900 - 1100	3hrs 20 mins	Discussion on the case study -2		BK
1100 – 1115	15mins	Snack Break		All
1115 – 1215	1hr 40mins	Case Study 3: Writing of Standard Operating Procedure (SOP)		BK
1215 – 1315	1hr 40mins	Audit and its associated activities (what is audit? why audit is done? How audit is done?)		BK
1315 – 1400	45mins	Lunch Break		All
1400 - 1545	3hrs 5mins	Group Exercise: Conduct of mock audit		Gupta
1545 – 1600	15mins	Snack Break		All
1600 - 1700	1 hr	Process of Accreditation		RF
1700 - 1730	30 mins	Preparation and logistics for site visit		
Overall Impact: Participants will apply the basic concepts, knowledge and skills in their practice to improve the quality and safety of medical laboratory diagnosis on the continent				



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Day 4	Duration	Content	Objectives	Facilitator
0830 - 0900	30mins	Review of Day 3	to equip participants with the requisite knowledge and skills set in risk assessment and biosafety issues in medical laboratory	Elom
0900 - 1020	1hr 20 mins	Risk Assessment 1		Raymond
1020 - 1050	30 mins	Snack Break		All
1050 - 1150	1 hr	Risk Assessment 2		BK
1150 – 1300	1hr 10mins	Laboratory biosafety and biosecurity		Raymond
1300 – 1330	30 mins	Activity: Photo-audit		Raymond
1330 – 1430	1 hr	Lunch Break		All
1430 – 1600	1hr 30 mins	Preparation and logistics for site visit		Gilbert
1600		Close		
Day 5	Duration	Content	Objectives	Facilitator
0830 - 0900	30mins	Travel to field exercise	To equip participants to perform an internal quality audit; to enable participants prepare an audit report, follow-up & close the loop; to equip participants with the basic competencies & characteristics of an effective internal auditor	Elom
0900 - 1100	3hrs 20 mins	Site activity + Snack		BK
1100 – 1115	15mins			All
1115 – 1215	1hr 40mins	Travel back to class		Gupta
1215 – 1315	1hr 40mins	Report preparation		RF
1315 – 1400	30mins	Lunch Break		All
1400 - 1530	1hrs 30mins	Presentation of field report		Gupta
1530 – 1545	15mins	Break		All
1545 - 1715	55mins	Written Test		BK
1700 - 1730	30 mins	Course Evaluation, Certificate Presentation, Close		



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What is covered in the course for Quality Manager for Medical Laboratory as per ISO 15189?

(a) Quality Management System as per ISO 15189:

Management Requirements	Technical Requirements
Organisation and Management responsibility	Personnel
Quality management system	Accommodation and environmental conditions
Document control	Laboratory equipment, reagents and consumables
Service agreements	Pre-examination, examination and post-examination processes
Examination by referral laboratories	Ensuring quality of examination results
External services and supplies	Reporting of results
Advisory services	Release of results
Resolution of complaints	Laboratory information management.
Identification and control of nonconformities	
Corrective action	
Preventive action	
Continual improvement	
Control of records	
Evaluation and audits	
Management review	

(b) Internal Audit:

- What is audit
- Types of audits
- What is Internal Audit
- Process of Internal Audit including planning and execution
- Internal Audit Report writing
- Follow-up and Closing the loop



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The Course Faculty include Renowned Professionals:

B.K. Rana

The first expert on ISO 15189 from India, Dr. B.K. Rana is the Founding CEO of Quality & Accreditation Institute (QAI) and former Director of NABH, the national healthcare accreditation body. He served International Society for Quality in Health Care (ISQua) as elected Vice-Chairman-Accreditation Council (2008-2014) and Chairman- Accreditation Council (2014-2016). He was appointed member on ISQua Board from 2014 to 2016, and now **elected as Member of the ISQua Board for 2017-19**. Concurrently, he served as President of Asian Society for Quality in Healthcare (ASQua) in 2011 & 12 and now serving as Member on its Board. He has many honours to his credit such as ISQua Expert, Assessor and Advisor. He also served as External Consultant of WHO on setting hospital accreditation program and also served as temporary advisor. He achieved rare distinction by becoming part of United Nations Framework Convention on Climate Change (UNFCCC) as an Expert/Assessor for Clean Development Mechanism (CDM). **He is a former APLAC Evaluator**. He sits on many national and international committees including **ISO/ TC 210 WG1**. **He is also appointed** ISQua Fellowship Program Curriculum Advisor. He is the Chief Advisor of the "Academy of Medical Laboratory Auditors (AMLA)".

Gilbert Buckle

Dr. Gilbert Buckle is a purpose driven individual of integrity and a strong yet gentle presence. He is a Public Health Physician and Consultant in Health Systems Strengthening, with over 22 years of experience (in both the public and private sectors). He is an accomplished and resourceful executive, with experience in designing healthcare programs and leading healthcare systems and organisations to enhanced performance and quality care outcomes. He has been successful in identifying and solving complex health related concerns of communities and health systems throughout Ghana. In pursuit of his fundamental passion for developing the potential of people and organizations to make them better, Gilbert is a certified executive coach with the International Coach Federation as well as an Organizational Development Certified Consultant. He is adept at strengthening health systems and healthcare organisations, developing long-term policies, building partnerships with key stakeholders, raising funds and providing health care in resource-limited environments with a focus on improving the quality of health outcomes. He is a change agent acknowledged for balanced judgment, stability, and capacity to steer consensus among core business disciplines with diverse agendas and visions. He exhibits natural leadership skills with a special talent for transitioning strategy into action and achievement, he is also an articulate communicator. His additional competencies include critical thinking, analysis, & strategic planning; Health Systems Strengthening & Optimisation; Healthcare Quality Improvement Initiatives; Leadership Coaching & Capacity Development; and Organisational System Transformations. Significant highlights of his career achievements include: Leading a whole system transformation



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programme at the Korle Bu Teaching Hospital that enhanced leadership's focus and commitment towards the provision of high quality service; raising the profile and influence of the Christian Health Association of Ghana through the establishment of strategic partnerships with government, local, and international bodies; optimising health service delivery of the National Catholic Health Service through organizational restructuring and spearheading various primary and institutional programmes; Leading the design and execution of quality improvement interventions that resulted in improved under-five mortality rates as well as innovative public health programs that enhanced mental health services in health facilities. Gilbert has served as a Temporary Technical Advisor to the World Health Organisation in Geneva and in the African Regional Office.

Gajendra Gupta

Dr. Gajendra Gupta is Medical Director & Head of Department, Department of Pathology and Transfusion Medicine at S.D.M. Hospital Jaipur. He is accreditation committee member as well as lead assessor for NABL, the national laboratory accreditation body. He has conducted over hundred NABL assessments and conducted several training courses on lab and transfusion medicine accreditation. He is also a member of the governing council of Asian Association of Transfusion Medicine. He has received many awards including 'outstanding contribution award for HIV Prevention' by Rajasthan State AIDS Control Society and 'Chikitsa Vibhusan award' by Jaipur Medical Association (JMA).

Raymond D. Fatchu

Raymond Donbezier Fatchu is the Director of Frayd Consulting . He is committed to shaping health outcomes by promoting the value and contributions of quality health systems through continual improvement of such health systems and practices. He holds a Bachelor's degree in Medical Laboratory Technology from the Kwame Nkrumah University of Science and Technology. He has worked extensively in the field of health systems strengthening with particular focus to laboratory quality management systems. He is the first Ghanaian resident mentor to lead the first public sector medical laboratory in Ghana to ISO 15189 accreditation. He has assessed, mentored and provided technical assistance to several medical laboratories in both public and private laboratories throughout Ghana.

Elom Hillary Otchi

OTCHI, Elom Hillary is one of the WHO Global Experts on Patient Safety, and the Prevention & Management of Falls. He is a conference speaker and a panel of several quality & patient safety conferences. He has worked as a National & International Consultant for UNICEF Ghana and WHO Sierra Leone supporting the implementation of the global Quality of Care (QoC) efforts for maternal, newborn and child health. In Ghana, he has played various roles in advancing the quality



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and safety of healthcare across the continuum of care. He is a Fellow of the International Society of Quality in Healthcare (ISQua) and a PhD Candidate of the University of Ghana School of Public Health.

Eligibility

1. Practicing Biomedical Scientist/Laboratory Technologist/Technician
2. Laboratory Medicine Physician

Registration

The registration fee for the five (5) days program is: Two Thousand Five Hundred Ghana Cedis (GHS2,500).

Payment can be made at:

Bank Name: GCB Bank

Branch: Haatso, Accra

Account Number: 1621180000540