Effective Implementation and Internal Audit of ISO 15189:2012
"Medical Laboratories – Requirements for Quality and Competence"

Organized by
FICCI QUALITY FORUM
June 25 – 28, 2014
Mumbai

1. Introduction

Medical laboratories are a critical part of the healthcare system. A patient's diagnosis and treatment are often based on test results, and an incorrect test results could lead to a misdiagnosis – which could have potentially fatal consequences. This is why accurate test results are critical each and every time a test is conducted.

ISO 15189 requires medical labs to implement a quality management system to ensure lab technologists always understand and follow correct method when conducting a test.

From October 2013 onward NABL has been accepting application of Medical Testing Laboratories as per the new standard ISO 15189:2012. All laboratories accredited till date as per previous version are required to ensure compliance with the revised version when they are reassessed during scheduled Surveillance/ Reassessment audits or as a separate assessment.

All laboratories are required to ensure laboratory's compliance as per the new standard ISO 15189:2012 before October 2015.

This course is suitable for quality/technical managers and professionals working in medical laboratories.

2. Course Objectives

The aim of this course is to provide comprehensive training on requirements & implementation of ISO 15189:2012. At the end of the course the participants will be able to:

- ✓ Understand the requirements of ISO 15189 including changes etc from previous version
- ✓ Implement ISO 15189 effectively
- ✓ Conduct an effective gap analysis/internal audit/ third party audit of LMS
- ✓ Meet NABL criteria for training of Quality Managers

3. You should attend this course if,

- ✓ You want to understand terminology and interpretation of ISO 15189 requirements
- ✓ You want to implement ISO 15189 in your laboratory
- ✓ You want to standardize process in your laboratory
- ✓ You want to perform internal audit in your laboratory
- ✓ You are looking to expand your skills in the area of good laboratory practices
- ✓ You are involved in preparing your organisation for assessment /accreditation by NABL or you are already a Quality/Technical Manager in NABL accredited laboratory
- ✓ You want to assess LMS of your supporting laboratories

4. Course Material

Course kit comprising detailed course material with several worked out examples which will help participants to understand subject matter.

5. Methodology & Certification

A judicious mix of class room presentations, exercises, group discussion, case studies and hands-on practice will be used. Participants will be encouraged to relate the learning to live situations.

Participants who successfully complete the continuous assessment during the course and also the written examination conducted on 4th day of the course will be issued a certificate by FICCI.

6. Course schedule, Venue & Registration

Date: Jun 25 – 28, 2014

Timing: 09:30 – 17:30 hrs

Nature: Non- Residential

Venue: Hotel Suba International, Mumbai

Participation Fee: Rs. 16,850/- + 12.36% Service Tax (Total Amount: Rs. 18,933/- includes cost of

training, course kit, lunch & tea)

Registration: Send registration form along with Cheque/DD in favour of "FICCI Quality Forum"

The seats in the course are limited and registration will be done on first come first serve basis

For further details & to reserve your seat, please contact:

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7. About Our Faculties

Our technical expert **Dr. A.S. Kanagasabapathy** began his career in CMC Hospital, Vellore, in 1966 and remained until retirement in 2000 as Professor and Head of Clinical Biochemistry. For over three decades he has been deeply involved in promoting the quality of laboratory services and also in teaching and research. He has published over 100 papers in national/international journals. As the convenor of the QC committee of the Association of Clinical Biochemists of India, he started a national level external quality assurance programme 35 years ago with 50 laboratories, which today has over 2000 participants. He was President of ACBI for the year 2000 -2001.He has conducted nearly 100 quality control workshops for the benefit of clinical pathologists and medical laboratory personnel. In 2007 ACBI honored him with the award for Distinguished Services in Clinical Biochemistry.

Dr. Kanagasabapathy is associated with the WHO in various laboratory QC activities and has been the author/co-author of 3 WHO documents.

He is a Fellow of the Association of Clinical Biochemists of India as well as the National Academy of Clinical Biochemistry of the US.

In 1997 Dr. Kanagasabapathy was the Chairman of Technical Committee constituted by the NABL for formulating specific guidelines criteria for medical laboratories. He has contributed significantly towards the preparation of NABL document # 112 of 2005.

He is a regular speaker on lab related topics nationwide. Dr. Kanagasabapathy is a member of Clinical Chemistry Trainee Advisory council Board of "Clinical Chemistry", the official journal of the American Association of Clinical Chemistry.

Our management system expert **Mr. Basudev Bhattacharya** has rich experience of 43 years in the field of designing, functioning, & managing members of Pilot Test House of the Government testing laboratories. He was one of the founders of Pilot Test House, Ministry of Commerce, a premier test and calibration centre for testing export products from the country.

Mr Bhattacharya was trained on Laboratory Management in UK in 1988 under the Indo-EEC Co-operation. He has been an International consultant in the field of laboratory accreditation on behalf of International Trade Centre (ITC) a UN Agency. He was Chairman of Technical Committee on Photometry of NABL and member of the NABL technical committees on Clinical & Food Testing Laboratories.

He has presented and published more than 30 papers on a variety of technical subjects in National and International Journals, seminars and conferences. He has conducted more than 180 in-house workshops and training programmes on LMS in India, Bangladesh, Mauritius, Dubai, Abu Dhabi & Kuwait, and has trained more than 2200 persons. He has been providing auditing services to accredited laboratories and certified organizations as per ISO/IEC 17025, ISO 15189 & ISO 9001 Standards, and has conducted more than 75 such audits.

He has also provided LMS implementation support to 13 laboratories in different disciplines (viz. Chemical, Clinical, Mechanical, Electrical testing etc and Calibration of Mass-Dimension-Thermal-Pressure which have successfully achieved NABL accreditation.

8. About FICCI Quality Forum

FICCI Quality Forum (FQF) is a specialized division of Federation of Indian Chambers of Commerce and Industry (FICCI) set up with objective to sharpen the competitive edge of Indian Industry. FQF provides training, consultancy and research services focused on enhancing the quality quotient of clients and partner organization.

For the past 20 years, FQF is providing training

on various ISO management systems and has a pool of highly competent & experienced trainers to conduct training courses.

FQF has collaboration arrangements with Nigel Bauer and Associates, UK for providing IRCA, UK approved Auditor/Lead Auditor training courses on ISO 9001 Quality Management System (QMS), ISO 14001 Environment Management System (EMS), ISO 22000 Food Safety Management System (FSMS) and Occupational Health and Safety Management System (OHSAS) 18001 standards. A summary of feedback given by past participants of these courses is included in this brochure.

In addition we also provide training on Six Sigma Green and Black belt certification, and Project Management. We also provide consultancy support on effective implementation of above management systems including LMS leading to certification/accreditation. A summary of feedback given by past participants of our laboratory management systems related trainings are included in this brochure.

9. Course Content

1. Introduction

1.1. Certification and Accreditation

1.2. The Global scenario and APLAC, ILAC MRA

2. Overview of concept of Laboratory Management System (LMS) & structure of ISO 15189

3. Comparison between ISO 15189:2007 and ISO 15189:2012

4. Summary of changes in ISO 15189:2012

5. Understanding Management Requirements of ISO 15189:2012 with detailed examination of important management system elements

5.1. Organization and management responsibility

5.2. Document control

5.3. Identification and control of non-conformities

5.4. Corrective action

5.5. Preventive action

5.6. Management review

6. Understanding Technical Requirement of ISO 15189:2012 Standard with detailed examination of important technical operations

6.1. Personnel

6.2. Laboratory equipment, reagents and consumables

6.3. Pre-examination processes

6.4. Ensuring quality of examination results

6.5. Laboratory information management

7. Auditing practice

7.1. Contents of clause 4.14 of ISO 15189 - Evaluation and audit

7.2. Introduction to audit

7.3. Types and methods of Audit

7.4. Checklist preparation, audit planning and audit schedule

7.5. The audit process

7.6. Identification of non-conformities

7.7. Preparation of Audit Report

7.8. The internal audit process

8. Implementation of laboratory management system with evidence leading to accreditation

9. Understanding the specific criteria of NABL accreditation on Clinical Laboratories

10. The accreditation process of NABL

10.1 Adequacy audit on receipt of application compliant to NABL requirement

10.2 Pre-assessment by Lead Assessor

10.3 Final assessment after closure of NC if any on pre-assessment

10.4 Examination of assessment report by Accreditation Committee after closure of NC if any raised during final assessment

10.5 Issue of accreditation certificate after recommendation by Accreditation Committee

11. Syndicated exercise on:

11.1. Management requirement

11.2. Developing documented procedure

11.3. Technical requirements

11.4. Developing standard operating procedure

11.5. Preparation of checklist for Audit

11.6. Identification and writing of NCs

11. Some Comments from participants of LMS Training Programs conducted by FICCI

- The course and the manner in which it was delivered certainly deserve high grades on the scale. It has gone beyond what I had actually expected before being part of it.
- The friendly and tension free environment created by the trainers.
- Calmness of trainers in answering all the queries.
- The learning that comes with each course is always good but the way it is given is really important. The Course material/learning were very well disseminated and the ease with which I could learn was good. I enjoyed learning.
- I had wonderful experience which is full of knowledge and information which will be not only useful in my professional life but also in personal life
- Overall arrangements, ambience and faculty were excellent and I would like to further participate in such other Quality training programmes
- I have really gained a lot of understanding on the concept of LMS & I really am thankful to FICCI for conducing such courses
- The structured methodology and experience and expertise level of the faculty.
- Training material was very clear and sequential methodology was conducive to learning.
- The deliberations by Faculty were the best thing. His pace & pitch during the entire course was constant which led to good learning.
- The trainer has vast knowledge and the skill of imparting training is unmatchable. His valuable inputs will definitely help our ability to do well in future course.
- Getting training from such a great experience trainer is really a great experience. Thank you very much, sir for such a wonderful training!!!
- Trainer given very good presentation and transform and described each and every point related to training. Please continue it for next time. It will be very helpful for laboratory