



HAFFKINE INSTITUTE FOR TRAINING RESEARCH & TESTING

An Autonomous Institute of Govt of Maharashtra.
Recognised as "Scientific & Industrial Research Organization (SIRO)
By Govt Of India, Ministry of Science & Technology.



ANNOUNCES A TRAINING PROGRAM ON
"LABORATORY MANAGEMENT & INTERNAL AUDIT"
as per ISO 15189:2007 ON 16,17,18 and 19 NOVEMBER 2009

This training program is designed for the Clinical Testing laboratory professionals; Quality Assurance personnel and professionals interested to work in clinical laboratory management & accreditation

COURSE OBJECTIVES:

1. To design and implement ISO 15189 requirements for Laboratories.
2. Enable participant to develop quality system documentation as required by the standard.
3. To learn about internal auditing – types, stages, phases, conducting audit & reporting

DURATION & TIMINGS

Four days **16,17,18 AND 19 NOVEMBER 2009**
0900 hrs to 1730 hrs on Day 1- 3; 0900 hrs to 1530 hrs on Day 4.

ELIGIBILITY CRITERIA

Consultants such as Pathologist, Microbiologist, Biochemist or Technician in a laboratory with relevant work experience in the field of measurements either in maintenance, inspection, testing/calibration laboratory or QA

COURSE CONTENTS

- Basic Quality Concepts
 - o National/International relevance of Accreditation
 - History & Evolution of ISO 15189:2007
 - o Understanding Standard Requirements
 - Documentation – Structuring & developing Quality Manual/Procedures
 - o Internal Audit – understanding types, stages, phases of conducting audit
 - Hands-on training on auditing clinical Laboratories & Audit reporting.
 - o Accreditation Process details

COURSE MATERIAL

The delegates will receive Specific designed Course notes, copy of ISO 15189 standard, NABL 112 document & Stationery.

METHODOLOGY

Lectures, highly interactive sessions, group exercises and case studies. Mock laboratory audit will be on 3rd day afternoon session.

CERTIFICATION

The participants are awarded 'Certificate of Participation'

COURSE FEE

Rs. **10,000** /- participant + service tax @ 10.30%, total Rs. **11,030/-**
Non- Residential. However Accommodation can be organised at Mumbai-GUEST HOUSE BY PAYING Rs. 225 PER NIGHT PER PERSON BY CASH on first come, first serve basis. 10% discount in the fee given for 3 or more participants from the same organization. Fees are to be paid by DD only in favour of 'Director Haffkine Institute' payable at Mumbai. Delegate fee is non-refundable however changes in nominations are acceptable. The fee is to be paid in advance or on first day of the course.

NOMINATIONS: The nominations are accepted on 'first come-first serve' basis. Interested, send your nomination by email or on plain paper / sponsoring organizations' letter head to the address below. The confirmation is only after the receipt of DD.

CONTACT:

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Director
Haffkine Institute

NATIONAL ACCREDITATION BOARD
FOR
TESTING & CALIBRATION LABORATORIES

**“Laboratory Quality System & Internal Audit as per ISO 15189:2007”
PROGRAMME**

Time (Hrs.)	Lecture / Activities
DAY - I	
0900 – 0930	Registration
0930 – 1000	Introduction to the course
1000 – 1100	Laboratory Accreditation International Prospective
1100 – 1130	Tea Break
1130 – 1300	ISO 15189:2007 : Interpretation of Management requirements
1300 – 1400	Lunch Break
1400 – 1530	ISO 15189:2007 : Interpretation of Management requirements (<i>Continued</i>)
1530 – 1600	Tea Break
1600 – 1730	Exercise No. – 1 : Identification of Clauses w.r.t. ISO 15189:2007 (Clause 4)
1730 – 1745	Brief on CASE STUDY – I Study of ISO 15189:2007: w.r.t. Policies, Procedures, Records -- for Clauses 4 & 5
1745 – 1815	Tea Break
1815 – onwards	Case Study – I – continued
DAY - II	
0900 – 0930	Review of Day – I
0930 – 1100	ISO 15189:2007: Interpretation of Technical Requirements Exercise – Technical Manager appraisal
1100 – 1130	Tea Break
1130 – 1300	ISO 15189:2007: Interpretation of Technical Requirements (<i>Continued</i>)
1300 – 1400	Lunch Break
1400 – 1530	Exercise No. - 2 : Identification of Clauses w.r.t. ISO 15189:2007 (Clause 5)
1530 – 1600	Tea Break
1600 – 1700	Discussion on Case Study – I
1700 – 1715	Brief on Case Study – II : Evaluation of Quality Manual for its Adequacy
1715 – 1745	Tea Break
1745 – onwards	Adequacy of QM continue

“Laboratory Quality System & Internal Audit as per ISO 15189:2007”

PROGRAMME

Time (Hrs.)	Lecture / Activities
DAY – III	
0900 – 0930	Review of Day – II
0930 – 1100	About <ul style="list-style-type: none"> Principles of Audit • Types of Audit • Audit Conduct
1100 – 1130	Tea Break
1130 – 1300	Discussion on Case Study – II
1300 – 1400	Lunch Break
1400 – 1530	Audit in the Laboratory
1530 – 1600	Tea Break
1600 – 1700	Audit in the Laboratory; <i>Continue</i>
1700 – 1715	Brief on Development of Procedures :- Exercise
1715 – 1745	Tea Break
1745 – onwards	Development of Procedures :- Exercise - <i>Continues</i>
DAY – IV	
0900 – 0930	Review of Day – III
0930 – 1100	Presentation/ Discussion on Procedures
1100 – 1130	Tea Break
1130 – 1300	Presentation on Audit Findings
1300 – 1400	Lunch Break
1400 – 1500	NABL Accreditation Programme/ Route to Accreditation
1500 – 15:30	Valedictory
15:30	Tea Break

