## Sir Ganga Ram Hospital Department of Biochemistry

Name of the course: "Total Laboratory Quality Management & Internal Auditor - ISO 15189:2012" Type of Course: Certificate course

**Introduction:** This is a specialized training program for all sections of medical testing laboratories

(Biochemistry, Genetic Medicine, Hematology, Histopathology & Cytopathology and

Microbiology) (as per ISO 15189:2012)

**Duration:** 1 month

**No. of candidates :** 2 candidates

### **Eligibility:**

• MD/DNB in Biochemistry/ Genetics/ Microbiology/ Pathology

• DCP (Diploma Clinical Pathology)

PhD in Biochemistry/ Biotechnology/ Genetics/ Microbiology

**Selection Process:** Interested candidates are required to submit their CV along with the application form

(available on link provided). All the applications will be screened and the shortlisted

candidates will be called for interview.

**Course fees:** Rs. 10,000/-

Objective of the course: To train the candidates in Total Quality Management of all sections of medical

testing laboratories.

**Faculty**:

Course Advisors: Dr. S.P.Byotra Dr. Kusum Verma

Director, Clinical Laboratory Services Dean, GRIPMER

**Course Director:** Dr. Seema Bhargava

Chairperson, Deptt. of Biochemistry

Course Coordinators: Dr. Sunita Bhalla Dr. Chand Wattal

Chairperson, Deptt. of Pathology Chairperson, Deptt of Microbiology

Dr. Jyoti Kotwal Dr. Ratna Puri

Chairperson, Deptt. of Hematology Chairperson, Institute of Genetic Medicine

Dr. Anjali Manocha Dr. Mamta Kankra

Sr. Consultant, Deptt. of Biochemistry Sr. Consultant, Deptt. of Biochemistry

Quality Manager, Clinical Lab. Services Dr. Parul Singla

Consultant, Deptt. of Biochemistry Dr. Manushri Sharma

Assoc. Consultant, Deptt. of Biochemistry

#### **Course content:**

- 1. Overview of Good Laboratory Practices
- 2. ISO 15189 and NABL 112

# Sir Ganga Ram Hospital Department of Biochemistry

- 3. How to write Quality Documents (e.g Quality Manual, Mandatory Procedures, Primary Sample Collection Manual)
- 4. How to maintain documentation and the trail of Policy-Procedure-Record
- 5. How to write an SOP [Standard Operating Procedure]
- 6. Root cause analysis and Corrective and Preventive Actions
- 7. Addressing Complaints/Feedbacks
- 8. Assuring customer satisfaction
- 9. Risk Management
- 10. Continual Improvement and Key Quality Indicators
- 11. How to conduct Internal Audit and MRM
- 12. Ethics and Confidentiality
- 13. Patients Rights and Responsibilities
- 14. Personnel- Training and Competency Assessment
- 15. Lab Safety and Occupational Hazards
- 16. Primary Sample Collection Facility- Requirements and Management
- 17. Internal Quality Control [IQC] and External Quality Assessment [EQA]-Review and resolution of outliers
- 18. Specific training in each section of clinical laboratory services on how to handle IQC and EQAS in the respective sections (Biochemistry, Genetics, Histopathology and Cytology, Haematology and Clinical Pathology, Microbiology)
- 19. Basic statistical procedures for Quality Control
- 20. Sigma Calculation & review
- 21. Report Attributes and Review of Results
- 22. Biological Waste Management
- 23. Hospital Infection Control
- 24. Laboratory Information System
- 25. Co-ordination between Laboratory and Clinicians
- 26. Overview of NABH Standards for Clinical Laboratory Services
- 27. Seminars and journal clubs by candidate
- 28. Inventory Management
- 29. Equipment Records (IQ/OQ/PQ)

### **Schedule:**

Mornings (9 am -1 pm):

1. Department of Biochemistry: 1 month

Afternoons (2 -5 pm):

2. Department of Histopathology & Cytology: 1 week3. Department of Haematology: 1 week

4. Institute of Genetic Medicine: 4 days (1 day/ Biochemical Genetic / Cytogenetic /

HLA Genetic/ Molecular Genetic)

5. Department of Microbiology: 1 week

Exit Exam: 2 hours' written exam with MCQs and short questions