## SHREYAS QUALITY MANAGEMENT SYSTEM



# **Training on**

# Laboratory Quality Management System and Internal Auditor Training as per ISO 15189:2012 NABL & NABL112

Course Duration: Four Days Fee: Rs.15,000/- + GST (18%)

### Lead Faculty:

Dr. R. R. LAKHE, Director, SQMS, Nagpur

Registered Sr. Consultant for ISO 9001, Business Process Management, Lean Manufacturing consultant & Lab Management System (NABL) with Quality Council Of India, Govt.of India.

## SHREYAS QUALITY MANAGEMENT SYSTEMS

CDC, GOI/QCI Accredited and IMS Certified Training & Consultancy for

 TQM - Quality Award, Quality Cost, SQC, Six Sigma, Lean, RCA.
 ISO 9001, ISO 14001, ISO 45001, ISO 50001, ISO 17025/15189 (NABL Accredition), Adm office: 3<sup>rd</sup> floor Tulsi Vihar, 11, Abhyankar Nagar. Nagpur 440010
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#### INTRODUCTION

Laboratory accreditation is gaining importance as the quality, reliability and accuracy of the test result are increasingly for better and on time treatment. ISO has introduced the lab accreditation standard, 15189 for the General Testing Laboratory for accreditation, and the large numbers of lab both from government and private organization are going for accreditation. This training has been planned to understand the requirements of ISO 15189:2012 RA 2019 standard, its clauses, implementation requirements and auditing as per this new standard.

#### **BENEFITS OF ACCREDITATION**

- Establish confidence of management and customers on your test results as well as test reports and increase customer trust as well as market share.
- Continually improving data quality and laboratory effectiveness. It will give better image of lab as a Quality Testing Lab in Local and Global market.
- Better control of laboratory operations and feedback to laboratories as to whether they have sound Quality Assurance System and are technically competent.
- Laboratory will be participating in Inter laboratory Comparison program so that quality level of the lab with respect to other accredited lab can be determined.
- Quality control checks will be carried out periodically due to which system is always maintained and improved.

#### CONTENTS

- Introduction to ISO 15189:2012
- Understanding the standard requirements
  - Management requirements
    - Organization and management responsibility
    - Quality management system
    - Document control
    - Service agreements
    - Examination by referral laboratories
    - External services and supplies
    - Advisory services
    - Resolution of complaints
    - Identification and control of nonconformities
    - Corrective action
    - Preventive action
    - Continual improvement
    - Control of records

- Evaluation and audits
- Management review

#### Technical requirements

- Personnel
- Accommodation and environmental conditions
- Laboratory equipment, reagents, and consumables
- Pre-examination processes
- Examination processes
- Ensuring quality of examination results
- Post-examination processes
- Reporting of results
- Release of results
- Laboratory information management

#### Quality Assurance in Medical Labs

- Use of quality control materials (Kit Controls/Masters).
  - LJ Chart & its interpretation using Westgard Rule
- Conducting intermediate checks on measuring equipments.
- Retesting of retained items.
- Participate in inter laboratory comparisons (ILC)
- Participate in External quality assessment program(EQAS)

#### Internal Audit

- o Internal audit documentation, methods
- o Report/NCR writing,
- Conduction of mock audit

#### **BENEFITS OF TRAINING**

- □ You will know the accreditation system for Laboratory.
- You will get the detail knowledge related to Quality Management System Requirement,
  Documentation, internal audit, Record Keeping as per ISO 15189:2012.
- You will know the technical requirements related to personnel, equipment, calibration, handling of material, validation, test report preparation, metrological traceability, inter lab comparison, proficiency testing programme as per ISO 15189:2012.
- You will understand the Quality assurance practices and requirement in a lab.
- □ You will prepare ISO 15189:2012 implementation plan for your lab.
- □ You will be able to conduct internal audit of the laboratory.

#### METHODOLOGY

- Online interactions
- □ Individual/ Group Exercises

- Practical Exercises/case studies of Laboratory
- Exam will be conducted on last day
- Successful candidates will be given the certificates.

#### CERTIFICATE

Participants qualifying examination shall be awarded certificate of successful completion of the course.

#### WHO SHOULD ATTEND

- The Owners, In-charges, HODs, Quality/Technical Manager, technicians and laboratory personnel from various Medical (Molecular/Microbiology/Pathology/Radiology etc.) laboratories.
- Individuals who wish to acquire knowledge on ISO 15189 & NABL112.

#### ABOUT SQMS

Shreyas Quality Management Systems is a management training & consultancy firm focused on organizational performance improvement through the globally accepted tools such as Lean manufacturing, 5S, ISO 9001QMS, ISO14000 EMS,ISO 45001 OSHAS, ISO50001EnMS, TPM, ISO17025/15189 Lab Accreditation NABL, NABH, TQM, quality costs, Lean Six Sigma, Design of Experiments etc.

\*SQMS was accredited by Consultancy Development Centre, Govt of India, and ISO9001 QMS, ISO14001EMS & ISO 45001 OHSAS certified, MSME registered and is Quality Council of India Registered Lean and Business Process Improvement , Lab Management System(NABL) Consultant. QCI NABET has approved SQMS as the Lab Consultancy Organization. It is the first and only one to be recognized by QCI for consultancy work for NABL accreditation in India.

It is lead by Dr.Ramesh R Lakhe who has completed his Doctoral Program from NITIE Mumbai and is Registered Sr. Consultant for ISO 9001, Business Process Management & Lab Management System with NRBPT, QCI, New Delhi. SQMS has well qualified, trained and experienced team in diversified areas.

SQMS has been associated with Institution of Engineers (I) Nagpur and has conducted many programmes on professional development. For last more than 10 years SQMS along with Institution of Engineers (I) Nagpur is organizing All India Seminar 'Quality Progress''. This seminar provides platform for researchers, academicians, professionals to interact and present case studies and research. This seminar also conducts the competitions for organizations such as

"Quality Circle competition, 5 S & Kaizen Competition, Six Sigma Competition" etc. in which participation from very large number of small, medium, large, Govt, public sector & private organization takes place.

**SQMS** has association with many engineering & management Institutes like Shri Ramedobaba College of Engineering & Management Nagpur, YCCE Nagpur, Raisoni Engineering College, BNCOE Pusad etc. and have signed MOU with them. This has resulted in availability of expert resources, facilities like library, centres for the training and consultancy projects. Many of the faculty members of the institutes are associated with us in the training & consultancy projects.

**SQMS gives emphasis on learning & development.** It regularly conducts in house trainings for its members on new areas and provides opportunity to them through web as well as classroom learning. This keeps the knowledge level of its members updated.

SQMS also give importance to research & development. Under the guidance of

Dr. Ramesh Lakhe, Director,SQMS, 14 scholars have completed their PhD research on the themes such as Lean Manufacturing, TPM, TQM, Six Sigma, ISO etc. and many more are perusing. Also there has been significant contribution to the literature through the publication of 25 books on Total Quality Management, ISO systems, Six Sigma, QC Tools, SPC etc and more than 200 papers/articles in International and national Journals/Conferences.

SQMS is committed for social development & is conducting "5 S "training for students of engineering and motivating them in its implementation so as to improve housekeeping and also contribute towards inculcating culture of Swaccha Bharat amongst the students. SQMS has also helped conduction of Pranayama and meditation programmes for organizations such as Art of Living. AS its CSR activity, SQMS has provided consultancy for development of systems and obtaining ISO9001 certification to organizations such as Central Prison, Nagpur.

SQMS has helped many organizations both from manufacturing and service sectors to analyses and improve their performance through well established systems. It has team members possessing a wide spectrum of professional qualifications, experience and expertise which could effectively and efficiently address improvement issues which are of importance to business / organization. It has provided consultancy to more than 100 organisations both from manufacturing and service sector (Organizations cover small, medium, large scale units from various sectors such as Power, Health care, Software, Logistics, Laboratory, Furniture, etc.) for process, productivity & profit improvement.

The **major clients of SQMS** include NTPC, Adani Thermal Power Station, Indiabulls, Reliance Power, Reliance Industries Ltd., MAHAGENCO, MAHATRASCO, MAHADISCOM, Mahindra & Mahindra, Pix Transmission, Grind-well Norton, Indian Sky Tanking, MECL, NCL, SCCL, SMS Group, PESO, IBM,NEERI, JNARDC, Spacewood, Micropro Software Sol, ICAR, CICR, Tata Steel, NMC, Bilaspur Municipal Corporation, NEERI etc.

The details of SQMS can be obtained on www.sqmsindia.com

#### **Consultancy Services Offered**

- ISO 9001 : 2015 QMS, ISO14001:2015 EMS , ISO 45001, ISO 15189, ISO17025 , ISO50001 ENMS, ISO 27001 ISMS
  - o Training and consultancy for certification
  - o Maintenance of the system through regular audits
  - o Documentation of the system
  - o Internal audit
  - o Pre-certification audit
- ✓ TQM Training and Implementation consultancy
- Design of Quality Cost Collection System and Analysis
- ✓ Six Sigma Green Belt Training & Consultancy
- TPM training and Implementation Consultancy
- Lean manufacturing tools and techniques Implementation Consultancy
- Quality Award (CII Exim, Rajiv Gandhi National Quality Award, Bajaj Quality Award)
  Preparation
- Consultancy for Process mapping & improvement
- ✓ Good Manufacturing Practices (GMP)

#### Training Programmes Offered

Training programmes will be designed as per the requirements of the organization on various diversified topics pertaining to process improvement which includes the following:

- ISO 9001 : 2015 QMS,ISO14001:2015 EMS ,ISO17025/15189 NABL ,ISO 27001 ISMS, ISO50001 ENMS,ISO45001:2018OHSAS: Awareness, Documentation, Internal Audit & Lead Auditor Training
- NABL-Lab Quality Management System
- Safety, First Aid
- Green Audit
- Design of Experiments
- Quality Costs
- Total Quality Management
- ✓ Six Sigma
- Lean Manufacturing tools and techniques
- ✓ ISO/TS Tools like APQP, PPAP, MSA, Control plan,
- Statistical Process Control
- Total Productive Maintenance
- 5 S, Kaizen, Pokayoke

#### ✓ Value Engineering

#### Auditing

SQMS conducts Green Audit, Safety Audit, Vendor audits, ISO Management system internal audits, 5 S audits for the orgnisations.

#### Organised by-

#### SHREYAS QUALITY MANAGEMENT SYSTEM (SQMS)

(Consultancy Development Centre, Govt. of India Accredited, and IMS certified Training & Consultancy Organization)

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"Coming Together is Beginning, Sharing Together is Progress; Working Together is a Success" Let's Work Together For Success.....