

National Workshop on Laboratory Quality Management System in Diagnostics

September 05 - 07, 2017

National Institute of Biologicals, Noida





Program Details

ABOUT US

NIB

National Institute of Biologicals (NIB) is an autonomous Institute under Ministry of Health & Family Welfare, Government of India.

www.nib.gov.in

CDSA

Clinical Development Services Agency (CDSA) is an extramural unit of Translational Health Science and Technology Institute, Department of Biotechnology, Ministry of Science & Technology, Government of India.

www.cdsaindia.in

Both NIB and CDSA have a common mandate of capacity and capability building by supporting the national goal of "Make in India" program, therefore jointly organizing the National Workshop on Laboratory Quality Management System (LQMS). The one conducted by NIB and CDSA on February 08-10, 2017 was **first of its kind to be held in the country in the area of Diagnostics.**

OBJECTIVE

To provide a learning platform through a highly intensive, hands-on-training in NIB's state-of-the-art laboratory accredited as per 17025:2005 requirements.

This workshop will comprise of a coherent set of lectures, exciting range of breakout discussions and problem solving exercises to understand, implement and practice LQMS in the area of Diagnostics. This workshop will expose the participants to adapt to the best global practices in quality testing with step-wise laboratory improvement towards achieving ISO 17025 accreditation so that the laboratories provide safe, timely and accurate results.

DATE: September 05 - 07, 2017

SEATS: 40

WORKSHOP WILL FOCUS ON:

- Applicable Global standards of Quality Systems & product specifications for Diagnostics.
- Analytical Control Strategy & Expectations.
- Understanding the role of National Control Laboratory (NCL) in test and analysis.
- Importance of review of Manufacturers & CDL test data.
- Accurate interpretation of the Quality Control Plan
- Global Reference Standards
- Assessing the magnitude and direction of error when results are OOS (Out Of Specification)

ASSESSMENT:

A written assessment shall be conducted at the end of the workshop to evaluate effectiveness of the learning and assessment of participant's performance.

LEARNING OBJECTIVE & EXPECTED OUTCOME:

By attending this workshop, the participants will be able to acquire theoretical and practical understanding on the basics of LQMS. They will understand various steps taken towards seeking LQMS compliance for all applicable accreditation standards.

Expected learning outcomes are:

1. To be aware of all LQMS requirements as per ISO 17025:2005 for an effective performance of attesting laboratory for conformity assessment.
2. To be able to develop & implement relevant policies, procedures and processes, for Quality System.
3. To 'Train the Trainers' by creating a platform for meeting India's emerging needs.

AREAS COVERED UNDER DIAGNOSTICS:

1. Blood Grouping Reagents
2. Biochemical kits
3. Immunodiagnostic kits
4. Molecular Diagnostics

COURSE MATERIALS

Each participant will receive extensive course materials.

FEE STRUCTURE

No participation fees will be charged for attending this residential program.

All travel expenses including local travel) should be borne by the participant. Boarding and lodging of all selected participants will be arranged by NIB on twin sharing basis at NIB Guest House, Noida.

HOW TO APPLY

Interested participant may apply in the prescribed **Application Form** duly recommended by the Controlling Officer of the Department/ Organization till August 09, 2017 directly to training.cdsla@hsti.res.in with a copy endorsed to cdsla.dbt.trg@nib.gov.in within submission deadline.

CERTIFICATE

Certificate of Participation will be given to all, who complete the entire course by achieving minimum 70% in the written assessment.

ELIGIBILITY CRITERIA:

Educational Qualifications: Master's Degree in Life Sciences/ Pharmacy or Bachelor's degree in Engineering.

Experience: Minimum **three years** of experience in relevant area (regulatory function or regulatory research)/ Science & Technology Management.

Desirable: Preference will be given to nominees having an exposure to Quality Systems.

WHO SHOULD PARTICIPATE?

- Personnel involved in Diagnostics functions at CDSCO, CDTL, CDL, DBT, Pharmacopoeial bodies.
- Laboratory personnel involved in QC & QA activities in the area of Diagnostics & aspiring to achieve accreditation.
- Analytical Research Scientist dealing with development of new products.
- Personnel involved in Regulatory Affairs or working with ISO Standards.

IMPORTANT DATE:

- **Last date of applications:** August 09, 2017
- **Selection List:** August 14, 2017
- **Confirmation of Participation:** August 17, 2017

PROGRAM FORMAT:

Three days full time residential program

VENUE:

National Institute of Biologicals,
Plot No.: A-32, Sector 62, Institutional Area,
Noida, Uttar Pradesh INDIA
Pin 201309

CONTACT INFORMATION

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IMPORTANT NOTE: All participants should bring their own laptop and preferably data card (internet) with them.