

1. **Name:**
2. **Address:**.....
3. **Phone & Email:**.....
4. **Qualification:**.....
5. **Experience, if any:**.....
6. **Organization:**

(Note: Training course fee includes registration kit, lodging and manual on “Clinical Research Management”. However, food charges will be paid as per actual and will be borne by trainees. Registration will be done on first come first serve basis for only 10 seats.)

About The Institute

The Institute of Biotechnology (erstwhile State Vaccine Institute established in 1903) at Patwadangar (located on Delhi-Nainital highway 9 km before Nainital in the State of Uttarakhand in India at an average altitude of 1600 meter). The Institute is well recognized in the area of Biotechnology and is a hub of Hand's on Training activities in the frontier areas of Molecular Biology, Biotechnology, Immunology, Medicinal and Aromatic plants and Chromatography. A number of trainings on Rabies, ELISA, Animal Cell Culture, Immunomodulation, Chromatography (HPLC), PCR and Related Techniques, Role of Nanotechnology in Health and Disease and Vermibiotechnology and Organic Farming had already been organized which were attended by the Post Graduate students, PhD Scholars, Lecturers, Associate Professors from all over the country including Kerala, AP, Maharashtra, MP, Orissa, Punjab, Karnataka, Agartalla, Tripura, Delhi, UP, Uttarakhand, Rajasthan, J&K and West Bengal etc. The Institute has a very strong research programme on following areas:

1. **Development of Vaccine and Diagnostics of Rabies using Molecular Techniques.**
2. **Antiviral, Anticancer and Antibacterial Activities of Herbs.**
3. **Immunomodulation using Bioprospective Molecules from Panchgavya and Herbs.**
4. **Studies on Reversal of Antibacterial Resistance of Antibiotics.**
5. **Detection of Pesticide Residues and Mycotoxins in Food and Feeds.**
6. **Vermibiotechnology.**

How to Reach

Patwadangar is situated 9 km before the Nainital on Kathgodam – Nainital Highway (NH 87); from Highway (Baldiakhan bus stop), link road starts to Patwadangar which is situated at a distance of about 3 km. Kathgodam is well connected from Delhi, Kolkata, Dehradun through rail and road. The nearest airport is at Pantnagar which is about 50 km from Patwadangar. One can reach through rail at Kathgodam or by air at Pantnagar Airport and then onward journey can be performed through bus/taxi. Distances to major places: Nainital (12 km), Kathgodam (29 km), Haldwani (34 km), Lalkuan (49 km), Delhi (290 km), and Dehradun (335 km).

Climate

Patwadangar is located in Kumaon hills at a height of 1600 meters above sea level. Generally, climate remains cold and temperature never goes above 30⁰ C in summer. While visiting this place, woolen clothes are often required. In winter, sometimes one can also see snowfall.

Contact us

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Short Term Training on **Clinical Research Management** August 26-31, 2010



Institute of Biotechnology
(G.B. Pant University of Agri. & Tech.)
Patwadangar -263 128 (Nainital)
Uttarakhand, India

Clinical Research Management

Clinical Research is a branch of medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens for humans. It is performed as a systematic study in order to discover or verify the clinical, pharmacological and adverse effects, with the object of determining their safety and efficacy. Clinical Research divides into three main categories: 1. Patient-Oriented Research, 2. Epidemiologic and Behavioral Studies, 3. Outcome and Health Services Research.

Test facilities which are involved in conducting safety studies on chemicals (viz. industrial chemicals, pharmaceuticals, veterinary drugs, pesticides, cosmetic products and food products, etc), are using Good Laboratory Practice (GLP) guidelines followed by Good Clinical Practices (GCP).

Good Laboratory Practice (GLP)

To harmonize practices and generate mutually acceptable data for non-clinical health and environmental safety studies, the Organization for Economic Cooperation and Development (OECD) evolved Good Laboratory Practice (GLP) guidelines. India is a signatory to OECD and a National GLP Compliance Monitoring Authority established by the Department of Science & Technology, Government of India, which provides GLP compliance certification to the test facilities involved in conducting safety studies on chemicals (viz. industrial chemicals, pharmaceuticals, veterinary drugs, pesticides, cosmetic products, food products, feed additives, etc).



the safety of drugs became a key issue and GLP was seen as a means of ensuring that scientists did not invent or manipulate safety data and a means of ensuring that GLP compliant studies are properly managed and conducted.

The Fundamentals of GLP

All GLP texts, whatever their origin or the industry targeted, stress the importance of the following points:

- 1. Resources:** Organization, personnel, facilities and equipment.
- 2. Rules:** Protocols and written procedures.
- 3. Characterization:** Test items and test systems.
- 4. Documentation:** Raw data, final report and archives.
- 5. Quality assurance unit.**



Good Clinical Laboratory Practices (GCLP)

In an effort to harmonize and gain consensus on international clinical laboratory operations, Good Clinical Laboratory Practice (GCLP) guidelines were originated by merging GLP and ICH-GCP Principles. Global clinical laboratory work performed under harmonized operations

is a central component for the successful clinical trials in multiple fields of science and medicine. However, global harmonization of clinical laboratories for the analysis of specimens from clinical trials are for generation of similar results acceptable internationally.

Good Clinical Laboratory Practices should be used by all laboratories where tests are done on biological specimens for diagnosis, patient care, disease control and research such as:

- Microbiology & Serology
- Hematology & Blood Banking
- Molecular Biology and Molecular Pathology
- Clinical Pathology
- Clinical Biochemistry
- Immunology (Immunohematology and Immunobiochemistry)
- Histopathology/Pathology and Cytology



Levels of Laboratories

The laboratory services are integrated with the 3-tier public health system at the primary, secondary and tertiary levels.

Good Clinical Practice (GCP)

Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects.

Drug safety Evaluation

Drug Safety evaluation is the scientific term for a test or study of a drug, therapy, surgical procedure, medical device, or of nutrition or behavioral changes in people. The tests are done to find out if the drug, therapy, procedure, etc. is safe and effective to use.

There are four phases of drug testing: 1. Phase I, 2. Phase II, 3. Phase III and 4. Phase IV.

Programme

The following areas will be covered in the training programme:

- 1. Introduction of Clinical Research.**
- 2. Safety and Ethical Considerations in Clinical Research.**
- 3. Good Laboratory Practice (GLP): Laboratory Facilities, Equipment and Materials.**
- 4. Good Clinical Laboratory Practices (GCLP) and Requirements of GCLP.**
- 5. Drug safety and risk assessment.**
- 6. Quality Control.**

There will be practicals on the following topics:

- 1. Standard Operating Procedures (SOP's) and Documentation.**
- 2. Test Facility Management.**
- 3. Post mortem Examination and Quality Control Checks.**
- 4. Collection, Preservation and Dispatch of Material to Laboratory.**
- 5. Quality Control – Pesticide and Mycotoxin Estimation.**

Training course fee: Rs. 2000/-.

Registration: Send your fee in the form of DD/ Local Bank's Cheque in favour of **Director, Institute of Biotechnology**. Payable at **Nainital** along with details in the following proforma:

