



UNIVERSITY OF LEEDS

## Developing and sustaining India's capacity for pre-clinical Drug Discovery

“Train the Educator” course for educators/trainers who provide education, training and continuing professional development in laboratory animal sciences for early career researchers

# Prospectus / Guidelines

**The application preferably is submitted online with appropriate approval letters from respective authorities. The hard copies can be submitted in case of non availability of e-facilities.**

## 1. Introduction:

The Indian Pharmaceutical industry is a major player in the global discovery, development and production of medicines. It makes a significant contribution to the Indian economy through exports and in addressing the healthcare needs of the Indian population. This Sector is growing rapidly, with the Government's vision (*PharmaVision 2020*) that the Sector reaches a Compound Annual Growth rate of 24% by 2020. However, like many countries, India has a substantial shortage of scientists, with the necessary knowledge and skills to undertake studies using laboratory animals, a legally-required, go/no-go step in the discovery and development of new medicines, biomedical technologies and devices, or in the safety assessment of medicines, devices, GMO's, LMO's and technologies developed elsewhere for the Indian market and population.

As per the regulatory guidelines of any country, before any medicine or medical technology to be applied for clinical application, the preclinical evaluation in-vitro & in-vivo in experimental animals is a mandatory requirement.

In India, prior to the use of animal species belonging to rodent (rat or mouse) & non-rodent (rabbit, dog, pig, occasionally monkey) for experimental purposes, permission must be obtained from the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory Committee under Chapter 4, Section 15(1) of the Prevention of Cruelty to Animals Act 1960.

The approvals to conduct animal experimentation are governed by Institutional Animals Ethical Committee (IAEC) which will be the registered committee with CPCSEA.

## **2. Objectives:**

Our aim is to enhance India's capabilities for preclinical drug development by creating and providing a sustainable programme of education, training and Continuing Professional Development opportunities for pre-clinical laboratory animal scientists and biotechnology entrepreneurs.

Our objectives are to:

1. Develop industry-relevant learning outcomes and curricula, to internationally recognised standards, for the education, training and Continuing Professional Development of pre-clinical laboratory animal scientists and entrepreneurs, tailored to India's needs;
2. Develop and deliver self-sustaining "Train the Trainer" programmes for these activities, creating a pan-Indian network of such trainers;
3. Disseminate and share the resources developed as free (and without time limit), open access e-learning resources across India;
4. Harmonise the education, training and Continuing Professional Development of pre-clinical laboratory animal scientists and entrepreneurs across India;
5. Guide trainers in the subsequent development and delivery of their courses;
6. Develop educational and training links and partnerships between India, the UK and relevant professional bodies;

## **3. Scope:**

Pre-clinical pharmacological assessment of the efficacy, safety and toxicological profile of potential new medicines, medical devices and technologies, and the safety assessment of these products developed elsewhere in the world for the Indian market and population are necessary, and legally required by Regulatory Authorities before use in humans, in order to determine their therapeutic potential.

#### **4. General Instruction:**

1. Before applying, please go through the detailed Instructions available on the website of ICMR-NIN ([www.nin.res.in](http://www.nin.res.in)). The online submitted application form should be sent by email (msde.ukieri.nin@gmail.com) in PDF format.
2. You will be paid 2<sup>nd</sup> class return AC rail fare through shortest route Please plan your travel date a day before the course.
3. Local hospitality will be provided which includes boarding and lodging as per ICMR rules from 7<sup>th</sup>-13<sup>th</sup> July 2019. However charges are applicable for stay before or beyond the mentioned dates.
4. The confirmation of participant should reach us by 5<sup>th</sup> June 2019. Prior intimation of cancellation is to be sent through proper channel (email is provided). Next candidate who is eligible will be preferred for the course.
5. You may contact Drugs Division, ICMR-National Institute of Nutrition near Tarnaka flyover. Jamai-Osmania PO, Hyderabad-500 007, India. Ph No: #+914027197322 / 290, Email: msde.ukieri.nin@gmail.com

#### **5. Selection Criteria :**

- I. Public / Private/ Industries Institutions / Organization Registered under DSIR working under various ministry involved in non clinical studies. Preference will be given to DSIR registered organizations.
- II. Mandatory requirement
  - i. Existence of Animal house with IAEC and CPCSEA Registration
  - ii. Academic and research work
    - a) National Priority programs in drug development
    - b) Development of Human Resource in non clinical investigations
    - c) Capabilities to undertake training program for new entities

#### **6. Nominations :**

Nominations of 2-3 candidates in the relevant field who can continue in the areas of research outlined in the application form. Following training, they must agree to transfer

the knowledge gained to others by delivering similar courses within their organisations or networks.

**7. Eligibility Criteria:**

1. Doctorate in Pharmacology/ Life sciences /Post Graduate in medicine sciences, Pharmacology / Veterinary sciences, Allopathic/ Ayurvedic/ Homeopathy Siddha.
2. Experience in drug discovery which has to be proved through Publications/Patent.
3. Age should not be more than 40 years.
4. Scientists : Scientist C (Sr. Research Officer) / Scientist D (Assistant Director) with experience in conducting Pre Clinical Toxicology work.
5. Academicians : Assistant Professor with 5 years of experience in Pre Clinical Evaluation in academic cadre
6. Industries : Junior manager cadre with 5 Years experience in conducting Pre Clinical Toxicology work
7. Infrastructure profile of the facility available in the premises of the organization.
8. Selection will be done based on criteria
9. The maximum candidates will be 30 out of which 20 will be from Public Institutes and 10 will be from Private institutions. The travel and accommodation support will be given to candidates selected from Public Institutes. The 10 members can make their payment after the selection list announced.

**8. Supporting Agencies:**

UK-India Education and Research Initiative (UKIERI) and Ministry of Skill Development and Entrepreneurship (MSDE) (IC&T Division) F. No. 8-6/14-SD& E-II under the UKIERI Phase III, the MSDE-UKIERI Skills Thematic Institutional Partnerships.

**9. Course Duration: 5 Days**

**10. Post training Requirement:**

1. Each educator/trainer will be required to deliver a minimum of 2 courses within their organisation or network, resulting in a minimum of 3,600 scientists trained (60 x 2 x 30).

2. Dissemination and sharing of the curricula and education resources with the community as free, open access e-learning resources.
3. Trainers to develop and deliver courses, using the above curricula and resources, within their own Institutions, Organisations or networks, thereby creating a national, sustainable and harmonised programme of courses and Continuing Professional Development activities.

**11. Important of Timelines:**

<b>S. No</b>	<b>Activity</b>	<b>Timelines</b>
1	Last date for submission of the applications	15 <sup>th</sup> May 2019
2	Screening and selection	25 <sup>th</sup> May 2019
3	Information to selected trainees	30 <sup>th</sup> May 2019
4	Nomination of the selected trainees from the respective institutes	5 <sup>th</sup> June 2019
5	Course dates	8 <sup>th</sup> -12 <sup>th</sup> July 2019