CSIR Integrated Skill Imitative

Pharmaceutical Product Development and Quality Control

CSIR-CDRI

CSIR-CDRI is a unique R & D Institution in the country with state of the art infrastructure for new drug discovery and development from "Concept to Commercialization". It is poised to become a global leader through cutting edge science & technology. For New India, the Institute is re orienting itself into a multidisciplinary nodal centre for development of drug for the unmet medical needs as well as the expectation of the industry. While focusing on the discovery & development of drugs, the institute is aligned & contributing towards the national missions programmes such as Make in India, Swatch Bharat, Skill India, Digital India, Start-up India, Accessible India and Sashakt Bharat.

CSIR-CDRI invites applications for the course as per the details given below:

Title of the Course	**: Pharmaceutical Product Development and Quality Control**
Duration	**: 04 Weeks (20th March to 14th April 2023)**
No. of Seats	**: 10**
Educational Qualification	**: Pre-requisite for this certificate program is a Bachelor of Pharmacy**
Venue of the course	**: CSIR-CDRI, Lucknow**
Course Fee	**: Rs. 10,000/-**
Last Date for submission of applications	**: 08th March 2023**
Course Coordinator	**: Dr. Prabhat R. Mishra (E-mail: prabhat_mishra@cdri.res.in)**

TRAINING CURRICULUM

The program is composed of 12 classes of two hours each to complete the Certificate Program. Students will be assigned an advisor to specialize a path specific to the career interest of each student.

Topics to be covered:

- Introduction to drug discovery and development processes and pre-clinical translational research.
- Analytical and Bioanalytical method development and validation of active pharmaceutical ingredient and new chemical entity (NCE) by HPLC or LC-MS/MS and demonstration of methods for pharmaceutical analysis.
- Establishment of quality control specifications of API, NCE, and phytopharmaceuticals in terms of quantitation of chemical markers.
- Introduction to pre-formulation studies, establishing pharmaceutical specifications, development of different dosage forms.
- Pre-formulations studies- It deals with studies of physical, chemical, analytical, and pharmaceutical properties related to API that will provide an insight about suitable modifications required in API for better performance. It will introduce about quantitation of solubility in various solvents, partition coefficient, pKa determination, dissolution rate, permeability, crystallinity, DSC, stability as per regulatory guidelines, hygroscopicity etcetera.
- Chemistry, Manufacturing, and Controls (CMC) and drugability.
- Introduction to manufacturing of conventional dosage forms including tablets, capsules, suspensions, emulsions etcetera containing API/NCE/Phytopharmaceuticals. Introduction to development of particulate drug delivery systems like, liposomes, niosomes, nanoparticles, nanoemulsions, nanocrystals etcetera.
- Quality control parameters of developed conventional formulations.
- Establishing pharmaceutical specifications of particulate drug delivery systems.

- Pharmacokinetic studies: In-vitro studies in simulated intestinal and gastric fluid, permeability, plasma stability, plasma protein binding, and metabolic stability etcetera.
- In-vivo oral/intravenous pharmacokinetics of active pharmaceutical ingredients and pharmaceutical formulations. Calculation of various pharmacokinetic parameters including Cmax, Tmax, $T_{1/2}$, AUC, clearance, bioavailability and mean residence time etcetera.
- Generation and Compilation of Data Required for Regulatory Approval.
- Guest lecture (Case study Bench to Market)
- Guest lecture (Case study Repurposing of drugs to improve clinical benefit)
- Guest lecture (Case study Nanomedicine)
- Guest lecture (Regulatory guidelines for product development)
- Guest lecture (Introduction to Good Laboratory Practices)

MANAGEMENT AND FACULTY: CSIR-CDRI has unmatched expertise in drug research with state-of-art facilities and talent. Faculties for this course are highly experienced and extremely well trained experts in this area.

SALIENT FEATURES OF THE TRAINING

- 40% Theory and 60% Practical Sessions as per the course curriculum
- Tutorials based on the specific needs of the candidates and/or industry
- This course includes theory/lectures and practical/ hands-on sessions through selected software modules
- Instruction methods involve lectures and hands on practice
- Interactive session
- Guest lecturers of experts from Industry/Academia
- Focus on current needs of Pharma/ Life Science industry

EVALUATION OF TRAINEES

Evaluation will consist of the following components
- Theory Courses (50 Marks)
- Practical Courses (50 Marks)

CERTIFICATION

The certificate will be issued to the successful candidates for the course

IMPORTANT DATES

Receiving of application by E-mail (last date): 08/03/2023
Intimation to selected candidates: 10/03/2023
Fee submission (last date): 13/03/2023
Course Start: 20/03/2023

Dr. Prabhat R. Mishra
Dr. Manish K. Chourasia
Dr. Jiaur R. Gayen

Kindly send Application by E-mail only (sdp@cdri.res.in)

For more details and registration, kindly visit the link;
https://www.cdri.res.in/skilldevelopment.aspx

Contact:
Dr. Sanjeev Kumar Shukla
Coordinator, Skill Development Programme
CSIR-Central Drug Research Institute
Sec-10, Jankipuram Extension, Sitapur Road
Lucknow 226031 (Uttar Pradesh)
E-mail: sdp@cdri.res.in