PHARMA Genie
ADVANCING INTELLIGENCE

LIFESCIENCES
INDUSTRIAL TECHNICAL TRAINING PROGRAM

NAAN MUDHALVAN PROJECT

நான் முதல்வன்
உலகை வெல்லும் இளைய தமிழகம்
VAKIL SEARCH

COURSE CURRICULUM

Sector: LifeSciences

PHARMAGENIE COMPLIANCE CHENNAI

COURSE DETAILS:

Program Code	**NMP-005**
Course Title	**International Regulatory Requirements for Clinical Trials and Data Management**
Hours	**45**
Mode	**Physical**
Minimum Batch size	**600**
Eligibility criteria	**Bachelors/Masters in Lifesciences**

COURSE OBJECTIVE:

- Developing skills on key activities in the quality assurance domain such as Change management, deviation, investigation, etc., Applying the concepts of industrial Clinical quality system for producing quality lifesaving drugs.

COURSE CONTENT FOR 5 Units (Module wise)

Module	Titles
Module 1	Introduction to Clinical Research Industry and Basics of Clinical Trials
Module 2	Pharmacology-Concepts and Application in clinical trials
Module 3	Drug Development Process
Module 4	Ethics and Ethical Guidelines for Clinical Trials and Good Clinical Practice (GCP)
Module 5	Regulations Guiding the Clinical Research Industry- History and Basics of National and International Regulatory Bodies
Module 6	Outsourcing Clinical Trials, functioning of Clinical Research Organisations
Module 7	Clinical Trials- Phases and Trial Designs
Module 8	Documentation and Data Management in Clinical Trials
Module 9	Safety Reporting Techniques and Pharmacovigilance
Module 10	Quality Control and Clinical Trial Management
Module 11	Clinical Trials: Medical Devices
Module 12	Protocol Writing and Designing

Module 13	Clinical Trials -Latest updates: New Drugs and Clinical Trials Rules

COURSE OUTCOMES:

Students will be able to:

- Analyse the concepts of Clinical trials and data management requirements in the clinical studies
- Hands on Experience on Ability to thinking critically on the importance of quality in Clinical research organisation
- Building next generation professionals with Quality mindset and Quality culture

ONLINE REFERENCES:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trialsguidance-documents

https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulationsgood-clinical-practice-and-clinical-trials

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerationsclinical-trials-step-5_en.pdf

https://apps.who.int/iris/bitstream/10665/43392/1/924159392X_eng.pdf

https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/clinical-trials/

SOFTWARE REQUIREMENT:

NA

HARDWARE REQUIREMENT:

NA

INDUSTRY SCOPE:

On Completion of this course, participants get an opportunity to work in the Clinical research organisation in Quality Assurance/Quality Control and data management departments as a Trainee or Junior Executive or Quality Analyst.

INDUSTRY USE CASES

- Provide support for site related training related activities
- Conduct literature reviews
- Collect and analyse data

- Prepare materials for submission to granting agencies and foundations
- Maintain accurate records of interviews, safeguarding the confidentiality of subjects, as necessary
- Provide ready access to all experimental data for the faculty researcher and/or supervisor
- Request or acquire equipment or supplies necessary for the project
- Supervise undergraduate students working on the research project (maintaining records on assignment completion, acting as liaison/mediator between the undergraduate students and the faculty researcher)
- Travel to field sites to collect and record data and/or samples as appropriate to the specific objectives of the study
- Develop or assist in the development of interview schedules; contact potential subjects to introduce and explain study objectives and protocol and to arrange interviews, either in person or by telephone
- Identify and compile lists of potential research subjects in accordance with study objectives and parameters, as appropriate to the individual position

Conduct and record face-to-face and/or telephone interviews with subjects, in accordance with predetermined interview protocol, data collection procedure