LIFESCIENCES
INDUSTRIAL TECHNICAL TRAINING PROGRAM

NAAN MUDHALVAN PROJECT

COURSE CURRICULUM

Sector: LifeSciences

MAY 8, 2023

PHARMAGENIE COMPLIANCE
CHENNAI

COURSE DETAILS:

Program Code	**NMP-005**
Course Title	**International Regulatory Requirements for Clinical Trials and Data Management**
Hours	**40**
Mode	**Hybrid**
Online Training Platform	**Google Meet / MS Teams**
Minimum Batch size	**600**
Eligibility criteria	**Bachelors/Masters in Lifesciences / Doctors etc., Bachelors/Masters in Pharmacy**

COURSE OBJECTIVE:

- Understanding the concept of quality system and its importance in the clinical studies.
- Gaining advanced knowledge on key activities in the quality assurance domain such as Change management, deviation, investigation, etc.,
- Applying the concepts of industrial Clinical quality system knowledge for producing quality lifesaving drugs.
- Understanding the importance of Good Clinical Practices, product quality, patient safety, efficacy of the drugs being tested ats clinical sites.
- Knowledge about preclinical and clinical testing requirements
- Gaining experience of clinical data management
- Understanding the concepts of Data integrity assurance.

COURSE CONTENT:

Module	Titles	Hours
Module 1	Introduction to Clinical Research Industry and Basics of Clinical Trials	2
Module 2	Pharmacology-Concepts and Application in clinical trials	2
Module 3	Drug Development Process	3
Module 4	Ethics and Ethical Guidelines for Clinical Trials and Good Clinical Practice (GCP)	3
Module 5	Regulations Guiding the Clinical Research Industry- History and Basics of National and International Regulatory Bodies	2

Module 6	Outsourcing Clinical Trials, functioning of Clinical Research Organisations	2
Module 7	Clinical Trials- Phases and Trial Designs	4
Module 8	Documentation and Data Management in Clinical Trials	4
Module 9	Safety Reporting Techniques and Pharmacovigilance	4
Module 10	Quality Control and Clinical Trial Management	4
Module 11	Clinical Trials: Medical Devices	4
Module 12	Protocol Writing and Designing	2
Module 13	Clinical Trials -Latest updates: New Drugs and Clinical Trials Rules	4
TOTAL HOURS		**40**

COURSE OUTCOMES:

Students will be able to:

- Understand the concepts of Clinical trials and data management requirements in the clinical studies
- Importance of patient safety and risk to non-compliance
- Ability to thinking critically on the importance of quality in Clinical research organisation
- Building next generation professionals with Quality mindset and Quality culture
- Immediate job opportunities in Clinical studies and data management
- Identify subjects or clinical trials, collect data, evaluate results, monitor clinical trials, and take notes on activities.

ONLINE REFERENCES:

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

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

https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-8-general-considerations-clinical-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