#### **Certification Course in**

## **CLINICAL RESEARCH**

(NSQF Level 4 and NHEQF Level 3)

### Offered by:

# Department of studies and Research in Biotechnology and Microbiology, Tumkur University

Duration of the Course: 6 Months (1 Semester)

Mode of delivery: **Hybrid (Online/Offline)** 

On-campus/Off-campus/Internships/Regular/Evening

Maximum Number of admission: 20

Fee for the complete course: Rs. 8,000/-

#### **Eligibility Criteria:**

Candidates who have passed any Undergraduate Degree from any University recognized by UGC and other statutory bodies all over the country with 50 % aggregate for general students and 45 % for SC/ST/OBC/CAT1 students are eligible for Certification Course in Clinical Research

#### **About the programme:**

The Certification Course in Clinical Research is a focused 6-month, one-semester program designed to equip students with essential skills and knowledge in the field of clinical research. This course provides a comprehensive overview of the clinical research process, including the development and management of clinical trials, data analysis, and regulatory compliance. It is ideal for individuals looking to enter the healthcare, pharmaceutical, and biotechnology sectors or for professionals who want to enhance their expertise in clinical trial management.

The curriculum includes key topics such as clinical trial design, Good Clinical Practice (GCP) guidelines, ethical considerations, patient safety, and data management. Students will learn to handle the complexities of clinical trials, including protocol development, patient recruitment, and data interpretation. By the end of the course, graduates will be well-prepared for roles in clinical operations, regulatory affairs, data management, and other areas within the clinical research field, offering promising career opportunities in a growing industry. The highlight of the course is the curriculum is designed and delivered by industry professionals also providing project dissertation and internship in best CRO industries.

#### Who will benefit from the course?

Clinical research courses benefit a range of individuals. Aspiring researchers gain skills in study design and data analysis, while healthcare professionals enhance their ability to apply research findings in patient care. Pharmaceutical and biotechnology workers deepen their understanding of trials and regulatory processes. Regulatory affairs specialists learn about compliance standards. Academics and research scientists update their methodologies, and students in related fields complement their studies with practical knowledge. Data analysts improve their skills in data interpretation, and medical writers refine their ability to produce clear, accurate documentation.

#### **Job opportunities:**

- Clinical Program Manager
- Clinical Research Administrator
- Regulatory Affairs Specialist
- Clinical Research Associate (CRA)
- Clinical Research Coordinator
- Pharmacovigilance Specialist
- Clinical Research Manager
- Clinical Trial Manager
- Research Coordinator
- Clinical Data Manager
- Clinical Program Coordinator

## **Certification course in Clinical Research**

## **Course structures and Credits**

| Semeste<br>r |   | Instructi<br>on<br>Hours<br>per<br>Week | No.<br>of<br>credi<br>ts | Duratio<br>n of<br>the<br>Exam | Marks                      |                             |                    |
|--------------|---|---|--------------------------|--------------------------------|----------------------------|-----------------------------|--------------------|
|              | Paper   |   |                          |                                | Internal<br>Assessme<br>nt | Semest<br>er<br>End<br>Exam | Total<br>Mark<br>s |
| I            | Introduction to<br>Clinical<br>Research                       | 4                                       | 4                        | 3                              | 30                         | 70                          | 100                |
|              | Clinical Trial Design and Management                          | 4                                       | 4                        | 3                              | 30                         | 70                          | 100                |
|              | Study Setup<br>Process and<br>Management                      | 4                                       | 4                        | 3                              | 30                         | 70                          | 100                |
|              | Quality Assurance, Compliance & Auditing in Clinical Research | 4                                       | 4                        | 3                              | 30                         | 70                          | 100                |
|              | Project dissertation  | 4                                       | 4                        | 3                              | 30                         | 70                          | 100                |
|              | Total   | 20                                      | 20                       |                                | 150                        | 350                         | 500                |