Post Graduate Diploma in Clinical Research & Regulatory Affairs (PGDCRA)

Duration : One Year

Eligibility : Graduates / Post graduates degree in medicine, dental, homoeopathy, ayurvedic, life sciences, Pharmacology, Pharmacy, Medical Laboratory, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and hospitals.

Methodology : Distance, Face to Face Contact Sessions, Online Study Material, Printed Training Modules and Practical Hands on Training.

Course Objectives : To provide a comprehensive introduction to the clinical research and regulatory affairs process. Learn the skills, knowledge and competencies of a candidate for the various job prospects in all aspects of Clinical Research and/ or regulatory affairs. Become more familiar with roles/jobs as part of the study team.

Admission Criteria : Group Discussion and Personal Interview

Examination : Final Written Exam, Assignments, Exercises & Project work.

Evaluation Criteria : 20% (Assignments) + 80% (External examinations)

Certification : To be awarded by Manonmaniam Sundaranar University.

Placement Support : 100% Job placement support is provided to the students.

Program Details :

Semester – 1				
Code	**Subject**	**Total Marks**	**External Examinations**	**Assignments**
CRA101	Introduction to Clinical Research	100	80	20
CRA102	Principles of Pharmacology & Drug Discovery	100	80	20
CRA103	Roles & Responsibilities of Key Stakeholders	100	80	20
CRA104	Laws, Ethics & Regulatory Requirements	100	80	20
CRA105	Planning for Clinical Trials	100	80	20
CRA106	Essential Documentation in Clinical Research	100	80	20
Semester – 2				
CRA201	Introduction to Regulatory Affairs & Global Regulatory Environment	100	80	20

CRA202	Pharmaceutical Regulations Practices & Procedures	100	80	80
CRA203	Quality Assurance & Regulation	100	80	20
CRA204	Import & Export of Drugs in India	100	80	20
CRA205	Regulatory Aspects in Pharmacovigilance	100	80	20
CRA206	Regulations Governing Clinical Trials & New Drugs	100	80	20

Recommended Books :

- FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics by Douglas J. Pisano (Editor), David Mantus (Editor)
- Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual By Helene I. Dumitriu
- http://www.newdrugapprovals.com/
- 'Cliniminds & University Course Material'