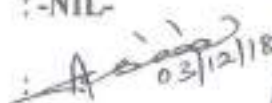
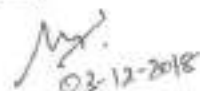




MOU for Certificate Course

Details for CR, PV & CDM (Vocational) – 150 hrs

1. Department : BPHARM, MPHARM, PHARMD
2. Name of the Course :
 - Clinical Research
 - Pharmacovigilance
 - Clinical Data Management
3. Name of the College / Institute : Bhaskar Pharmacy College, Hyderabad
4. Course fees : Rs. 15000 Per Candidate
5. Mode of Payment from the college : Online
 - a. Account Name : INDIAN HEALTHCARE BPO
 - b. Account No : 2271-5005-0800-283
 - c. Branch Name : TAMILNADU MERCANTILE BANK
 - d. IFSC Code : TMBL0000227
6. Requirements to run the course :
 - Class Room, White Board or Projector
 - Volunteer, Water
7. Material / Service provided by INDIAN HEALTHCARE BPO :
 - Book Material, Training
 - Certification, Placement
8. Any amount other than fees paid by the students : -NIL-
9. Signature of College Principal :  03/12/18
10. Signature of CEO - Indian Healthcare BPO :  03-12-2018



Enclosures:

- Profile
- Course content



MODULE for
Pharmacovigilance, Clinical Research and Clinical Data Management

Duration : 150 Hours

CLINICAL RESEARCH:

- 1) Introduction of drug development process
- 2) Phase 1, 2, 3, & 4 clinical trials
- 3) Abbreviated new drug application (ANDA)
- 4) Investigational New Drug (IND) Application
- 5) CRO roles & responsibilities
- 6) Principles of ICH GCP
- 7) Standard Operating Procedures for conducting clinical trials
- 8) Institutional review board/independent ethics committee (IRB/IEC)
- 9) Roles and responsibilities of principle investigator, Sponsor and site staff
- 10) Informed Consent of Subject in clinical trials
- 11) Explanation study protocol for clinical trails
- 12) Clinical Trials of Vaccines
- 13) **Ethical Guidelines** in clinical trials
- 14) Investigator's brochure (IB)
- 15) Case report form
- 16) Inclusion & exclusion criteria for enrolling subjects in clinical trials

PHARMACOVIGILANCE:

- 1) Introduction and Definitions in Pharmacovigilance
- 2) Pharmacovigilance Regulations
- 3) EUDRAVIGILANCE & Reporting Serious Adverse Reactions
- 4) SAE reporting forms MEDWATCH form & CIOMS forms
- 5) Adverse Events Coding System
- 6) Reporting timelines for SUSAR reports, LT, Death and serious cases
- 7) Adverse Event Detection in the Pharmaceutical Industry
- 8) Types of cases in Pharmacovigilance
- 9) Vaccine Pharmacovigilance
- 10) Assessment of Adverse Drug Reactions
- 11) Reporting to Regulatory Agency
- 12) Risk Minimization and Risk Management Program





- 13) Crisis Management in Pharmacovigilance
- 14) DECHALLENGE/RECHALLENGE of study drugs in Pharmacovigilance
- 15) Objectives of MEDDRA (Medical Dictionary for Regulatory Activities) and its hierarchy
- 16) SIGNAL DETECTION
- 17) Benefits-Risk Assessment in Pharmacovigilance
- 18) Crisis Management in Pharmacovigilance
- 19) ORACLE ARGUS
- 20) Types of causality in PV & seriousness criteria of events

CLINICAL DATA MANAGEMENT:

- 1) Introduction to Clinical Data Management
- 2) Case report form (CRF) in CDM
- 3) Various roles involved in CDM
- 4) Data flows in CDM
- 5) Data queries in CDM
- 6) Data Management Technologies
- 7) Data Collection Instruments
- 8) Data Capture in CDM
- 9) **Planning and Implementation** of clinical trials data in CDM
- 10) Data validation
- 11) **Quality Assurance and Clinical Data Management**
- 12) Systems Software Validation Issues Clinical Trials Database Environment
- 13) Working with Contract Research Organizations

