Indian Healthcare BPO

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

BHASKAR PHARMACY COLLEGE * Bhaskar Nagar, Yenkapally (V), Moinabad (M), R.R. Dist. T.S. * HYDERABAD-75.

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Enclosures:

- Profile
- Course content

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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

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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

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