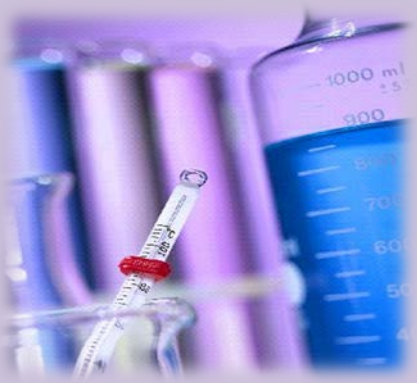
QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC

Somerset New Jersey USA

Private Vocational School



Clinical Research Monitor Training (CRMT)

monitoring clinical trials

Our Mission

Our mission is to provide the best-in-class job oriented career development Elearning training courses and programs in clinical research, SAS data management and business analysis for students and l professionals requiring a skills refresh – or the development of new skills and experience for job entry, advancement, and placement

About Clinical Research

Clinical research monitor is a rapidly expanding field, creating exciting job opportunities. Clinical Research Monitor works in a broad range of research settings, including: academic health centers, government agencies and departments, contract research organizations, and pharmaceutical, biotechnology and medical device firms.

Overview of the Curriculum

Designed by industry experts for students and young professionals. The training program provides in depth knowledge of roles and responsibilities of Clinical Research Monitor including theoretical aspect of the field and exposure to real time scenario cases based on industry requirements.

LIST OF TOPICS:
THEORETICAL ASPECT OF THE FIELD

1. Role of Clinical Research Associate
2. Drug Discovery Research Process
3. Pre-Clinical Trials
4. Introduction to Clinical Trials
5. Phase I Clinical Trials
6. Phase II Clinical Trials
7. Phase III Clinical Trials
8. Phase IV Clinical Trials
9. FDA and EMEA Regulations
10. ICH Guidelines for Good Clinical Practice
11. Institutional Review Board (IRB)
12. SOP Development
13. Conducting Multinational Clinical Trials
14. Communication with Cross functional Team
15. Overview of Clinical Protocol
16. Role of CRA (Monitoring)
17. Clinical Protocol Design and Development
18. Subject Recruitment and Informed Consent
19. Case Report Form (CRF) Design and Development Monitoring Prospective
20. Study Initiation
21. Planning for Site Visits
22. Site Monitoring
23. Source Documentation. Retention and Compliance
24. Drug Accountability Plan
25. Investigator –Monitor Meetings and Follow up
26. Introduction to Adverse Events (AE) Reporting and Classification
27. Clinical Trial Onsite Audit
28. Study Close Out
29. Informed Consent Preparation
30. Understanding Monitoring Worksheets

LIST OF EXERCISES:
PRACTICAL EXPOSURE TO DAILY ROLES AND REPOSIBILITIES

1. Exercise 1 - Planning for Site Initiation
2. Exercise 2 - Planning for Site Visit
3. Exercise 3 - Protocol Assessment and Understanding
4. Exercise 4 - Subject Recruitment Process
5. Exercise 5 - Informed Consent Verification
6. Exercise 6 - IRB and Ethics
7. Exercise 7 - Site Monitoring
8. Exercise 8 - Case Report Form Review
9. Exercise 9 - Source Documentation Verification
10. Exercise 10 - Co-Monitoring Visit
11. Exercise 11 - Drug Accountability Verification
12. Exercise 12 - Clinical Trial Onsite Audit Planning
13. Exercise 13 - Site Close-out and Database Lock

TECH Professional Development Center

The Main Roles and Responsibilities of
Clinical Research Monitor/Clinical Monitor/ Trial Monitor/Medical Monitor

- ❑ Monitor the progress of clinical study sites participating in a clinical study to assure the protocol is followed and data is reported accurately
- ❑ Assure the protection of the rights, safety and wellbeing of human study subjects
- ❑ Analyze and evaluate clinical data to ensure that investigator's and site compliance is aligned with the study drug protocol, clinical objectives, FDA regulations, ICH Guidelines, Good Clinical Practice (GCP), and HIPAA
- ❑ Help in recruiting and screening candidates to take part in clinical trials
- ❑ Identify and help in the study site selection process, initiation stage, and closure of clinical study sites
- ❑ Assure that adverse events are correctly documented and reported
- ❑ Review all case report forms and compare them with source document
- ❑ Coordinate staff activities, train and mentor junior staff, and visit testing sites to ensure that the proper protocol is being followed
- ❑ Make on-site visits and control clinical site activities
- ❑ Check the accuracy and completeness of the CRF entries, source data, documents, and other trial-related records
- ❑ Travel to clinical monitoring and research sites required
- ❑ Verify safety of staff and facilities (such as laboratory and equipment) involved in conducted trial

Do You Know…?

Hiring Clinical Research Monitor professionals:

- ✓ 99% of the employers choose candidates with **clinical research** degree or experience
- ✓ 75% of the employers choose candidates with **pharmacology or toxicology** degree
- ✓ 80% of the employers choose candidates with **nursing** degree
- ✓ 40% of the employers choose candidates with **Biological Science** degree
- ✓ 80% of the employers choose candidates with **public health** degree
- ✓ 65% of the employers choose candidates with **Biotechnology** degree
- ✓ 90% of the employers choose candidates with **Medicine** degree

Do you want to know more? Connect with us!

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