QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Private Career School

Clinical Research Associate / Coordinator - CRAT

In-House / Monitor

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 professionals requiring a skills refresh – or the development of new skills and experience for job entry, advancement, and placement

APPROVED

Clinical Research Associate / Clinical Research Coordinator professional training program is approved by State of New Jersey, Department of Education and Department of Labor and Workforce Development and listed on Eligible Training Provider List

STATE OF NEW JERSEY
DEPARTMENT OF EDUCATION

STATE OF NEW JERSEY
DEPARTMENT OF LABOR
AND WORKFORCE DEVELOPMENT

Website: www.qtech-solutions.com **Email:** qpdc@qtech-solutions.com

About Clinical Research

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

Overview of the Curriculum

Program was designed by industry experts for students and young professionals. The training provides in depth knowledge of roles and responsibilities of Clinical Research Associate/ Clinical Research Coordinator, including theoretical aspect of the field and exposure to variety exercises based on industry requirements.

LIST OF TOPICS:
THEORETICAL ASPECT OF THE FIELD

1. Drug Discovery and Research Process
2. Pre-Clinical Research
3. Introduction to Clinical Trials
4. Role of Clinical Research Associate
5. Phase I Clinical Trials
6. Phase II Clinical Trials
7. Phase III Clinical Trials
8. Phase IV Clinical Trials
9. Good Clinical Practice and ICH Guidelines
10. FDA Regulations
11. Institutional Review Board (IRB)
12. Overview of Clinical Protocol
13. Clinical Protocol Design and Development
14. SOP Development
15. Case Report Form (CRF) Design and Data Capture
16. Clinical Trial Budget
17. Conducting Multinational Clinical Trials
18. Communication with Cross Functional Team
19. Clinical Research Associate / Coordinator In House Responsibilities
20. Selection of Investigator
21. Vendor Selection and Management
22. Informed Consent Preparation
23. Roles and Responsibilities of Investigator
24. Investigator Meetings and Timelines
25. Selection of Investigator Site
26. Study Initiation
27. In-House Monitoring and Reporting
28. Trial Master File (TMF)
29. Introduction to Adverse Events (AE) Reporting and Classification
30. Preparation for Internal Audit
31. Role of CRA Monitoring
32. Subject Recruitment Process and Informed Consent
33. CRF Design and Development Monitoring Perspective
34. Source Documentation, Retention and Compliance
35. Drug Accountability Plan
36. Site Visits
37. Site Monitoring
38. Investigator-Monitor Meetings
39. Understanding Monitoring Worksheets
40. Clinical Trial and Site Audit
41. Study Close Out

LIST OF REAL TIME CASES: PRACTICAL EXPOSURE TO DAILY ROLES AND REPOSIBILITIES

Case 1: Introduction To Clinical Trial

Case 2: FDA EMEA Regulations

Case 3: Institutional Review Board (IRB)

Case 4: Protocol Design and Development

Case 5: Clinical Trial Budget

Case 6: Case Report Form (CRF) Design

Case 7: Investigator Meeting

Case 8: Site Management and Initiation

Case 9: Informed Consent Preparation

Case 10: Trial Master File

Case 11: Adverse Event Monitoring and Reporting

Case 12: Audit

Main Roles and Responsibilities of Clinical Research Associate - CRA/ CRC

- ✓ Writes, edits and assists in writing protocols
- ✓ Coordinates protocol review for clinical studies
- ✓ Writes and reviews patient informed consents
- ✓ Designs and develops case report forms (CRFs)
- ✓ Helps, writes, assembles, and distributes investigator brochures, SOP documents and study/CRF instruction manuals
- ✓ Prepares and submits documents required to meet regulatory, GCP, and SOP requirements
- ✓ Determines order, ships, and tracks investigational drug supplies
- ✓ Evaluates and selects investigators (sites), plans and conducts investigator meetings
- ✓ Develops study budgets and grant payment schedules
- ✓ Sends study packages such as protocols, brochures, and contracts/agreement letters to field monitors for site initiation
- ✓ Assures all adverse events (AEs) are reported according to regulation and company policy
- ✓ Prepares final study reports and assist in the response or reporting to any FDA inspections

Hiring CRA 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

Contact Information

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