QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses

Clinical Trials Management (CRPM)

Are you currently working as junior CRA or on other entry level CRA position?
Are you ready for Career Advancement to the higher level of CRA role?
Did you complete basic CRA training, but you wish to add new skill set?

Self-Paced Online Training

Our Mission

Our mission is to provide the best-in-class job oriented certification and skill based courses towards Clinical research, Drug Safety, Pharmacovigilance, Clinical Data Management, Clinical SAS Data Analytics and Healthcare business. We offer Entry-Mid and Senior programs for students and professionals, looking for skills refresh or career advancement

CAREER FOCUSED PROGRAM

(Learning for Job)

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

Overview of the Curriculum

Designed by industry experts for professionals looking to add new skill set.

LIST OF LESSONS

BASICS

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
16. Clinical Trial Budget
17. Conducting Multinational Clinical Trials
18. Communication- Cross-Functional Team
19. CRA / CRC – In House Responsibilities
20. Selection of Investigator
21. Vendor Selection and Management
22. Informed Consent Preparation
23. Roles and Responsibilities of the 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- AE Reporting
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

ROLE BASED PROJECTS

1) Clinical Trial Budget
2) Investigator Selection
3) Pre-Study Visit
4) Protocol
5) Informed Consent Preparation
6) Investigational New Drug (IND) Application
7) Institutional Review Board (IRB) Regulatory Correspondence
8) Case Report Form (CRF)
9) Site Monitoring
10) Co-Monitoring Visits
11) Study Initiation Visit
12) Clinical Trial Management Systems (CTMS) Tracking Recording
13) Trial Master File
14) Database Lock
15) Audit

ADVANCED LESSONS

1) Risk Based Monitoring (RBM)
2) FDA Audit process for Clinical Research
3) Clinical Trial Project Management and Time-lines
4) Development of Monitoring Plan
5) Protocol Deviation/Violation Management
6) Trial Master File and QC Management
7) Clinical Data Reconciliation and Archiving
8) Management and Reconciliation of Investigational Product
9) Advanced Clinical Research Management
10) Planning and Conducting Global Clinical Trials
11) Management of a Successful Clinical Research Site

Responsibilities of Clinical Research / Study Manager

- Execute overall clinical trial plan and select, initiate and motivate clinical study sites
- Drive the successful activation of trial sites according to time, quality / scope and budget parameters
- Plan and drive patient recruitment and retention
- Oversee development and approval of clinical study execution plans and tools
- Ensure the clinical team adhere to the appropriate training needs and performance indicators to ensure the validity, correctness, and completeness of the clinical data reviewed and collected at assigned sites as dictated by ICH GCP, protocol and client requirements
- Take the initiative to move the project/program forward and leads in country and global projects where applicable
- Manage clinical vendors with focus on deliverables
- Support Clinical Affairs/Clinical Operations Management in the development and review of the protocol / study design, case report forms, informed consent forms and other trial documents
- Ensure transparent and proactive communication regarding study progress and trial issues through use of dashboard, trackers and update communication tools
- May serve as initial point of contact for all clinical management and monitoring issues, vendors and other functional areas, escalating as required
- Work with the Data Management team to identify data related issues and risks to clinical activities; assists in the development of mitigation plans to minimize risk
- Escalate issues and provide escalation path for the team
- Perform any other duties required to ensure the success of the trial

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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