QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Clinical Science Training Institute

Clinical Trial Assistant (CTA)

Are you currently in school and persuing a Undergraduate or Associate Degree in Life Sciences or Pre-Med or Nursing. You are eligible to get enrolled into this training program. This program emphasizes on details to how to become an Clincial Trial Assistant with Pharmaceuticals, Clinical Research Organizations and Hospitals. Few Employer look for XII grade (Health Science) background candidates.

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.

Clinical Trial Assistant (CTA)

LIST OF LESSONS

1. Clinical Trial Assistant
2. Drug Discovery and Research Process
3. Pre-Clinical Research
4. Introduction to Clinical Trials
5. Phase-I Clinical Trial
6. Phase-II Clinical Trial
7. Phase-III Clinical Trial
8. Phase-IV Clinical Trial
9. FDA Regulation
10. Good Clinical Practices and ICH Guidelines
11. Institutional Review Board (IRB)
12. A 6 Month Process for planning Multinational Clinical Trials
13. Communication with Cross Functional Team
14. Overview of Protocol
15. In House CTA Responsibilities
16. Informed Consent Preparation
17. Investigator Meetings and Timelines
18. Clinical Trial Budget
19. Source Documentation Retention and Compliance
20. Investigator-Monitor Meetings
21. Trial Master File (TMF)
22. Preparing for Internal Audit

EXERCISES

1. Introduction to Clinical Trials
2. FDA Regulations
3. Institutional Review Board (IRB)
4. Informed Consent Preparation
5. Investigator Meetings and Timelines
6. Clinical Trial Budget
7. Trial Master File (TMF)

CLINICAL TRIAL ASSISTANT JOB TITLES

- Clinical Trial Assistant
- Documentation Assistant
- Administrative Assistant
- Clinical Data Assistant
- Research Assistant
- TMF Assistant

Responsibilities of Clinical Trial Assistant

- Provide support to the clinical department to assist with execution and maintenance of clinical studies, including:
- Creating and maintaining the trial master file (TMF).
- Tracking incoming and outgoing clinical and regulatory documentation and maintaining study documents, binders, manuals, and supplies to ensure adequate inventory for Clinical Operations and clinical sites;
- Ensuring assigned study compliance with company SOPs and guidelines; tracking study-specific metrics as assigned by the study CRA or CTM;
- Reviewing monitoring visit reports and follow up letters in accordance with assigned study monitoring plan(s)
- Coordinate Clinical Operations team meetings and preparing materials for investigator meetings, partner meetings, scientific meetings, including: complex coordination of multiple stakeholders, preparation and distribution of meeting minutes and poster preparation and printing for conferences.
- Deliver general administrative support, such as formatting documents and slide. presentations, drafting and revising departmental SOPs,
- Collaborating with departmental members to identify Clinical Operations process and resource needs,
- Assisting other departments (e.g. QA, regulatory affairs) as needed with the Document Control System and regulatory submissions, assisting with travel coordination and support budget tracking.

Hiring CTA professionals:

- ✓ 99% of the employers choose candidates with **Nursing** degree
- ✓ 99% of the employers choose candidates with **Life Science** degree
- ✓ 99% of the employers choose candidates with **Public health** degree
- ✓ 99% of the employers choose candidates with **Pre_Med** degree
- ✓ 70% of the employers choose candidate with XII grade with Health Science.

Contact Information

Qtech-Sol Prof Dev Center

120 Howsington Place
East Windsor, NJ USA
Phone: (732) 770-4100
(732) 207-4564