QTECH SOLUTIONS INC.

Job Focused Clinical Science Courses

Clinical Research Associate (CRAT)

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.ca **Email:** qpdc@qtech-solutions.ca

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 LESSONS
THEORETICAL ASPECT OF THE FIELD

- Role of CRA (General)
- Drug Discovery and Research Process
- Introduction to Preclinical Trials
- Introduction to Clinical Trials
- Phase I Clinical Trials
- Phase II Clinical Trials
- Phase III Clinical Trial
- Phase IV Clinical Trial
- FDA and EMEA
- Good Clinical Practices and ICH Guidelines
- Institutional Review Board
- SOP Development
- Conducting Multinational Clinical Trials
- Communication with a Cross Functional Team
- Overview of Protocol
- Role of In-House CRA
- Design and Development of Protocol
- Clinical Trial Budget
- Investigator Selection Process
- Responsibilities of Principal Investigator
- Selection of Investigator Site
- Study Initiation
- Vendor Selection and Management
- CRF Design and Data Capture
- Investigator Meeting and Timelines
- Introduction to Adverse Event Reporting & Classification
- Trial Master File
- Informed Consent Preparation
- Audit Planning

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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