

Qtech Solutions Inc

**Clinical Research Associate Training
(CRAT)**



Seminars



What Is A Clinical Research Associate (CRA)?

A Clinical Research Associate, also known as a Monitor, oversees the progress and conduct of a clinical trial usually implemented by physicians at a hospital, clinic, or physician's office. The CRA is required to oversee the initiation, progress, and conduct of the trial to ensure the integrity of the scientific data collected, in addition to protecting the rights, safety and well-being of the human study subjects. CRA's often have a

health care or science background (e.g. Nurse, Medical Technologist, or Physical Therapist; or Bachelor's, Masters, or Ph.D in a Science). The CRA is usually employed by a pharmaceutical company, Contract research organization, academic institution, or site management organization. A CRA can work either in-house or in the field, requiring 50 - 70% travel. A Field monitor will visit multiple sites and interacts with the study coordinator and the investigator conducting the trial.

E-Learning



CRA's responsibilities

Include but are not limited to the following:

- Monitoring the physician's adherence to Good Clinical Practices and the study protocol;
- Performing study drug accountability;
- Verifying the documentation of the informed consent process for each study subject;
- Ensuring that non-serious and serious adverse experiences are properly documented and reported;
- Comparing the case report form to the subject's medical record to assure completeness and accuracy;
- Ensuring the filling and maintenance of the required regulatory documents.

Candidate Requirements

Applicants for the Clinical Research Associate Training Program are recommended to have one of the following:

- Bachelor's, Masters, or a Ph.D in a Science or Allied Health Field (OR)
- Healthcare Professional (e.g. RN,PA,MD,PT, RPh, PharmD or Medical Technologist)

Candidate Requirements

Training (Classroom Setting): The Part 2 "Training" Session requires two weeks of Classroom attendance, this session applies the knowledge acquired from the online course utilizing. Case studies, workbook exercises, and group discussions.

- ✓ All Classes: Two Consecutive weeks, **Monday to Friday 9: 30 AM - 5:30 PM.**
- ✓ Comprehensive review of the Part1 online Course.
- ✓ Case Studies simulating CRA activities.
- ✓ Course examinations and pre-exam review.
- ✓ Resume evaluation and Career guidance.

We help our students

1. Resume writing and providing interview tips as guidelines,
2. Narrative Preparation and Mock interviews with Experienced CRAs.
3. Student resumes will be evaluated by experienced Clinical Research Professionals.
4. Focus on career goals of candidate and help them to achieve their training objective.
5. Job Placement Assistance for the right candidate.
6. Legal Assistance for needed.

The Benefit

Courses Listed by Curriculum

I. The Food and Drug Administration Past and Present.

- ✓ The Establishment of the Food and Drug Administration.
- ✓ The History of the Legislation and Regulations, which Govern the Clinical Research Process.
- ✓ The History of the Legislation and Regulations, which protect the Rights, Safety, and well-Being of Human subjects.

II. Overview of Medicinal Product Research and Development.

- ✓ Drug Discovery and Pre- Clinical Research
- ✓ The Clinical Research and New Drug Application Approval Process.
- ✓ The Biologics Research, Development and Licensing Process.
- ✓ Medical Device Research, Development and Marketing Approval / Clearance.

III. Good Clinical Practice (GCP).

- ✓ Investigational New Drug Application 21 CFR 312; Sponsor's Obligations.
- ✓ Investigational New Drug Application 21 CFR 312: Investigator's Obligations.
- ✓ Investigational Device Exemption 21 CFR 812
- ✓ Institutional Review Boards 21 CFR 56
- ✓ Protection of Human Subjects 21 CFR 50
- ✓ Financial Disclosure 21 CFR 54

IV. International Conference of Harmonization

- ✓ The History of the International Conference of Harmonization
- ✓ The ICH Good Clinical Practice Consolidated Guideline(E6)
- ✓ The ICH Clinical Safety Data Guideline (E2).

V. Clinical Trial Development.

- ✓ Protocol Design and Development
- ✓ Case Report Form Design and Development.

- ✓ Principals of Data Management and the Query Resolution Process.
- ✓ The Study Types Providing Expanded Access to Investigational Products.

VI. Clinical Trial Management.

Investigator Site Perspective: Coordinating a Clinical Trial at the Site.

- ✓ Essentials of Source Documentation
- ✓ Maintaining and Managing Essential Documents.
- ✓ Recording and Reporting Non-Serious and Serious Adverse Events.

Sponsor's Perspective: Managing a Clinical Trial

- ✓ Selecting Investigators and Monitors
- ✓ Maintaining and Managing Essential Documents (e.g. FDA from 1572)
- ✓ Case Report from Data Transmission and Generation of the Clinical Study report.
- ✓ Reviewing and Reporting of Serious Unexpected Adverse Drug Experiences.
- ✓ Implementing a Monitoring Plan and Performing Quality Assurance Audits.
- ✓ Preparing for an FDA Audit.

VII. Monitoring Obligations and Methods.

- ✓ Monitoring Role and Responsibilities According to the FDA Guideline and the ICH GCP (E6) Guideline.
- ✓ Monitoring Responsibilities: Type of Monitoring Visits, Monitoring Activities Pre-Visit, On-Site, And Post Visit.
- ✓ Monitoring Method: Implementing a Systematic Monitoring Approach to Effectively Monitor a Multi Center Trial.
- ✓ Problem Solving and Trouble Shooting GCP / ICH Issues.
- ✓ Writing Strategic Monitoring Reports and Follow-Up Visit Letters.
- ✓ Electronic Data Capture and 21 CFR 11.



Qtech Solutions Inc

“Qtech Solutions Inc.” is a new jersey (USA) based company founded in 1999. We specialize in Clinical Research / data management/ SAS® Software Solutions for various Pharmaceuticals, Clinical organizations. We provide product development services to various Pharmaceutical, biotechnology, and Medical device industries in support for conducting Clinical trials from Phase 1 through IV. Qtech professionals bring in scientific, regulatory, IT and Clinical Research expertise for the completion of timely, accurate and cost-effective trials. Our services have benefited organizations to process data more efficiently, to reduce time and increase profit benefits for patent-protected products.

<http://www.qtech-solutions.com>

About 70% of graduates obtained employment as Clinical Research Professionals (e.g. CRA, CRC, CDM and Drug Safety Specialist).



LOCATIONS

New Jersey, USA

Qtech Solutions Inc.
1 Executive Drive,
Suite 110, Somerset,
New Jersey 08873, USA.
Phone: 732-770-4100,
Telefax: 732-748-0100
Email: info@qtech-solutions.com

California, USA

Qtech Solutions Inc.
100 Pringle Avenue,
Suite 540, Walnut Creek,
California 94596, USA
Phone: 925-588-7475.
Email: info@qtech-solutions.com

Hyderabad, India

UBN Qtech Solutions (I) Pvt. Ltd.
#408, 5th Floor, Sai Pragathi Towers,
Himayath Nagar, Hyderabad
Andhra Pradesh - 500 029, INDIA
Phone: 91-40-66256475 / 76
Telefax: 91-40-66255558
Email: info@qtech-solutions.com