# QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC

Somerset New Jersey USA

Private Vocational School

## ADDITIONAL CLINICAL RESEARCH LEARNINGS

Risk Based Monitoring

FDA Audit Process

Clinical Data Reconciliation and Archiving

Clinical Trial Project Management

Trial Master File / QC Management

Planning and Conducting Global Clinical Trials

# Clinical Research Associate / Project Managment

*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**

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

This program emphasis on Clinical Research Project management Roles and Tasks performed by Clinical Research Associate. The student must have gone thru Basic and Advanced Clinical Research Associate Training to qualify

# 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. Risk Based Monitoring (RBM)
2. FDA Audit process for Clinical Research
3. Clinical Trial Project Management (CTPM) 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 -1
10. Advanced Clinical Research Management -2
11. Advanced Clinical Research Management -3
12. Advanced Clinical Research Management -4
13. Planning and Conducting Global Clinical Trials
14. Management of a Successful Clinical Research Site - A
15. Management of a Successful Clinical Research Site - B

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

## 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

## Do You Know…?

**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

**Do you want to know more? Call us!**

### Contact Information

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