

QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses



CRA Role Based Projects (CRAP)

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 a 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

Clinical Research Associate

Drug Discovery and Research Process

Pre-Clinical Research

Introduction to Clinical Trials

Phase-I Clinical Trials

Phase-II Clinical Trials

Phase-III Clinical Trials

Phase-IV Clinical Trials

Good Clinical Practices and ICH Guidelines

IND Application

Informed Consent Preparation

Informed Consent Form

FDA Regulations

IRB Regulatory Correspondence

Overview of Protocol

Protocol Design and Development

Protocol

CRF Design and Development Monitoring

Perspective

CRF Design and Data Capture

Case Report Form (CRF)

Clinical Trial Budget

Clinical Trial Budget - Advanced

Selection of Investigator

Roles and Responsibilities of Investigator

Investigator Selection

Investigator Meetings and Timelines

Investigator-Monitor Meetings

Site Visits

Site Monitoring

Site Monitoring - Advanced

Pre-Study Site Visit (PSSV)

Co-Monitoring Visits

Study Initiation Visit

In-House Monitoring and Reporting

Understanding Monitoring Worksheets

Trial Master File (TMF)

Trial Master File - Advanced

CTMS Track Recording

Clinical Trial on Site Audit

Preparing for Internal Audit

Database Lock

Audit

Education Preferred by Employers Hiring for CRA positions:

Pharmacy - 40%
Pharmacology or Toxicology - 60%
Nursing - 50 %
Public health - 40%
Biotechnology - 30%
Medicine - 30%

Clinical Research - 99%

The typical career pathway of CRA begins from entry level position working as Clinical Research Assistant.

The promotion to mid level positions comes with progress and experience while the opportunities remain open for Clinical Research Associate and Documentation Specialist.

TYPICAL CAREER PATH OF Clinical Research Associate

CRA (Monitor, In House); Clinical Research Documentation Specialist; Project Coordinator; CRA I, II; Senior CRA; Principal CRA



Entry Level

Mid Level



Clinical Research Trial Monitor; Clinical Project Manager; Clinical Research Manager; Associate Director of Clinical Research; Director of Clinical Research

Management Level

What is the Difference Between Basic CRA and Advanced CRA?

C R A

Basic and core topics and exercises

Certain educational background is strongly recommended to enter the industry

Designed for non experienced individuals to enter into field

In depth knowledge of roles and responsibilities of CRA + theoretical aspect with projects which help to understand industry requirements

Advanced

Advanced topics and exercises

Prior training or relevant experience is required

Designed for experienced professionals to add new skills set

Exposure to diverse CRA exercises, real time documentation + advanced learning supported by practical case scenario tasks and follow up process



Contact Information

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