# QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC

Somerset New Jersey USA

## Private Vocational School

# Drug Safety Associate

## CLIENT SETTING PROGRAM

*Drug Development and Support in Clinical Trials*

### 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**

APPROVED

Drug Safety Associate 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

State of New Jersey
Department of Education

State of New Jersey
Department of Labor and Workforce Development

**Website:** www.qtechelearncenter.com **Email:** qpdc@qtechelearncenter.com

## Drug Development

The process of Drug development is generally divided into to stages: (1) new lead discovery (preclinical research), and (2) new product development (clinical development). Drug safety associate works in both the hospital sector and research industries, such as academic health centers, government agencies and departments, contract research organizations,and pharmaceutical, biotechnology and medical device firms.


## INT - CLIENT SETTING PROGRAM

Program was designed by industry experts for students and young professionals. This Training program provides in depth knowledge of roles and responsibilities of Drug Safety Associate performed at various Pharmaceutical and Research Organizations. Interested Student must enroll into the program for participation. Recent graduate students who have completed their graduation (past 12 months) or Currently pursuing their graduation are eligible for this Training. Proof of eligibility must be submitted when requested.

## Lessons

Introduction to Clinical Trials
Fundamentals of Drug Safety
ICH Good Clinical Practice Guidelines
Drug Safety Regulations and Guidelines
Introduction to Adverse Events
Adverse Event Classification and Reporting
Elements for Transmission of ICSR
Drug Safety Database and Software
Role of Drug Safety Associate
SAE Reconciliation
Communication with Cross Functional Team
Case Narratives

## Certification and Post Training Assistance

At the end of this Training program student will take a Scenario Based Objective Online Exam to get course completion certificate. Exam fee applies. The Student must secure minimum 75% score in final exam. The Student can purchase reading material book for their future reference. After the course completion, students will be assisted in their resume preparation, narrative writing and mock interviews for applying jobs.

## Delivery

This Training program is ONLINE. Each student will be provided access to Learning Material for 30 Days. The Student must spend min 3 hours/day (Mon thru Fri). During this period they will attend scheduled Online classes and will submit the exercise questions by lesson for evaluation using our Online Learning Management System. All Questions and Queries during the Training program will be addressed via email. This is a Long Distance Training program. Project Assignments will be provided for delivery. QPDC Terms and Conditions Apply for participation into this program and QPDC reserves the right for admission and determines the eligibility for participation.

TECH Professional Development Center

## Typical Duties of Drug Safety Associate

- ❑ Checking the accuracy and ccohesiveness of clinical drug trials adverse event and serious adverse event reports and establishing their priority
- ❑ Preparing and reviewing safety reports
- ❑ Responding to product safety inquiries, i.e., originating from regulatory authorities, healthcare professionals, patients
- ❑ Assessing patient eligibility for clinical trials
- ❑ Entering data into safety databases and reporting systems
- ❑ Processing adverse event reports from various sources to ensure compliance with regulations
- ❑ Initiating quality assurance analysis on specific drug cases
- ❑ Reviewing the work of other DSAs
- ❑ Representing drug safety operations at meetings, presentations, and training programs
- ❑ Preparing comprehensive reviews of adverse or serious-adverse events
- ❑ Identifing potential sources of product litigation
- ❑ Processing case-related information
- ❑ Writing case narratives
- ❑ Ensuring compliance with the MedDRA (Medical Dictionary for Regulatory Activities) coding, retrieval and analysis terminology
- ❑ Performing safety audits for the trial clinical data
- ❑ Contributing to the development and training of staff members

## Who Can Qualify…?

**Education Qualification:**

- ✓ 99% of the employers choose candidates with **Doctor of pharmacy (PharmD)**
- ✓ 80% of the employers choose candidates with **nursing** degree
- ✓ 90% of the employers choose candidates with **medicine** degree
- ✓ 80% of the employers choose candidates with **public health** degree
- ✓ 80% of the employers choose candidates with **pharmaceutical chemistry** degree

### Do you want to know more? Connect with us!

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