



# **QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC**

**Somerset New Jersey USA**

**Private Vocational School**



**Drug Safety / Pharmacovigilance  
Clinical Safety / PV Associates**

*Drug Safety and Reporting*

## **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**



**Drug Safety / Pharmacovigilance 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**



# DRUG DEVELOPMENT

The process of drug development is generally divided into two stages: (1) new lead discovery (preclinical research), and (2) new product development (clinical development). Drug Safety - Pharmacovigilance Associate can work in Pharmaceuticals, Medical Device, Hospitals and research institutions, such as academic health government agencies and departments, contract research organizations/ centers. Their primary role is to identify safety and risk information, evaluate and report with regulatory authorities.



## OVERVIEW OF THE CURRICULUM

Designed by industry experts for students and young professionals. The training program provides in depth knowledge of roles and responsibilities of Drug Safety / Pharmacovigilance Specialist including theoretical aspect of the field and exposure to variety exercises based on industry requirements.

### LIST OF TOPICS: THEORETICAL ASPECT OF THE FIELD

1. Introduction to Clinical Research
2. Drug Development Process
3. Introduction to Drug Safety / Pharmacovigilance
4. Role of DSA / PVA (Trials)
5. Introduction to Adverse Events
6. ICH-Good Clinical Practice Guidelines
7. Drug Safety Regulation and Guidelines
8. Overview of Clinical Trial Protocol
9. Characteristics of a Case
10. Sources of Individual Case Reports
11. Drug Safety Data Extraction and Pre-Processing
12. SOP Development
13. Communication with Cross Functional Team
14. Understanding 21 CFR Part 11 and HIPAA
15. Basic of Coding in Drug Safety
16. Case Follow up approaches and handling of Cases
17. Clinical Trial Safety Surveillance
18. Phase IV Trials and Pharmacovigilance
19. Case Narratives
20. SAE Reconciliation
21. Drug Safety Database and Software
22. Special Scenarios

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

- CASE 1. Introduction to Adverse Events
- CASE 2. Role of DSA / PVA
- CASE 3. Characteristics of Case
- CASE 4. Medical Record Extraction
- CASE 5. Basics of Coding
- CASE 6. Triage
- CASE 7. Case Narratives
- CASE 8. SAE Reconciliation
- CASE 9. Drug Safety Database and Software



## The Main Roles and Responsibilities of Drug Safety / Pharmacovigilance Associate

- Checking the accuracy and cohesiveness of clinical drug trials adverse event and serious adverse event reports and establishing their priority
- Preparing and reviewing safety reports, such as DSUR, PSUR/ PBRER, PADER,
- 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 DSA / PVA.
- Representing drug safety operations at meetings, presentations, and training programs
- Preparing comprehensive reviews of adverse or serious-adverse events
- Identifying 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

### Do You Know...?

#### Hiring DSA professionals:

- ✓ 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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