



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

**Somerset New Jersey USA**

**Private Vocational School**

## **ADDITIONAL DRUG SAFETY LEARNINGS**

**Aggregate Reporting**

**CAPA Management**

**Product Technical Complaints**

**Risk Management Plan**

**Medical Causality**

**Argus Database**

**MedDRA**

### **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

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

# 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.

## TYPICAL CAREER PATH OF Drug Safety Associate



## 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

- Introduction to MedDRA
- MedDRA Coding Guidelines- Part 1
- MedDRA Coding Guidelines- Part 2
- MedDRA Coding Guidelines- Part 3
- MedDRA Coding Guidelines- Part 4
- AE Causality assessments
- ICSR Medical Causality assessment
- Introduction to Risk Management Plan (RMP)
- Introduction to Risk Management Plan (REMS)
- Argus Safety End-User Training - Module 1
- Argus Safety End-User Training - Module 2
- Argus Safety End-User Training - Module 3
- Argus Safety End-User Training - Module 4
- Argus Safety End-User Training - Module 5
- Product Technical / Quality Complaints (PTC / PQC)
- Corrective and Preventative Actions (CAPAs)
- Overview of Aggregate Reporting (PSUR/ PBRER)
- Overview of Aggregate Reporting - PADER
- Overview of Aggregate Reporting - PRAC / DSUR



## 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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