QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC

Somerset New Jersey USA

Private Vocational School

Training Division of Qtech Solutions Inc.

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

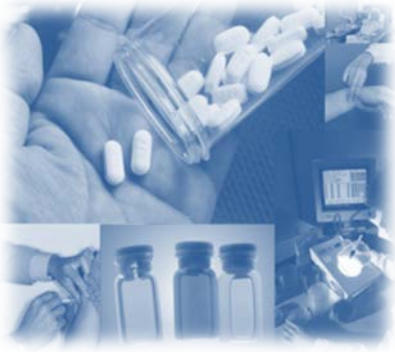
The process of drug development is generally divided into to stages: (1) new lead discovery (preclinical research), and (2) new product development (clinical development). Drug Safety - Pharmacovigilance Associate can work in Pharmaceuticals, Medical Device, Hospitals and research institutions, such 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

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
- ❑ 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

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!

Qtech-Sol Professional Development Center LLC

3 Executive Drive Suite 320
Somerset, NJ 08873
Fax: (888) 532-0210
Phone: 732-770-4100

Trng. Website: www.qtechelearncenter.com **Email:** qpdc@qtech-solutions.com