QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Private Career School

Drug Safety Pharmacovigilance - Role based Projects (DSAP)

Are you currently working as entry level drug safety associate? Are you ready for career advancement to the higher level of DSA role?

If your answer is yes to any of the questions above, starting advanced DSA training program might be the right decision. Your job promotion depends on work experience, but also motivation, and possessing advanced skills.

STATE OF NEW JERSEY
DEPARTMENT OF EDUCATION

STATE OF NEW JERSEY
DEPARTMENT OF LABOR AND WORKFORCE DEVELOPMENT

APPROVED

Advanced Drug Safety Pharmacovigilance 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

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

CURRICULUM

DRUGSAFETY-PHARMACOVIGILANCE ROLE BASED PROJECTS

Designed by industry experts for professionals looking to add new skill set.

LIST OF TOPICS

*** Real time scenario cases are assigned to each topic:**

ROLE BASED PROJECTS - EXCERCISES

SlNo	LESSON NAME
1	Role of DSA
2	Introduction to Adverse events
3	Basics of Coding in Drug Safety
4	Medical Record Extraction
5	Triage
6	Characteristics of a Case
7	Case Processing
8	Data Entry
9	Case Narratives
10	Case Follow up and Handling of Cases
11	Drug safety Database and Software
12	CIOMS Line Listing
13	Signal Detection
14	Case Processing and FDA Reporting-Medical Device
15	Drug Labeling and Edit Checks
16	Revision of SOPs
17	Quality Control Procedures
18	SAE Reconciliation
19	SAE Reconciliation
20	Resolution of Queries for Pending Cases
21	PSUR Reporting
22	SUSAR

HIRING TRENDS

Education Preferred by Employers Hiring for DSA positions:

Doctor of Pharmacy - 99%
Nursing - 75%
Medicine - 50%
Pharmaceutical Science -25%

Role of Drug Safety 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
- ❑ 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
- ❑ 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
- ❑ Review and develop Aggregate Reports required for submissions (PSUR, DSUR, PADER etc)

Hiring Drug Safety / Medical Reviewer Professionals:

- ✓ 99% of the employers choose candidates with **Doctor of pharmacy (PharmD)**
- ✓ 80% of the employers choose candidates with Registered N**ursing (RN)**
- ✓ 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

Contact Information

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