



QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Private Career School



Drug Safety- Pharmacovigilance Data Management (DSPM)

**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 a right decision. Your job promotion depends on work experience, but also motivation, and possessing advanced skills.

APPROVED

Drug Safety Pharmacovigilance Data Management 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

CURRICULUM

DRUG SAFETY DATA MANAGEMENT

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

LIST OF TOPICS

*** The real time scenario case is assigned to each topic:**

ADVANCED DRUG SAFETY TOPICS

1. Medical Record Extraction
2. Adverse Events Case Processing
3. CIOMS Line Listing
4. Case processing and FDA Reporting for Medical Devices
5. Revision of SOP Quality Control Procedure
6. SAE Reconciliation
7. PSUR - Periodic Safety Update Reporting
8. Triage
9. Data Entry
10. Signal Detection
11. Labeling Edit check
12. Quality Control Procedure
13. Resolution of queries of pending cases
14. SUSAR – Suspected Unexpected Serious Adverse Reaction

DRUG SAFETY DATA MANAGEMENT

1. Introduction to MedDRA
2. MedDRA Coding Guidelines- Part 1
3. MedDRA Coding Guidelines- Part 2
4. MedDRA Coding Guidelines- Part 3
5. MedDRA Coding Guidelines- Part 4
6. AE Causality assessments
7. ICSR Medical Causality assessment
8. Introduction to Risk Management Plan (RMP)
9. Introduction to Risk Management Plan (REMS)
10. Argus Safety End-User Training - Module 1
11. Argus Safety End-User Training - Module 2
12. Argus Safety End-User Training - Module 3
13. Argus Safety End-User Training - Module 4
14. Argus Safety End-User Training - Module 5
15. Product Technical / Quality Complaints (PTC / PQC)
16. Corrective and Preventative Actions (CAPAs)
17. Overview of Aggregate Reporting (PSUR/ PBRER)
18. Overview of Aggregate Reporting - PADER
19. Overview of Aggregate Reporting - PRAC / DSUR



HIRING TRENDS

**Education Preferred by Employers
Hiring for DSA positions:**

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



Responsibilities Senior Drug Safety / Medical Reviewer

- 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 Nursing (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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