QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER
Clinical Science Training Institute

Advanced Drug Safety Pharmacovigilance Program (ADPP)

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

Entry Level – Drug Safety Assistant, Medical Record Extractor, Clinical Safety Specialist

Mid Level – Safety Surveillance Officer, Drug Safety Associate, Senior Drug Safety Associate

Management Level – Medical Reviewer, Medical Director

Self-Paced Online Training

Our Mission

Our mission is to provide the best-in-class job oriented certification and skill based courses towards Clinical research, Drug Safety, Pharmacovigilance, Clinical Data Management, Clinical SAS Data Analytics and Healthcare business. We offer Entry-Mid and Senior programs for students and professionals, looking for skills refresh or career advancement

CAREER FOCUSED PROGRAM
(Learning for Job)

Curriculum
Drug Safety - Pharmacovigilance data management

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

LIST OF TOPICS

* Real time scenario cases are 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 Associate / 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 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

C o n t a c t   I n f o r m a t i o n

Qtech-Sol Prof Dev Center

120 Howsington Place
East Windsor, NJ USA
Phone: (732) 770-4100
          (732) 207-4564

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