QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses

Advanced Drug Safety Associate (ADSA)

Pharmacovigilance

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

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

ADVANCED DRUG SAFETY ASSOCIATE

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

ADVANCED DRUG SAFETY TOPICS

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

This course includes advanced theoretical and Practicum concepts as case studies related to MedDRA Coding and Guidelines, AE Causality assessments, ICSR Medical Causality assessment, Introduction to Risk Management Plan (RMP), Introduction to Risk Management Plan (REMS), Argus Safety Tool Training, Product Quality Complaints (PTC / PQC), Corrective and Preventative Actions (CAPAs), Overview of Aggregate Reporting (PSUR/ PBRER / PADER/ PRAC / DSUR).

Project Management Concepts: This course includes theoretical concepts from the Project Management Institute, PMBOK® as introductory project management course for the clinical research professional. Whether you are looking to become a clinical research project manager, are already in an entry-level project manager role, or a project manager without formal project training, this hands-on program will provide you with project management skills as well as the necessary tools and processes required to successfully manage projects in clinical research settings.

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

Contact Information

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