



QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER

Job Focused Clinical Science Courses



DRUG SAFETY GUIDELINES AND SOP (CPDS)

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 LESSONS

(Learning for Job)

SKILL BASED LESSON

Overview of the Curriculum

This Program is designed by industry experts for students and professionals. The training provides in depth knowledge about Role of a Drug Safety personnel towards Clinical Trial and Pharmacovigilance Operations. This program offers details about the Basics of clinical trial, Role of DSA , Drug Development process and Communication of Drug Safety person across various teams.

LIST OF TOPICS

DRUG SAFETY GUIDELINES AND SOP

- Clinical Protocol and Drug Safety Guidelines
- Overview of Clinical Trial Protocol
- Phase IV Trials and Pharmacovigilance
- Understanding of 21 CFR Part 11 and HIPAA
- ICH Good Clinical Practice Guidelines
- Drug Safety Regulation and Guidelines
- Drug Safety Data Extraction and pre processing
- SOP Development
- Revision of SOPs



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

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