TRACON PHARMA	Job Description

Position Title:	**Associate Director of Pharmacovigilance**
Department:	**Clinical Development**

POSITION SUMMARY

Reports to Chief Medical Officer (CMO). Responsible for ensuring TRACON's compliance with FDA, and relevant local country (e.g., Canada and EU) pharmacovigilance regulations, directives and guidelines for reporting adverse drug experiences associated with Investigational Medicinal Products used in TRACON studies. Oversight of activities associated with independent data monitoring committees (IDMC), independent safety assessment committee (ISAC), internal safety review board, and adjudication committees.

RESPONSIBILITIES AND DUTIES

- Coordinate with medical monitor, regulatory, and clinical operations for TRACON products to evaluate the impact of potential safety findings during clinical trials on individual study protocols and the overall product development
- Work with medical monitor, regulatory, and clinical operations to determine reportability of safety findings (in aggregate and individual cases)
- Participate in relevant study and program level team meetings
- Lead safety meetings and provide regular safety updates
- Participate in Independent Safety Assessment Committee and internal TRACON Safety Monitoring Committees
- Assist with safety signal detection
- Participate in development of new SOPs and periodic review/updates of existing SOPs that impact and/or include pharmacovigilance responsibilities
- Ensure that safety processes are conducted in compliance with GCP, relevant SOP's & regulatory requirements
- Review safety summaries for regulatory submissions such as INDs, Development Safety Update Report (DSURs), annual reports, investigational brochures, protocols, clinical study reports etc. as requested
- Determine case reportability along with regulatory affairs and the relevant medical monitor
- Coordinate with external pharmacovigilance vendor responsible for SUSAR submissions outside of the United States (if applicable)
- Coordinate with TRACON regulatory affairs for SUSAR submissions in applicable countries
- Write safety narratives for relevant safety events and oversee the reconciliation process once data in Electronic Data Capture system has been fully monitored
- Assure that all serious adverse events that occur across all TRACON-sponsored studies are tracked by product

- Communicate with development partners regarding safety information per executed safety contracts
- Prepare MedWatch/CIOM reports for relevant safety events
- Oversee and track Suspected Unexpected Serious Adverse Reaction reporting
- Reconcile case narrative information with clinical database and query sites as needed
- Perform study specific overall safety data review enabling database lock
- Coordinate the collection of needed case source with sites and site monitors (and work with study managers and monitors to have information translated as needed)
- Provide appropriate case source, final MedWatch/CIOM reports and narratives to responsible study manager for filing in the trial master file

QUALIFICATIONS

- Bachelor of Science (in Nursing or similar medical degree), Master of Science (in Nursing or similar medical degree) preferred
- A minimum of 8 years of industry experience and at least 5 years of direct experience in pharmacovigilance (patient safety) area.
- US and international patient safety experience.
- NDA submission experience.
- Management experience.
- Excellent verbal and written communication skills.
- Experience with Microsoft Office products.
- Troubleshooting and problem-solving skills.
- Ability to work independently and as part of a team.

Special Considerations:

- Working from home/remote is an option
- Some travel is to be expected when appropriate
- This job may necessitate working outside “regular” work hours

- Customary compensation will be in line with experience