



Position Title: Senior Director, Drug Safety and Pharmacovigilance

Department: Clinical Development and Medical Affairs

Reports To (title): Vice President, Medical Affairs

Location: Boston, MA or King of Prussia, PA (preferred)

Date: 9/8/17

Exempt Non-Exempt

Summary of Position:

The Senior Director Drug Safety and Pharmacovigilance (DS&PV) will be a senior leader in the Clinical Development and Medical Affairs (CDMA) organization responsible for leading pharmacovigilance and risk management activities. This is a highly visible role that will interface across all levels of management and functional areas and is responsible for identification of safety signals, signal investigation and proactive management of the benefit-risk profile of Paratek products.

Position Responsibilities:

- Accountable for global oversight of drug safety processes and compliance, and drug safety deliverables.
 - Provides detailed, accurate and timely medical review of aggregate and/or individual clinical trial and post-marketing adverse event reports (AERs).
 - Performs signal detection using the medical literature and relevant medical databases, as appropriate.
 - Medically reviews individual case study reports from clinical trials, as well as evaluates all relevant cases in depth, including MedDRA coding.
 - Performs regulatory assessment for expectedness and seriousness of AEs.
 - Oversees the delivery of Periodic Adverse Drug Experience Reports.
 - Accountable for SAE narrative generation; SAE database; and investigator alerts for clinical trials.
 - Ensures timely and appropriate drug safety contributions to NDA periodic reports.
 - Oversees the regular review of NDA safety data with respect to safety label updates and modifications.
 - Directs the creation and maintenance of company core safety information.
 - Reviews and approves safety sections of all clinical study reports (CSRs) (including interim as well as final reports).
 - Oversees the preparation of NDA documents, specifically the Integrated Summary of Safety (ISS) or equivalent document, and all safety related review comments or questions.
- As needed, Develops and oversees Risk Minimization Plan (RMP) and/or Risk Evaluation and Mitigation Strategy (REMS).
- Collaborates with cross functional team to develop Risk Assessment Plan, with continued monitoring throughout the development and life cycle activities.
- Oversees development, implementation and reporting of pharmacoepidemiology studies when needed.
- Responsible for the safety agreements with DR&PV vendors and clinical trial CROs.
- Contributor to key clinical and regulatory documents such as Investigator Brochures (IBs), IND packages, and other safety documents to support CTAs, NDAs or Annual Reports.
- Stays informed of new safety regulations and guidance from the regulatory authorities.

- Manages pharmacovigilance provider; supports vendor identification and contracting as required.

Candidate Requirements:

- Advanced Life Science degree required (PharmD, PhD; MD or DO preferred).
- A minimum 7 years combined in pharmacovigilance and clinical research/clinical safety experience in the pharmaceutical industry.
- Ability to synthesize and analyze safety data from various sources. Proficiency in problem-solving within a highly complex environment.
- Knowledgeable in international regulations governing drug safety. Experience in managing compliance or audits. Working knowledge of relevant FDA, EU, ICH guidelines, initiatives and regulations governing both Safety reporting and processing.
- Strong communications skills, both written and spoken, ideally with demonstrable experience in medical / scientific writing.
- Excellent networking and relationship building skills for successful cooperation with internal and external customers.
- Excellent interpersonal skills with the ability to develop important relationships with key stakeholders and influence others.

Additional Information:

- Technology needs: Microsoft Office (Word, Excel, PowerPoint and Outlook) and PV platforms and tools (ARUS, Medra).
- Travel requirements (%): 10-15%, as needed.