clementia

March 2019

JOB DESCRIPTION, PVRM SR. SCIENTIST

Backdrop. Clementia is a clinical-stage company innovating treatments for people with ultra-rare bone disorders and other diseases with high medical need. The Company is preparing for a 2019 NDA submission to the FDA to seek approval of its lead product candidate, palovarotene, a novel RARγ agonist, for the treatment of fibrodysplasia ossificans progressiva (FOP). The ongoing Phase 3 MOVE Trial is evaluating an additional dosing regimen of palovarotene which includes a chronic 5 mg daily dose in addition to the episodic 20/10 mg dosing regimen at the time of a flare-up. Palovarotene is also in a Phase 2 trial, the MO-Ped Trial, for the treatment of multiple osteochondromas (MO, also known as multiple hereditary exostoses, or MHE). In addition, Clementia has commenced a Phase 1 trial for an eye drop formulation of palovarotene for the potential treatment of dry eye disease and is also investigating other conditions that may benefit from RARγ therapy.

Clementia's Pharmacovigilance and Risk Management (PVRM) team is a newly established department recently launched in Q4 2018. PVRM is tasked to provide pharmacovigilance/patient safety and risk management subject matter expertise. We are seeking a talented Pharmacovigilance Sr. Scientist (Associate Director/Director level) to join our growing PVRM team at this critical and exciting time in Clementia and its lead compound palovarotene's history. This key position reports directly to the Vice President of Pharmacovigilance and Risk Management and includes the following responsibilities:

Clinical Trial Safety

- Perform on-going ICSR quality review on behalf of Clementia PVRM and identify data entry errors, missing data, document these errors and effectively communicate with CRO on findings
- Identify case management processes that are inconsistent or not well defined and communicate this to the PVRM team/supervisor
- Reviews clinical study-related documents impacting patient safety and brings observations to Safety/Medical and clinical teams.
- Reviews AE coding and oversees reconciliation activities for safety data from clinical studies and between various vendors
- Contributes to Safety Management Plans and regulatory reporting plans for Clinical Trial programs
- Performs detailed vendor oversight of safety activities including review of metrics, PI and IRB/EC submissions and deliverables from vendor
- Reviews standard design of tables, figures and listings for safety data from clinical studies
- Reviews, documents, and escalates concerns and issues to PV management

Periodic (Aggregate) Safety Reporting

- Supports and project manages the activities related to the aggregate report preparation with other functions involved, in collaboration with the assigned external vendor
- Provides input and review for aggregate reports (i.e., DSUR, IND annual, 6-month line listings, etc.) for submission to the health authorities and other stakeholders, as needed
- Provides assistance with the preparation of safety reviews to address specific safety issues when needed.

Submissions and Other Regulatory Filings

- Assists in the preparation and review of safety assessments and evaluations for ad hoc regulatory safety reports such as responses to health authorities' requests, Health Hazard Evaluation, and responses to inquiries from internal and external customers
- Provides PV input to the development of product Reference Safety Information (Core Company Safety Information, US Package Insert, Developmental Core Safety Information, Investigators Brochure, etc.), Summary of Clinical Safety, Integrated Summary of Safety, etc. in collaboration with the responsible PVRM Physician

Signal Detection, Evaluation, And Management

- Completes initial assessment of safety signals and prioritizes safety signals for full evaluation by PVRM Physician
- Alert PVRM management (PVRM VP and PVRM MD) as soon as a potential signal or trend is recognized.
- Performs case series review or review of tabulated data as preparation for team interpretation of reviewed data
- Maintains schedules, minutes, tracking sheets and ensure follow-up of decisions and assigned tasks for relevant safety activities
- Assists in the preparation of presentation materials, documents and white papers when needed, including documentations supporting the decision process through the established safety governance model in place

Minimum Basic Qualifications

- Pharmacy degree with 3 years of PV experience, or MS in health-related field or BSN with 3 years of PV experience, or BS in life sciences related field with 5 or more years PV experience.
- In depth understanding of medical terminology
- In depth knowledge of global clinical safety regulations, guidances, and reporting processes
- Must be detail-oriented and must have strong organizational and communication skills
- Experience with MedDRA, WHODrug coding and safety database systems

Preferred Qualifications and Experience

- At least 3 years of biotech/pharmaceutical industry experience, including at least 2 year of experience in clinical safety / Pharmacovigilance. 3 years relevant clinical safety, regulatory, or risk management experience strongly preferred
- Knowledge and experience with safety surveillance, signal detection, labeling analyses, and ad hoc safety analyses
- Experience in the review of relevant safety information from all sources and analysis of safety data
- Experience with development, authorship and review of aggregate reports (i.e., PSUR, DSUR, IND annual, NDA annual, etc.), Risk Management Plans, and Risk Evaluation and Mitigation Strategies
- Experience with safety surveillance and regulations for global early access/compassionate use programs

Competencies

- Excellent writing and verbal communication skills.
- Must be experienced with Office suite programs (Word, Excel, Power Point) and safety data base packages (Aris-G preferred).
- Proven ability to critically think through complex medical/safety reports and effectively summarize key information in a concise narrative presentation
- Ability to manage multiple projects simultaneously and complete those projects on time while effectively demonstrating the ability to influence others and accomplish goals within a team environment

- Experience in vendor management preferred
- Excellent English oral and written communication skills
- Flexible, highly organized with the ability to prioritize and detail oriented
- Self-motivated with the ability to function well in a cross functional team
- Strong interpersonal skills
- Strong commitment to business ethics