Job Description

1 Position in the Organization	
Job Title:	Director, Drug Safety & Pharmacovigilance
Department:	Clinical Research & Development
Manager Job Title:	Senior Director, Clinical Research & Development
GxP Functions:	☐None ☒All GxP ☐GLP ☐GCLP ☐GCP ☐GPvP ☐GMP ☐GDP
Location:	King of Prussia, PA

2 Description

This position is responsible for directing and overseeing the activities of the Drug Safety & Pharmacovigilance function and ensuring corporate compliance with all applicable US and foreign legal and regulatory requirements for adverse event reporting & safety management of medicinal products, both approved and in development.

This position will report to the Senior Director, Clinical Research & Development.

3 Duties and Responsibilities

- Sets Corporate direction for drug safety and pharmacovigilance activities for ensuring Corporate compliance with all applicable laws and regulations and as appropriate, local and foreign regulatory reporting requirements, for the processing and reporting of adverse events associated with Nabriva sponsored drug products, including both drugs in development and marketed products.
- Establishes the direction, standards, and processes, and oversees the daily activities of the Pharmacovigilance function.
- Oversees the activities of contract research/service organizations and individuals, contracted to perform drug-safety and pharmacovigilance activities.
- Oversees the activities for monitoring adverse event reports for potential drug-safety related issues and provides recommendations when potential issues are identified.
- Provides leadership and assists in collaborations with Clinical Research & Development and Medical Affairs and applicable functional specialists to identify, evaluate and manage safety signals.
- Leads the development of signal management, safety surveillance and risk management plans for drug development programs.
- Provides leadership and assists in the preparation of expedited and aggregate safety reports (e.g., 15-day Alert Report, SUSAR, PSUR, US PADER, Annual Safety Report, DSUR, IND Annual Report etc).
- Provides expert functional advice and assistance to other functions as needed.
- Assists in the preparation and revision of company product labeling and RMP as appropriate.
- Assists in the preparation and review of safety section(s) of investigator brochures, protocols, informed consent forms, statistical analysis plans, clinical study reports, NDA/BLA/CTD submissions and other.
- Facilitates and ensures communication with departments that may be involved with receiving, investigating, or reporting AEs.
- Collaborates with and provides pharmacovigilance guidance and support for

interdepartmental and/or corporate initiatives.
- Collaborates with corporate partners in order to ensure proper exchange of drug-safety data.
- Algins departmental activities in support of corporate goals, as appropriate.

4 Qualifications and Skills

- Health Sciences degree (e.g., MD, DO, Pharm.D., R.N.) or other relevant training and education in the biomedical field required.
- 8+ plus years of relevant experience in pharmaceuticals/biotech required.
- Strong working knowledge of global PV requirements (e.g., US Code of Federal (CFR) regulations; European Union (EU) Volume 10 clinical trials directive; Guideline on Good Pharmacovigilance Practices (GVP) and ICH Guidelines) required.
- Demonstrated experience in managing CRO/vendors required.
- Thorough understanding of the cross functional drug development processes (Clinical Operations, Biometrics, and Regulatory Affairs) and context applicable to safety surveillance activities required.
- Knowledge of MedDRA terminology and its application required.
- Experience in the preparation and authoring of pre- and post- aggregate safety reports, RMPs, and RSI required.
- Proficiency with standard desktop computing programs (e-mail, Word, Excel) and relational databases required.

5 Competencies

- **Customer-centric & entrepreneurial mindset**. Ability to address issues, communicate, and develop programs, and take on other tasks as assigned with a customer focus based on a foundation of ethics, integrity, and quality.
- **Results-driven individual** with strong levels of perseverance, resilience, and resourcefulness; works toward both individual and team goals. Demonstrates high degree of emotional intelligence, personal initiative/self-leadership, self-motivation and the ability to be involved at various levels and willingness to “roll up sleeves” to drive results and outcomes. Ability to adapt quickly and act with urgency, welcoming change, while producing high quality work with minimal direction.
- **Continuous learner** showing a desire and ability to solve complex business problems and provides innovative, value added solutions.
- **Superior organizational/project management skills**. Demonstrated ability to manage multiple assignments/projects, strict timelines, and to identify project interdependencies, resource needs, potential risks/pitfalls and mitigation plans. Recognized as an integrator and solution provider.
- **Highly collaborative workstyle**; with an ability to see the “big picture’ and influence others across businesses, functions, geographies and levels, motivated by collective success.
- **Communicate with clarity both verbally and non-verbally**; be clear, concise, detailed and actionable. Seeks and provides meaningful feedback. Trusted advisor.