Job Description

1 Position in the Organization	
Job Title:	Manager, Medical Information
Department:	Medical Affairs
Manager Job Title:	Sr. Director, Medical Affairs
GxP Functions:	☒None ☐All GxP ☐GLP ☐GCLP ☐GCP ☐GPvP ☐GMP ☐GDP
Location:	King of Prussia, PA

2 Description

The Manager, Medical Information is responsible for the development and maintenance of medical information-related documents and projects for Nabriva products. This role is responsible for planning, development, maintenance and dissemination of clinically accurate information for product education. The ideal candidate will have relevant experience in Medical Information and experience with assimilating data from scientific publications, clinical and non-clinical summary reports and other relevant scientific documents.

The Manager, Medical Information will assist in the successful completion of Medical Information operational objectives (e.g., product launch preparedness and expansion of value-add services in support of Medical Affairs, Medical Science Liaisons, Sales Training, and Commercial) and will provide medical and scientific support for assigned products.

3 Duties and Responsibilities

- Contributes to the internal review of medical information resource documents and ensures the content and structure of responses are scientifically accurate and contains the appropriate fair balance.
- Assists on expanded cross-functional teams to apply company and regulatory standards for medical/promotional review, and ensures content is scientifically accurate and medically sound.
- Supports the development of current, accurate, balanced and relevant standard response letters.
- Develops, updates, and reviews scientific Medical Information Response Documents and FAQs.
- Review educational materials for internal and external documents that contain data from clinical/pre-clinical programs (e.g., scientific platforms, dossiers, and presentations) for medical accuracy.
- Assists with the PRC/MLR process in Veeva.

4 Qualifications and Skills

- Post-graduate qualifications (PhD or PharmD preferred). RPh, MS, MSN or other scientific degree will be considered.
- Minimum of 2 years in Medical Information or Medical Information fellowship. Infectious Diseases experience is desirable.
- Product launch experience is desirable.

Job Description

- Demonstrated ability to generate, analyze, and interpret clinical trial and published data.
- Experience working within regulatory and legal guidelines regarding medical communications.

5 Competencies

- Strong analytical skills, with demonstrated capabilities to be agile and nimble in a start-up organization.
- Ability to effectively prioritize multiple priorities and meet established deadlines through the use of excellent project and time management skills.
- Strong negotiation and strategic-thinking skills and ability to effectively influence others.
- Strong technical writing and verbal communication skills across all levels of the organization.
- Strong compliance orientation within a pharmaceutical environment and attention to detail.
- Demonstrated strong interpersonal skills, a flexible, collaborative and team/solutions-oriented approach to problem solving, and an ability to work in a fast-paced, rapidly changing environment.
- Advanced computer experience with MS Word, Excel, PowerPoint, Access and Outlook.