Position: Sr. Director/Director, Medical Affairs (CINV)

JOB DESCRIPTION:

Provides leadership and mentoring in strategy, process development, compliance, assessment, implementation, and problem solving for Medical Affairs Operations. This position is responsible for daily Medical Information Services and Pharmacovigilance functions consistent with strategic, operational, and budgetary goals. Works in collaboration with the VP, Medical Affairs, Executive Director Medical Affairs (Shared Services), and internal stakeholders to ensure the successful achievement of company vision by developing and implementing strategic initiatives to achieve department goals and objectives in compliance with established policies and procedures.

ESSENTIAL DUTIES & RESPONSIBILITIES:

General

- Assist in the development, execution, and communication of the following functions within Medical Affairs:
  - Medical Information Content
  - Medical Information Quality Programs
  - Pharmacovigilance (PV)
  - Medical Information Services (MIS)
  - Medical review
- Provide leadership and mentoring to internal stakeholders and staff including process development, compliance, assessment, implementation, and problem solving.
- Oversee the coordination of internal and external cross functional plans and teams to ensure smooth and expedited alignment and execution of projects and goals within Medical Affairs.
- Keep current on the external environment, with respect to regulations and compliance with all external codes and ethical standards.
- Develop strong, positive, professional relationships with KOLs, physicians, and key staff at academic and community practices.

Medical Information Services

- Responsible for the development of standard and custom customer response letters that clearly and concisely communicate medical information to the appropriate audience.
- Follow established procedures to ensure timely review and updates to standard content.
- Oversee the quality program for evaluating responses provided by the Medical Information Contact Center (MICC) for responses to questions related to Heron CINV portfolio.
- Prepare (MICC) reports related to medical information inquiries and response for internal stakeholders.
- Responsible for conducting literature searches for Medical Affairs and other internal stakeholders.
- Collaborate with internal stakeholders and MICC vendor on communications related to product complaints.

- Provide review and input for medical, scientific and promotional documents, and support of business development activities as requested.
- Provide Medical Information Services for major US and international Congress Planning as needed.
- Collaborate with other Medical Affairs Team members to write, direct or review medical guidelines, and compendia and dossier submissions in a timely manner to meet the goals of the company.
- Direct resource planning, budgeting, and timelines to meet the company's needs.

Pharmacovigilance/Safety

- Oversee the quality program for evaluating the intake of adverse event and product complaint reports by the MICC.
- Ensure the MICC has sufficient staffing sources and budget to meet the needs of Heron Therapeutics CINV portfolio.
- Provide medical review of individual case safety reports for Heron CINV products to support Heron Therapeutics Pharmacovigilance (PV).
- Review Periodic/Annual Reports (FDA) and Periodic Safety Update Reports and other Benefit/Risk Update Reports (FDA and Global Regulatory Authorities) for the Heron CINV portfolio in collaboration with internal PV and regulatory stakeholders.
- Review responses to ad hoc regulatory queries, and signaling topic reports in conjunction with regulatory colleagues as needed.
- Collaborate with PV on the review of potential safety signals for the Heron CINV portfolio.

Medical Affairs Technology

- Assess and prioritize technology needs and develop scope for related projects Evaluate vendors and organize project team meetings to assess technology fit and recommend vendors to meet the needs; negotiate contracts for purchase of critical technologies, e.g. medical databases, library services, etc.
- Oversee the planning, development, implementation, training, and evaluation of new technologies.

REQUIREMENTS:

- Advanced scientific degree (Doctorate or Masters Level), PharmD, PhD, MS required.
- At least 10 years of industry experience in Medical Affairs with an intimate working knowledge within Medical information. PV experience with a pharmaceutical or biotech company including at least 3 years in leadership role.
- At least 3 years of relevant oncology experience; some clinical experience preferred.
- Proven experience with medical writing; e.g. guideline, compendia, dossier submissions, standard and custom response letters.
- Good understanding of the commercial drivers of product marketing success and ability to "partner" successfully with the commercial organization.
- Clear understanding of regulations governing Medical Affairs activities and PV.
- Clear understanding of compliance regulations governing the pharmaceutical industry.

- Experience with US based oncology practices.
- Self-motivated and with a strong collaborative work ethic.
- Strong interpersonal skills and demonstrated success achieving results through cross-functional matrix teams.
- Excellent oral and written communication skills.
- Proven attention to detail and ability to understand, interpret and explain complex clinical data.
- Good business instincts, acumen and a high ethical standard.
- Must be able to travel within US at least 25%; possibly some on the weekends.

The above description is intended to describe the general nature of the job and may include other duties as assumed or assigned; it is not intended to be all inclusive or limit the duties of the position.

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