



# PharmAffinity

**Achieve your Ambition**

# Associate Director, Medical Affairs

## Description and Requirements

Opportunity for a physician/Medical Affairs specialist to become a Therapy Lead Specialist and be an integral part of M&D Leadership team assuming responsibility of the Nephrology portfolio of products.

As the TA Lead you will be responsible for providing strategic Medical Affairs Leadership in overseeing all MA activities / deliverables for the Therapy Area, act as a final Medical Signatory for the approval process.

The successful candidate will have previous demonstrable experience in more than one TA, as well as proven experience of direct line management of a team and Matrix Leadership by developing and maintaining integrated partnership with stakeholders, ensuring all Medical Affairs deliverables address local business needs to bring value to patients and advance the medical/scientific understanding of Astellas products to help ensure safe and appropriate use across their lifecycle.

## Essential Job Responsibilities:

### Medical Final Signatory

Ensure adherence to internal policies relating to healthcare compliance standards and interactions with Healthcare Professionals (HCPs), Healthcare Organisations (HCOs) and Patient Organisations (POs). To act as a source of advice and counsel relating to compliance-related matters and maintain currency of knowledge and expertise, enabling the business to anticipate and respond to changes in the external environment  
To act with integrity and be an ambassador for the company with internal colleagues and external experts and regulatory bodies.

### Core Responsibilities and Authority

- To develop a clear understanding and insight into the therapeutic area objectives. To support and constructively challenge the development of such objectives where clarity is lacking.
- Ensure medical input to the therapeutic area brand teams including the planning, preparation and approval of:
  - internal and external scientific product presentations
  - publication plan development, implementation and scientific materials
  - external meetings, advisory boards and symposia
- To ensure that the therapeutic area objectives are realised with compliance within the Local Code of Practice, Local regulations law and sign off all applicable materials and activities including publications as compliant with the Code, Local Law and internal Policies/SOPs.
- To ensure all sign off processes are efficient and timely and well communicated with the Medical, Marketing and Sales Departments.
- To chair internal and external meetings as required.
- Provides strategic leadership and direction across all functions of the TA MA department to ensure all TA MA activities/deliverables are based on scientific validity, clinical importance, fiscal feasibility and aligned to both the Core Medical Plans and local business needs.
- Strategically leverage regional and/or global medical initiatives to meet local business needs, while maintaining an enterprise view.
- Ensure successful execution of all TA MA activities and deliverables.
- Serves as a recognized Medical Affairs authority by maintaining and communicating up-to-date knowledge of industry standards and practices, keeps abreast and proactively responds to market trends and/or shifts in the external medical affairs environment to predict and maximize positive impact to Astellas.
- Inspires the Therapy Area MA department, gains commitment to the MA value narrative and motivates them to consistently deliver a standard of excellence and superior results.

- Seek and identifies relevant trends in external stakeholders' insights to shape Therapy Area MA strategies and deliverables.
- Proactively identifies and develops necessary processes and continuous framework enhancements to ensure consistent delivery of strategic scientific/medical leadership.
- Maintains working knowledge of company's key products/disease states and educational needs across the department.
- Ensures all medical affairs activities support the company's commitment to integrity and delivery of the highest standard of quality and in compliance with all applicable internal regulations, external procedures and ethical standards.

#### **Internal/External Relationships**

- Maintains an integrated partnership with Medical Affairs and cross-functional colleagues to identify collaborative opportunities, ensure optimal alignment, leverage resources, and support business priorities.
- Develops and supports strong relationships with advocacy stakeholder groups and serves as a key company medical spokesperson with governmental agencies, regulatory bodies, professional association, special interest groups, and the healthcare community at large.
- Provide meaningful MA Value metrics, quality assurance controls, and operational assessment/analysis plans relevant to TA MA activities and deliverables.

#### **Learning & Development**

- Supports the training and compliance of MA staff to ensure therapy area expertise, integrity and to optimize performance, efficiency and quality.

#### **People Management**

- Utilizes a proactive approach to attracting, hiring, developing and retaining a high-performing TA MA department. Supports growth and development experiences that prepares the department for broader responsibilities and creates initiatives to ensure the retention of strong performers.
- Ensure that an appropriate and stretching Personal Development Plan is in place for all direct reports and provide timely, evidence based and constructive feedback. Ensure performance is regularly appraised, including conducting annual performance appraisal reviews.
- Provides coaching and timely feedback to ensure a productive, professional and motivated team and a highly valued work environment.
- Foster a culture of innovation, teamwork and accountability with the Medical affairs department to ensure commitment to MA excellence.
- Maintain up-to-date job descriptions for all direct reports to reflect any material changes. Ensure a current version is placed on HR file at each year's performance review.
- To deputize for the Head of Medical Affairs when required.

#### **Requirements for the role:**

- MD with specialist qualification in the therapeutic area (preferred),.
- Solid demonstrable scientific/medical experience in research-based pharmaceutical industry in the areas of Medical Affairs and/or Medical Affairs & Development.
- Experience of working in a leadership capacity
- Strong knowledge of local Regulatory/Payer/HTA bodies, ICH GCP guidelines, Industry regulations, and quality standards.
- Proven team management skills, including global and/or regional and/or local matrix leadership.
- Financial and budgetary expertise.
- Strong scientific analytical and problem solving skills, strategic capabilities, project management, planning and organization skills with excellent communication, writing and presentation skills.

- Experience with medical information IT retrieval systems; Proven ability to utilise medical/ scientific knowledge
- Project management capability. Track-record of leading planning process with excellent organisational and collaboration skills.
- Ability to proactively grasp complex sets of information and act/plan accordingly
- Understanding and awareness of information sources and how to utilise them
- Proven compliance expertise; to understand and comply with industry laws and relevant regulations.
- Coaching and collaboration skills to interact with all levels of personnel to achieve shared goals.
- Demonstrable examples of ability to develop, coach and enable high performance teams and proactively promote best practice and knowledge sharing.
- Proven ability to influence, (appropriately) challenge and engage diverse senior stakeholders.
- Fluent in written and verbal business English.