**Associate Director, Legal Regulatory Counsel**

Astellas Pharma, US

Career Link: <https://astellascareers.jobs/northbrook-il/assoc-director-legal-regulatory/7A8BD1A9AE5A401AB1DB3EF54E97890F/job/>

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The Associate Director, Legal Regulatory reports to the Executive Director, Legal Regulatory (Oncology and Cell Therapy).

Responsible for providing full range of legal support for all legal regulatory matters involving marketed products and pipeline compounds in Astellas' global Oncology portfolio and, as needed, other matters and strategic priorities for the organization. Works closely with members of all functions across the Astellas enterprise, including Sales and Marketing, Market Access and Commercial Capabilities, Regulatory Affairs, Commercial Strategies, Commercial Capabilities, Pharmacovigilance, Quality Assurance, Global Market Access, Medical Affairs, Development, Corporate Communications, and Ethics & Compliance.

Works closely, collaborates, and coordinates with other teams reporting into the Legal Head of Commercial, Regulatory and Privacy (including the Legal Regulatory Lead for Medical Specialties and Gene Therapy) as well as the Legal Heads of Governance, Corporate Strategy and Administration; Legal Strategic Transactions; Litigation, Investigations, and Strategic Learning; IP Legal and Legal Transformation.

**Required qualifications include**:

* Law Degree (Juris Doctor and licensed to practice law).
* Minimum of 5-7 years' related experience working in a law firm or corporate legal department.
* Prior legal experience handling regulatory counseling matters for a company in the pharmaceutical or medical device industry.
* Deep understanding of the legal issues affecting the pharmaceutical industry, including regulatory processes for prescription drugs and fraud and abuse principles
* Experience in promotional material review, FDA-related matters, and PhRMA Code compliance.
* Strong ability to grasp legal issues quickly, exhibit strong analytical problem solving and decision making skills, exercise sound judgment and provide practical and constructive legal advice.
* Strong negotiation and communication skills (both oral and written). Ability to communicate legal issues in a clear and understandable manner. Inspires trust and confidence through effective communication and interpersonal skills.
* Strong work ethic and ability to manage large workload, multi-task, focus on critical priorities, and otherwise effectively meet client needs. Ability to produce high-quality work under deadline pressures.
* Team player and able to build relationships, both internally and externally, on a global scale.
* Strong organization and teamwork skills. Detail-oriented, self-motivated and able to motivate others.
* A strong commitment to integrity and professionalism and demonstrated passion for excellence.

**Purpose of Position**

The Associate Director, Legal Regulatory is responsible for managing a breadth of complex legal and legal regulatory matters and providing practical, timely, strategic, and high quality legal regulatory advice and counsel to a broad spectrum of clients across the Astellas enterprise with primary responsibility for marketed products and pipeline compounds in Astellas' U.S. Oncology portfolio and other strategic initiatives.

This role is accountable for balancing business opportunities with associated legal and compliance risks in a complex and fast-evolving regulatory environment to minimize legal and regulatory exposure and reputational damage in an area of high potential liability. This position is also accountable for proactively identifying and mitigating risks to the Company's ability to achieve its corporate objectives under the Corporate Strategic Plan.

**Essential Job Responsibilities**

The Associate Director, Legal Regulatory will be responsible for the following, working closely with the Legal Regulatory Lead for Oncology and Cell Therapy and the Executive Director, Legal Regulatory (Oncology and Cell Therapy):

* Providing robust legal regulatory and healthcare compliance support to Astellas functions and stakeholders, including Oncology Sales & Marketing, Market Access and Commercial Capabilities, Regulatory Affairs, Medical Affairs, Development, Commercial Strategies, Commercial Capabilities, Corporate Communications, and Ethics & Compliance, ensuring best-in-class legal advice, consistent with best practices in the pharmaceutical industry, the company's global legal strategy and local/regional legal practices and requirements.
* Providing robust legal regulatory and healthcare compliance support to U.S. Oncology brand teams, including reviewing and approving brand plans, promotional materials, and strategic planning tools; supporting product launches and life-cycle management; handling crisis management; managing and resolving marketing and promotional disputes; advising on advisory boards and other non-promotional activities; and representing the Legal Department in relevant meetings and on committees.
* Coordinating with Legal Regulatory lawyers with global responsibilities for Oncology brands to assure matters are handled consistently across the brands and with global policies and practices taking into account unique local or regional legal requirements that may exist.
* Providing robust legal regulatory and healthcare compliance support to Medical Affairs teams responsible for Astellas Oncology compounds, including advising on Medical Affairs strategies and tactics (including core medical plans).
* Reviewing internal and external presentations and materials (including news releases, policies, industry presentation and position statement materials), ensuring that all such presentations and materials meet applicable legal and regulatory requirements, coordinating with other colleagues in Legal, IP, and Ethics & Compliance as may be necessary.
* Staying abreast of and providing business clients with updates on changes in legal regulatory and enforcement-related developments affecting the pharmaceutical industry, coordinating with other leaders in the Legal function, as may be appropriate.
* Working with the Legal Regulatory Lead for Oncology and Cell Therapy and the Legal Regulatory Lead for Medical Specialties and Gene Therapy to ensure a globally consistent approach to legal regulatory support taking into account unique aspects required for a particular client group as well as specific jurisdictional legal requirements.
* Performing special projects as assigned and demonstrate leadership ability when helping the company to analyze innovative approaches.
* Representing the Legal department on various cross-functional committees.
* Supervising and directing outside counsel effectively, and efficiently managing legal expenses consistent with global budget for Legal Regulatory matters, coordinating closely with Legal Transformation.
* Coordinating closely with Ethics & Compliance colleagues.
* Acting as a member of legal-related industry or business community committees such as PhRMA, or other regional or local bodies.
* Supporting a legal culture of excellence within his/her team which includes driving and fostering: (1) an agile, adaptive culture; (2) a value-based organization based on Legal's mission and objectives; (3) a culture of innovation, transparency and trust; (4) proactive identification/mitigation of risk in a balanced approach; (5) empowerment and engagement of the team members; (6) a collaborative culture with close coordination with other members of Legal and IP as appropriate to leverage synergies and efficiencies; (7) a culture of compliance and good corporate governance; and (8) a continuous expectation of high performance, where "ok" is not good enough.
* Leading other projects as may be requested by the Executive Director, Legal Regulatory (Oncology and Cell Therapy); Legal Regulatory Lead for Oncology and Cell Therapy; Legal Head of Commercial, Regulatory, and Privacy; or General Counsel.
* Overnight travel, including international travel, as needed.