Executive Director, R&D Legal and FDA Regulatory Legal Lead

Job ID
REQ-10024599
Oct 17, 2024
USA

Summary

Location: East Hanover, NJ US

The Novartis Legal team is seeking an Executive Director for its R&D Legal Team responsible for providing U.S. legal and FDA regulatory counsel in support of drug development, patient safety, and quality matters. This individual will support the Global Regulatory Affairs function on a broad range of matters spanning drug development, approval strategies, data integrity, and health authority regulatory requirements and interactions. They also will provide legal counsel and contract support for the conduct of Novartis clinical trials in the Americas.

About the Role

Key Responsibilities:

- Counsel on a broad range of issues in support of Novartis clinical trials, including in the areas of informed consent, site selection, patient recruitment and reimbursement, institutional review board negotiations and approval, study fees and fair market value, data use, and scientific and data integrity.
- Legal advisor to Global Regulatory Affairs and Development program leads on FDA strategies and matters involving drug development programs and drug/medical device regulations, including pre-clinical regulatory requirements, program filing strategies, investigational new drug applications, FDA approval pathways, regulatory exclusivity, pediatric and orphan drug requirements, decentralized clinical trials, FDA advisory committee hearings, clinical trial reporting, medical device requirements, and FDA investigations and enforcement actions related to the conduct of clinical trials.
- Provide holistic strategic legal advice to help Novartis navigate complex drug development issues within the context of a global regulatory environment. This involves providing legal counsel and support to senior leaders in Global Regulatory Affairs on a broad range of development and drug safety matters beyond those just before the FDA. Serve as a global legal regulatory advisor on rapid response teams and other priority matters involving Novartis development programs.
- Advise on GxP matters from a U.S. legal perspective in support of research and development activities, namely good clinical and laboratory practices. Responsibilities include counseling on deviations, internal monitoring and audit activities, corrective action plans, FDA reporting requirements, and GCP and GLP-related FDA inspections, investigations and enforcement actions.
- Provide legal regulatory advice on U.S. pharmacovigilance compliance and drug safety matters, including FDA reporting requirements, internal monitoring and auditing, corrective action plans, dear healthcare provider letters, and FDA inspections, investigations and enforcement actions involving

pharmacovigilance.

- Monitor drug development industry and policy trends and proactively advise on strategies to shape the landscape and support the success of Novartis drug development programs in the context of an evolving and competitive external environment. Provide legal-regulatory advice on proposed legislation, regulations and FDA guidance to inform advocacy efforts.
- Advice on business development deals from a technical R&D legal perspective to support due diligence of pre-clinical and clinical stage external assets, deal terms, FDA regulatory strategies, and legal integration activities involving the transition of acquired development programs.
- Legal review and advice on Novartis policies, SOPs and trainings to ensure compliance with FDA regulatory requirements.
- Provide legal advice and contracting support for the conduct of clinical trials in the Americas with a focus on priority programs, trial acceleration, and access. Adapt global contracting templates and playbooks as needed to reflect local requirements.
- Coordinate and collaborate with various other internal stakeholders as necessary regarding global legal regulatory matters and regional development issues. Such stakeholders include R&D IP, International Legal, Regulatory Affairs, Procurement, Tax, Ethics, Risk and Compliance, and others.
- Anticipate and proactively advise on strategies to simplify or streamline the work of business teams and/or create impact to advance business priorities.
- Actively support the R&D Legal team and broader Security and Legal organization by mentoring, coaching, sharing knowledge and best practices, and contributing to the culture and community.

Essential Requirements:

Education: Law degree and bar admission required.

Fluency in English essential

Experience / Skills/ Competencies:

- At least 15 years' post bar admission experience in the life sciences industry (preferably biotechnology or pharmaceutical), with the U.S. Food and Drug Administration, or a top-tier law firm representing pharmaceutical clients.
- At least 15 years of experience advising on FDA regulatory strategies and issues involving drug development, including pre-clinical regulatory requirements, program filing strategies, investigational new drug applications, FDA approval pathways, regulatory exclusivity, pediatric and orphan drug requirements, device regulations, and advocacy strategies to shape the evolving FDA policy and regulatory landscape. Legal advising in support of an FDA advisory committee review is preferred.
- At least 10 years of experience advising on innovator drug development programs in the United States or Americas region more broadly, including the conduct of Phase 3 clinical trials and related health authority regulatory strategies and issues.
- Experience advising on Good Clinical Practices and issues involves scientific and data integrity.
- Experience advising on U.S. pharmacovigilance regulatory requirements is preferred but not required.
- Ability to analyse complex legal issues.
- A connector with an enterprise mindset and organizational savvy to deliver results.
- A pragmatic problem solver, driven not only to identify issues but to actively seek innovative and practical solutions.
- Strong verbal & written communication skills, together with a high ability to influence and negotiate.
- Sound experience in handling a high volume of activity involving multiple, often complex projects simultaneously.
- Professional & culturally sensitive work ethic.

- Financial and business acumen.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $233,600.00 - $350,400.00 USD per year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity & Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams’ representative of the patients and communities we serve.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients’ lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in

your message.

Division
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Business Unit
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Location
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East Hanover
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Employment Type
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Shift Work
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Executive Director, R&D Legal and FDA Regulatory Legal Lead

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