

Vice President, Head of R&D Legal, Americas

Job ID
REQ-10025199
Oct 17, 2024
USA

Summary

Location: Cambridge, MA US

The Novartis Legal team is seeking a Vice President, Head of R&D Legal for the Americas, responsible for leading the legal support for the Biomedical Research organization in the U.S. and all clinical development and study operation activities across the Americas, and managing a team of legal and administrative personnel.

About the Role

Key Responsibilities:

- Lead the development and implementation of legal strategies and counsel in support of the Biomedical Research (BR) organization, with a focus on U.S.-based activities in particular. Key accountabilities include:
 - Legal leadership responsibility for regulatory, transactional and business legal counseling in support of the BR organization, with primary responsibility for the legal work arising out of the Cambridge, San Diego and Emeryville sites. Areas of legal support span across pre-clinical research and early-stage clinical development and include academic research collaborations, Global Health projects, data use and sharing, trade secret protection, advising on new modalities and technologies including AI/machine learning platforms, counseling on issues involving scientific integrity, and advising on CRO and other research outsourcing arrangements.
 - Advising senior leaders in BR on priority programs and strategies by providing pragmatic counselling and proactively identifying opportunities and creative solutions to advance BR business priorities.
 - Collaborating with other legal teams that support BR, including R&D IP and Legal Transactions, to ensure the delivery of seamless legal support to BR holistically. Partner with R&D IP to ensure the ownership, control and protection of inventions.
- Legal leadership responsibility for all legal and regulatory counsel and contracting support for development activities in the region. Key accountabilities of the R&D Legal, Americas team include:
 - Legal advising to support the conduct of clinical trials in the region, including informed consent, patient recruitment and reimbursement, site selection, site and clinical vendor contracting and payments, IRB negotiations, data integrity, and related health authority regulatory issues. Adapt global contracting templates and playbooks as needed to reflect local requirements.
 - Counselling on regulatory issues involving development filing strategies, regulatory exclusivity, device requirements, trial and protocol transparency reporting, the handling and reporting of drug safety issues, fair market value requirements, Good Clinical Practices, orphan drug qualifications, pediatric obligations, and other development-related matters specific to the region. Also, partner with Regulatory Affairs and local country attorneys to advise on regulatory policy developments in the

region and proactively develop policy shaping strategies to support Novartis research and development objectives.

- Supporting 3rd party relationships on behalf of the Global Clinical functions as they relate to study activities in the region, including advising on and assisting in the negotiation of clinical procurement agreements and outsourced clinical trials. Develop legal strategies to streamline and simplify the overall contracting process.
- Provide pragmatic counselling to leaders in the Development organization and proactively identify business opportunities and creative solutions that reflect a solid understanding of needs across the Novartis RDC continuum.
- Ensure compliance with applicable laws, regulations, Novartis policies and overall legal governance. Advise on compliance legal issues and policies as they relate to research and drug development. Monitor the external landscape from an industry and legal perspective to identify trends, anticipate developments, and proactively advise senior leaders to ensure Novartis stays ahead of the curve to deliver on its Biomedical Research and Development priorities and other objectives and remains competitive.
- Anticipate and proactively advise on strategies and practices to simplify or streamline work to advance business priorities.
- Lead, develop and manage employees in the R&D Legal, Americas team. Define career paths, promote collaboration, and ensure best practices and the sharing of knowledge and information with others to drive legal effectiveness and efficiency. Foster community and culture in line with Novartis values. Promote and maintain high team performance.
- As member of the R&D Legal Leadership Team (LT), provide collective leadership in support of the broader Research and Development legal practice and team members, and lead LT projects and programs as required.

Essential Requirements:

Education: Law degree and bar admission required.

Fluency in English essential

Experience / Skills/ Competencies:

- At least 15 years' post bar admission experience ideally gained within an international life sciences and/or pharmaceutical environment or alternatively, with a top-tier law firm representing pharmaceutical clients.
- Experience of managing a team of attorneys and successfully supporting their professional development.
- At least 10 years of experience advising senior leaders on all aspects of research and drug development programs in one or more jurisdictions in the region, including the support of pre-clinical research, research collaborations, molecule and platform licensing, and the conduct of early and late-stage clinical trials and related health authority regulatory matters.
- Legal experience supporting outsourced trials through Contract Research Organizations, and complex contracting negotiations with clinical vendors.
- Demonstrated success developing and driving cross-functional organizational process improvements to create business efficiency and/or advance corporate priorities.
- Experience advising and training on regulatory, legal compliance and risk management issues related to research and drug development.
- Ability to analyze 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.
- A science background is preferred but not required.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$284,000.00 - \$426,000.00 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

Legal

Business Unit

Corporate

Location

USA

Site

Cambridge (USA)

Company / Legal Entity

U061 (FCRS = US002) Novartis Services, Inc.

Functional Area

Legal & Intellectual Property & Compl.

Job Type

Full time

Employment Type

Regular

Shift Work

No

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