NOVARTIS

Head Quality Operations, Legal

Job ID
REQ-10024987
Dec 03, 2024
USA

Summary

The ideal location for this role is the East Hanover, NJ site but remote work may be possible (there may be some restrictions based on legal entity). Please note that this role would not provide relocation as a result. If associate is remote, all home office expenses and any travel/lodging to East Hanover, NJ for periodic live meetings will be at the employee's expense. The expectation of working hours and travel (domestic and/or international) will be defined by the hiring manager.

The Novartis Legal team is seeking a new Head Quality Operations responsible for Good Manufacturing Practice (GMP) Quality matters in Novartis Operations Legal. This individual will be the first point of contact for regulatory, quality and supply matters relating to manufacturing and lab work for Novartis. They will be a critical advisor to the Global Head of QA and its leadership team.

About the Role

Key Responsibilities:

- Serve as legal advisor to Senior Quality leaders.
- Act as the first point of contact for QA organization within Operations of Novartis.
- Handle issues as they occur within the Quality area.
- Contribute in setting standards in the Quality area.
- Act as an advisor to colleagues in the Legal Team in quality matters.
- Prepare teams for quality audits (especially in manufacturing and supply area) with the main focus on audits conducted by the US FDA.
- Managing quality relevant documentation, such as quality agreements, SOPs, corresponding with authorities etc.

Essential Requirements:

- Law school graduate and bar membership required.
- Minimum of 10+ years post bar experience gained either within a multinaional corporation (preferably within the pharmaceutical industry), working with relevant government authorities or at a top tier law firm.
- Good understanding of pharmaceutical law.
- Legal experience to include regulatory counseling, contracting support, and advising on GMP compliance and risk mitigation.
- Experience serving as a legal advisor to sr. research leaders and cross -functional teams in the pharma industry.
- Extensive FDA legal regulatory expertise required. Experience advising on FDA regulatory policy matters in support of shaping the regulatory landscape.

- Experience in working with FDA, especially in audit and GMP quality settings.
- Proven record of stakeholder management with the ability to build, maintain and influence strong relationships with diverse stakeholder groups and to motivate and guide network members towards achieving objectives.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $212,000.00 - $318,00.00 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. 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.

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
CTS
Location
USA
State
New Jersey
Site
East Hanover
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
Apply to Job

Job ID
REQ-10024987

Head Quality Operations, Legal

Apply to Job

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