

Head Quality Operations, Legal

Job ID
REQ-10024987
Nov 06, 2024
USA

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 multinational 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 - \$318,000.00 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.

Role Requirements

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>

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Division

Legal

Business Unit

CTS

Location

USA

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

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