NOVARTIS

Associate Director, Clinical QA

Job ID
REQ-10020334
Sep 24, 2024
USA

About the Role

Key Responsibilities:

- Proactively provide QA leadership to the business strategy for assigned programs/trials by ensuring considerable organization awareness (e.g. Interrelationship of departments and business priorities),
- Drive implementation of quality strategy within GCT/CTT under responsibility
- Regularly monitor the implementation of the annual Quality Plan pertaining to the assigned programs/studies
- Ensure adequate oversight of proactive quality risk management process in the overseen areas including quality risk assessments and submission/inspection readiness activities and ensure that CTP processes are in control
- Provide robust and clear quality oversight in the following areas of clinical development:
    - Support/collaborate with key stakeholders (e.g., CDQ, DUs, GCT and/or CTT members) to ensure that risks are detected and remediated.
    - Support core governance for quality incident management for critical and major deviations pertinent to the programs being assigned and ensure timely escalation when required.
    - Provide GCP guidance to day-to-day questions arising from Clinical trials deliverables.
    - Collaborate with Country Development QA and ESP QA to drive initiatives relevant to internal monitoring and outsourced activities Quality oversight.
    - Support inspections preparation and facilitation in collaboration with other QA groups within RDQ.
    - Support audits and inspections follow-up activities including CAPA preparation.
- Actively leverage audit/inspection outcomes/trends to sustain improvement in clinical trials conduct.
- Active participation in continuous improvement initiatives (including Work streams) and ensure that areas identified as weaknesses are properly being addressed and executed for sustainability
- Be QA point of contact for the defined trials and attend the meetings and ensure quality is embedded in the decision taking processes.

Essential Requirements:

- Bachelor’s degree in life science or healthcare field required. Advanced degree or equivalent education/degree in life sciences/healthcare preferred (PhD/MD/ PharmD/ Masters).
- 7 years of involvement in regulated activities (GCP/PV), clinical development
- and/or QA positions.
- Broad understanding of global expectations of Health Authorities in the area of
- Clinical Development and profound understanding of the science of product
- development.
- Prior experience in RLT strongly preferred

- Ability to work independently and in a global/matrix environment.
- 3 or more years' experience in managing projects.
- Strong skills in GCP, quality and/or clinical development

The pay range for this position at commencement of employment is expected to be between $158,400 and $237,600 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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.

The ideal location for this role is East Hanover, NJ, where hybrid working principles apply. A distant working arrangement may be considered in certain states for US associates who are not within a daily commutable distance (more than 50 miles one way). Distant workers are responsible for the cost of home office expenses and periodic travel/lodging to East Hanover site, as determined necessary by hiring manager. This position will require 10% travel as defined by the business (domestic and or international)

Commitment to Diversity and Inclusion:

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people

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

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

Division
Development
Business Unit
Innovative Medicines
Location
USA

Site
East Hanover
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Associate Director, Clinical QA

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