NOVARTIS

Quality Assurance Specialist II

Job ID
REQ-10022716

10月 02, 2024

USA

摘要

This position is responsible for assuring compliance with internal procedures, applicable Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) regulations and Good Clinical Laboratory Practice (GCLP), CLIA regulations, College of American Pathologists (CAP), ISO 15189 and ISO 13485 guidance, and state and federal regulations as applicable for a clinical trial/in vitro diagnostic development testing laboratory. This position will primarily support internal and external audits/inspections as well as laboratory licensure and CAP/CLIA activities.

About the Role

LOCATION: This opportunity is located at the Navigate BioPharma Services Carlsbad, CA site and will not have the ability to be located remotely.

ESSENTIAL DUTIES AND RESPONSIBILITIES

Note: Other duties may be assigned.

- Works in a GMP/GCP/GLP/CLIA regulated environment and is responsible for following all applicable regulations.
- Support quality activities and provide quality oversight within the CLIA/biopharma laboratory to ensure
- compliance for clinical trial and nonclinical study specimen testing to GCP/GLP/GCLP requirements.
- Assist and/or conduct internal audits as assigned including ensuring completion of audit reports and audit responses.
- Assist with coordinating and supporting external audits/inspections.
- Assist in the monitoring of sub-contracted laboratories for compliance to regulatory and Navigate BP requirements.
- Assist in review of assay validations and reports.
- Assist in resolution of quality events, including preventive action.
- Assist with the performance of routine compliance checks.
- Assist in maintenance of appropriate CAP/CLIA, and state licenses for a CLIA medical laboratory and CAP and ISO accreditations.
- Contribute to development and monitoring of quality improvement initiatives and quality metrics
- Assist Quality Management in other activities as appropriate.

OTHER RESPONSIBILITIES

- Ensuring that Quality Events such as incidents and deviations are proper documented, and for supporting/owning the immediate remediation and preventative actions.
- Ensuring change requests are properly initiated, completed, and approved prior to the use of the assay, system, instrument, software, etc. being changed.
- Maintaining up-to-date training records and ensuring training is complete prior to performing specific job functions.
- Following approved and effective procedures to perform specific job functions, and ensuring procedures accurately reflect activities being performed.

Minimum Requirements:

Education

- BS in engineering, medical technology, biological sciences, or related field.
- Clinical Laboratory Scientist (CLS) License

Years of Experience Required

- Minimum of five (5) years of related experience in a clinical lab or biopharma setting participating in audits and/or assay validations.

Required Skill Sets & Knowledge

- Strong organizational skills and detail oriented.
- Demonstrated knowledge of GxP, CLIA regulations and CAP guidelines is preferred.
- General familiarity with laboratory processes. Knowledge of flow cytometry, cytogenetics and/or molecular techniques is preferred.

Languages:

- English

Why Novartis: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

The pay range for this position at commencement of employment is expected to be between $92,800 and $139,200/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

You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

Handbook. https://www.novartis.com/careers/benefits-rewards

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

Join our Novartis Network:
If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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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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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

站点
Carlsbad

Company / Legal Entity
U441 (FCRS = US441) Navigate BioPharma Services, Inc.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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