NOVARTIS

Clinical Bioanalysis Monitor, PK Sciences (Principal Scientist)

Job ID
REQ-10006304
Jul 14, 2024
USA

Summary

-Clinical Bioanalysis Monitor, PK Sciences (Principal Scientist)

About the role:

#LI-Hybrid

This position will be located in East Hanover, NJ or Cambridge, MA and will not have the ability to be located remotely.

In the Translational Medicine Bioanalytical group, we are at the core of drug development as we develop, validate, and implement immunogenicity, pharmacokinetic and pharmacodynamic assays as endpoints used to evaluate safety and efficacy of biologics during clinical trials. We are seeking a highly skilled and motivated Clinical Bioanalysis Monitor to join our team in Cambridge, MA or East Hanover, NJ.

As the Clinical Bioanalysis Monitor, you will:

• Have overall responsibility for method development, validation, and implementation of immunogenicity, pharmacokinetic (PK) and pharmacodynamic (PD) assays for biologics development during clinical studies
• Working on the latest modalities including, but not limited to, monoclonal antibodies, multi specific antibodies, Therapeutic proteins, Gene therapies, Antibody drug conjugates, oligonucleotides, Chimeric Antigen Receptor Therapies
• Work as part of both the clinical bioanalytical team and clinical trial team to a high degree of quality and rigor, ensuring compliance with regulatory guidance, internal SOPs and the preparation of high-quality regulatory submissions

About the Role

Key responsibilities:

- Manage all aspects of assay outsourcing at CRO which includes, contract review, assay development, validations in support of clinical trials for biologics.
- Coordinate and monitor PK, PD, anti-drug (ADA) and neutralizing antibodies (nAb) assay analysis activities during clinical trials ensuring accurate and timely data delivery.
- Support emerging new modalities such as oligonucleotides and Cell and Gene therapies platforms.
- Act as liaison between clinical teams and CROs, be a representant for clinical outsourced biologics to ensure alignment of study objectives, timelines, and deliverables.
- Act as scientific leaders with our CRO partners; focusing on the fundamental science providing bioanalytical assays that answer emerging scientific questions during trials.
- Contribute to the clinical bioanalytical strategy considering state-of the art technology and current health authority guidelines.
- Review and interpret PK, PD, and immunogenicity data, providing insights and recommendations to support clinical development strategies.
- Provide technical and scientific oversight of external development and implementation of regulated immunogenicity and molecular biology assays.
- Provide consultation and technical support for clinical Immunogenicity strategy discussions within Global Bioanalysis, and data interpretation consistent with current industry and health authority expectations.
- Contribute to relevant bioanalytical sections to regulatory and submission documents (e.g. IB, CTD, BLA, ISI).
- Stay updated with the latest scientific advancements and industry trends related to PK, PD, and ADA analysis for biologics

Essential Requirements:

- Ph.D. Life Science or Master's degree in a relevant scientific discipline required
- 2 plus years post-PhD relevant experience preferably within the pharmaceutical industry or CRO
- Subject matter expert / clinical bioanalytics, bringing scientific knowledge to the global Bioanalytical team with experience managing internal and external stakeholders.
- Ability to understand the industry landscape, Health Authority expectations, and bring scientific expertise
- Hands-on experience developing ligand binding assays
- Fundamental understanding of immunogenicity assay development and validation
- Excellent project management skills, with the ability to prioritize and multitask effectively
- Strong analytical and problem-solving skills, with a keen attention to detail.
- Excellent communication and interpersonal skills, enabling effective collaboration with internal and external stakeholders.
- Experience working in a cross-functional team environment.

Desirable Requirements:

- Some experience with qPCR techniques and / or cellular assays (e.g. Flow Cytometry assays, Receptor occupancy assays, Cellular Immunogenicity assays)
- experience in writing bioanalytical sections of regulatory and submission documents

Novartis EVP Manifesto.mp4

Benefits and Rewards:

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: Novartis Life Handbook

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between $118,400 to $177,600/year (Principal Scientist I) $130,400 -$195,600/year (Principal Scientist II); 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.

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.

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