

GCP Bioanalysis Sr Principal Scientist

Job ID
REQ-10018459

10月 25, 2024

USA

摘要

Onsite - Cambridge, MA

Are you looking to build and grow your leadership opportunities? As a Senior Principal Scientist in the Translational Medicine Drug Disposition Bioanalytical group, you will have the opportunity to make a difference. If you have a collaborative nature, a commitment to teamwork across an organization and a relentless focus on improving patient care we want you to apply. In this vital leadership role, you will use your leadership skills, scientific acumen, operational excellence, and regulated bioanalysis experience to lead a team of scientists in method development, validation and sample analysis focusing on our novel modality biologics portfolio.

About the Role

In setting the standard for efficient operations in a regulated bioanalytical lab:

Your key responsibilities will include:

- Responsible for overseeing the development/validation/sample analysis for mass spectrometry assays for pharmacokinetic and immunogenicity bioanalysis for all therapeutic modalities (proteins, mono, bi and tri-specific molecules, gene therapy, cell therapy, radioligand therapeutics and more).
- Managing clinical study timelines and ensuring accuracy of project progress through company tracking tools.
- Contributing to the strategic and operational aspects of the team and proposing/implementing modifications and improvements, both operationally and technologically, with a focus on continuous quality and efficiency improvements.
- Contributing and reviewing relevant bioanalytical sections to regulatory and submission documents (e.g. IB, CTD, ISI).
- Contributing to various advisory councils and stakeholder meetings representing the Bioanalytical group to facilitate your team 's contributions.
- Hire and lead a team of up to 5 scientists carrying out bioanalytical development/validation and regulated sample analysis.

Minimum Requirements:

- M.S. with 10+ years GCP experience in a pharmaceutical, CRO or related industry.
- Demonstrated success building, leading and developing a scientific team.
- Hands-on experience with the development of mass spectrometry assays with the proven ability to develop BA strategies across a variety of modalities using different technologies, including biologics. Preference given to candidates who have additional experience in working

on protein and RNA therapeutics.

- Strong engagement, interpersonal communication skills and ability to work in a dynamic matrix environment with frequently shifting priorities and timelines.
- A thorough understanding of industry landscape and Health Authority guidelines.
- Experienced in writing and supporting others contributing to the bioanalytical sections of regulatory and submission documents.

Preferred Qualifications:

- PhD

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Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$151,000 - \$226,000/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.

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Biomedical Research

Business Unit

Pharma Research

地点

USA

站点

Cambridge (USA)

Company / Legal Entity

U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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