

GCP Bioanalysis Principal Scientist

Job ID
REQ-10023106

11月 04, 2024

Switzerland

摘要

As a Principal Scientist in our Translational Medicine Drug Disposition Bioanalytical group, you will lead the development and execution of bioanalytical strategies for novel modality biologics. Responsibilities include designing assays, analyzing data, managing study timelines, and supervising a small team. Strong laboratory background and experience in regulated bioanalysis are required. We offer a flexible working environment, a collaborative culture, and opportunities for growth and development. Competitive salaries and benefits provided.

About the Role

In the Principal Scientist role, you will apply your bioanalytical expertise and leadership skills to design and conduct studies for our novel modality biologics portfolio in clinical development. To conduct bioanalysis in a regulated GCP lab:

Your main responsibilities will include but are not limited to:

- Designing, developing, validating assays and performing clinical sample analysis using biological techniques for PK, PD and immunogenicity following SOPs and guidelines, in a contributing/mentoring role.
- Participating in or leading the bioanalytical strategy sub-team discussions and overseeing the execution of the strategy.
- Data processing, evaluating results, interpreting data, and drawing relevant conclusions. Critically analyzing data on study and project levels, and communicating findings in a clear and timely manner.
- Keeping timely raw data records in accordance with company and health authority guidelines.
- Managing study timelines and ensuring accuracy of project progress through company tracking tools.
- Authoring study protocols, reports, and contributing to health authority documents.
- Supervising, coaching and/or mentoring in a matrix team laboratory environment.

Essential Requirements

- College/university degree in biological related sciences or equivalent, with 7+ (PhD) or 10+ (Masters/Bachelors) years of experience. Experience in biologics bioanalysis, both as an individual contributor and a supervisor/mentor, preferred.
- Strong laboratory background with proficiency in several biological techniques (ELISA, ECL, PCR, etc.) and their associated software. Experience in regulated bioanalysis preferred.
- Strong understanding of GCP guidelines, FDA regulations, and ICH guidelines related to analytical method validation and sample analysis. Familiarity with GLP (Good Laboratory Practice) is a plus
- Ability to work independently, supervise a small team, and organize work across multiple projects to meet timelines.
- Eagerness to take on additional responsibilities when required; flexibility to adapt to changing priorities and strategies.
- A collaborative spirit and willingness to mentor/coach peers within and outside of immediate team.

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部门

Biomedical Research

Business Unit

Pharma Research

地点

Switzerland

站点

Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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