# **U** NOVARTIS

## 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.

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: <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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

Accessibility and accommodation: Novartis is committed to working with and providing reasonable

accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusion<u>ch@novartis.com</u> 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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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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