生物分析总监

Director, Bio-analytical Development

Responsibility:

1．Be responsible for developing assays including instrumentation and bioactivity for biotherapeutic molecules, such as monoclonal antibodies, cytokines, recombinant protein or viral vaccines, immunotoxins, and etc.

2．The individual will lead a team of 5-10 scientists to conduct analytical development, supporting technology transfer, production scale-up, and regulatory submission, GMP production, and product characterization.

Requirement:

1．Minimum 5 years biopharmaceutical industrial experiences after Ph.D. training in related fields of chemistry, biochemistry, analytical chemistry, and/or biological sciences.

2．Must have CGMP experiences in biologics.

3．Previous leadership in analytical development field is appreciated. Previous experiences in regulatory submission is a plus.

4．Excellent communication skill both in Chinese and in English is required.

主要职责：

1．负责分析方法的开发，包括对生物治疗性分子进行仪器分析和生物活性检测。（“生物治疗性分子”主要包括但不仅限于，单克隆抗体，细胞因子，重组蛋白或病毒疫苗，免疫毒素等）

2．负责带领 5 至 10 人的科学家团队进行分析方法的开发,支持技术转移，放大生产，药品报批，GMP 生产等部门的工作.

3．负责产品特性的分析工作。

具体要求：

1．化学、生物化学、分析化学、生物科学或其他相关专业博士或同等学历；需 5 年以上相关工作经历；

2．具备符合 cGMP 生产的生物检测经验，精通 cGMP 相关知识及要求；

3．在生物分析开发领域具有管理经验的候选人优先考虑；有药产品报批经验的候选人优先考虑。

4．具有流利的英语口语和读写能力。

5．具有国内外大型生物制药企业工作经验的候选人优先考虑。