Job Code CBA-ZJ-02

About GenScript

GenScript Biotech is the world leader in biotechnology industry, with an open platform for pre-clinical discovery, clinical development, and clinical and commercial manufacturing. As a public company (HK Stock: 01548), our mission is to make human and nature healthier through biotechnology. Established in 2002, the company headquarter is located in Nanjing, China, with production and development sites in Nanjing and Zhenjiang in China, and in New Jersey, United States. There are also R&D center in Ireland, logistics center in Netherland, and branch in Japan. With these facilities, we have been serving clients in more than 100 countries, with 200,000+ customers around the world for more than 16 years. For more details, please refer to our website www.genscript.com

Position: QC Director/Senior Manager
Location: Zhenjiang, China

Position info:

GenScript is looking for a professional QC Director/Senior Manager to manage the whole QC team including microbiology platform, plasmid & viral vector's testing platform, raw material testing platform, operation group and technical group.

Key Responsibilities:

Establish quality procedures, standards, and specifications

1. Oversee the execution of QC management process and procedure, improve and optimize continuously;
2. Assist the line-manager to break BU's strategic goals down to clarify dependencies, understand the task better, ensure the accomplishment of the department's annual goals;
3. Carry out and implement various QC activities to ensure the timely and high-quality delivery of the project, including but not limited to raw materials sampling and testing, in-process and release testing of pilot runs, daily monitoring of the system;
4. Continuously improve the compliance of the QC to meet the audit requirements of client and regulatory authorities;
5. Lead the daily operation and management of the QC to meet the requirements of GMP, DI and EHS;
6. Complete quality investigations on time, create appropriate CAPAs to continuously improve the QC quality system;
8. Ensure that QC personnel complete relevant training and obtain corresponding qualifications before engaging in GMP-related activities.

Education/Experience:

Bachelor degree or above, major in biology, analytical chemistry or pharmacy.

Work experience:

Job Code CBA-ZJ-02

At least 10 years working experience in GMP laboratory, at least 5 years management experience.

Ability and skills:

1. In depth understanding of QC procedures and relevant legal standards GMP and pharmacopoeia requirements of various countries;
2. Strong analytical and problem-solving ability, critical thinking and conscientious;
3. Outstanding communication, coordination, organization skills, ability to solve emergencies;
4. Proficiency in English communication and writing

Personality and quality:

Withstand pressure, be good at solving complex problems, pay attention to details, good leadership, execution, communication ability and teamwork**.**

Please send inquiry with Job Code identity to:

tammy.chen@genscript.com

Job Code CBA-ZJ-02

公司介绍

金斯瑞生物科技（GenScript Biotech）是全球生物试剂定制化服务领域的领导者（香港联交所股票代码HK 01548），也是开放式的技术驱动型生物药研发服务平台，致力于利用生物科技让人类和自然更健康。公司成立于2002年，总部位于中国南京，在中国南京和美国新泽西州都有生产和运营中心，并在欧洲设立了爱尔兰研发中心和荷兰物流中心，在日本亦有全资子公司，为全球100多个国家与地区的20余万客户提供优质和便捷的服务。更多资讯，欢迎登陆我们的官网查阅www.genscript.com.cn.

职位名称： QC 经理
工作地：**南京**
直线上级：AD/QC 总监

职位描述：

金斯瑞正在寻求一位 QC 实验室管理人才，以协助 AD/QC 总监对 QC 和运营团队进行管理和并进行业务支持。

工作职责：

1、 监督QC部门的各项管理流程和执行，并持续完善和优化；
2、 协助直线经理分解事业部的战略目标以更清晰的理解，并保证部门年度目标的实现；
3、 开展并实施QC部门的各类活动，保证所有项目的及时和高质量交付，包括但不限于原辅料的取样和检验，中试产品的中控和放行检验，洁净系统的日常监控；
4、 规范和完善QC部门检测流程，提高运营效率，降低分析成本，实现年度财务目标；
5、 领导质量控制部的日常运行和管理以符合GMP、数据可靠性和EHS；
6、 持续性提高QC部门的合规性，满足客户和监管部门的审计要求；
7、 在规定时限内完成各类质量事件调查，制定适当的纠正预防措施，持续提高QC质量体系；
8、 确保QC人员完成相关培训，保证从事GMP相关活动前取得相应的资质。

任职资格：

教育背景：本科及以上学历，制药或生物相关专业
工作经验：10 年以上实验室工作经验，具备 GMP 制药企业从业经验，3 年以上管理经验。

能力与技能：

1、 熟悉制药行业QC实验室运营流程，深刻理解各国临床药物GMP，行业指南及药典要求；
2、 较强的分析、解决问题能力，思路清晰，考虑问题细致；
3、 熟练使用办公软件、办公自动化设备；

4、具有很强的人际沟通、协调、组织能力，具备解决突发事件的能力。

个性与品质：能承受压力，善于解决复杂的问题，关注细节， 良好的领导力、执行力、沟通技巧和团队合作精神。