Job Code CBA-NJ-01

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: QA Director
Location: Nanjing, China

Job Description

The QA director is responsible for the maintenance and improvement of quality systems and quality operation at the site. Interface with operation and other departments to ensure quality compliance while improving operational efficiency. Scope of compliance includes quality standards meeting regulatory requirement of China, US, and EU.

Key Responsibilities

- Responsible for all aspects of quality assurance in support of development, preclinical and GMP production
- Responsible for incoming raw material management, including receiving, inspection, storage, issuance
- Responsible for maintenance and continuous improvement of quality systems
- Responsible for review and approval of quality system procedures
- Responsible for in-process QA role for production activities
- Responsible for utility and equipment compliance and validation status
- Responsible for review and approval of production related documentation, including batch records, production logs, forms, study plan, study protocols and reports, and other related documents
- Responsible for review of QC test records
- Responsible for handling and follow-through of deviation, OOS, CAPA and change requests
- Responsible for document control
- Responsible for release of products and other client materials, and associated deliverables
- Responsible for maintenance, trending, and continuous improvement of quality systems
- Interact with other operations departments to effectively define and implement quality practices
- Review facility, utility, equipment, process, and assay validation protocols and reports
- Participate in and contribute to other QA and cross-functional projects as required

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Qualification

- BS/M in life science
- 15+ years experience in drug/biologics quality assurance field, 10 of which in management role
- Experienced in implementation and improvement of international quality systems and operation
- Experienced in compliance requirements for cGMP production for Drug Substance and Drug Products
- Experience in early stage biologics drug development helpful
- Experience in QC operation preferred
- Broad based quality perspective
- Acute business sense
- Works independently, self-motivated, and results oriented
- Command of English language at technical and business level

Compensation

- Competitive compensation package
- Relocation available
- Vacation & holiday
- Medical insurance

Please send inquiry with Job Code identity to:

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