

## Scientist - Position Description

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**Position :** Associate Scientist

**Department or Group:**

Bioanalysis

**Location:**

259 Prospect Plains Road, Bldg H, Suite 168,  
Cranbury, NJ, USA 08512

**Full Job Descriptions:**

We are a startup CRO seeking scientists to join our young but experienced and passionate team of scientist. In this technical-based role, the selected scientist will be responsible for carrying out bioanalytical quantitative analysis for biologics drug in support of pre-clinical and clinical studies.

**Key Responsibilities:**

- Develop and validate novel bioanalytical assays (ligand binding based, ELISA, cell-based Immunohistochemistry, nucleic acid-based, flow cytometry, qPCR etc.) to support pre-clinical and clinical study.
- Execute PK/PD and immunogenicity assays under a GLP-environment.


**Qualifications:**

- BS/MS/PhD in life science (biology, molecular biology, immunology, chemistry, etc.)
- Experience in protein chemistry, ELISA, cellular biology, molecular biology, tissue biology, LC/MS.
- Previous PK/PD/ADA/NAb experience in a GLP organization is highly desired.
- Excellent communication skills.
- Excellent organization and record keeping skills.
- Self-driven, be passionate to work in fast-growing organization.

**Benefits:**

- Retirement investment plan -401(k)
- Vacation/PTO
- Medical, vision, and dental care
- H-1B Visa Sponsorship

## Flow Scientist - Position Description

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<b>Position :</b> Flow Scientist		
<b>Department or Group:</b> Bioanalysis	<b>Location:</b> 259 Prospect Plains Road, Bldg H, Suite 168, Cranbury, NJ, USA 08512	
<b>Full Job Descriptions:</b> The scientists must have strong backgrounds in both multi-parameter flow cytometry and immunology		
<b>Key Responsibilities:</b> <ul style="list-style-type: none"> <li>Flow cytometry- based phenotyping/biomarker/receptor occupancy assay development, optimization, validation, and execution supporting potential drug programs targeting the immune system.</li> <li>Execution of assays under a GLP-environment</li> <li>Will be responsible for data quality and oversight of subordinates</li> <li>Data analysis and interpretation for client for decision making support</li> <li>Accurate record keeping of procedures</li> <li>Be point of contact for pharma clients to understand to ensure scientific, compliance and efficiency.</li> </ul>		
<b>Qualifications:</b> <ul style="list-style-type: none"> <li>Post-graduate degree in immunology related field 3+ years of flow cytometry experience</li> <li>Must understand flow cytometry data analysis and interpretation</li> <li>Understanding of validation principles for flow cytometry assays for clinical assays</li> <li>Must have excellent communication skills</li> <li>Must have excellent organization and record keeping skills.</li> <li>Previous industry experience in a GLP lab is a plus</li> <li>Experience with ligand binding assay, IHC assay, qPCR is a plus</li> <li>Experience with BD and Beckman flow cytometers is a plus</li> <li>Passionate to work in a fast-growing environment</li> </ul>		
<ul style="list-style-type: none"> <li><b>Benefits:</b> Retirement investment plan -401(k), Vacation/PTO, Medical, vision, and dental care, H-1B Visa Sponsorship</li> </ul>		

## QA - Position Description

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<b>Position :</b> QA Manager		
<b>Department or Group:</b> QA	<b>Location:</b> 259 Prospect Plains Road, Bldg H, Suite 168, Cranbury, NJ, USA 08512	
<b>Key Responsibilities:</b> <ul style="list-style-type: none"> <li>• Schedule/conduct facility inspection, special inspection, computerized system audit, vendor/contractor audit, etc., and review SOP when necessary.</li> <li>• Schedule/conduct study-based audit; including plan/protocol review, experimental phase inspection, data audit, report audit and report verification etc.</li> <li>• Promptly report any inspection results in writing to management and to the Principal Investigator(s)/Study Director(s), when applicable; Follow up implementation of CAPA, when applicable.</li> <li>• Sign QA statement for final report within the related GLP areas.</li> <li>• Interact with client, regulatory authority, etc., during the visit/inspection.</li> <li>• Lead QA group to support the GLP. Provide advice/consultation on regulatory issues and quality management systems.</li> <li>• Work closely with all levels of the management team of the company to develop strategic planning and execute the plan for the development of the QA department. Lead the improvement on quality system.</li> <li>• Hire and train new employees to build a sufficient high-quality working force to conduct quality activities. Manage/supervise the QA auditor, including performance reviews, objective setting, and career development etc.</li> <li>• Maintain, generate, and verify Master Schedule.</li> <li>• Ensure appropriate and timely discard of QA records if applicable. Remove closed project files from the active files.</li> <li>• Maintain QA files, including but not limited to facility inspection files, computerized system inspection files etc., and archive the files timely.</li> </ul>		
<b>Qualifications:</b> <ul style="list-style-type: none"> <li>• The ability to understand the basic concepts underlying the activities being monitored. Have a thorough understanding of the Principles of GLP/GCP.</li> <li>• Be familiar with the test procedures, standards, and systems.</li> </ul>		

- Be trained or have expertise and experience with the requirements of the OECD, FDA and EMA, ICH, etc., GLP/GCP guidelines as well as other applicable regulations.
- Have good communication skills, both written and verbal, and work in a team-oriented manner.
- Have good leadership and working experience in quality management. At least five years' experience work in a GLP/GCP or GMP laboratory.
- Have an engaging and dynamic attitude towards rapid issue resolution and communication.
- BS or above in a science discipline.

**Benefits:**

- Retirement investment plan -401(k)
- Vacation/PTO
- Medical, vision, and dental care
- H-1B Visa Sponsorship