C = Contract
CH = Contract to Hire
DP = Direct Placement
DOE = Depending on experience

**Scientist II – CH – Sorrento Valley**
- $45-70k+
- **FLIPR**, Calcium cell based assays, GPCR, G proteins, 384, HTS, calcium and/or ion channels, single transfection

**Qualifications:**
- B.Sc. or M.Sc. in biology and **at least 2 industry exp. FLIPR**

**Performance Expectations:**
- Bachelors in cell biology or biochemistry with a minimum of 2 years relevant industry experience in a HTS setting
- Proven expertise with cell based signaling assays (i.e. GPCR cAMP and Ca2+ second messenger assays).
- Documented experience with multimode plate readers and FLIPR instrumentation required
- Experience with engineered cell lines for GPCRs and ion channels highly desirable

**Preferred Education and Experience**
- Experience with database-based analysis software preferred
- Basic cell culture experience is a plus
- Experience with automated liquid handling workstations

**Supervisory Responsibility**
- This position will not have any supervisory responsibilities.

**Work Environment**
- This position operates in a BSL1/2 laboratory setting. There is potential for exposure to human tissues and fluids.

**Bioinformatics Associate I – DP – UTC**
- $60-90k DOE
- Open to New PhD or someone in/out of post doc. Linux, Perl, Python. Ideally experience with Mol Bio (NGS) data
- The Bioinformatics Associate I’s main responsibility is to work within the bioinformatics team to develop, improve and maintain tools, pipelines and software for the analysis of complex NGS datasets that meet or exceed the quality expectations and regulatory requirements for molecular diagnostic assays and research products. This position also requires the employee to follow company quality and development policies, including documentation and validation of analyses to ensure that products and assays meet the required specifications.
- Accurate and efficient bioinformatics analyses are essential for extracting value from generated NGS data. Successful performance contributes to the quality and regulation of products and assays that play a significant role in the growth of the company.
- Maintains, troubleshoots and improves existing bioinformatics tools, pipelines and software.
- Conducts genetic interpretation and application of results from NGS data.
• Writes documentation and updates version control for new and existing bioinformatics tools, pipelines and software.
• Runs software validations and provides comments/reviews for regulatory documents.
• Ability to follow Standardized Operating Procedures (SOPs) as well as written and verbal instructions.
• Proficient in Microsoft Office Suite (Outlook, Word, Excel and Power Point).
• Ability to analyze NGS and other complex data, troubleshoot technical issues and make valid scientific conclusions.
• Excellent written and verbal communication skills.
• B.S. Degree in bioinformatics, computational biology, computer science, molecular biology, or related field with at least 2 years of post-graduate bioinformatics/computational experience.
• Experience with bioinformatics data analysis and software/algorithm development.
• Experience with Linux and fluency in at least one programming language (e.g., Perl, Python) with the capability to quickly learn and adopt new tools is required. Experience with R would be beneficial.

QC Tech II or III – DP – Torrey Pines
• $40-60k (DOE)
• BS degree with (PCR OR QC) AND (GMP OR NGS). They want true Molecular Biologists.
• Requires knowledge and skills normally acquired through the successful completion of a BS Degree in a scientific discipline.
• 2-8 years of experience in a GMP-regulated industry or equivalent combination of education and experience.

QC Analyst II x2 – CH – Torrey Pines
• $16-25/hr DOE
• BS/MS Chemistry with HPLC experience. Ideally 6 months of industry exp.
• The purpose of the QC Analyst II is to carry out assigned laboratory duties which may include sampling, testing, and evaluating analytical data on samples such as raw materials, in-process and final products. In addition, will also participate in the development and validation of analytical methods.
• 2 years of relevant hands-on laboratory experience.
• BS degree in scientific discipline from an accredited college or university or equivalent experience.
• Demonstrated computer proficiency, e.g., word processing, spreadsheets, graphing, etc
• Good knowledge of cGMPs and laboratory practices.
• Proficient in the operation and maintenance of basic laboratory instruments such as HPLC and GC.
• Excellent observation skills and problem solving abilities.
• Ability to follow analytical procedures and protocols.
• Good laboratory techniques.
• Conduct laboratory tests in compliance with established internal Standard Test Methods, compendial and vendor/partner supplied methods.
• Maintain organized records of tests performed and results obtained following company policies.
• Assist in performing laboratory investigations. Write investigation report as required.
• Maintain a level of technical knowledge and understanding in the assigned areas of responsibility that are consistent with the current scientific requirements of the company.
• Understand and comply with all company policies, safety procedures, and SOPs, including cGMPs and cGLPs.
• Assist in the preparation of analytical data for internal and external meetings and presentations.
• Provide technical assistance and training to other laboratory personnel.
• Participate in the transfer of methods to/from the Quality Control department.
• Represent functional area in Project Teams, as required.
• Write documents for GMP compliance such as standard test methods, validation reports, and SOPs.

**Scientist I and Scientist III – DP – Torrey Pines**
• $80-100k, $100-120k
• Must have PhD, must have experience with: API’s, Pharma, HPLC, GC, LCMS, dissolution testing, analytical (method) development
• Provide technical and analytical assistance to support new product development and manufacture of commercial products.
• Develop, evaluate (qualify/validate) new analytical methods.
• Design, execute and interpret experimental results. Critically evaluate the experimental results of all group members.
• Summarize findings for internal distribution/presentation (e.g. slide presentations, reports).
• Summarize findings in presentations, technical reports, and manuscripts for external distribution and/or presentation.
• Write documents for regulatory submissions and/or review (e.g. INDs, NDAs, SOPs, STMs, batch records, qualification and validation protocols and reports).
• Represent department at project team meetings.
• Provide team leadership. Coordinate project goals and tasks. Act as liaison with corporate partners.
• Maintain high level of technical knowledge in areas of responsibility.
• Maintain good working knowledge of the use, maintenance and repair of laboratory and manufacturing equipment.
• Supervise less experienced team members, where appropriate.
• Apply the knowledge, skills and experience obtained to increase efficiency in solving new problems.
• Provide training and technical assistance to less experienced lab personnel.
• Comply with cGMPs where appropriate.
• Maintain cooperative working relationships with other departments (e.g. QC, QA, Formulation, process development).
• Maintain good documentation and exercise clear, concise communication skills.
**Bioinformatics – DP – Torrey Pines**

- $85-105k
- Open to New PhD or someone in/out of post doc. R, Perl, Python, NGS data is ideal. Ideally experience with oncology

**Education & Experience:**
- Ph.D. or equivalent breadth of experience and understanding in Bioinformatics or related scientific discipline.
- The Research Scientist 1, Bioinformatics demonstrates expertise in genomic analyses, preferably with a research background in oncology and/or immunology. This scientist will support projects that aim (i) to identify molecular markers that are predictive of patient response following treatment with company’s propriety gene therapy technology and (ii) to characterize virus-host interactions, in patients’ tumors and cell culture systems. The primary responsibility of this position is to help program and analyze genomics data coming out of key clinical trials.
- Duties and Responsibilities Include But Are Not Limited To:
  - Develops and optimizes robust workflows for next-generating sequencing datasets, including DNA and RNA sequencing.
  - Identifies molecular features from genomics datasets that correlate with clinical outcomes.
  - Works on informatics problems of diverse scope, including novel genomics applications.
  - Reads pertinent scientific journals and articles, maintains relevant current scientific awareness, prepares written reports and in collaboration with other scientists, and writes original proposals for research projects.
  - Significantly contributes to defined documentation practices in support of regulatory filings, white papers, patent filings, publications, grants and other company documents.
  - Co-authors scientific papers and/or journal articles and present research results to colleagues at scientific meetings.

**Desired Knowledge and Abilities:**
- Expertise in analysis of human next-generation sequencing data and knowledge of best practices.
- Competency in informatics-related programming languages and interfaces such as Python, Perl, R and Linux.
- Familiarity with publicly and commercially available bioinformatics tools.
- Requires knowledge of discipline including knowledge of protocols, scientific method and its applications, and use of specialized equipment.

**CAR-T Scientist – DP – UTC**

**THIS DEPARTMENT WILL LOOK AT CANDIDATES WHO HAVE AT LEAST 1 YEAR OF MAMMALIAN CELL CULTURE FOR OTHER LOWER LEVEL OPENINGS!!!!!!**

- $DOE
- We currently have openings for
- R&D positions including Scientist, Postdoctoral Fellow, Research Associate/Technician in chimeric antigen receptor engineered T cells (CAR-T) for cancer immunotherapy. These positions will be responsible for preclinical/clinical development of CAR-T cells for cancer immunotherapy, including chimeric antigen receptor construction, retroviral/lentiviral vector
packaging, T cell culture and gene transduction, T cell functional assays, animal tumor model studies, and clinical trial patient biopsy specimen assays.

- GMP positions including GMP facility manager, manufacturer technician, QC, and QA positions for retroviral vector or CAR-T cells GMP manufacturing.

**THIS DEPARTMENT WILL LOOK AT CANDIDATES WHO HAVE AT LEAST 1 YEAR OF MAMMALIAN CELL CULTURE FOR OTHER LOWER LEVEL OPENINGS!!!!!!**

### CAPA Specialist – C – Sorrento Valley

- **$35-47/hr**
- Need at least 6 mos-1 year experience with CAPA’s
- PART TIME- working 8-5 on Tuesdays and Thursday, potentially Monday, Wednesday, Fridays on 1/2 days. Approximately 20 hours/week
- Filling in for someone who is going to school
- Perfect Opportunity for someone who is in school and looking for additional work/experience!
- The CAPA Specialist II is responsible for ensuring the CAPA system is being managed effectively as part of the CAPA Administration group. They must work well with others in the organization to ensure Quality System processes are compliant to internal and external requirements.
- Preferred educational background:
  - Bachelor’s degree in a related technical field is preferred but not required.
- Preferred experiential background:
  - Must have at least 2 to 4 years’ experience working in a professional environment where compliance was of vital importance.
  - Knowledge of the QSR or ISO 13485 is a plus.
  - Working knowledge of Quality Assurance in a medical device manufacturing environment, preferably in-vitro diagnostic.
  - Knowledge of MS Office.
  - Excellent organization skills – must be able to manage a large number of simultaneous projects
  - Attention to detail – must have precision in their work, especially as it relates to understanding and documenting complex quality issues
  - Excellent writing skills – must be able to summarize complex issues in a clear, succinct, and accurate manner. Must be able to write in a manner that effectively conveys complex issues to the reader.
  - Effective interpersonal skills – Work with peers throughout the organization and be effective in engaging resources throughout the organization
  - Excellent critical analytical skills – ability to find root cause of why an issue occurred. Ability to review action plans and determine if the actions taken effectively address the issue

### QA Inspector – C – Sorrento Valley

- **$16-19/hr**
- Non degreed ideal, anyone with GDP or GMP experience in QA, Doc Control or Med Device okay!

Qualifications – Preferred educational and experience:
• High School Diploma; or combination of education and work experience acceptable.
• Previous experience within a medical device or pharmaceutical environment is an asset.
• Proficiency in Microsoft Excel and Microsoft Word

Job Summary
• The Quality Assurance Inspector is responsible for review and approval of in process and final product documentation to ensure that quality standards are aligned with existing specifications. The QA inspector will review Device History Records prior to release. This position requires a high level of attention to detail, as the Quality Assurance Inspector is responsible for strictly adhering to the organization's quality assurance policies, and identifying defects and or production errors in order to prevent these materials from entering the supply chain.

Training to Start: Monday-Friday, 7:30am to 4:00pm
After training: Shift will be Tuesday-Saturday, 11:00am-8:00pm (Sunday and Monday off)

Tasks and responsibilities:
• Performs review of Device History Records and other documentation for compliance to established procedures and Good Documentation Practices.
• Scans and maintains all Device History Records.
• Issues Certificates or Compliance and Certificates of Analysis for all Finished Good Lots.
• Approves the release of materials to next step in the process.
• Rejects subassemblies or finished products as required.
• Conducts and documents process and system audits using written procedures as audit standards.
• Maintains all controlled document files and test records in a timely and accurate manner.
• Participates in the construction and/or revision of SOPs for the Quality Assurance function.
• Assists in the writing and updating inspection procedures, protocol, and checklists.
• Generates Quality Incidents where required for identified non-conformances.
• Evaluates problems and makes initial recommendations for possible corrective action
• Works with production management and Quality Control to provide feedback regarding accuracy of procedures and documentation improvement.
• Be capable of assessing current processes and making continuous improvements.
• Develops, reviews, and maintains metrics in relation to tasks assigned.

Lab Technician I x2 – C – Sorrento Valley
• $14-16/hr
• NON-DEGREE ideally! Someone who is okay working with samples, ideally with medical/clinical background.
• The main function of a lab technician is to perform routine medical laboratory tests for the diagnosis, treatment and prevention of disease. A typical lab technician may work under the supervision of a medical technologist.
• Education/Experience:
  • High school diploma or GED required. Associate's degree in medical technology or vocational training preferred
  • 0-2 years of experience required
• Skills:
  • Verbal and written communication skills, attention to detail, and problem solving skills.
- Basic ability to work independently and manage one’s time
- Basic knowledge of the information and techniques needed to diagnose and treat human injuries and diseases
- Basic ability to analyze data and accurately document and record results

Job Responsibilities:
- Set up, adjust, maintain and clean medical laboratory equipment.
- Analyze the results of tests and experiments to ensure conformity to specifications, using special mechanical and electrical devices.
- Analyze, gather and record test data to issue reports that use charts, graphs and narratives.
- Obtain specimens, cultivating, isolating and identifying microorganisms for analysis.
- May examine cells stained with dye to locate abnormalities.
- Consult with a pathologist to determine a final diagnosis when abnormal cells are found.

Technical Writer (5623) – C – Torrey Pines
- $30-39/hr
- Responsibilities will include, but are not limited to the following:
  - Preparation of pharmacology and cell biology reports for regulatory filings.
  - Formatting reports in accordance with company style guides.
  - Will work closely with senior scientists to provide high quality drafts for editing and will be responsible for report completion.

Knowledge/Skills/Abilities (KSA’s):
- Bachelor's degree required.
- 3+ years of writing experience.
- Science writing experience.

Associate Process Group Chemist – CH – Sorrento Valley
- $16-19/hr
- 6 months exp. outside of coursework. BS/MS okay. Chemist or Biochemist okay.
- The Associate Process Group Chemist, in accordance with forecasted requirements and assignment, participates in the Chemistry Manufacturing department via:
  - Manufacture products within QSR and ISO regulations
  - Review/reconcile documents and work orders
  - Support assigned projects with supervision
  - Support departmental troubleshooting and process improvement teams
  - Participate in product transfers
  - May write/revise documentation with supervision
  - May train lab technicians
  - Display improving working knowledge of business processes as they relate to manufacturing
  - Maintain daily adherence to Production goals relating to MUV/LUV, labor utilization, work order closure, and schedule adherence

Education and Experience
• B.S./B.A. Life/Applied Sciences or equivalent experience and a preferred minimum of 6 months related work experience in a GMP environment.

Knowledge/Skills
• Basic algebraic, statistical and mathematical skills
• General computer knowledge
• Good organizational skills
• Laboratory skills, such as protein purification, antibody conjugation, solution preparation
• ELISA experience, assay development skills, etc.
• Good verbal and written communication skills
• Good interpersonal skills
• Knowledge of QSR’s and ISO 9001
• Knowledge of experimental design

ESSENTIAL FUNCTIONS:
• Manufactures (i.e. Formulates bulks, and Quality Controls) products (i.e. Lateral flow devices, controls/calibrators and microtiter systems) while adhering to regulatory requirements and business polices /procedures and schedules.
• Support departmental troubleshooting and process improvement teams. Support cross-functional projects and training.
• Reviews completed Device History Records and performs financial review of work orders. Reports on variances to supervisor.
• Carries out all duties in a professional manner and in compliance with established business practices.

QA Manager, Engineer – DP – Sorrento Valley
• $120-130k+
  • DESIGN CONTROL IS MOST IMPORTANT
  • This position is a working manager role that provides guidance to the QA Quality Engineering team and in providing direct support for new product development projects. Emphasis is on immunoassay diagnostics devices; however molecular diagnostic devices and instrumentation diagnostic devices are also supported. Responsibilities include supporting new product design / development activities utilizing internal and external quality derived industry standards. The incumbent may also lead corrective action / preventive action projects.

Education/Experience
• Must have engineering development experience or equivalent, Quality engineering preferred: 6+ years
• Must have experience as a medical device engineer or equivalent, Quality engineering preferred, on new product development: 4+ years
• Must have experience working and managing time lines/deliverables.
• BA/BS in Scientific field required, QE certification desired.

Knowledge/Skills
• New product development design control processes
• Project planning
• Strong analytical and problem solving skills
• Good organizational skills, and the ability to manage multiple tasks
• Experience in experimental design
• Ability to work within cross functional teams
• Strong communication skills, written and verbal
• Must exhibit professionalism, confidence, maturity, desire to succeed and be proactive/ self-motivated
• Strong knowledge of relevant Quality and analytical tools
• Ability to participate in planning and managing project deliverables
• Working knowledge of manufacturing tools and processes (i.e. BOM, Routings, SPC Charts, Risk Management, Quality Test Plans and Master validation plans)
• Knowledge of related quality systems regulations and processes

Manufacturing Technician (Upstream OR Downstream) – C/CH – Sorrento Valley
• $16-22/hr
• MUST HAVE one of these:
  o GMP AND (CELL CULTURE or PURIFICATION
  o Master’s with 6 months experience with UP or DOWN stream
  o Bachelor’s with 1+ years undergrad with UP or DOWN stream
• Under supervision, employee will perform routine manufacturing activities in GMP manufacturing areas including solution preparation, bioprocessing support and autoclave operation. Operations will be performed according to Standard Operating Procedures (SOPs) and batch records. Fundamental knowledge of current biologics regulations and cGMP for drug substance operation are preferred. Employee will perform manufacturing steps, execute routine batch records, and revise documents such as batch records and SOPs as needed. Candidate must be detailed oriented, a strong team player and has ability to collaborate cross functionally. Flexible shift schedule and overtime may be required.

Education:
• Minimum of High School with 2 plus years experiences in biotech/pharmaceutical industry. Associate or Bachelor degree is preferred.

Experience:
• cGMP manufacturing for biological product required
• Proficient with Microsoft Word and Excel
• Ability to work with pressurized systems, steam, and corrosive chemicals with necessary safety precautions.

Manufacturing Supervisor x2 – DP – Carlsbad
• $70-85k
• Must have 5+ years in manufacturing, must have experience directly supervising 5+ employees. Can come from any type of company – just must have supervisor/management and manufacturing experience.
• The Supervisor provides leadership and technical support to the manufacturing organization. In this role, you will assist in development of, drive and achieve departmental short and long-term
goals enabling the manufacturing organization to achieve New Product Development, Continuous Improvement, Quality, Compliance and Operational objectives.

Essential Duties and Responsibilities

- Supervise production personnel and activities to effectively meet forecast, customer demand, R&D and New Product Introduction requirements.
- Develop and execute manufacturing training plans to ensure proper resources and talent are in place to support manufacturing requirements.
- Develop production schedules in alignment with forecast and customer demand.
- Develop, implement, analyze, summarize and report key performance indicator data and metrics for areas of responsibility. Responsible for identification of root cause and implementation of sustainable corrective actions for missed targets.
- Responsible for ensuring compliance to quality systems (FDA, GMP, QSR, ISO), product specifications, process instructions, safety requirements and company policies.
- Responsible for identification, resolution and follow-up on manufacturing issues that may arise.
- Responsible for identification and resolution of non-conformances via NCR and CAPA process including initiation, root cause analysis and implementation of sustainable corrective action.
- Collaborate with and provide manufacturing input and support to New Product teams, including the design for manufacturing (DFM) guidance, input on process / tooling development and developing/refining manufacturing instructions.
- Develop and sustain the manufacturing team as a quality minded culture driven by focusing on customer service (external and internal), outstanding compliance, continuous improvement activities that support business objectives.

Supervisory Responsibilities

- Up to 30 non-exempt personnel, additional exempt and/or non-exempt personnel as required
- B.S. degree in Engineering or Science, or AA degree plus 5 years supervisory experience in medical device, pharmaceutical or similarly regulated environment, or High School Diploma plus 7 years supervisory experience in medical device, pharmaceutical or similarly regulated environment
- A minimum of 10 years of manufacturing experience in a medical device, pharmaceutical or similarly regulated environment.

Skills – Technical

- Working knowledge of quality system requirements (QSR), good manufacturing practices (GMP), ISO and FDA regulations.
- Experience with a clean room environment including development and implementation of environmental procedures.
- Working knowledge of manufacturing/MRP systems (QAD preferred)

**MLT x5 – DP – San Diego**

- $60-65k
- 4-5 openings for Medical Laboratory Technicians – ALL DIRECT HIRE!

**QUALIFICATIONS**

- Bachelor's degree in Medical Technology, Biology, Chemistry or related field.
- CA MLT License
• Experience in Chemistry, Hematology, Immunology (Point of Care Urinalysis)
• 1 - 3 years or more of related generalist experience. Immunology testing experience preferred.
• Basic computer literacy ability to comply with department needs and expectations.

PRINCIPAL RESPONSIBILITIES

• Independently perform laboratory procedures and tests necessary for the diagnosis and treatment of patients per physician’s orders.
• Responsible assuring the accuracy of test systems and results prior to releasing such results. Follow quality control procedures. Provide input on procedures.
• Use or operate clinical laboratory instruments and equipment in the collection, processing, description, and analysis of specimens.
• Troubleshoot and perform maintenance on laboratory equipment.
• Maintain inventory of laboratory supplies. Maintain logs and order supplies.
• Work from broad policies and on general objectives using broad exercise of discretion and independent judgment with respect to matters of significance within the HQ or mobile lab.
• Contribute to a safe and secure environment for patients, visitors, physicians and co-workers by following established safety standards and procedures; complying with legal regulations.
• Maintain patient confidence by keeping laboratory information confidential.
• Serve and protect the clinical community by adhering to professional standards, clinic policies and procedures, federal, state, and local requirements, and Clinic standards.
• Enhance laboratory services and clinical reputation by accepting ownership for accomplishing new and different requests; exploring opportunities to add value to job accomplishments.
• Maintain compliance with all company policies, quality systems, and procedures.
• Perform other duties as assigned by supervisor.