Executive QA – DP – UTC
- Up to $150k

GENERAL PURPOSE OF JOB:
- Provides Quality and cGMP Compliance oversight across all internal Companies. Advises and makes decisions on the acceptable processing, manufacturing, and final release of GMP products – including providing direction, and oversight of the department. Provides written and verbal communications to management regarding potential compliance issues, deviations, corrective actions, preventative actions, and quality trends. Implement Quality Program and resolve quality and cGMP compliance related issues.

ESSENTIAL DUTIES AND RESPONSIBILITIES:
- Leads and directs Corporate Quality Assurance. Directs and manages Quality Program at company’s family of companies to ensure compliance with internal policies and procedures, applicable regulatory guidelines and current applicable phase appropriate cGMP.
- Oversee the environmental monitoring and stability programs.
- Establish Quality Policies and Quality Manual to reflect company’s goals and objectives.
- Establish and maintain a centralized Document Control System. Ensure adequacy of procedures to ensure document security, archival, retrieval, and record retention.
- Ensure there are written procedures (SOPs, batch production records, etc.) in place for all GMP work. Review and approve documents, investigate, unexplained discrepancies, failures, and out-of-specification results for products manufactured at or on behalf of company. Evaluate the possible impact to process/product and determine batch disposition for release or rejection. This activity ensures that the identity, purity, potency, and quality attributes meet pre-approved acceptance criteria.
- Oversee the review and approval of documents that support GMP work and regulatory submissions. Responsible for product disposition of GMP batches manufactured by or on behalf of company for Clinical Use.
- Provide Quality Oversight by reviewing and approving change requests as it applies to raw materials, specifications, Method Validation Protocols and Reports, SOPs, analytical test methods, facilities, equipment, processing steps, packaging and labeling and computerized systems.
- Review documents provided to Regulatory Affairs for submissions for data accuracy and completeness.
- Manage GMP Compliance Audits & Regulatory Agency inspections on site. Provide support for Regulatory Agency cGMP inspections on behalf of company at the CMO site. Provide response to inspectors for on-site inspections and assist CMO with written responses to observations at their site on behalf of company.
• Oversee Supplier Evaluation, Approval and Management Program from a Quality & cGMP Compliance perspective. Prepare Supplier Audit Plans, for paper and on-site audits, review audit reports for to assure compliance with phase appropriate GMP requirements.
• Prepare and establish Quality Agreements/Statement of Work with critical suppliers (CMOs, Contractors, etc.). This should indicate the demarcation of responsibilities as it would relate to the GXP compliance requirements.
• Promote growth, training, continuous improvement and safety.
• Establish training program and training records for personnel involved with cGMP activities.
• Perform cGMP/GXP training for company employees (i.e. data integrity, good documentation practices, basic GMPs, lab notebook usage, etc.) at least twice every 12 months.
• Oversee audits performed by consultants and PAI readiness of products filed with the agency pending approval. Notify appropriate Executive Management of significant issues.
• Perform GMP audits of CMOs/Contract Labs for evaluation of their Quality Management Systems.
• Provide Quality support for cGMP facility upgrades and changes.

EDUCATION:
• BS or higher degree, PhD preferred, in science field, e.g., Chemistry, Biology, Immunology, Microbiology and formal training in cGMP, cGCP, cGLP, regulatory requirements and compliance for drugs and biologicals.

Sr. Production Associate – CH – Torrey Pines
• $25-30/hr
Job Description: Responsibilities
• Works within a production-based DNA synthesis and assembly pipeline as well as DNA sequencing pipelines for verification of synthetic DNA clones.
• Able to quickly troubleshoot and identify solutions to keep pipeline moving.
• Works closely with internal scientists on DNA synthesis and sequencing needs.
• Customer driven focus and willingness to manage and track numerous orders at once.
• Interfaces with scientific team members to understand new methods pertaining to synthetic genomics technologies.
• Willingness to constantly innovate and reduce costs without sacrificing quality standards.
• For production processes, willingness to closely follow established procedures.
• Applies best practices in the development, initiation, planning, execution, control and closing of orders.
• Work Environment: Production based high throughput DNA synthesis lab. cloning, PCR, DNA extraction
Qualifications: Requirements
• Requires a Bachelor’s or Master’s degree in Biochemistry, Molecular Biology or related discipline with 5+ years’ experience in industry.
• Firm understanding of and experience in molecular biology techniques, including PCR, SDM, digestion, ligation, and transformation.
• Experience managing numerous orders simultaneously.
• Proven utilization of QA/QC methodologies.
• Hands-on experience within high-throughput genomic pipelines.
• Experience operating automated laboratory equipment (e.g. QPix, Biomek, ABI 3730 XL DNA Sequencer, Next-Gen sequencing, etc.).
• Familiar with computational biology tools (BLAST, Vector NTI).
• Experience utilizing robotic platforms a plus.
• Familiar with DNA sequencing analysis software a plus (CLC, Sequencher).

Bioinformatics Associate I – DP – UTC

• $60-90k DOE

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.
• Manages personal goals and tasks to ensure scope and timelines meet the aims of company.
• Regularly communicates accomplishments and progress to team members and management.
• Proactively communicates with co-workers to help ensure analytical goals are achieved.
• Coordinates and interacts closely with other scientists on data quality and file management; implements these formats and metrics for project data.
• Shares expertise; provides training and guidance to team members as needed.
• Participates within a team of scientists to foster a culture of scientific excellence.
• Cooperates and respectfully communicates with external and internal customers.
• Other duties, as assigned.
• 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.
• Ability to work independently as well as in a team environment.
• Meticulous and detailed oriented especially in regard to documentation, communication of results and training of coworkers.
• Ability to manage multiple complex projects and changing priorities while consistently meeting critical deadlines.
• Demonstrated ability to learn and take on new challenges.
• Highly-motivated, self-driven, and able to focus on project goals.
• 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.

Annotation Scientist – DP – UTC
• $70-80k
• The Annotation Scientist will be responsible for the collection, maintenance, and quality control of genomic data, variant annotation and clinical content as a part of a dynamic team that develops NGS tests for hematological and other cancers. The scientist will assist with building and maintenance of the IVS customized knowledgebase.
• Accurate and efficient content curation of genomic variants is critical for the delivery of the results from NGS genetic tests to customers. Successful performance contributes to the quality and regulation of products and assays that play a significant role in the growth of the company.
• Annotation and interpretation of genomic variants and other biomarkers, based on scientific literature and database searches
• Writing reviews of literature and data regarding biomarkers and oncological therapeutics
• Generation of NGS clinical reports for patients, physicians and other vested parties
• Timely delivery of scientific content and clinical reports
• Update scientific content and database entries based on the current literature and clinical trials
• Perform data quality control
• Develop and draft SOPs
• Assist team with database development
• Participate in calls and other communication with physicians and scientists to discuss patient care, research, and algorithm developments
• Manage personal goals and tasks to ensure scope and timelines meet the aims of company.
• Regularly communicate accomplishments and progress to team members and management.
• Proactively communicate with co-workers to help ensure analytical goals are achieved.
• Attention to detail
• Ability to adapt to dynamic working environment
• Ability to multitask and work on multiple high-priority projects as required
• Show motivation for continuous learning and professional development
• Share expertise; provide training and guidance to team members as needed.
• Participate within a team of scientists to foster a culture of scientific excellence.
• Cooperates and respectfully communicates with external and internal customers.
• Other duties, as assigned.
• Ability to analyze NGS and other complex data, troubleshoot technical issues, and make valid scientific conclusions.
• Excellent written and verbal communication skills.
• Ability to work independently as well as in a team environment.
• Meticulous and detailed oriented; especially in regard to documentation, communication of results, and training of coworkers.
• Ability to manage multiple complex projects and changing priorities while consistently meeting critical deadlines.
• Ability to follow Standardized Operating Procedures (SOPs) as well as written and verbal instructions.
• Willingness to learn and take on new challenges.
• Highly-motivated, self-driven, and able to focus on project goals.
• Ph.D. or MD with experience in molecular biology, genetics, genomics, or equivalent (or Master’s with 2 years of experience)
• Experience in cancer genomics, monogenic diseases, or pharmacogenomics, including variant annotation and interpretation
• Experience with bioinformatics data analysis and command line analyses in Linux would be beneficial.

FOUR QC CHEMIST, ONE RA, TWO SCIENTIST OPENINGS AT A TOP PHARMA!

QC Analyst II x2 – CH – Torrey Pines
QC Analyst II x2 – DP – Torrey Pines
• $16-25/hr DOE
• 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 eGLPs
• 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.

**Research Associate II – DP – Torrey Pines**

- $40-60k
- BS/MS in Chemistry/Pharm Chem with HPLC, API, dissolution testing experience
- 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.
- 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.

**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.

**Manufacturing Technician – CH – Sorrento Valley**
- $15-25/hr DOE
- Bachelor’s Degree in Biochemistry, Biology, Chemistry, or a related field
- 1-5 years of experience in antibody purification or protein purification
- Solid understanding of antibody structure and hands-on experience with chromatography
- Good computer skills
- Follow SOP’s
- Perform all essential functions related to antibody purification manufacturing, including centrifugation, making buffers, using the spectrophotometer, running SDS-PAGE gels, and performing endotoxin tests
- Perform basic math calculations to determine the concentration and amount of antibodies
- Perform column chromatography manually as well as using FPLC
- Use of ERP database to execute production orders
- Maintenance of laboratory equipment and supplies

**Recombinant Antibody Manager – DP – Sorrento Valley**
- $120-145k
- The Recombinant Antibody Manager will be responsible for leading the Recombinant Antibody group by developing methods of achieving a high level of antibody expression and ensuring that those methods are implemented to product high quality antibodies. This position will functional as an integral part of the Recombinant Antibody Development and Production Teams.
- PhD in Biochemistry, molecular biology, cell biology, bioengineering or related Biological Science area
- 5 years of related industry experience, focusing on transient and/or cell line development for recombinant antibody expression and production
- Previous project management and personnel management experience
- Expertise with stable cell line development for recombinant antibody production
- Extensive experience with recombinant antibody engineering and development
- Expertise with high level expression of recombinant antibodies in different expression systems such as CHO, NS0, and HEK 293
- Technical expertise in cell culture and stable cell line generation, process development, and optimization
- Experience with the scale up recombinant antibody production to an industrial level
- Extensive experience with media optimization and scaling-up of bioreactor processes
- Strong Microsoft Word, EXCEL, PowerPoint, and FM database skills
- Familiarity with ISO 9001/ ISO13485, GLP or GMP compliance
• Lead the Recombinant Antibody Program, which will include designing and optimizing recombinant antibody expression in both transient and stable expression systems
• Develop and maintain detailed and accurate electronic records related to cell line development to support recombinant antibody manufacturing and process improvement
• Interface with manufacturing groups to provide on time and accurate material transfer support
• Analyze results of data and prepare recommendations for improvement or trouble shooting

**QC Associate (Flow Cytometry) – CH – Sorrento Valley**
• $17-24/hr
• From HM: “No FACS (that is sorting of the cells), we just run and analyze them without sorting, but if the candidate has FACS experience, that is Great, we will gladly take them! That is just a little more advance Flow Cytometry than what we do here. As for the # of colors, most of the time we do simple Flow, so just 1-2 colors; we can train the candidates on running more colors at a time, once they feel comfortable with 1-2.”
• This is in their QC group, they will be handling the mice in this role as well. There is probably about 10% animal work. They will be doing lots of pipetting in this role. Probably ELISA and cell culture too. Immunofluorescence. They will set up cell based assays (transfections and proliferation assays).
• They only require some FLOW experience.
• The primary responsibility for this position includes all the essential functions related to the testing, optimization and validation of products for research in flow cytometry and related areas and timely documentation of experiments, data analysis, and progress reports.
• Typical duties and functions:
  • Perform immunological assays such as flow cytometry and immunofluorescence
  • Analyze data and prepare and maintain clear and precise documents according to company policies and ISO requirements
  • Follow experimental protocols and Standard Operating Procedures (SOP’s)
  • Setup functional assays such as cell proliferation, differentiation, and transfection of primary cells and cell lines
  • Monitor project progress
  • Maintain facilities, lab equipment, and supplies as needed
  • Perform other duties as assigned
• Qualifications:
  • Bachelor's degree in life science or related discipline
  • 1+ year of hands-on lab work experience
  • Proficiency in aseptic technique and tissue culture is highly desired
  • Working knowledge of flow cytometry and immunofluorescence is desired

**Development Associate – DP – Sorrento Valley**
• $50-60k, might go to $70-75k for a GREAT candidate

Job Summary
This position will be responsible for driving the growth of the lyophilized products by assisting with hands-on testing, development, and manufacturing of lyophilized products including, but not limited to, Veri-Cells and lyophilized cocktails.

**Essential Functions**
Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Lyophilization
- Flow cytometry
- Maintaining inventory and overseeing future inventory requirements
- Using the computer databases for inventory management
- Other duties as assigned

**Minimum Qualifications - Education and Experience**
- Bachelor’s Degree in Science
- 2 years of experience with lyophilization

**Preferred Qualifications – Education and Experience**
- Master’s Degree
- Experience handling of cells and/or cell lines
- Flow cytometry and cell culture experience

**Work Environment & Physical Demands**
- Typical working environment in a laboratory setting. While working in this position the employee needs to be able use equipment such as lyophilizer, computer, flow cytometers, centrifuges, micropipettes and dispensers. This position requires data entry, management of databases and keeping physical inventory organized.

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**Research Associate (Cell Separation) – DP – Sorrento Valley**

- $35-55k
- The Research Associate Product Development will be involved in product and reagent development for cell separation related applications. This position will have the opportunity to independently drive research projects from conception to completion, and will interact with multi-disciplinary teams.

**Essential Functions**
- Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.
- Primary cell preparation tasks
- Development and optimization of assays aimed at cell isolation and cell analysis
- Cell preparation, cell separation, and cell staining using conjugated antibodies to identify the isolated cell purity and yield
- Identification and implementation of new assay technologies that have an impact on assay throughput and/or performance
- Preparation of detailed Standard Operations Procedures (SOPs) that enable transfer of validated assays to project teams
- Keeping all of the experimental records
• General lab duties such as helping to keep the lab organized and clean, cleaning the incubators, and ensuring that buffers are available for use when needed

Minimum Qualifications - Education and Experience
• Bachelor’s Degree in a Life Sciences related area
• 2+ years of hands-on experience handling cells, such as cell preparation, immunofluorescent staining, cell culture, and cell separation
• Experience with primary cell preparation, tissue culture, and cell separation

Preferred Qualifications – Education and Experience
• Working experience with immunofluorescence microscopy or immunohistochemistry
• Experience with flow cytometry

Research Associate I – C – Sorrento Valley
• $16-20/hr
• More of a “technician” molecular biologist type role
• BS DEGREE REQUIRED.
• Participate in preparation of methods, materials and documentation required for development studies.
• Requirements: Laboratory experience and aseptic lab techniques required.
• Experience with pipetting and molecular testing required.
• Microbiology experience and experience with DNA/RNA extraction helpful.
• Must have experience with and be willing to work with biological material.

CAPA Specialist – C – Sorrento Valley
• Coming soon!
• 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

**Scientist, Pharmacology (5613) – C – Torrey Pines**

- $45-65/hr

**Responsibilities:**

- The position is within the Pharmacology Dept at the San Diego Celgene site.
- The successful candidate will work with senior scientists to design, plan and execute in vivo studies focused on identifying drug candidates within the area of oncology.
- Primary responsibilities include testing new chemical entities utilizing in vivo oncology models, data analysis and presentation.
- Additional responsibilities include data generation using techniques such as ELISA, Mesoscale, Western Blot and histology/immunohistochemistry.

**Qualifications:**

- The position requires a BS or MS in Biology or related discipline with approx 6 years of industrial experience. Prefer to avoid PhD candidates.
- Successful candidate must have hands-on experience in evaluating small molecules in oncology in vivo models and must be proficient in animal handling, dosing, sample preparation, experimental design and data analysis.
- Candidates must absolutely have oncology animal experience. Don't bother to submit candidates without this.
- Hands-on experience with ELISAs, Western blots, histology or immunohistochemistry is preferred.
- The candidate should have excellent written and oral communication skills and the ability to work in a fast-paced, team-oriented drug discovery environment.

**Research Associate (5654) – C - Torrey Pines**

- $17-24/hr

**Responsibilities will include, but are not limited to, the following:**

- We are seeking a highly motivated Research Associate to conduct in vivo studies in rodents.
- In particular, this person will be responsible for formulation preparation, animal dosing (oral gavage, IP, SubQ, IV tail vein injection), blood sampling (retro-orbital, cardiac puncture), and plasma preparations in a fast-pace drug discovery setting.
- Responsibilities also include harvest tissues in support of tox/pharmacology studies.
- Experience with automatic blood sampler and surgery will be a plus.
Skills/Knowledge Required:
- A BS or an equivalent degree in animal science, biology or pharmaceutical-related discipline with 1 - 2 years of industrial animal research experience and proficiency in formulation work, animal handling, dosing and sampling in rodents.
- This individual is also expected to be highly organized, detail oriented and responsive to instructions, a team player, enthusiastic about drug discovery, and a strong communicator with strong work ethics.

**Research Associate (5582) – C- Torrey Pines**

**$28-38/hr**

**PREREQUISITES**
- Bachelor’s degree in a scientific discipline with at least 8 years work experience OR Master’s degree with at least 6 years work experience

**Summary/Scope**
- The successful candidate needs to have a strong background in molecular and cellular immune biology with experience in biologics drug discovery. The qualified candidate will participate in testing novel antibody candidates in functional assays in addition to performing mechanism-based in vitro studies. This candidate will implement existing HTS platforms to assess target binders for functionally in relevant systems to support multiple programs at varying stages of antibody discovery. Excellent communication and interpersonal skills demonstrated in a team environment are essential, as well as experience with software applications for storing, processing and presenting data.

**Responsibilities will include, but are not limited to, the following:**
- Coordinate the testing of incoming biologics including bispecific antibodies for cellular target binding and related functional activity.
- Based on directions from supervisor, design and execute complex human cell based assays and mechanism of action studies. Also, perform routine and complex data analysis to triage leads for affinity maturation.
- Isolate and expand human primary immune cell populations for in vitro functional assays.
- Perform routine Biotherapeutics assays on identified antibody leads prior to DC nomination, including FcγR binding, effector function, and human cytokine release.
- Cross-trained in multiple flow cytometry platforms. Also have the capacity to assist colleagues in performing flow analysis.
- Routine presentations of experimental plans and data in team and department settings

**Skills/Knowledge Required:**
- Solid understanding of cellular immunology
- Familiar with multi-parameter flow cytometry analysis (surface/intracellular staining) using LifeTechnology Attune, BD Celesta FACsCalibur etc. Experience in High Content Imaging system a plus.
- Proficiency with FlowJo, Prism, Microsoft office applications
- Expert understanding in tissue culture, human and cynomolgus immune cell isolations, and familiarity with gene reporter systems
Familiarity in molecular and biochemistry techniques, including cell transfections, Western blotting, DNA manipulations, and qPCR analysis, are desired.

Fundamental knowledge and understanding of drug discovery and antibody discovery process is preferred.

**GMP/QC Chemist – CH – Sorrento Valley**
- $14-30/hr DOE
- BS degree in Chemist, Chem Eng, Pharm Chem (maybe Biochem)
- **Must have experience working in an industry lab (clean room)**
- Will train on HPLC and Oligo purification and reagent prep.
- To assist with the manufacturing of synthetic compounds.
- “The ideal candidate must be flexible and able to multi-task in a fast pace laboratory environment. Good organizational skills and attention to detail are required. A great attitude and the desire to learn are attributes of a successful candidate. GMP and clean room background and experience is a plus!
- This individual will be involved in the synthesis, processing and purification of synthetic DNA and RNA compounds for research, diagnostic or therapeutic application. Techniques include oligonucleotide synthesis, HPLC analysis and purification, gel electrophoresis, gel filtration, conjugation chemistry and spectral analysis.”

**mRNA Assistant/Associate Biologist – CH – Sorrento Valley**
- $15-24/hr
- BS/MS in Biology, Biochemistry, Molecular Biology, Cell Biology with experience with PCR, DNA handling, reagents, solutions, buffers, pipetting
- Immediate opening for a Molecular Biologist to assist in the development of novel PCR and other molecular biology products. Bachelors Science degree minimum. Cleanroom experience of 1 year and GMP; Strong writing skills, attention to detail, and the ability to work independently is a must.
- Will work with mRNA. Utilize PCR, gels, MS, pipetting

**QA Manager, Engineer – DP – Sorrento Valley**
- $120-130k+
- 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

Additional responsibilities include;
• Support New Product Development through independent review / technical assessment of development documentation / activity
• Develop / Maintain Risk Management File
• Assist in development / maintenance of new product Device Master Record / Design Trees
• Monitor / support Development Trace Matrix requirements
• Generate Change Orders as required to support New Product Development and/or corrective / preventive action projects.
• Determine experimental sampling plans
• Assist in transitioning product from development to manufacturing
• Assist in development of raw material, production material and product specifications along with qualification test plans.
• Support Process Validation activities.
• Maintain project documentation in accordance with internal and external regulatory requirements as part of the design control process.
• Active participation with corrective action / preventive action projects in accordance with company’s Quality Management System.

Associate QC Director – DP – Sorrento Valley
• Up to $130k+
• Can change title to Director for right candidate
• The Associate Director of Quality Control is responsible for oversight of the Quality Control testing labs and contract test labs (CTL). This includes project management, method transfers, raw data/protocol/report review, release testing, stability programs, data trending, reference standards, external auditing, exceptions management (Deviations, CAPAs, OOSs/OOTs) and change control. The Associate Director is responsible for ensuring testing conforms to defined
requirements and stability programs are cGMP compliance with applicable regulations and ICH guidelines from early and late stage development through product licensure and post commercialization. The Associate Director will represent QC in cross-functional CMC teams and is accountable for managing, coordinating, and communication status on all QC related activities.

**Project Analyst – CH – Sorrento Valley**

- $20—22/hr
- Bachelor’s degree (B.A. or B.S.) in Science or related discipline. MUST have at least 1-2 years post graduate experience in academic or industry setting
- Will be expected to dilute specimens, run ELISA assays, validate assays, etc. following SOP's.
- Candidates MUST have experience multi-tasking, MUST be able to communicate effectively.
- Culture fit is VERY important
- Run assays (mainly ELISA) to meet final requirements of QAU review and release.
- Develop and validate analytical assays to meet final requirements of QAU review and release.
- Perform assays according to GLP guidelines.
- Writing of SOPs and contribution to final written SOPs in the laboratory.
- Write final validation reports and QC raw data that go into the report. Organize raw data notebooks.
- Responsible for following GLP guidelines for validation of assays.
- Responsible for general lab safety with regard to employees and clients.
- Responsible for keeping accurate inventory of supplies for laboratory operations.
- Responsible for accurate record keeping with regards to sponsor’s samples, data and reports.
- Responsible for communicating with client with regards to project.

**Associate Project Coordinator – CH – Sorrento Valley**

- $15-18/hr
- BS degree with experience manipulating formats in Microsoft Word and Excel. Must be ORGANIZED, have experience writing some type of reports (even in undergrad), STRONG PEOPLE SKILLS, solid email/phone COMMUNICATION.
- MOST IMPORTANT:
  - Comfortable with client communications via email and phone
  - Data management or data entry experience preferred
  - Good with time management
  - Good organization skills
- Responsibilities to include but not limited to setting up administrative and project notebooks, client files, review study protocol; update Master Schedule.
- Assisting Project Coordinator with sample receipt, sample reconciliation, tracking and storage; any necessary communications to site or client.
- Responsible for creating prep batches, worksheets, data reduction, data review and final analytical report that is written according to SOPs and ready review.
- Work closely with Project Coordinator to verify accurate sample numbers; review monthly sample analysis nominations and submit to Project Manager for approval.
Follow GLP guidelines and laboratory SOPs and maintaining a safe working environment.

**Client Services Manager – CH – Sorrento Valley**

- $22-24/hr
- Bachelor’s degree (BA or BS) required.
- 3+ years of relevant experience in sales, finance, account management or client services in a GLP environment.
- Interact with the Director of Project & Client Management with regular updates on client issues/concerns/delays.
- Serve as key client contact for assigned projects/clients.
- Ability to communicate effectively with clients and ability to proactively assess appropriate time to escalate issues to Intertek management.
- Attend all conference calls or ad hoc calls for assigned clients.
- Prepare and maintain Project Trackers and Gantt charts as required for assigned clients.
- Monitor project schedule and scope of work to ensure both remain on track.
- Monitor timelines and deliverables, escalating any delays immediately to the Director of Project & Client Management.
- Prepare any required metrics, volume reports or budget request for clients.
- Actively participate as operational lead in internal Project Review meetings, in conjunction with a Principal Investigator and/or Laboratory Manager/Supervisor, depending on size and scope of work.
- Establish strong working relationships with client project teams to enhance client satisfaction and promote repeat business.
- Ensure effective teamwork across project team members both internally (ensure sufficient resources dedicated to project) and with external ancillary services (Accessioning, QC, QA, IT, etc.).
- Manage project resource needs and establish succession plans for key resources.
- Work closely with QC/QA scheduler to monitor progress of timelines and deliverables, revise as necessary and communicate any delays immediately to management and/or client.
- Engage in quality assurance and risk management activities to ensure project deliverables are met according to both Intertek and client requirements.
- Demonstrate teamwork, excellent communication skills (written and verbal) and organizational skills (ability to prioritize and work independently, make wise decisions).

**Manufacturing Supervisor x4 – DP – Carlsbad**

- $70-85k
- 2 openings 1st shift, 1 opening 2nd shift (5% shift differential), 1 opening 3rd shift (10% shift differential)
- 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.

Collaborate closely with Engineering, R&D, Technical Operations, Quality Assurance and Regulatory teams to ensure proper implementation, sustainability and compliance of manufacturing processes and systems.

Utilize lean manufacturing principles to improve quality, increase productivity, reduce costs and reduce cycle times.

Responsible for management of Kanban system for manufacturing components and supplies in close collaborate with Planning, Supply Chain, Quality, Finance and Logistic teams.

Build and provide leadership for an effective team in a high growth environment including hiring, on-boarding, developing, goal setting and performance improvement in alignment with individual, department and company goals and objectives.

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)
• Experience, training and/or certification in LEAN Manufacturing principles and/or Six Sigma methodologies. Experience with Statistical Process Control a plus.
• Hands-on with a strong sense of urgency, discipline, commitment and organization

QC Chemist – CH – Mira Mesa
• $20-25/hr
• Bachelor's degree in Chemistry, Biology, or equivalent experience. Knowledge of laboratory techniques and instrumentation (i.e. HPLC, GC/MS). Ideal candidate has experience testing raw materials, but not required. Knowledge of cGMP.
• Looking for an Analytical Chemist with expertise in mass spectrometry. Experience in MS peptide sequencing is desirable. Hands-on experience of other analytical methods and procedures is essential (HPLC/UPLC, GC, UV, FTIR, etc.). Work experience in a GMP regulated environment is necessary. Knowledge of FDA relevant regulations, ICH, EU Ph. and USP guidelines is preferred.

ESSENTIAL FUNCTIONS:
• Prepare samples for analysis, analyze, and report results.
• Prepare controlled documentation in support of the sampling, analysis, and reporting of results.
• Analyze data with respect to standards or to previously determined parameters.
• Perform routine review in support of GMP.
• Perform sampling and testing of raw materials according to procedures.
• Perform API testing according to procedures.
• Perform method qualification and validation according to protocols.
• Prepare material for shipment to customers.
• Represent with a high level of integrity and professionalism.
• Adhere to policies and support management decisions in a positive, professional manner.
• Keep meticulous and current notebook, logbook and electronic records, related to the work performed.
• Be current with all job related trainings.

OTHER JOB FUNCTIONS:
• Perform other duties as assigned, such as, but not limited to
• Perform stability studies testing and keep the related records.
• Initiate and or complete OOS, OOT, Deviation reports, RMS, DSS, Change Controls and relevant responses to audit findings (CAPAs).
• Create protocols and/or execute method, development, qualification, verification, transfer and validation.
• Provide hands on training on instruments and methods for other analysts.