

C = Contract
CH = Contract to Hire
DP = Direct Placement
DOE = Depending on experience
GTW = Go To Work (no interview)

HOTTEST OPENINGS ARE HIGHLIGHTED

Project Coordinator – CH – UTC

- \$17-25/hr
- Bachelor's Degree in the biology or chemistry is preferred. Minimum of 3-4 years of college coursework in the sciences, or equivalent work experience is required.
- Aseptic manufacturing experience is strongly preferred.
- Good documentation, strong organizational and record keeping skills are essential.
- Excellent verbal and written communication skills are required.
- Must be a team player, customer service oriented, willing to learn, and able to work flexible hours.
- The Project Coordinator is responsible for coordinating and running processes associated with the manufacture of the customer's product in manufacturing. This includes working with Project Managers in communication with the customer, ensuring inventory is available to begin the process, and coordinating the scheduling of the job including the needs of personnel, equipment and space. The Project Coordinator is directly involved in the set-up, formulation and aseptic filling and lyophilization of buffers and solutions, and the timely completion of all associated documentation throughout the entire process. They are to ensure that personnel follow all regulations and written procedures applicable to the job. Project Coordinators will also write procedures, perform validations, and investigate failures as necessary. The ideal candidate should be able to work with minimal instructions, and should be able to provide some direction to area technicians

Director, Downstream – DP – UTC AND Director, Upstream – DP – UTC

- They have openings for both. Please let me know which one you're a TECHNICAL match for**
- \$DOE
- BS/MS or PhD with 5 years+ upstream processing, prefer prior director- would probably look at associate director
- DEPARTMENT: MANUFACTURING/OPERATIONS
- As a member of the senior management team, this individual will be involved in the production and processing of recombinant proteins for clinical use.
- ESSENTIAL DUTIES AND RESPONSIBILITIES:
- Manage a complex workload for cell line development, upstream process development, and upstream manufacturing activities.
- Responsible for leading a team of supervisors and technicians.
- Provide support to cross-functional teams to meet production or timeline demands.
- Demonstrate understanding and provide oversight on technical operations, safety, and Good Manufacturing Practice.

- Provide oversight on upstream processes as well as cleanroom facility and equipment operations.
- Develop staff capabilities, creating a culture of safety, maintain training objectives, compliance and collaboration while implementing process improvements where applicable
- Initiate, review, and revise cGMP Batch Production Records, SOP's, Process Development reports, and Manufacturing Summary reports.
- Ensure the completeness and accuracy of manufacturing documentation per approved procedures.
- **JOB REQUIREMENTS:**
- Expert in cell line development, upstream process development and upstream manufacturing processes
- PhD's degree in Life Sciences or Chemical Engineering with more than 7 years of relevant experience in GMP production including aseptic processing or a BS / MS degree in Life Sciences or Chemical Engineering with more than 15 years of relevant experience.
- Practical Experience with cGMP operations.
- More than 5 years of supervisory experience
- Must be proficient in Word and Excel.

Manufacturing Supervisor, Upstream – DP – UTC AND Manufacturing Supervisor, Downstream – DP – UTC

- They have openings for both. Please let me know which one you're a TECHNICAL match for**
- \$DOE
- BS/MS with 3 years+ upstream processing, wants prior supervisor
- DEPARTMENT: MANUFACTURING/OPERATIONS
- As a member of the senior management team, this individual will be involved in the production and processing of recombinant proteins for clinical use.
- **ESSENTIAL DUTIES AND RESPONSIBILITIES:**
- Manage a complex workload for cell line development, upstream process development, and upstream manufacturing activities.
- Responsible for leading a team of supervisors and technicians.
- Provide support to cross-functional teams to meet production or timeline demands.
- Demonstrate understanding and provide oversight on technical operations, safety, and Good Manufacturing Practice.
- Provide oversight on upstream processes as well as cleanroom facility and equipment operations.
- Develop staff capabilities, creating a culture of safety, maintain training objectives, compliance and collaboration while implementing process improvements where applicable
- Initiate, review, and revise cGMP Batch Production Records, SOP's, Process Development reports, and Manufacturing Summary reports.
- Ensure the completeness and accuracy of manufacturing documentation per approved procedures.
- **JOB REQUIREMENTS:**
- Expert in cell line development, upstream process development and upstream manufacturing processes
- PhD's degree in Life Sciences or Chemical Engineering with more than 7 years of relevant experience in GMP production including aseptic processing or a BS / MS degree in Life Sciences or Chemical Engineering with more than 15 years of relevant experience.

- Practical Experience with cGMP operations.
- More than 5 years of supervisory experience
- Must be proficient in Word and Excel.

Bioanalytical Scientist – DP – Torrey Pines

- \$80-100k
- We are dedicated to developing and commercializing genomic-driven solutions to address global challenges. We are currently seeking a Bioanalytical Scientist within our Analytical Chemistry group to join our fast-growing, dynamic and collaborative team in La Jolla, CA.
- The Bioanalytical Scientist provides technical expertise and hands-on bioanalytical method development within the Analytical Chemistry laboratory in support of all of the business units' needs. The successful candidate will have a strong background in protein mass spectrometry and will be abreast of modern protein mass spectrometry tools and techniques. He or She will be responsible for designing and conducting laboratory experiments, interpreting complex datasets, reporting results to supervisors, and for supporting cross-functional collaborations across diverse research programs.
- The Bioanalytical Scientist will develop and implement mass spectrometry based analytical methods for full protein characterization including post-translational modifications. Hands-on experience with characterization of other macromolecules is a strong plus.
- Expert knowledge in sample preparation for protein mass spec, mass spectrometer maintenance/operation and data analysis is required.
- A strong background in mass spectrometry including top down and bottom-up proteomics and hands-on proficiency with instruments such as Thermo Q Exactive Plus, Thermo LTQ Orbitrap XL and Agilent 6538 QToF is required.
- A detailed working knowledge of analytical software packages from both Agilent and Thermo is required
- A detailed understanding of liquid chromatography method development is required and troubleshooting/experience with other analytical techniques such as GC/MS and spectrophotometric/electrophoretic techniques is desirable.
- A working knowledge of biophysical characterization methods is a strong plus.
- The candidate should have a track record of successful independent research and also be able to work efficiently and collaboratively in a fast-paced team environment.
- Strong organizational skills, orientation to detail, ability to multitask and prioritize effectively are required.
- Critical thinking skills, a high degree of self-motivation, flexibility and adaptability to changing priorities and resources are necessary.
- The candidate must possess excellent interpersonal skills, have strong oral and written communication abilities and will be expected to contribute significantly to the overall success of scientific program(s), on-going projects, critical patents, grants and scientific publications.
- Required Experience
- A Ph.D. in Analytical Chemistry, Biochemistry, Physical Chemistry, or other relevant discipline with 0-5years hands-on post-degree experience in protein based mass spectrometry in an academic or industrial setting

- demonstrated state-of-the-art technical capabilities, particularly with protein mass spectrometry
- A strong, diverse knowledge of protein chemistry, biochemistry, organic chemistry, inorganic chemistry and synthetic biology
- Experience with handling and analysis of complex biological samples
- Experience with modern mass spectrometry based data acquisition and analysis software
- Proven ability to operate, maintain, and troubleshoot versatile analytical instrumentation to maintain high standards of performance
- Experience working with external contractors, such as partner companies or external laboratories involved in chemical analysis

Microbial RA – CH – Torrey Pines

- \$40-60k
- Requires a Bachelors or Masters degree in, Molecular Biology, Genetics, Microbiology or related life-sciences fields with a minimum of 3-6 years of experience in industry or academic labs.
- Hands-on experience with advanced molecular biology techniques (PCR, DNA sequencing on traditional as well as Next-Gen platforms, gene cloning, synthetic biology, RNA isolation, SDS-page, etc.).
- Proven ability to budget time and manage several distinct projects at once.
- Eagerness to learn, adopt, and develop new methods.
- Experience working with industrial or non-traditional strains is preferred

Molecular Biologist, RA II (Vaccines) – CH – Torrey Pines

- \$24-27/hr
- Required Skills:
- Molecular biology (e.g. PCR, gel electrophoresis, nucleic acid purification, restriction digest).
- In vitro transcription and RNA handling.
- Experience in one or more of the following areas are preferred:
- Sequence and ligation independent cloning (SLIC)
- Recombinant virus production and/or characterization
- Biochemical and/or cell based assays relevant to virology/immunology
- Protein expression analysis techniques (e.g. protein concentration determination, Western Blot, ELISA)
- Flow cytometry experience
- Education and Work Experience:
- Requires a BS in Molecular Biology, Cell Biology, Immunology, Virology or related field, Master's degree preferred

Senior Production Associate – CH – Torrey Pines

- \$20-30/hr
- 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.
- 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).

Development Associate I – DP – Torrey Pines

- Supports manufacturing technical support projects that can include generating analytical data for an FDA submission.
- Performs the design, execution and documentation of moderately complex experiments that support existing reagents and assays. Experimental design will include all of the appropriate controls.
- Independently writes study protocols and reports that may be auditable.
- Maintains a laboratory notebook that records all aspects of experimental design and results, following good documentation practices. When applicable, maintains electronic copies of experiments, procedures, instructions, data and analysis in appropriate locations.
- Uses laboratory techniques such as preparation of buffers and media, aseptic technique, cell culture, specimen processing, PCR, gel and capillary electrophoresis and sequencing.
- Independently operates laboratory equipment such as thermocyclers, spectrophotometers, fluorometers, centrifuges, cell counters, autoclaves, scales, capillary electrophoresis instrumentation, sequencers, real-time PCR platforms and DNA isolation workstations.
- Performs data analysis using available software such as Microsoft Excel, JMP and GeneMapper.
- Cooperates and respectfully communicates with external customers and internal customers.
- Other duties, as assigned.

Development Associate II x1-2 – DP – Torrey Pines

- \$50-55k
- Molecular Biologist with industry experience
- Will be doing development, supporting manufacturing

- 3+ years of experience in R&D (not just research), development and/or manufacturing
- Supports manufacturing technical support projects that can include generating analytical data for an FDA submission.
- Performs the design, execution and documentation of moderately complex experiments that support existing reagents and assays. Experimental design will include all of the appropriate controls.
- Independently writes study protocols and reports that may be auditable.
- Maintains a laboratory notebook that records all aspects of experimental design and results, following good documentation practices. When applicable, maintains electronic copies of experiments, procedures, instructions, data and analysis in appropriate locations.

Development Associate III x1-2 – DP – Torrey Pines

- \$55-65k
- Molecular Biologist with industry experience
- Will be doing development, supporting manufacturing
- 5+ years of experience in R&D (not just research), development and/or manufacturing
- Supports manufacturing technical support projects that can include generating analytical data for an FDA submission.
- Performs the design, execution and documentation of moderately complex experiments that support existing reagents and assays. Experimental design will include all of the appropriate controls.
- Independently writes study protocols and reports that may be auditable.
- Maintains a laboratory notebook that records all aspects of experimental design and results, following good documentation practices. When applicable, maintains electronic copies of experiments, procedures, instructions, data and analysis in appropriate locations.

Technical Support Representative (QC Tech II) – DP – Torrey Pines

- \$45-75k DOE
- BS degree with (PCR OR QC) AND (GMP OR NGS)
- 95% customer service/TSS, 5% lab
- 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.
- Molecular Biologist to handle questions and emails

QC Tech III x2– DP – Torrey Pines

- \$49-59k (DOE)
- BS degree with (PCR OR QC) AND (GMP OR NGS)
- QC Tech III = 90% lab, 10% customer service/TSS
- 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.

Associate Project Manager – CH/DP – Torrey Pines

- \$up to 110k DOE
- Design Control experience is VERY important for this role as well as experience in IVD/Biotech.
- At least three to four years experience as a project manager in IVD product development working with pharma clients.
- Undergraduate degree in science, preferably concentration in molecular and/or next generation sequencing. Advanced degrees are preferred.
- Experience working with internal and external collaborators, multiple teams and projects.
- Working knowledge of design control and FSA QSR requirements.
- Very knowledgeable and skilled in the use of Microsoft Project Management software. Certification strongly preferred. Three years experience or better required.
- Very knowledgeable in Design Control and managing projects through all stages.
- Highly pro-active and driven, able to successfully complete tasks and goals, yet friendly, likable and excellent at relationship building. Superior emotional intelligence skills.
- Analytical and able to generate alternative solutions when necessary. Must be able to adapt to changing needs and parameters caused by time, budget or other constraints in a very dynamic environment.
- Actively and constructively contributes to a team effort through networking internally and externally.
- The Project Manager supports and assists the Director, Program Management in managing the development of companion diagnostics with external partners that requires involving departmental or cross-functional teams to be focused on the development and delivery of new products. Supports and assists in scheduling, monitoring budget/spending, monitoring and facilitating completion of project team activities and tasks, identifies and helps project team mitigate program risks and organizing interdepartmental activities to help ensure the completion of the project/product according to schedule.

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

Bioinformatics (HTS) – CH – Sorrento Valley

- Up to \$60k
- Summary
- Responsibilities shall include execution and analysis of high-throughput screening experiments in a team environment. Primary responsibilities to include data analysis and troubleshooting (using the scientific method to design, execute, and interpret hypothesis-driven experiments); and generation of study reports.
- Key role in a centralized screening team conducting data analysis for automated high throughput screening, statistics and QC principles
- Leveraging cutting edge instrumentation and technologies to drive Drug Discovery
- Developing and performing multiple cell-based and biochemical assays which support diverse innovative projects
- Documenting, compiling, analyzing, and presenting experimental data
- Required Education/Experience/Competencies
- Bachelor's or Master's degree in the life sciences or physical sciences
- 2+ years of experience at a pharmaceutical / biotechnology company or research institute
- Preferred Education and Experience
- Experience in pharmacology, enzymology, or assay development
- Experience with high throughput data analysis, curve fitting and reporting
- Expertise with development of fluorescence, luminescence and FRET cellular assays

Scientist I – CH – Sorrento Valley

- \$18-21/hr
- Summary
- Responsibilities shall include execution of high-throughput screening experiments in a team environment; preparation and QC of key reagents. Eventually lab responsibilities to include data analysis and troubleshooting (using the scientific method to design, execute, and interpret hypothesis-driven experiments); and maintenance of laboratory supplies and infrastructure.
- Essential Functions
- Basic laboratory skills, including liquid handling, reagent preparation, and chemistry-related calculations- including calculations of stock concentrations, making serial dilutions, etc.
- Capable of multitasking and properly prioritizing tasks
- Experience with basic Microsoft Office programs (Excel, Word, etc.)
- Enthusiasm and outstanding written and oral communication skill
- Required Education/Experience/Competencies
- Bachelor's or Master's degree in the life sciences or physical sciences
- Independent undergraduate research experience
- 0-2 years of experience at a pharmaceutical / biotechnology company or research institute
- Preferred Education and Experience
- Experience in pharmacology, enzymology, or assay development

Tech Support Specialist – CH – Sorrento Valley

- Up to \$25/hr DOE
- BS in sciences with experience with customer service
- Responds to customer product inquiries via telephone or in written internet-based email or chat sessions.
- Resolves customer concerns raised during installation, operation, maintenance or product application or compatibility matters.
- Interpersonal skills and technical product knowledge and expertise are critical to responding to daily customer-centric activities.

Documentation Specialist – C – Sorrento Valley

- Up to \$41/hr
- This role will support the Global Quality department in specific Design Control activities. Specifics of the job are as follows:
- Aid in writing, formatting and subsequent processing of documents (SOPs, MPs, RMS, Labeling) relating to the implementation of new products that are under design control.
- Write/update procedures by using a template/feedback provided by a subject matter experts (R&D, Quality, Operations).
- Initiate required forms to process the documents through an electronic or paper based document management system.
- Develop and write user documents for use of software application
- Coordinate and process documentations pertaining to DHF for products in development phases.
- Assist the team with additional tasks as needed (example: documenting meeting notes, following up on action items)
- Communicate with team members to ensure alignment of various document related information.
- Bachelors Degree in a biological science or engineering discipline or equivalent experience.
- Preferred experience:
- 3-5 years of Technical Writing or Document Control experience in an FDA regulated environment, preferably medical devices and/or in vitro diagnostics.
- Experience with Design Control.
- Experience with revision control.
- Experience in a GMP type environment (production, lab) preferred.

Research Associate (5384) – C – Torrey Pines

- \$32/hr
- B.S. in protein sciences, biochemistry, life science or related fields and at least 6 years of research experience in antibody/protein discovery
- Design, plan and execute scientific experiments with minimal supervision
- Antibody/protein engineering, purification and characterization such as SDS-PAGE, immunoblotting, analytical SEC, and endotoxin testing/remediation
- Antibody/protein interaction assay development by SPR, immunoprecipitation, and ELISA
- General assay development for hit-to-lead identification and characterization
- Antibody/protein engineering by rational design and/or display (phage or yeast)

- Molecular biology, mammalian cell culture and protein expression
- Purification of antibody and protein biologics
- Functional assays including SPR, ELISA, and FACS
- Data presentations and updates in the project team meetings
- Providing technical solutions to anticipated problems

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

Product Management Assistant – CH – Sorrento Valley

- \$15-20/hr
- BS Degree in sci. Marketing /customer service role, phone work, office
- Assist PM/Associate in managing assigned product lines, which may include quotes, customer correspondence, inventory control, sales reports, marketing reports and projections.
- Assist with various projects as needed to support the Marketing & Sales department
- PM Assistant, The position would be to take orders, so great customer service, some filing and attention to detail. Science background

QA Specialist – CH – Sorrento Valley

- \$15-30/hr
- Seeking an individual to release final products.

- BS in science required, preferably in chemistry.
- 2-5 years' experience in a controlled industrial environment a required (cGMP/GLP).
- Good writing skills, high degree of organization and excellent attention to detail are necessary.
- The successful candidate will also demonstrate an ability to work independently.
- Upon conversion, this position will also assist the Director of Quality Assurance in internal audits, drafting quality assurance documentation, raw material analysis and release, CAPA & NCMR systems, light lab support duties/facilities assistance in GMP lab environment as a cross train into QC tactic.

QA/QC Technician (Raw Materials) – CH – Sorrento Valley

- \$15-25/hr
- The responsibilities will depend somewhat on the aptitude of the candidate.
- The primary responsibility for the position will be processing incoming raw materials including ordering qualification tests and maintaining the related documentation.
- The candidate must have a BS in science and one year experience in the lab or QA.
- They should have enough experience to have a basic understanding of the materials they are handling.
- ****DEGREE IS NOT REQUIRED IF THEY HAVE THE RIGHT INDUSTRY EXPERIENCE**
- Raw Materials Release
- Detail oriented is essential as well as accuracy and simple math & organized.

Technical Support Specialist I & II – CH/DP – Sorrento Valley

- \$20-23, \$24-27/hr DOE
- SUMMARY OF POSITION:
- Provides technical support to medical professionals, sales representatives and laypersons primarily via the telephone. Demonstrates medical knowledge and communication skills while providing excellent customer service to facilitate resolution of customer problems. Works closely with domestic Sales, Marketing, Customer Service,
- QA, QC, Research and Development to address customer concerns, determine corrective action and customer follow-up.
- Education/Experience: B.S./B.A. in Life Sciences, or equivalent experience.
- Knowledge/Skills
- Ability to accept ownership and responsibility for meeting deadlines.
- Strong technical skills regarding principles of product technology and disease processes as they relate to our products.
- Good communication (speaking and listening) and interpersonal skills.
- Good telephone skills / phone manner.
- Solid organizational/time management skills.
- Good follow up skills.
- Good understanding of computer skills. Must be able to quickly learn new programs and/or modifications to the existing system.
- Ability to work well under pressure and prioritize multiple tasks while maintaining a positive attitude.

- Attention to detail.
- Ability to handle highly confidential subject matter.
- Ability to accept direction and constructive criticism.
- Ability to handle time sensitive projects with short notice.
- Ability to handle multiple tasks in a fast paced environment.
- Moderate supervision.
- Works on problems of minimal and occasionally diverse scope where analysis of data requires a review of identifiable factors. Exercises judgment within generally defined practices and policies in selected methods and techniques for obtaining solutions. Generally receives moderate instructions on routine work and more in depth instructions on new assignments or issues which are more complex in nature.
- Recognizes recurring issues and takes actions towards resolution or refers to appropriate individuals or team. Able to provide concise correspondence of investigative results to customers. Able to respond to customer questions and troubleshoot issues.

Technical Manager – DP – Sorrento Valley

- \$90-100k
- ESSENTIAL FUNCTIONS:
- Trains, develops and coaches Team to continuously improve their knowledge, productivity and effectiveness in projecting a professional image and providing excellent customer satisfaction whenever interacting with a Customer (internal or external). Typical contact points would be: telephone and or email communication, meetings and training classes as requested by Sales or Marketing.
- Actively participates in Customer Complaint Committee Meetings. Effectively communicates with crossfunctional
- Teams with respect to inquiries and complaints received by end use customers and/or distributors, as well as results of customer satisfaction surveys.
- Creates, analyzes and reports on department metrics and efficiencies.
- Works closely with IS to ensure best practice and continuous improvement in LN and/or other operating systems.
- Manages and monitors global customer complaint system to ensure procedures are being followed according to ISO requirements and that Quidel's corporate goal for processing time is being met.
- Takes lead on international complaints and ensures proper training on handling and communication.
- Collaborates with cross functional teams to resolve escalated customer complaints.
- Participate in internal and external audits pertaining to functions of Technical Support Team
- Provides and/or coordinates training for internal employees, distributors, and end-use customers as needed. May provide training in person, via WebEx or via phone.
- Manages, monitors, and reports to Marketing and Management Team on all applicable proficiency programs. Works closely with R & D regarding any troubleshooting and/or improvements required based on proficiency results.

- Responsible for monitoring and maintaining the instrument tracking system in our ERP system and for assisting with any instrument upgrade programs.
- Education/Experience
- B.S. /B.A. in Life Sciences, or equivalent experience
- 6 years related experience
- Minimum 3 years in Technical Support in leadership role
- Experience with diagnostics industry, hospital, and/or physician office laboratory strongly preferred
- Knowledge/Skills
- Lead, motivate and mentor individuals with different personalities that require different levels of support
- Able to maintain a professional attitude at all times and work calmly under pressure
- Quality focused
- High degree of ethics and professionalism while interacting with customers, vendors and co-workers.
- A positive attitude demonstrated during company functions and public events to encourage team camaraderie and enthusiasm for growth in market share and revenue.
- Ability to work in a fast-paced, and results-oriented environment, handling time sensitive projects often with short notice

Scientist, Purification – DP – Sorrento Valley

- \$80-100k
- Requires MS or PhD in chemical/biochemical engineering, biochemistry, or related scientific discipline with minimum of 3 years industry experience post PhD or 12 years industry experience post BS
- The Purification Senior Scientist is responsible for leading all aspects of purification process development from process definition to process characterization for support of pipeline projects.
- The appropriate candidate will be able to manage and design a series of advanced scientific experiments applying engineering and scientific principles to process definition, process optimization, scale-up, technology transfer, process characterization, and process validation activities associated with the purification of biopharmaceuticals.
- The candidate must be experienced in the application of DOE and statistical analysis to the development of purification operations including filtration and chromatography.
- Experience with supporting a clinical manufacturing environment is preferred.
- Must have experience leading collaborations across teams and must be an effective communicator of ideas, project goals, and results across functions.

Manufacturing Technician x2 – C/CH – Sorrento Valley

- \$16-24/hr
- Minimum of High School with 2 plus years experiences in biotech/pharmaceutical industry. Associate or Bachelor degree is preferred.
- 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.
- 1 - 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.
- 2 - Under supervision, employee will perform routine manufacturing activities in GMP manufacturing areas including cell culture/fermentation and the associated sub-processes/preparation. 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 regularly draft and revise documents such as batch records, SOPs and technical reports. Candidate must be detailed oriented, a strong team player and has ability to collaborate cross functionally. Flexible shift schedule and overtime may be required.

QC Analyst, Micro – CH - Sorrento Valley

- \$15-30/hr
- Performs activities in support of EM, to include surface, viable air, non-viable air, and personnel monitoring. Perform growth promotion testing of media.
- Performs activities in support of bioburden testing of water, clean rinse samples, and product, conductivity, TOC, and chemical testing of compressed gases.
- Performs activities in support of final product release testing (e.g. tests applicable for potency, endotoxin, sterility, and toxicity) and raw material testing (e.g. microbial limits, endotoxin, and potency) where required.
- Perform investigations for out of specification or limits occurrences and deviations.
- Determine preventative and corrective actions for laboratory investigations.
- Outsource ID testing of recovered microorganisms. Interpret microorganism ID results to determine impact on facility.
- BS in Microbiology or a Life Sciences related discipline.
- Minimum of seven (3) years' experience in the pharmaceutical industry, to include: EM and experience with microbiological testing such as bioburden, microbial identification, Gram staining, water testing as per USP (membrane filtration, conductivity, and TOC), and growth promotion assay.
- Experiencing working in varying ISO grade clean rooms.
- Working knowledge of microbiological compendial assays (USP <61> and USP <62>).
- Experience writing quarterly/ annual reports for EM and water trending.
- Knowledge of cGMP and ICH.
- Possess a strong work ethic along with a solid organizational, time management, problem-solving, decision-making, judgment, and interpersonal skills.

Sr. Scientist, Analytical Development – DP – Sorrento Valley

- \$80-100k+ DOE
- Years of industry experience very important: Bachelor's/Master's degree in biology, chemistry, or similar discipline and 5 to 10 years of experience working with biologics/biopharmaceuticals, or Ph.D. and 5+ years' experience
- Really looking for an Analytical Chemist/Biochemist – need to have that analytical background
- Will need to be able to develop and validate analytical test methods
- Experience/ knowledge of large molecule characterization
- Summary Description of Role:
- The Scientist/Senior Scientist candidate will assume an exciting leadership role focused on supporting Analytical Development to meet company pipeline objectives. The candidate will actively identify, design, execute, and evaluate analytical activities to advance preclinical/clinical stage novel vaccines through development, regulatory submission and approval. He/She will supervise a team of scientists engaged in product characterization, method development, and method validation activities. The candidate will assure timely and appropriate product characterization and method development activities to meet project target profiles and ICH, USP, FDA, and EMA standards through a combination of internal and contracted activities. Vaccine projects will include a broad range of methods for characterization and product testing requiring strong competencies in chemical and physical techniques applied to in-process materials, drug substance and drug product. The candidate must be able to effectively communicate results and issues to peers, management and customers, internal and external (CRO/CMO), with excellent professional standards.
- Responsibilities:
- Large molecule characterization by various techniques, including biochemical/biophysical, chromatographic, spectroscopic/spectrometric methods.
- Develop, qualify, validate, and transfer analytical test methods for testing in process materials, drug substance, and drug product
- Supervise internal scientists engaged in analytical activities, including method development/validation, product/molecule characterization, and testing pipeline products
- Interact with contract service providers to facilitate method development, characterization, and testing activities
- Author and review protocols, reports, test methods, and SOPs
- Conduct and document investigations following SOPs and company requirements
- Maintain accurate and complete laboratory notebooks and records following GMP and good documentation practices
- Generate analytical data and reports needed for the CMC sections of INDs, NDAs and other regulatory filings
- Perform and/or manage maintenance and calibration of laboratory instruments and equipment
- Qualification Requirements:
- Bachelor's/Master's degree in biology, chemistry, or similar discipline and 5 to 10 years of experience working with biologics/biopharmaceuticals, or Ph.D. and 5+ years experience
- Strong leadership experience

- A minimum of 3 to 5 years in a supervisory role in a GMP biopharmaceutical environment
- Experience in analytics of biologics or large molecule characterization and testing from early through late stage development
- Good understanding of regulatory requirements, including ICH, USP/EP, FDA/EMA
- Ability to work independently and manage projects in a timely manner
- Strong interpersonal skills with an eagerness to support colleagues in Analytical Development and internal CMC and Quality teams
- Excellent verbal and written communication skills
- Proven collaboration skills, learning agility, conceptual and strategic thinking, passion for results, and ability to navigate ambiguity

Sr. Research Associate – C – Sorrento Valley

- \$20-40/hr DOE
- Experience with optimization and scale-up of protein expression in mammalian and insect cells.
- Experience with generation and establishment of stable cell lines.
- Experience with DNA and RNA expression vectors, cloning, western blotting and flow cytometry
- Ability to critically analyze, interpret and document results.
- Additional Virology or protein purification or process development experience is a definite plus.
- Write standard operating procedures and technical reports.
- Ability to adapt and be flexible to new tasks and challenges.
- Team player with integrity and accountability.
- Ability to organize and prioritize work to meet timelines.
- Excellent communication, organization and problem solving skills.

Process Development Scientist – DP – Sorrento Valley

- \$80-100k
- This company is open to an UPSTREAM OR DOWNSTREAM candidate, but only have approval for one. They will hire whichever comes/fits first.
- **For upstream:** bioreactor and cell culture experience (has to have), not just using it, but developed the process.
- The candidate will be in a process development and clinical manufacturing team. The candidate will focus on the development work of upstream cell culture and virus amplification/virus-like-particles transfection with disposable bioreactors, and support downstream purification with Chromatography method.
- Cell culture experience is necessary.
- Bioreactor experience is necessary
- Design of Experiment (DoE) is necessary
- Electroporation experience is preferred
- Anion Exchange Purification experience is preferred
- Diafiltration/Ultrafiltration experience is preferred
- Good data analysis skills
- cGMP experience is preferred

- Molecular biology and virology knowledge is preferred
- Good aseptic techniques
- Good writing skills
- **For downstream:** Chromatography purification (AKTA avant and AKTA ready), need development capability.
- The candidate will be in a process development and clinical manufacturing team. The candidate will focus on the development of downstream purification of virus and virus-like-particles with Ultrafiltration/diafiltration, Chromatography purification, filtration method.
- Design of Experiment (DoE) is necessary
- Anion Exchange Purification experience is necessary
- Diafiltration/Ultrafiltration experience is necessary
- Cell culture experience is preferred.
- Electroporation experience is preferred
- Bioreactor experience is preferred
- Good data analysis skills
- cGMP experience is preferred
- Molecular biology and virology knowledge is preferred
- Good aseptic techniques
- Good writing skills
- Minimum of 5 years' relevant industry experience with a M.S degree or 2 years' experience with a Ph.D. degree.
- Master or Ph.D. of Science/engineering in Biology, chemistry, chemical engineering, or related discipline is preferred
- Team player and quick learner

QA Associate – C – Sorrento Valley

- \$35-45/hr//\$70-90k
- BS in Life Sciences and a minimum of 5-7 years of experience in the pharmaceutical / biotech industry
- Minimum 5 years of experience in Quality Assurance, preferably supporting GMP manufacturing/testing of biologics for clinical and commercial use
- Working knowledge of cGMP principles with respect to FDA and EMA regulations
- Experience in reviewing and approving cGMP related documents (analytical data, equipment qualification, SOPs, protocols, reports)
- Experience in deviations, investigations, determining root cause, and developing corrective action plans
- Knowledge of drug development process
- Ability and demonstrated experience to identify technical testing and manufacturing problems and suggest resolution of issues
- Problem solving skills, effective written and verbal communication skills
- Excellent documentation skills and attention to detail
- Highly organized and ability to manage multiple priorities

- Ability to work independently and collaboratively with various work groups
- Working knowledge of MS Office suite (Word, Power Point, Excel)
- Experience with electronic documentation systems
- Quality Assurance (QA) Associate with in-depth experience in drug substance and drug product manufacturing/testing for an 8 months' contract. Reporting to the Director, Quality Assurance, the QA Associate will provide Quality support for the manufacture and testing of clinical and commercial products. The QA Associate will be accountable for assuring compliance with Quality System and quality oversight at the project level.

QC Chemist II – CH/DP – Sorrento Valley

- \$60-70k
- Qualifications
- B.S. degree in a physical or biological science, Chemistry preferred.
- Chemist II: 3-5 years of applicable laboratory experience, or a MS in a scientific discipline with 0-1 years of applicable laboratory experience
- Chemist III: 5+ years of applicable laboratory experience, or a MS in a scientific discipline with 2+ years of applicable laboratory experience
- Strong written and oral communication skills.
- Excellent accountability, high attention to detail, and strong organizational skills
- Proficient in a variety of analytical techniques (HPLC (including reversed-phase chromatography, ion-exchange chromatography, enantiomeric purity), dissolution, GC, UV/Vis spectroscopy, general wet chemistry, and compendial methods such as Karl Fischer analysis and FT-IR) and have ability to become familiar with many common standard lab practices in order to assess the quality of pharmaceutical products under limited supervision.
- Essential Duties and Responsibilities include the following. Other duties may be assigned.
- Independent execution of HPLC methods and preparation of sample, data packets, and data summaries
- Analysis of pharmaceutical products, including the set-up and execution of GMP in-process, release and stability testing using a variety of analytical techniques
- Creation of stability data sheets and Certificates of Analysis to summarize analytical testing and participation in revision of protocols and test methods
- Performance of stability-indicating HPLC/UPLC analytical method qualifications and validations
- Conduct experiments and communicate results to supervisor
- Participation in Out of Specification investigations and the writing of analytical variances
- Prepare documents and technical reports for clients
- Understand and apply ICH and FDA guidance where needed

QA Associate, Data Review x3 – CH/DP – Sorrento Valley

- Up to \$55k (maybe \$65k for the right candidate)
- Candidate will have a BS/BA science degree (Chemistry or Biochemistry preferred).
- Candidate will have 1 to 2 years of analytical chemistry/HPLC experience (candidates without this experience WILL NOT BE CONSIDERED).

- Candidate must also be highly detail-oriented and organized, able to work both independently and as a team player with a positive attitude. This position requires a high level of interaction with multiple departments, as well as clients.
- Responsibilities include, but are not limited to the following:
- Review and approve release and stability data, certificates of analysis, development and validation reports, analytical testing protocols, and stability chamber validations
- Maintain Quality Assurance logbooks for document change control, instrument calibration schedule, stability pull schedule, test method and technical reports, and certificates of analysis
- Perform internal audits of the analytical laboratories and Quality Assurance systems as well as in-phase audits of GLP studies
- Support GMP manufacturing activities including release of GMP materials, performance of line clearances in a Class 100,000 environment, maintenance of clinical trial material inventory logs
- Supportive role in hosting client and regulatory audits

Scientist, Analytical Method Development– CH/DP – Sorrento Valley

- \$\$TBD
- Requires B.S. in life sciences, ideally Chemistry, Biochemistry, Pharmacological Chemistry or Biology
- 7+ years' experience in analytical development
- Thorough knowledge and experience in HPLC stability-indicating method development and validation
- Strong oral and written communication
- Previous supervisory experience preferred
- An individual at the level of Scientist, Analytical Methods Development will be expected to build and lead a team focused on the development of analytical methods for small molecule and peptide drug products. The main focus will be HPLC/UPLC-UV stability-indicating methods using various separation chemistries including but not limited to reversed phase, ion-exchange, and chiral. However alternate detection methods such as ELSD may be employed. In addition, the individual may be responsible overseeing development of assay, dissolution, water content, and physical characterization methods for oral and injectable drug products. The individual will assist in the researching and introduction of new analytical technology to characterize drug products. There is an expectation of both direct hands-on laboratory work as well as supervision of 1-3 direct reports and mentoring/training of other colleagues as needed.
- They must be independently proficient in a variety of analytical techniques and regulatory areas including, but not necessarily limited to: analytical balances, pH meters, high performance liquid chromatography (HPLC), UV/Vis spectroscopy, USP dissolution testing apparatus, moisture analysis by Karl Fischer, and analytical method validation. Experience with disintegration, DSC, TGA, hardness, and friability testing also desired. Methods that are developed within the group will be qualified or validated as appropriate for the stage of development. In addition, the individual may assist in troubleshooting existing methods internalized to Pharmatek from other vendors.
- The individual will be able to communicate results both internally and externally through oral and written updates and formal reports as necessary. The individual may be required to assist in the

creation and/or revision of company SOPs. Collaboration with Quality Assurance and Quality Control on analytical method validation and compliance issues is expected.

COMING SOON:

Sr. RA and RA II

- In Vivo roles