

Status: Exempt

Reports To: *Department Manager*

Job Description

Position requires thorough knowledge of BioProcess design and engineering techniques. Responsible to plan and conduct independent work requiring judgment in the evaluation, selection, application and adaptation of engineering techniques, procedures and criteria. Devise new approaches to problems, and prepare or modify drawings, specifications, calculations, charts and graphs, and monitor work for compliance to applicable codes, accepted engineering practices and Client and/or Eichleay standards.

Typical Duties:

Typical duties will include but not be limited to the preparation and/or modification of the following:

- Conceptual engineering and design.
- Detailed engineering and design.
- Process development reports.
- Block Flow Diagrams (BFD) and Process Flow Diagrams (PFD).
- Process and Instrumentation Diagrams (P&ID).
- Process engineering calculations.
- Mass/Enthalpy balance.
- Basis of design process scope documents.
- Process equipment specifications and data sheets.
- User Requirement Specifications (URS).
- Project status reports.
- Equipment lists, line lists, and valve lists.
- Process equipment construction specifications.

Typical duties of more experienced Bio Process Engineers will also include but not be limited to the preparation and/or modification of the following:

- Working drawings.
- Process analysis.
- Equipment selection and recommendation.
- DQ, IQ, OQ documentation.

Essential Functions:

Responsibilities will include but not be limited to the following:

- Accountable for the successful completion of assigned engineering tasks and preparation of engineering deliverables.
- Interface with other internal engineering disciplines (mechanical, civil/structural, electrical, instrumentation, automation, architecture, etc.) to ensure a coordinated design and complete engineering deliverables.
- Participation in Client/contractor meetings, resolving technical issues, preparation of meeting minutes and action items lists.
- Field trips to Client site as required to determine existing as-built conditions.
- Size and select equipment, materials, and process systems.
- Assist in the preparation of engineering project proposals.
- Check vendor drawings to insure design accuracy and compliance with specifications.
- Construction support activities including responding to submittals and RFIs.

Responsibilities of more experienced Bio Process Engineers will also include but not be limited to the following:

- Develop process and project requirements.
- Coordinate and check engineering deliverables.
- Perform process simulations/calculations.
- Develop PFDs and P&IDs.
- Monitor/supervise less experienced BioProcess Engineers.
- Attend meetings with Clients to discuss design details.
- Develop standard system designs.

Design Experience:

Systems design experience should include but not be limited to the following:

- Bioreactors (Fermentation/Cell Culture).
- Product Recovery (Centrifugation, Cell Disruption, Cryopreservation).
- Purification (Chromatography, UF/OF/TFF/Lyophilization).
- Biowaste Deactivation/Neutralization.
- Bulk Solid Storage and Delivery.
- Bulk Liquid Storage and Delivery (Caustic, Acid, Volatile Solvents).
- Process Utilities (Chilled Glycol/Water, Plant Steam, Compressed Air, CDA, Hot/Cold Heat Transfer Media and Systems).

- Clean Steam.
- Hot/Cold Water for Injection (WFI).
- Reverse Osmosis (RO)/DI Pharmaceutical Water Systems.
- Gas Storage and Delivery (Oxygen, Hydrogen, Nitrogen, Helium, Argon, CO₂, Vacuum).
- Sanitary Piping Design.
- Clean-in-Place Systems (CIP), Steam-in-Place Systems (SIP).

Design experience of more experienced Bio Process Engineers should also include but not be limited to the following:

- Process description narrative.
- Basis of Design.
- Custom equipment design.

Education/Experience:

- Bachelor of Science or Master of Science degree in Chemical Engineering.
- Over two years of experience in BioProcess equipment design. Additional over one year of experience in cGMP pharmaceutical manufacturing preferred.

Education/experience of more experienced Bio Process Engineers should also include but not be limited to the following:

- Over ten years of experience in BioProcess engineering
- Five years of project experience, and three years or more of supervisory experience is preferred.

Skills and Special Requirements/Licensing:

- Knowledge of AutoCAD a plus.
- BATC Safety Training.
- Licensed PE or EIT is preferred.
- Excellent computer skills in Microsoft Suite.
- Familiarity with API, ASME, ANSI and ISA standards a plus.
- Pre-employment drug and alcohol screening.
- Background screening including previous employment, education, criminal history, and driving record verification.

Skills and special requirements/licensing of more experienced Bio Process Engineers should include but not be limited to the following:

- Knowledge of regulatory guidelines, including FDA and cGMP.
- Knowledge of hazardous area requirements and certifications related to instrument installation.
- Experience with facility design and construction.
- Experience in working with multiple discipline engineering projects.
- Successful experience interfacing with Clients.
- Strong communication skills, including writing skills in preparing reports, analyses, etc.

Work Environmental & Physical Demands:

The characteristics described below are representative of those encountered while performing the essential functions of this position. Reasonable accommodations will be made to enable individuals with disabilities to perform the essential functions.

- While performing duties of this job, would occasionally be required to stand, walk, sit, reach with hands and arms, climb or balance, stoop or kneel, talk and hear, and use fingers and hands to feel objects, tools or controls.
- Must occasionally lift and/or move up to 25 pounds.
- Specific vision abilities required include close vision, distance vision, depth perceptions, and the ability to adjust focus.
- Overtime may be necessary as workload's dictate. This may include weekdays, weekends and/or holidays.
- Job will generally be performed in an office environment, but may require travel to visit a Client's office, production facility or industrial/construction job site. Conditions will vary at each location, but the conditions listed above will generally apply.
- May be assigned to work at a Client's office, facility or site for an extended period of time. Conditions will vary at each location, but the conditions listed above will generally apply. When performing outside Eichleay's office, appropriate safety training and safety equipment will be provided by Eichleay and/or Client as required.