

Downstream Purification Associate (PDM)

JOB DESCRIPTION

JOB TITLE: Downstream Purification Associate REPORTS TO: Purification Manager
RECORD: UPDATED: 26 Nov 2018
FLSA STATUS: Exempt LOCATION: Sioux Falls, SD
DEPARTMENT: Process Development & Manufacturing (PDM)

Position Summary:

The Downstream Purification Associate (DPA) is responsible for performing protein purification processes which include bench and cGMP scale to produce sterile therapeutic antibodies for human use. Reporting to the Purification Manager, the DPA will execute these tasks within a matrixed team environment and support general day-to-day laboratory operations and maintenance of equipment in all Process Development and Manufacturing (PDM) department facilities.

Essential Duties and Responsibilities:

With moderate supervision while demonstrating independent ownership of key program tasks, responsibilities will include but are not limited to:

- Performing protein purification on a bench and clinical scale.
- Executing procedures according to written SOPs.
- Developing and updating related SOPs and records as needed.
- Maintaining accurate records of purifications and proper Scientific Laboratory Notebook details.
- Working under GLP/cGMP guidelines.
- Assisting in optimizing current purification methods and protocols to increase yield and purity.
- Ensure all equipment, used in the PDM department, cGMP Facility, and BSL2 laboratory, is properly maintained.
- Operating and maintaining facilities: support facility cleaning, including regular laboratory areas and BSL2 laboratory area.
- Maintaining cGMP facility and equipment according to SOPs and ISO 7 industry standards.
- Responsible for general laboratory maintenance and material prep including, preparing buffers, ordering and maintaining supplies as needed, and sample inventory tracking.
- Assisting others in areas when needed.

Qualifications:

To perform this job successfully, an individual must be able to perform each essential duty. The requirements listed below are representative of the knowledge, skill, and/or ability required.

- Demonstrate and use aseptic techniques.
- Understand and create methods on chromatography software.
- Collaborate and work with people from different departments.
- Manage and complete projects as assigned.

Education, Experience and Certifications:

- Bachelor's degree biology, chemistry or related field.
- Demonstrated 2 years bench research experience.

- 1-2 years of experience in the biotech industry preferred.
- Previous work in a cGMP facility preferred.
- Specific experience in an ISO7 and aseptic ISO5 environment preferred.
- Computer programming knowledge of processing instrumentation is helpful.
- Strong time management and organizational skills.

Language Skills:

Individual should possess strong communication skills and proficiency in Microsoft Office software (Word, Excel, PowerPoint and Outlook) as well as the ability to effectively present information in one-on-one and small groups.

Mathematical Skills:

Basic mathematical skills to consist of addition, subtraction, multiplication and division. Able to calculate dilutions and molarity.

Physical Demands:

While performing the duties of this job, the employee is regularly required to walk, stand and sit. The employee must be able to move up to 50 pounds. Specific vision abilities required by this individual include close vision, peripheral vision, and the ability to adjust focus. The employee will view a computer monitor for long periods of time.

Physical Requirements/Working Conditions: Job requires good physical mobility. Ability to move over 100 pounds by mechanical means. Be able to sit for extended periods of time. Able to wear aseptic gowning for extended periods of time.

Working Environment:

Duties will be performed in normal laboratory, ISO 7 environment, and BSL2 laboratory settings and aseptic setting (ISO5 environment) from time to time.

ADA:

The employer will make reasonable accommodations in compliance with the Americans with Disabilities Act of 1990.

This job description will be reviewed periodically as duties and responsibilities change with business necessity. Primary and additional duties and responsibilities are subject to modification.

I have read and understand the responsibilities of the position. I also understand changes can be made as needed.

EMPLOYEE

DATE

SUPERVISOR

DATE