

## **Process Development Team Leader – Downstream**

**Ref: EBD116**

### **Job Purpose**

The Process Development Team Leader for Downstream will be responsible for and required to develop, optimise and scale-up purification strategies for the production of a wide range of biopharmaceuticals including but not limited to proteins, DNA and viruses. There will also be a requirement to scale-up/down and for the technology transfer of processes either internally to Eden's manufacturing group or externally, to and from third parties.

### **Job Summary**

An excellent opportunity for the right candidates to work within a dynamic, vibrant company whose continuing expansion within both the UK and the US requires a highly flexible and intuitive Process Development Team Leader within the downstream group, to work on a wide range of projects within Eden's microbial, mammalian and viral process development laboratories.

Eden's Downstream Development group is responsible for the development, optimisation and scale up/down of purification processes for the recovery and purification of proteins, DNA and viruses. The Process Development Team Leader for Downstream will be responsible for recruiting/training of the downstream team, project planning, design and execution of experiments, operating bench/pilot scale processes in addition to providing support for technical transfer activities externally to and from third parties and internally to the manufacturing teams.

There will also be the requirement for subsequent data review and report generation alongside and the upkeep of the process development laboratories. Eden also has a strong focus on cross-skilling; therefore the suitable candidate may also be required to work within different groups, such as upstream/analytical development and cGMP manufacture.

### **Key Responsibilities**

- Reporting to the Process Development Manager for Downstream.
- Supporting the Process Development Manager for Downstream in project planning to effectively deliver Eden's project deliverables.
- To support the broader Eden Biodesign team to effectively deliver projects.
- To recruit, train and oversee personal development of the Process Development Downstream Team.
- The design, execution, analysis and interpretation of experiments.

- To develop, optimise, scale up/down downstream processes.
- To interpret, analyse experimental results and generate reports and effectively communicate experimental findings.
- To draft documentation required for regulatory submission support.
- To work in conjunction with Manufacturing, Quality Control (QC), Quality Assurance (QA), Analytical Development (AD), Upstream Process Development (USP) and third parties:
  - ▶ technology transfer to/from third parties, and internally to/from manufacturing teams
  - ▶ training
  - ▶ process trouble shooting
  - ▶ the generation and review of Standard Operating Procedure (SOPs) and batch records
  - ▶ Data review and analysis
- To operate bench and pilot scale downstream purification systems as required.
- To ensure equipment is correctly maintained and controlled.
- Any other duties as may be required to fulfil the job purpose.

### **Skills and Knowledge**

The successful candidate will possess:

- Extensive downstream processing experience in a biopharmaceutical environment is essential.
- Experience of current Good Manufacturing Practice (cGMP).
- Experience of Process Technology Transfer to and from third parties and cGMP manufacturing.
- Experience in product/process development for regulatory approval.
- Ability to manage, design and execute experiments in an effective and timely manner.

### **Personal Attributes**

- Demonstrable team building and management skills.
- The ideal candidates should be thorough with a good attention to detail, adaptable, personable and technically competent.
- Excellent analytical and decision-making skills.
- Ability to analyse, interpret results both reporting and communicating experimental findings effectively.
- High level of IT proficiency.
- Demonstrable communication and interpersonal skills.
- Ability to work effectively within a dynamic team.

- Aptitude for identifying and implementing new technologies.

### **Experience**

- Extensive experience of downstream processing technologies directly applicable to bioprocessing.
- Process technology transfer to/from third parties including cGMP manufacturing.
- Demonstrable team management skills.

### **Education and Training**

- Bachelor's degree (or higher/equivalent) in life sciences or a Biochemical Engineering discipline.
- Evidence of career progression.