



## **cGMP Fermentation Scientist (Ref: EBD44)**

### **Job Purpose**

This role is within the Upstream Processing team and involves a wide range of activities associated with the upstream manufacture of cGMP biopharmaceutical Investigational Medicinal Products (IMPs) for clients. The cGMP Fermentation Scientist focuses primarily on bioreactor processing for microbial, mammalian and viral products, and is also involved in cell culture work. There is a requirement to ensure all work is in accordance with regulatory requirements and Eden Biodesign's Quality and HSE Policies and Procedures.

### **Job Summary**

The role involves technical transfer of up-stream processes for microbial, mammalian and viral products into the production group from our internal process development team or direct from the clients. The Fermentation Scientist provides specialist input into process design during the development and technical transfer of processes and translates development information into a cGMP compliant manufacturing process. The Fermentation Scientist also prepares manufacturing instructions and specifications and manufactures the products within the cGMP production facility to meet customer timelines, ensuring all documentation is completed compliantly. There is also a requirement to design and execute validation studies for the bioreactors.

In particular, this candidate will be expected to plan and organize the upstream manufacturing campaigns for the team and take a lead role in operating and maintaining the bioreactors within our facility. In addition, the role includes more routine operations associated with maintaining the production facility such as utility sampling and cleaning.

### **Key Responsibilities**

Reporting to Production Team Leader

- Perform all processing and support activities in compliance with cGMP and Eden Biodesigns' quality systems.
- Understand and comply with HSE policies and procedures associated with the manufacturing process and working within the manufacturing area.
- Carry out activities necessary to maintain a high standard of hygiene and housekeeping in the cleanroom areas.
- Complete all batch related documentation in a timely and compliant manner including participation in the review of batch documentation to obtain QA sign-off.
- Raise, investigate and close-out non-conformances, planned deviations and change control requests.
- Author and review Standard Operation Procedures and Manufacturing Instructions.
- Investigate and trouble-shoot technical issues.

- Communicate and work with other departments such as Process Development, QC and QA to ensure excellent customer service provision.
- Review, challenge and understand process information provided by Process Development or Clients in order to prepare Manufacturing Instructions as part of Technology Transfer.
- Carry out validation work as required depending upon work demands.
- Maintain a personal training record.
- Participate in regulatory and client inspections as required.
- Undertake other responsibilities (such as working in Process Development, Warehouse) as required depending upon work demands.

## **Skills and Knowledge**

### **Experience**

- Hands-on bioreactor processing experience required within a biopharmaceutical or pharmaceutical production or development environment - in mammalian, microbial or viral technologies.
- Aseptic processing skills
- Good working knowledge of cGMP and a broad knowledge of safety
- Supervisory experience advantageous
- Experience in writing and reviewing SOPs and batch records
- Experience in following SOPs and completing batch records
- Experience in the following advantageous:
  - technical transfer of products from development into a cGMP environment
  - execution of equipment qualification, cleaning validation and/or sterilisation validation desirable

### **Personal Attributes**

- Excellent team player - ability to get along with colleagues and work as part of a team
- Good organisational skills
- High attention to detail
- Drive, enthusiasm and ambition with a can-do approach
- Good oral and written communication skills
- Ability to multi-task, learn new techniques and implement change
- Problem solving skills
- Manual dexterity
- Flexible attitude to work - ability to adapt to changing demands and requirements
- Willingness to carry out all reasonable requests of his/her Team Leader

### **Qualifications and Education**

- Minimum of two science 'A' levels and 5 GCSEs including Maths and English
- Demonstrate a progressive attitude towards developing their knowledge and skills