

cGMP Upstream Production Operator

Job Purpose

cGMP Upstream Production Operator will perform a wide range of activities associated with the upstream manufacture of cGMP biopharmaceutical Investigational Medicinal Products (IMPs) for clients within the Production Facility at Eden Biodesign. There is also 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 manufacture of upstream processes for microbial, mammalian and viral technologies to cGMP within the cleanroom facility from cell culture through to harvesting bioreactors. The Upstream Production Operator will prepare manufacturing instructions and specifications and manufactures the products within the cGMP production facility to meet project timelines, ensuring all documentation is completed compliantly.

In particular, this candidate will be expected to plan and organize their workload to manufacturing schedules.

In addition, the role includes more routine operations associated with maintaining the production facility such as cleaning and environmental monitoring.

This role will involve moving to an unsociable hours working pattern for periods of time in line with the working hours policy to meet the project demands.

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.
- 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 processing experience required within a biopharmaceutical or pharmaceutical production or development environment.
- Good working knowledge of cGMP and a broad knowledge of safety.
- Experience in following SOPs and completing batch records.
- Aseptic processing, preferably with some cell culture experience.
- Experience in the following advantageous:
writing and reviewing SOPs and batch records, execution of equipment qualification
- Awareness of upstream processing technologies is 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 multitask, 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 GCSEs including Maths and English.
- Demonstrate a progressive attitude towards developing their knowledge and skills.