



cGMP Purification Scientist (Ref: EBD43)

Job Purpose

cGMP Purification Scientists perform a wide range of activities associated with the downstream 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 technical transfer of down-stream processes for microbial, mammalian and viral products into the production group from our internal process development team or direct from the clients. The Purification Scientist reviews technical development information and translates this information into a cGMP compliant manufacturing process. The Purification 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. In particular, this candidate will be expected to plan and organize the downstream manufacturing campaigns for the team and lead continuous improvement projects 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 downstream processing experience required within a biopharmaceutical or pharmaceutical production or development environment - in mammalian, microbial or viral technologies.
- 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 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 science 'A' levels and 5 GCSEs including Maths and English
- Demonstrate a progressive attitude towards developing their knowledge and skills