

Senior Process Operator with primary responsibility for Cell Culture and Bioreactor Processing

Reference: EBD119

Role Profile

The role reports to the Production Team Leader and has specific responsibility for leading manufacturing activities within the Production Cleanrooms to ensure delivery of the process in accordance with the Manufacturing Instructions and local HSE procedures. The Senior Production Operator is also responsible for ensuring the Operators are completing the documentation compliantly and in real time. The role holder takes the lead in deviations and investigations that are identified during the manufacturing process and is accountable for delivery of specific continuous improvement (OpEx) projects.

This role will be primarily focused on the technical delivery of the cell culture and bioreactor processing elements of manufacture of mammalian derived biological products.

The Senior Production Operator deputises for the Production Team Leader.

Management Responsibilities

Responsible:

- As the technical lead for the successful transfer of projects from Process Development or external organisations into Production, ensuring gaps and risks are highlighted and resolved prior to production processing.
- For the day-to-day production plans to deliver projects and ensuring plans are shared with other contributing departments (QC, QA, Engineering) as appropriate.
- For organising operations within the processing room during manufacture, to ensure compliance with HSE and GMP procedures and that any issues are flagged to the Team Leader and decisions made.
- For proposing and implementing actions as part of the continuous improvement program within the Production Department to improve operating efficiency and reduce the incidence of non-conformances.
- Supervise Operators.
- May have line management responsibility for Operators.

Operational Responsibilities

Responsibilities include:

- Perform all manufacturing activities in compliance with cGMP and HSE procedures.
- Carry out activities necessary to maintain a high standard of hygiene and housekeeping in the Production Cleanrooms.
- 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 in order to prepare Manufacturing Instructions as part of Technology Transfer.
- Carry out validation work.
- Participate in regulatory and client inspections as required.

Experience and Qualifications:

Education and Experience

- Preferably a qualification in a scientific subject and/or significant practical experience of manufacturing cell based products.
- Hands on experience of cell culture and bioreactor processing of mammalian, microbial and viral products.
- Good working knowledge of GMP requirements.
- Experience in writing & reviewing SOPs, manufacturing instructions and protocols for accuracy, traceability and compliance.
- Experience of reviewing completed Manufacturing Instructions for completeness and accuracy.
- Experience of investigating non-conformances.

Personal Attributes

- Strong organisational skills
- Excellent interpersonal skills, with ability to influence outcomes
- High attention to detail
- Good oral and written communication skills
- Problem solving skills
- Focus on continuous improvement - ability to evaluate systems to improve system functionality and efficiency.
- Flexible attitude to work - ability to adapt to changing demands and lead people through these changing demands.