

Job Description: Microbiology Manager

Reports to: Analytical and Quality Control Manager

Supervisory responsibility: Team Leader(s), Senior Scientists, Scientists

Budgetary responsibility: Project related: £3,000 to £9,999

Non-project related: £1,000 to £2,000

Location: Eden Biodesign, Liverpool

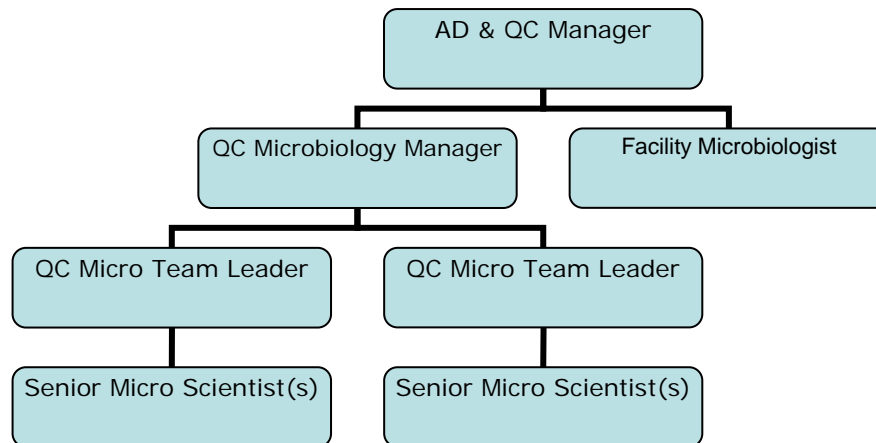
1. General Description and Responsibilities

As Microbiology Manager you are responsible for managing the transfer, application, qualification and validation of microbiological methodologies for, in-process and QC batch release and stability testing of a wide range of potential biopharmaceutical products. Key objectives and responsibilities include, but are not limited, to those below:

- The Microbiology Manager will manage the testing schedules of both project and routine samples to meet project and programme timelines. They will ensure that all work undertaken is adequately reported and prepare reviews of analytical data as required.
- The Microbiology Manager will collate and present analytical data generated by the Microbiology Team for both internal projects and externally where required. In addition they will support the Analytical Development and Quality Control Manager during regulatory audits, including presenting the Microbiology Department and supporting laboratory tours.
- The Microbiology Manager will line manage Microbiology Team Leaders, set their annual PMP targets and monitor accordingly. They will ensure that all work undertaken is done so in a safe and efficient manner to comply with the requirements of the Health and Safety Policy.
- The Microbiology Manager ensures technical expertise within their department through ongoing professional development of their team members.
- In addition, the Microbiology Manager will support Business Development through external presentations, meetings and technical input as required.

2. Management Structure

The Microbiology Manager will manage a group of approximately 10 to 15 staff.



3. Responsibilities

Management Responsibilities

- Manage the Microbiology team to ensure work is carried out in compliance with the Company Manufacturing License.
- Manage the Microbiology team to ensure deadlines are adhered to, wherever practicable.
- Maintain, and continually improve upon, the quality of all Microbiology activities.
- Ensure work is carried out in accordance with the requirements of GMP and Eden's SOP's/DOP's as required.
- Recruit and further develop existing staff to ensure a team that is strong across all analytical disciplines.
- Ensure Microbiology staff are trained appropriately to perform environmental monitoring and microbiology analysis of utility samples, raw materials, intermediates and products.
- Review/approve data, protocols and reports generated by Microbiology staff as required.
- To comply with the requirements of the Health and Safety Policy.

Operational Responsibilities

- Responsible for delivering all project work on time, to budget and to the required levels of technical quality by
- Ensuring that an effective facility Environmental Monitoring Programme is in place.

- Ensuring up to date microbiological trending data from the facility is available and presented in a suitable format.
- Ensuring appropriate standards of housekeeping, safety and discipline are applied within the Microbiology Laboratory.
- Ensuring that equipment is maintained/calibrated according to the schedules and that records are kept of maintenance and calibration activities.
- Liaising with other departments to determine microbiology testing requirements.
- Working closely with project managers to plan work, report status and manage resource clashes.
- Analysing and reporting microbiology data according to Eden policies and in a timely manner.
- Attending meetings and presenting data as required.
- Training of Microbiology Scientists in microbiological techniques.
- Writing Microbiology reports and microbiology sections of project reports when required.
- Reviewing/approving microbiology reports and sections of reports written by Microbiology staff.
- Writing/reviewing qualification / validation and method transfer protocols and reports.
- Maintaining a personal training record. Ensuring all staff in the group maintain a personal training record.
- Undertaking other responsibilities as required depending upon work demands

Limits of Authority:

- CAPEX. Identify and justify CAPEX within the Operations Group to deliver projects, deliver efficiency savings and to support technological advancements to maintain our technical excellence for the development of biotechnology products.
- Recruitment: Identify, justify and select suitable candidates to deliver Operational work programmes.
- Budget: Signing authority up to £10k for project related purchases and up to £1k for non-project related purchases.
- Delegated Responsibility: Deputises for Analytical Development and Quality Control Manager as requested. Authorised to sign development protocols and reports, and Technical Transfer documentation in the absence of the

Analytical Development and Quality Control Manager.



Experience and Qualifications

- Bachelor of Science and significant experience in leading microbiology laboratories/projects within the biotechnology industry.
- Experience with microbiological analysis of pharmaceutical/biopharmaceutical products, including but not limited to:
 - Experience/knowledge of the following: LAL testing, Identification – Gram Staining, Water testing, Bioburden testing, environmental monitoring.
 - Experience of quality systems within a GMP facility – Non Conformances, CAPA, Out of Specifications, Deviations.
- Knowledge of pharmaceutical standards and regulations, GMP.
- Writing technical reports.
- Writing and executing sections of qualification / validation protocols.
- Presenting data to an external audience.

Personal Attributes

- Leadership qualities
- Strong organisational skills
- Excellent interpersonal skills, with ability to influence outcomes
- Ability to solve complex problems
- Good oral and written communication skills
- Strong managerial skills with emphasis on coaching and development
- 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.