

Job Description

Microbiology Team Leader

EBD114

Reports to: (Microbiology Manager)

Supervisory responsibility: Microbiology Senior Scientists/Scientists

Budgetary responsibility: None

Location: Eden Biodesign, Liverpool

1. General Description of Responsibilities

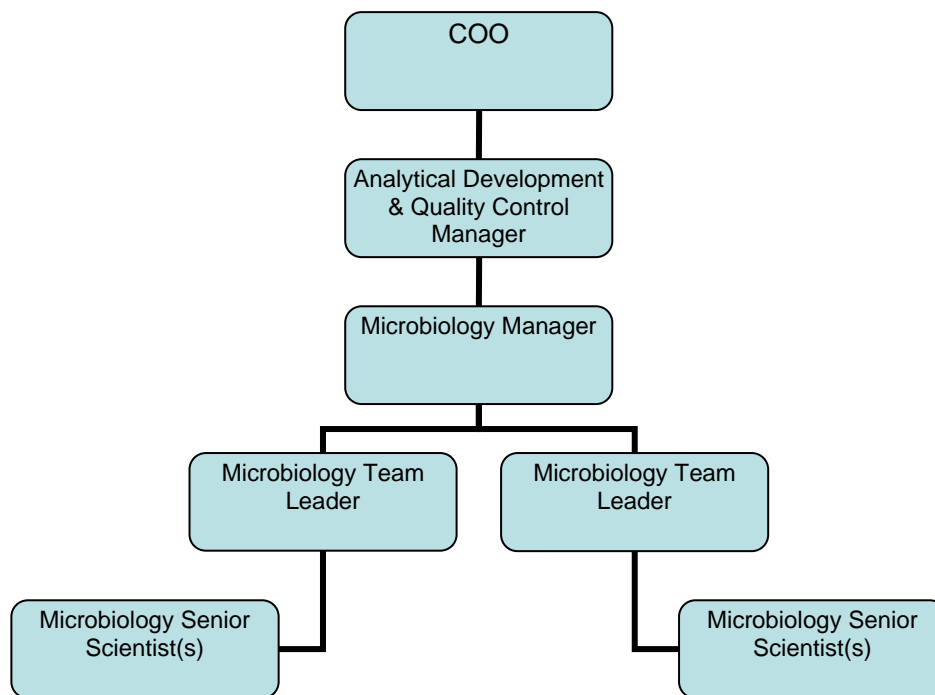
As Microbiology Team Leader you are responsible for managing the microbiological methodologies associated with environmental monitoring to provide accurate facility support results and data. Key objectives and responsibilities include, but are not limited, to those below:

- To support the Microbiology Manager to ensure safe, effective and efficient delivery of Microbiology facility support within Eden Biodesign.
- To line manage the Microbiology Senior Scientists and Scientists, set their annual PMP targets and monitor accordingly.
- To manage the microbiological testing aspects of environmental monitoring within the Quality Control function of Eden Biodesign to the requirements of cGMP.
- To manage the testing schedules of samples associated with environmental monitoring to meet project timelines.
- To assign appropriate Technical Leads to projects to ensure delivery were necessary.
- To liaise with external test houses as required to provide data in a timely fashion.
- To manage the initiation and closure of OOS, NCRs, Change Controls, Planned Deviations and CAPAs.
- Collate and present microbiological environmental data collected from the facility to provide up to date trending data.

- To 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.

2. Management Structure:

Organogram showing line management structure:



3. Responsibilities:

- To provide the Microbiology Manager with facility data in a timely manner.
- To manage the routine microbiological testing of all samples associated with environmental monitoring of the facility.
- To ensure all materials required to support environmental monitoring are in place, tested and available for use as and when required.
- To provide up to date microbiological trending data from the facility.
- Manage the Microbiology Senior Scientists to ensure deadlines are adhered to, wherever practicable.
- Maintain, and continually improve upon, the quality of all Microbiology activities.
- Recruit and further develop existing staff to ensure a team that is strong

across all routine Microbiological environmental tests and more specific project related disciplines.

- Ensure Microbiology personnel are trained appropriately.
- Liaise with other departments to determine Microbiological testing requirements.
- Work closely with project managers to plan work, report status, and manage resource clashes.
- Report Microbiology data according to Eden policies and in a timely manner.
- Collate, review and write sections, of Microbiology/QC sections of technical reports.
- Attend client meetings and present data as required.
- Write/review qualification/validation protocols and reports.
- Write/review method transfer protocols and reports.
- To comply with the requirements of the Health and Safety Policy.
- Ensure work is carried out in accordance with the requirements of GMP and Eden's SOP's/DOP's as required.
- To ensure appropriate standards of housekeeping, safety and discipline are applied within the Microbiology Laboratory.
- To ensure that equipment is maintained/calibrated according to the schedules and records are kept of maintenance and calibration activities.

4. **Experience and Qualifications:**

Experience with microbiological analysis of pharmaceutical/biopharmaceutical products.

Experience/knowledge of the following: Environmental Monitoring, LAL testing, Identification – Gram Staining, Water testing, Bioburden testing, Experience of quality systems within a GMP facility – Non Conformances, CAPA, Out of Specifications, Deviations.

Knowledge of pharmaceutical standards and regulations, GMP.

BSc or equivalent in Microbiology/Applied Biology with experience in Microbiology.

Supervisory Experience. Experience of line management.