

Job Description

Job Title: Quality Assurance Technician

Purpose and Scope of Position

Quality Assurance Technicians are responsible for reviewing and approving documentation involving all aspects of the production process. Documentation includes:

- Equipment readiness checklists
- Equipment cleaning and shutdown checklists
- Batch records
- Employee training records

The QA Technician is responsible for reviewing all Biomanufacturing team documentation. If a document is in compliance (filled out properly), the QA Technician will sign off on it and file it. If a document is not in compliance, the QA Technician will meet with the Biomanufacturing team. The team will work under the guidance of the QA Technician to determine the reason for non-compliance and to correct the problem.

Duties and Responsibilities

- Review of all team documentation in an accurate and timely manner.
- Investigation of any documentation that is not in compliance.
- Proper filing of all required documentation.
- Communicate with team members in a timely manner.
- Support of site internal audits, external client audits and regulatory inspections.
- Adhere to safe working practices.

Vocabulary

Documentation – This term refers to all documents that record information about the biomanufacturing process. This includes: employee training, batch records, product testing etc.

Audit - A GMP audit is a process by which an external or internal individual or team verifies that a manufacturer is following its documented Good Manufacturing Practices. It's similar to an audit in accounting or finance, except that the auditor is inspecting production processes for their adherence to quality control guidelines instead of financial records or data.