

Engineering Project Manager – Integrity Bio

Integrity Bio, Inc. is looking for an Engineering Project Manager with experience in the development, tech transfer, and scale up of parenteral formulation, filling/finish, and freeze-drying operations, who is motivated, creative and a respected team player. The ideal applicant should have a solid understanding of cGMP, aseptic processing and biotech technologies to join our Operations Group. If you enjoy working in a friendly, innovative, dynamic, fast paced environment, you should consider working for our organization.

Job Description Summary

The Engineering Project Manager is responsible for the maintenance and repair of building and manufacturing equipment and the Camarillo site's calibration program.

Job Description

Primary Responsibilities

- Responsible for the Maintenance and Calibration programs at the Camarillo Site.
- Manages maintenance and calibration personnel and outside contractors that engage in equipment repairs, calibration activities and preventive maintenance.
- Oversees the performance of facility and calibration contractors that perform work on the Camarillo site.
- Supports facility construction projects and new equipment specifications and purchases as required.
- Responsible for the control systems throughout the site, including PLCs, and the BMS.
- Assists with planning and coordinating office and cube moves.
- Functions as 24/7 point of contact for all facility related emergencies and acts as liaison between Operations and other department responders.
- Uses equipment data (i.e. failure analysis, C&E matrix, etc.) to drive improvements to the preventative maintenance and calibration programs.
- Performs GMP validation activities and author GMP documents.
- Performs other duties as assigned.

Quality Responsibility

- Maintaining of cGMP compliance is critical for the business. This is done by ensuring that all team members comply with processes, procedures and instructions for all activities in which the team participates.

Safety Responsibility

- Knowledgeable and complies with all pertinent safety policies, rules and regulations.
- Ensures that all team members comply with safety rules and regulations.

Leadership Responsibility

- Provides appropriate coaching and performance feedback to all direct reports and assures that all team members are being developed.
- Job Scope
- Works on complex problems where analysis of situations or data requires an in depth evaluation of various factors. Exercises sound judgment while ensuring minimal negative impact on manufacturing operations.

Requirements

- Your qualifications should include a technical degree (chemical engineering, chemistry/biology) such as:
 - PhD with minimum of 2 years relevant experience.
 - MS with minimum of 5 years relevant experience.
 - BS with minimum of 7 years relevant experience.
 - or an equivalent combination of education and experience
- Formulation, filling and freeze drying, primary packaging, aseptic processing, and protein chemistry knowledge.
- Requires a good understanding of the cGMP and regulations.
- Excellent verbal and written communication skills including writing of scientific / technical reports, presentations, and the ability to interpret and effectively communicate complex scientific findings and recommendations.
- Ability to work in a fast-paced, changing environment with tight deadlines.