

Labware Lead - Mfg

Job ID: 00414637

Job Function

Biologics Drug Substance Production

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Team Leader

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Responsible for producing innovative biotherapeutic medicine by interfacing with highly automated production systems and controls in cGMP manufacturing environment, and maintain areas in high state of inspection preparedness. Operates production equipment for cell culture or purification that may include culture growth, process monitoring, sampling, harvesting, purification, formulation, freeze thaw and transfer. Performs media/buffer solution preparation operations. Maintains records and clean room environment to comply with regulatory requirements utilizing current Good Manufacturing Practices (cGMP) and Standard Operating Procedures (SOP).

Responsible for assisting the shift supervisor by ensuring production goals are met throughout the day and distributing work assignments to technicians.

Job Responsibilities:

Lead TechnicianLead, coordinate and assign daily operations that include work tasks, breaks, and lunches. Provide coaching and training on technical aspects of the job, best practices and compliance to SOPs.

Assist Supervisor with meeting production quality standards by verifying the environment is in compliance with safe standards and SOPs are followed. Assist supervisor with approvals,

communications, and improvements. Identify areas for operational improvement. Provide data to supervisors summarizing schedule status. Resolve employee conflict independently and with supervisor.

Job Matrix

Through knowledge of biopharm technology, processes and the underlying scientific concepts.

Must demonstrate a comprehensive understanding of both general and specific aspects of multiple manufacturing departments.

Troubleshoots, investigates, and escalates complex problems, works with others to implement solutions.

Technician: Operate systems that clean and sterilize tanks and filtration systems.

Prepare solutions for the production process.

Review documentation and check all calculations (e.g. tickets, labels, equipment reading).

Trouble shoot equipment and process problems.

Comply with safety requirements, cGMP, SOP and manufacturing documentation.

Use of automation to perform production operations.

Provide support to Manufacturing to meet production demands.

Operate automated systems for equipment operation.

Assemble and prepare equipment for production.

Exhibit detail oriented documentation skills

Communicate effectively and ability to work in a team environment.

Exhibit professional interpersonal skills.

Work with coworkers and supervisor to effectively troubleshoot equipment and process issues.

Supplementary Responsibilities

Operate fermenters, centrifuges, other harvest systems and protein purifications units.

Operate and clean fixed tank and filtration systems

Operate large scale column chromatography systems.

Operate large scale UF/DF and Freeze Thaw systems.

Operate small-scale cell culture areas and systems by operating cleaning, set up, and maintaining 20L batch feed fermenters; inoculating and maintaining spinner seed cultures using aseptic techniques, maintaining cell banks; and performing general seed lab operations.

Perform Solution Preparation activities (media and buffer make-up)

Clean, assemble, and sterilize equipment using glass washers and autoclaves.

Perform automated CIP and SIP of fixed equipment.

Who You Are

Education and Experience

- Degree in Life Sciences and 3 year experience
- Or Associate Degree and 5 years of experience
- Or High School and 7 years experience
- Biotech certificate from approved program
- Must be flexible to work any shift
- Must be able to work prolong durations on your feet.

Knowledge, Skills, and Abilities

Excellent oral and written communication skills demonstrated by communicating with other functions and management regarding resolving investigations and theory.

Ability to lead department and/or cross functional meetings or projects.
Excellent oral and written communication skills
Capable of writing detailed reports and summaries.
Familiarity of computer-based systems
Background in Shared Services, Fermentation or Purification

Genentech is an Equal Opportunity Employer.