Director of Manufacturing Science & Technology, Biologics
Drug Substance Oceanside Campus

Job ID: 2565072711

Job Function
Manufacturing Science & Technology Engineers

Location
United States - California
Oceanside

Company/Division
Full-time

Schedule
Full-time

Job Level
Executive (Director/VP/SVP)

The Position
Purpose:
Maintain the site’s Right to Operate and enable excellence in manufacturing by providing technical support to the production organization that results in safe, high quality, and continuously improving production.

- Continuously monitor, analyze, optimize, and ensure validation of ongoing operations (production equipment, automation, and production and cleaning processes).
- Anticipate, respond to and permanently resolve issues that arise during production.
- Partner with external and internal functions to transfer, implement, validate, file, and license new products/processes.

Leadership & People Management:

- Create an environment of strong team spirit, timely and effective communications, sense of urgency, high motivation and inspire teams to achieve goals in the immediate and longer term. Be an active and visible change agent, promoting flexible and open mindsets to new opportunities.
- Establish strategic goals and objectives and maintain full strategic responsibility for the MSAT organization.
- As a site leadership team member, drive collaboration within site and across network activities, cross-functional planning, and decision making.
- Accountable for overall budget and financial performance of the MSAT organization.
- Proactively promote positive Safety Culture and cGMP operating principles.
- Embody PT lean leadership principles and methods while fostering a continuous improvement mindset.

Technical:
- Operate as one network: Partner with global MSAT teams and network peers at other
manufacturing sites to share and adopt best practices across the network that drive continuous improvement in all technical aspects of production.

- Serve as a core member of the relevant Technical Council, provide site contributions to network technology roadmaps, ensure funding and execution of assigned projects on the respective site level.
- Ensure Right to Operate through compliance with cGMP and regulatory requirements applicable to the department
- Direct areas of responsibility:
  - Validation: Own, execute and improve the validation program for equipment, processes, and cleaning, and ensure compliance with PQS and HA requirements. Represent Validation program during HA inspections.
  - Automation: Own, integrate, maintain and improve all production automation platforms at the site, and ensure compliance with PQS and HA requirements.
  - Tech Transfer: Partner with global and site functions to specify, transfer, file and license new products/processes in the plant.
  - Technical Services: Respond to and proactively identify issues, determine root cause, and solve forever: Develop, prioritize and drive continuous improvements that reduce safety risks, operational costs, lead times, and scrap/discrepancy rates across all aspects of production.
  - Process Engineering: Establish oversight to ensure production is performed in conformance with license requirements, cGMPs, and global Health Authority expectations, and represent state of compliance during Health Authority inspections.
  - Manufacturing Support: Provide technical support to manufacturing organization that includes process and product monitoring, master data and document management, compliance to Roche quality systems, and other readiness operational support activities.
  - For specific sites: Pilot Plant Operations: Build and maintain pilot plant operations to support Make-Assess-Release activities, tech transfers, and continuous improvement of the production plant.

Who You Are

Education

- Bachelors Degree (science or engineering preferred)
- Graduate or higher-level Degree is preferred

Experience (may vary depending on site size/scope)

- 12 or more years’ work experience in the pharmaceutical or related industry
- 8 or more years’ people management experience
- 4 or more years’ relevant engineering or project management experience in the pharmaceutical industry and/or a cGMP environment
- Extensive experience with start-up and validation of manufacturing equipment, utility and process systems, including requirements for documentation and testing

Knowledge/Skills/Competencies

- Expert knowledge of capital projects, project controls, and project scheduling
- Expert knowledge of clean room or classified area design/requirements
- Deep process, equipment, automation, validation and technical knowledge
Who We Are

A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 40 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. Genentech has multiple therapies on the market for cancer & other serious illnesses. Please take this opportunity to learn about Genentech where we believe that our employees are our most important asset & are dedicated to remaining a great place to work.

Genentech is an equal opportunity employer & prohibits unlawful discrimination based on race, color, religion, gender, sexual orientation, gender identity/expression, national origin/ancestry, age, disability, marital & veteran status. For more information about equal employment opportunity, visit our Genentech Careers page.