Genentech
A Member of the Roche Group

Date: 05/15/17

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

Job ID: 2565072711

Job Function
Manufacturing Science & Technology Engineers

Schedule
Full-time

Location
United States - California Oceanside

Job type
Regular Employee

Company/Division
Full-time

Job Level
Executive (Director/VP/SVP)

The Position

Purpose:

Maintainthe site's Right to Operate and enable excellence in manufacturing by providingtechnical support to the production organization that results in safe, highquality, and continuously improving production.

- Continuouslymonitor, analyze, optimize, and ensure validation of ongoing operations(production equipment, automation, and production and cleaning processes).
- Anticipate, respond to and permanently resolveissues that arise during production
- Partner withexternal and internal functions to transfer, implement, validate, file, andlicense new products/processes.

Leadership & PeopleManagement:

- Create an environment of strong teamspirit, timely and effective communications, sense of urgency, high motivationand 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 andobjectives and maintain full strategic responsibility for the MSAT organization.
- As a site leadership team member,drive collaboration within site and across network activities, cross-functionalplanning, and decision making.
- Accountable for overall budget andfinancial performance of the MSAT organization.
- Proactively promote positive SafetyCulture and cGMP operating principles.
- Embody PT lean leadership principlesand methods while fostering a continuous improvement mindset

Technical:

- Operate as one network: Partner with global MSATteams and network peers at other

manufacturing sites to share and adopt bestpractices across the network that drive continuous improvement in all technicalaspects of production.
- Serve as a core member of the relevant TechnicalCouncil, provide site contributions to network technology roadmaps, ensurefunding and execution of assigned projects on the respective site level.
- Ensure Right to Operate through compliance withcGMP and regulatory requirements applicable to the department
- Direct areas of responsibility:
    - Validation: Own, execute and improve the validation programfor equipment, processes, and cleaning, and ensure compliance with PQS and HArequirements. Represent Validationprogram during HA inspections.
    - Automation: Own, integrate, maintain and improve allproduction automation platforms at the site, and ensure compliance with PQS andHA requirements.
    - Tech Transfer: Partner with global and site functions tospecify, transfer, file and license new products/processes in the plant.
    - TechnicalServices: Respond to and proactively identify issues,determine root cause, and solve forever: Develop, prioritize and drivecontinuous improvements that reduce safety risks, operational costs, leadtimes, and scrap/discrepancy rates across all aspects of production.
    - ProcessEngineering: Establish oversightto ensure production is performed in conformance with license requirements,cGMPs, and global Health Authority expectations, and represent state ofcompliance during Health Authority inspections.
    - ManufacturingSupport: Provide technical support to manufacturingorganization that includes process and product monitoring, master data anddocumentation management, compliance to Roche quality systems, and otherreadiness operational support activities
    - For specificsites: Pilot Plant Operations: Build andmaintain pilot plant operations to support Make-Assess-Release activities, techtransfers, and continuous improvement of the production plant.

Who You Are

Education

- Bachelors Degree(science or engineering preferred)
- Graduate orhigher-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 pharmaceuticalindustry and/or a cGMP environment
- Extensive experiencewith start-up and validation of manufacturing equipment, utility and processsystems, including requirements for documentation and testing

Knowledge/Skills/Competencies

- Expert knowledge ofcapital projects, project controls, and project scheduling
- Expert knowledge ofclean room or classified area design/requirements
- Deep process,equipment, automation, validation and technical knowledge

*LI-OCN-AE

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.