

Senior, Principal Site Manager (Drug Substance) - Contract Manufacturing Organization

Job ID: 00405032

Job Function

Production & Manufacturing

Schedule

Full-time

Location

United States-
United States

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

Location: San Francisco, CA

Main Purpose of the Position

* Manage the lifecycle of contract manufacturing activities for commercial products at one or more bulk drug substance (DS) third-party contract manufacturing organizations (CMOs), including CMO selection, process technology transfer, routine cGMP manufacturing, and site decommissioning upon completion of the contract.

* Establish and maintain alignment between CMO site business, operational and quality objectives and plans and Roche's commercial and manufacturing strategies and plans.

* Establish and manage business, operations, and quality relationships and communications between Roche and the CMO as the Roche's single point of contact for the contract manufacturing relationship at the Joint Management Committee and Joint Steering Committee levels.

* Build and lead cross-functional teams of technical, quality, regulatory, manufacturing, engineering, supply chain and other subject matter experts to achieve CMO site business,

operational and quality objectives, plans, and performance goals.

- * Provide the single point of accountability for identifying and managing timely resolution of business, operational, and quality issues through the established CMO site governance structure.

- * Manage the performance and development of direct reports as required to achieve organizational and department goals and a productive work environment.

Job Duties/Responsibilities

Contract Manufacturing Lifecycle Management

1. Selection. Build and lead the Roche cross-functional team charged with for identifying, evaluating, and selecting and negotiating a contract with a CMO for bulk contract manufacturing, specifically:

- * Develop CMO selection plan, define contracting manufacturing requirements and evaluation criteria, and identify and screen CMO candidates.

- * Develop Request for Proposals (RFPs), and solicit and evaluate contract manufacturing proposals.

- * Lead due diligence visits, analyze and evaluate CMO proposals, and develop recommendation(s) for CMO selection. Drive decision-making for CMO recommendation through appropriate governance committees.

- * Lead contract negotiations for technology transfer and manufacturing and supply agreements.

2. Implementation. Build and lead the cross-functional team charged with transferring, qualifying, and achieving regulatory licensure the process and analytical technologies ("technology transfers" for manufacturing Roche's DS products at a CMO's manufacturing facility, specifically:

- * Lead the Technology Transfer project for Roche through regulatory licensure of the CMO's facility for routine cGMP manufacturing, including serving as the Leader of the Joint Management Team.

- * Plan and manage the transfer of Roche's DS manufacturing process(es), analytical testing technologies, and supply chain processes to achieve product and process comparability between the donor and receiving sites.

- * Manage the project governance structure, including identifying and managing issue resolution and milestone stage gate reviews.

- * Oversee and manage contractual commitments, obligations, and processes, including milestone dates, financial terms, dispute resolution, and materials and equipment.

3. Site Management. Build and lead the cross-functional team charged with managing contract manufacturing at CMO following regulatory licensure, specifically:

1.1. Business

- * Serve as Roche's Site Manager, actively managing the on-going relationship with CMO to ensure Roche's expectations for product quality, cGMP compliance, costs, and production

targets are clearly understood, well-documented and consistently met.

- * Lead project team meetings and technical operations meetings.
- * Coordinate and manage visits and contact between Roche personnel and the CMO.
- * Establish and maintain a Joint Service Agreement with the CMO that defines roles and responsibilities, business processes, systems and tools, supply chain assumptions and standards, and performance metrics to foster an effective and efficient business relationship.
- * Manage and monitor contractual commitments, obligations, and processes, including milestone dates, financial terms, schedules, materials, and equipment.

1.2. Operations

- * Serve as site Technical Lead, coordinating technical review of process data and proposed facility, equipment, system, or process changes with Roche Subject Matter Experts (SME's).
- * Facilitate issue resolution and problem solving within CMO site, with Roche functional departments supporting Contract Manufacturing, and through the agreed project governance structure as appropriate.
- * Coordinate cross-enterprise forecasting, capacity planning, scheduling, and inventory management processes for critical raw materials and DS.
 - o Coordinate product and raw material shipments to and from Roche or other CMO sites.
 - o Establish production and inventory management planning parameters for the CMO site.
- * Compile and report periodically on CMO performance against plan, including negotiating and monitoring improvement plans with CMO for adverse performance trends.

1.3. Regulatory, Quality, Compliance (RQC)

- * Support Roche's Quality Site Manager to ensure that the CMO complies with the terms and conditions of the Quality Agreement.
- * Participate in Roche's Quality Review Board (QRB) and Change Control Review Board (CRB) for deviations, investigations, and change requests at the CMO site.
- * Coordinate and support Roche's audits and regulatory inspections at the CMO site from planning through implementation, result evaluation and CMO response review. Support inspection readiness activities as required. Provide oversight for CMO close out of audit commitments and CAPAs.
- * Assist with the development of the CMC section of any CMO-related regulatory submissions.

4. Decommissioning. Build and lead the cross-functional team charged with decommissioning a CMO site following either termination or expiration of the manufacturing and supply agreement, specifically:

- * Develop and execute a comprehensive CMO site decommissioning plan in accordance with the contractual agreements between Roche and the CMO, and with Roche procedures.
- * Verify that all Roche and CMO contractual commitments have been met, and that all data, information, documents, software, product, raw materials, samples, materials, equipment

related to the manufacturing process, have either been returned, destroyed, archived, or retained per the contract(s).

Contract Manufacturing Department

- * As required, manage and administer tasks related to Roche's Employee Life Cycle for direct reports, including hiring, orientation, performance management, development planning, reward and recognition, and leaves, promotions, and terminations.
- * Coach and develop staff and/or project team members by providing an environment that encourages personal and professional growth. Manage and encourage staff and/or project team members to set realistic and achievable personal and/or project team goals and provide regularly scheduled feedback throughout the year. As appropriate, provide staff and/or project team members with appropriate opportunities to improve their skills, knowledge, and experience.
- * Establish specific CMO site annual business, operations, and quality goals to support PT and department goals.
- * Identify, develop, lead and/or participate in Class A and operational excellence / continuous improvement programs within Roche to improve cross-enterprise business processes at CMOs, or Roche business processes that support CMO operations.
- * Develop, execute, interpret and provide guidance to internal Roche stakeholders and CMOs on department policies, procedures, and practices.
- * Represent CMO and CMO site operations at Roche internal meetings.
- * Track, monitor, and report performance metrics related to operations, quality, cost, and customer service. Develop and distribute periodic reports on CMO performance, issues, risks, and schedules of key activities, events, or milestones.
- * Conduct and maintain a risk assessment at each stage of the Contract Manufacturing Lifecycle, including developing and implementing appropriate risk mitigation plans.
- * Design and implement periodic partner surveys to identify opportunities to either reinforce or improve the CMO relationship. Identify, plan, and lead any improvement efforts arising from the survey.
- * Develop, monitor, managing, and report on budget (capital and expense) for CMO operations.
- * Be accountable for behaviors described in Roche's Core, Common and Critical Competencies.

Who You Are

Qualifications: Education, Experience, Knowledge and Skills

- * B.S. or B.A. degree in Life Sciences, Physical Sciences, Engineering or related scientific discipline is required. Advanced degree (such as MBA) preferred.
- * 15 years of experience in the biotechnology or pharmaceutical industry.
- * Experience working in a cGMP-regulated environment within the biotechnology and/or pharmaceutical industry, preferably in a protein and/or small molecule process development,

manufacturing, or relevant operations role.

- * Experience with technology transfer of manufacturing process technology.
- * Experience in designing, managing, and leading large technical programs and high-performing cross-functional and/or multi-cultural project teams and individuals, including experience designing, implementing, managing, and improving business processes and/or leading operational excellence initiatives.
- * Experience managing contract manufacturing or other 3rd party client relationships.
- * International business experience is desirable.

Job Specific Requirements

- * Demonstrated interpersonal skills to develop effective working relationships with. Demonstrated interpersonal skills to work effectively with and/or manage internal stakeholders, external business partners and contractors, and cross-functional, cross-cultural project teams across multiple locations.
- * Proven ability to develop and translate supply chain and manufacturing strategy into executable actions and results.
- * Demonstrated leadership and project management skills to effectively and independently plan, manage, and lead large technical programs, personnel, and cross-functional, multi-cultural, cross-enterprise project teams. Motivates and inspires diverse groups to exceptional results without direct authority.
- * Strong track record of soliciting input and applying sound judgment to make timely, fact-based decisions.
- * Demonstrated ability to influence and negotiate win/win solutions both within and across organizations at all levels. Experience in developing, negotiating, and administering contracts, preferably manufacturing or supply chain contracts.
- * Excellent written and oral communication and presentation skills.
- * Strong project management, organization, facilitation, problem solving, quantitative analysis, and financial skills
- * Strong business and functional knowledge of biopharmaceutical and/or pharmaceutical Operations, Process Development, Finance, Supply Chain Management, Regulatory Affairs, Quality Assurance, and Quality Control.
- * Knowledge of cGMP's, FDA/EU regulatory guidelines, validation practices, and other relevant regulatory requirements.
- * Ability to travel domestically and internationally.

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