

Senior Site Manager, Contract Manufacturing

Job ID: 00414057

Job Function

Supply Chain & Procurement

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

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

- Serve as the Site Manager overseeing clinical contract manufacturing organizations (CMOs) or clinical distribution organizations (CDOs) that are needed to meet clinical supply requirements in supporting clinical labeling and packaging.
- Lead and collaborate with cross-functional teams of subject matter experts to achieve business, operations, and quality objectives in addition to performance goals for the contract manufacturing or business partnerships.
- Manage the operational activities of the CMO ensuring program cost, quality, metrics, delivery and technology objectives are met as well as manage the partner performance to achieve them.
- Develop solutions to complex issues with inter-organizational impact.
- Prepare Requests for Proposals (RFPs), Statements of Work (SOW) and negotiate supply agreements for clinical programs.
- Support development and continuous improvement of the supply relationship with IMP CMOs/partners.
- Position may be filled as an E3 or E4 depending on candidate's experience and qualifications.

Responsibilities:

- Responsible for overseeing execution activities of clinical contracting manufacturing

organizations (CMOs) to support labeling and packaging outsourcing activities for clinical studies. Scope is from release of DP at the Filling site through release of Final Packaged Goods at the label/pack site; scheduling and oversight of label/pack execution activities at the label/pack site; and ensuring the necessary DP materials and FG components are available for execution.

- Ensure reliable supplies of Final Packaged Drug Product (including Other Study Drugs as required) to our customers and our patients, while meeting acceptable quality standards and Genentech's financial and development goals. Proactively intercede if goals and timelines are jeopardized.
- Coordinate operational activities with internal cross-functional teams (Clinical Planning, External Quality, Distribution) to ensure on time release of packaged clinical product.
- Participate on cross-functional teams in evaluating and selecting CMOs for a particular project as requested.
- Prepare a Statement of Work (SOW) as required. The preparation of an SOW can include negotiation of project fees, negotiation of milestones, defining responsibilities between Genentech and the CMO and keeping Legal, Procurement and other groups up to date on SOW progress.
- Provide input to the internal CMO/partner SPOC ensuring that the overall relationship between Genentech and the CMO/partner is healthy.
- Develop, maintain and drive key health metrics between GNE and the CMO to ensure effective and continuous improvement of business performance and relationship.
- Participate in Master Service Agreement creation and maintenance as requested so that it accurately reflects the existing business relationship.
- Proactively identify risks. Create strategies to avoid or minimize their impact. Manage the execution of risk mitigation plans. Participate in and contribute to drug development telecons in an effort to proactively intercede if a relationship issue jeopardizes the project.
- Create purchase orders. Review and approve invoices for GNE payment and coordinate on-time CMO payments. Develop annual CMO budget (expense and capital) and monitor performance against plan on an ongoing basis.
- Serve as the manufacturing outsourcing team leader on cross-functional teams as requested in support of clinical finished good packaging.
- Report as needed on performance and operations at Operations Review.
- Support External QA in establishing QA agreements with all CMO's and assuring that Product Specific Requirements (PSR's) are established before projects are initiated.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems.
- International and domestic travel as required.

Requirements:

- Collaborative Leadership - Ability to strongly influence with or without authority, facilitate groups with diverse perspectives, bring teams to consensus/alignment. High tolerance for ambiguity, able to create order from chaos.
- Ownership and Accountability – Takes accountability for actions, drives results, learns from mistakes. Is direct and truthful and therefore widely trusted – delivers on promises, goals, and expectations. Makes quality decisions and resolves problems rapidly.
- Communication - Ability to communicate effectively at all levels of the organization, teach and present complex and/or new ideas with clarity and simplicity.
- Planning/Organization - Excellent planning and prioritization skills with the ability to multitask and adapt. Able to synthesize large amount of information. Able to deliver results despite shifting environment. Operate with a high degree of autonomy.
- Analytical Problem Solving – Ability to identify problems, define problem statement clearly and accurately and apply structured and disciplined methodology to identify data-driven root

causes. Innovative and effective in solution development, risk mitigation, and execution.

- Quality-Is customer focused. Able to mentor team members on quality improvement methodologies (Deming, Juran, Crosby) as appropriate to the situation. Uses quantitative approach (SPC, Six Sigma, Lean/DMAIC, etc.).
- Working knowledge and experience in SAP/ERP.

Who You Are

Education & Experience:

Minimum requirements

- B.S. Life Sciences, Business or Engineering.
- 5+ years or more experience in biotech/pharma industry.
- Clinical Packaging experience is beneficial (small molecule, biologic devices).
- Protein or small molecule manufacturing experience is beneficial.
- Working knowledge and experience of SAP or ERP system.
- Dexterity with presentation and spreadsheet tools.
- Demonstrated or developing ability to lead/direct a team.
- Demonstrated project management and financial skills.
- Collaboration/Influence Management, Decision Making, Leadership and Results Orientation.
- Ability to work effectively with cross-functional & multi location teams.
- Demonstrated track record of integrity and ability to instill confidence in colleagues and teams.
- Ability to learn quickly in unfamiliar territory and under minimal managerial training.
- Demonstrated ability to operate independently under general management direction and make sound decisions and be accountable for those decisions.
- Successful track record in execution and completion of deliverables. Changes in plans and updates are proactively communicated to management and teams.
- Strong analytical and creative problem solving skills.
- Strong quality orientation with attention to detail.
- Effective communicator at all levels; excellent written, oral and interpersonal communications and presentation skills.

Genentech is an Equal Opportunity Employer.