

Global Head Information Business Management

Job ID: 00414343

Job Function

Clinical Regulatory Affairs

Schedule

Full-time

Location

United States-California
South San Francisco

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Manager with Direct Reports

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

Regulatory Technology is part of the broader PDR organization that interprets the needs of worldwide health authorities and provides regulatory intelligence necessary to generate and present information that meets the needs of health authorities, patients, purchasers and prescribers for Roche's global Pharma Medicines Division, which includes all therapeutic areas and all phases of product development from early development to post-marketing. PDR is responsible for the timely submission of applications to health authorities for approval of new products and line extensions. PDR is committed to regulatory strategies that are the most innovative, ethical, and influential in the industry. Regulatory Technology Directors and their staff are assigned their responsibilities by varying PDR systems projects and systems maintenance support, as business needs dictate. Associate Directors typically have direct and indirect reports and oversee and guide Regulatory Technology management and staff in user needs analysis and requirements gathering, PDR systems project definition, development and implementation, and process design/redesign to support best-in-class PDR operations and compliance. Associate Directors may lead the site and/or regional Regulatory Technology management team and are standing members in the site and/or regional Regulatory Technology Leadership Team. Associate Directors may also have additional responsibilities, as assigned, to perform the role of Site Lead for the assigned function or cross-functionally for PDR. Associate Directors, by comparison to Directors, are either new to the director-level position, or assigned smaller and/or less complex business areas to support.

JOB DESCRIPTION- PRIMARY DUTIES AND RESPONSIBILITIES

1. Cross-Functional Teams

- Is a standing member of the site and/or regional Regulatory Technology Leadership Team
- May lead the site or regional Regulatory Technology management team. Drives best practices and operational excellence within the department and cross-functionally and ensures timely communication and information dissemination across the department and beyond
- As needed, ensures appropriate appointment of staff members as ad hoc members in Regulatory Affairs Functional Teams (RAFT); driving and ensuring effective and efficient support for cross-functional PDR coordination, appropriate resources, and timely, thorough and compliant execution
- As assigned, self and staff may act as standing or ad hoc members of other teams for special or ongoing initiatives and projects

2. Staff Leadership & Development

- Develops and manages annual and/or longer-range departmental budgets and resource plans
- Tracks departmental expense budgets to ensure compliance with agreed parameters
- Where applicable, self and team may participate in the negotiation with and commissioning of external vendor partners to support the work of Regulatory Technology
- Accountable for appropriate resourcing decisions for assigned Regulatory Technology function and staff
- Cascades strategic and other relevant goals and objectives as well as budget and other resources to direct reports
- Leads recruitment, hiring and on-boarding for his/her staff member positions. May include, as needed, short-term contract personnel
- Plays a lead role in creating and maintaining a positive work environment by encouraging mutual respect, innovation and accountability at all levels (global, site, functional, projects/programs)
- Ensures that performance of assigned Regulatory Technology management and staff is proactively managed and that management and staff are appropriately trained, developed and coached to maximize their contribution and ensure compliance with Roche and regulatory guidelines and standards. Accountable to ensure assigned management and staff consistently complete their deliverables and other responsibilities on-time, on-target and within-budget
- Conducts ongoing performance management and completes the required steps of Roche's performance management process and cycle. Includes individual development plans/career discussions and actively contributing to performance calibration, talent management and succession planning processes
- Actively participates in management and skill development programs for continued professional development
- Leads routine and ad hoc meetings with assigned Regulatory Technology management and staff
- Identifies, recommends, assigns or otherwise undertakes special projects that further the success and effectiveness of Regulatory Technology and/or PDR overall
- As needed or otherwise appropriate, acts as a substitute for his/her manager in various meetings, communications or other forums
- Consistently complies with all governing laws, regulations, Roche Standard Operating Procedures (SOPs), company HR policies & procedures and other guidelines and

ensures the same across his/her staff

3. Regulatory Technology

- Stays abreast of internal and external developments, trends and other dynamics relevant to the work of PD and PDR to maintain, at all times, a fully current view and perspective of internal/external influences and/or implications for Roche therapeutic areas and product development projects. Develops his/her knowledge base of relevant Roche policies, procedures, laws, regulations and guidelines governing the development, licensure and marketing of drugs and biologics. Ensures the same across assigned management and staff
- Ensures management and staff obtain and consistently apply knowledge of Roche and regulatory guidelines, procedures and best practices to their work
- Plays a lead role in annual and longer-term development of site, regional and/or global Regulatory Technology's vision, strategy, goals, objectives and infrastructure
- As needed, helps his/her staff and cross-functional stakeholders obtain the required resources for multiple projects and other assignments
- Maintains consistent oversight of deliverables across his/her staff. Ensures issues are escalated when needed and encourages resolution at the lowest possible level
- As needed, ensures staff members provide regulatory technology expertise to cross-functional teams and other groups
- Oversees and guides staff members and other cross-functional PDR teams in identifying and scoping new or updated technology requirements to support effective, efficient and compliant PDR cross-functional operations and work
- Oversees and guides user needs analysis and requirements gathering
- Ensures staff members work effectively with internal Informatics departments and teams to identify internal systems or other technology tools for potential leverage, as well as systems interface and other cross-functional requirements
- Ensures staff members appropriately identify, recommend and document new or updated business processes necessary for alignment to updated or new PDR systems and/or other technology-related tools
- Oversees and guides writing/updating of Regulatory Technology SOPs or Department Operating Procedures (DOPs). Includes providing feedback on global SOPs and, where assigned, acting as members of global committees or other relevant taskforces
- Ensures staff members develop, recommend, obtain approvals for and implement appropriate project plans for each of their PDR Technology projects
- Oversees and guides, as needed, user accept testing for new or updated PDR technologies
- Oversees technology or related project budgets and is accountable to ensure compliance with agreed parameters. Oversees and monitors routine and ad hoc budget reporting and other updates
- Accountable to ensure PDR Technology projects are completed on-time, on-target and within-budget
- Ensures staff members regularly communicate project status and milestones to relevant PDR and other stakeholders and partners
- As assigned, oversees and guides systems administrator support, including user set-up and configuration, data entry, reporting and training for PDR applications, databases and other systems and technology-related tools. Includes Regulatory Technology support in development of PDR new-hire processes and documentation
- As assigned, oversees and guides installation, configuration and troubleshooting for computers and other technology-related tools for PDR management and staff
- As assigned, oversees and guides project systems administration for product development projects; includes tracking and reporting on milestones and other key

activities

- As assigned, oversees and guides PDR systems, applications, database and other technology maintenance, including back-up services for PDR systems, applications, databases, desktops, laptops, etc.

4. Other

- Self and staff routinely monitor site, regional and/or global departmental practices, processes, and procedures to ensure ongoing effectiveness, efficiencies, scalability and sustainability. As appropriate, identifies and recommends opportunities to streamline or otherwise improve
- Oversees and/or otherwise completes other routine and ad hoc analysis and reporting. Accountable to ensure staff members keep all internal customers, partners and stakeholders abreast of progress and interim updates
- Proactively manages key partners and stakeholders at the site, regional and global levels through effective, ongoing communications
- May be assigned a role as Site Lead for Regulatory Technology or other PDR functions, which likely entails some or all of the following additional responsibilities:
- Acting as an alternate contact for staff not co-located with functional management for items normally managed through functional management
- Contributing to performance management and development plans
- Facilitating/ensuring that local staff are receiving consistent and accurate communications, announcements and updates. As appropriate, ensures functional management is made aware of differing or unique site communications
- As needed, conducts 1:1 meetings with local staff
- Approves local staff expenses in accordance with local budget practices and guidelines
- Manages local processes to ensure local staff receive training and other development support

Who You Are

Candidates for this position should hold the following qualifications, have the following experience, and be able to demonstrate the following abilities to be considered as a suitable applicant. Please note that except where specified as “preferred,” or as a “plus,” all points listed below are considered minimum requirements.

QUALIFICATIONS & EXPERIENCE:

- Bachelors Degree required (computer sciences, business or life sciences disciplines are preferred)
- Average of 10 or more years relevant information technology experience, at least some of which was gained in the pharmaceutical/biotechnology industry
- Some experience in regulatory affairs or related product development functions, including experience supporting regulatory groups with operations and regulatory submission processes is strongly preferred
- Average of 2 or more years previous people management experience. Experience managing teams across widely distributed geographic areas is a plus
- Proven expertise in budget, resource and project planning and management
- Some understanding of international regulations, processes and issues in drug/biologics development. Includes GxP (Good Practices for quality guidelines and practices in the pharmaceutical/biotechnology or related industry), GCP (Good Clinical Practice), ICH (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use), FDA, EMEA, NICE and other

- relevant guidelines, particularly as these relate to health authority policies and software standards for electronic and non-electronic regulatory submissions
- Extensive experience with implementation, training and administration for a variety of corporate and desktop applications
 - Demonstrated programming capabilities to develop and support databases and perform modifications to departmental systems and applications
 - Experience participating in and/or otherwise supporting global product development or other cross-functional teams
 - Fluent English and other language skills as needed

ABILITIES:

- Has impeccable ethics. Demonstrates, or has proven abilities to demonstrate, Roche Values & Leadership Competencies
- Outstanding attention-to-detail
- Has proven abilities to effectively lead and manage management and staff across multiple projects and teams. Has strong cross-functional team leadership skills
- Can build vision and strategy and lead others in the accomplishment of such
- Regarded as a subject matter expert
- Strong business acumen: has in-depth knowledge of the pharmaceutical/biotechnology industry, the multiple functions and roles involved in the product development process
- Outstanding time management and organizational skills: proven abilities to manage multiple, often complex and sometimes competing, objectives, goals and priorities to effective and efficient conclusion
- Outstanding interpersonal skills: proven track record of building strong and sustainable relationships with internal and external partners and stakeholders
- Outstanding written communication skills
- Comfort around all levels of management; has demonstrated managerial courage in past positions and responsibilities
- Strong influencing skills: proven abilities to get things done without formal authority
- Strong negotiation skills: is highly adept at identifying solutions that will meet the needs of all involved parties
- Strong communication and presentation skills: exhibits professional maturity, confidence and competence. Knows how to summarize and communicate the key points and business case for others to effectively and expeditiously make important business decisions
- Proven track record of effective decision-making: makes good business decisions and exercises sound judgment. Consistently and effectively balances decisions with imperatives for ethics and efficacy
- Outstanding orientation to teamwork: works collaboratively, effectively and efficiently with others internally and externally
- Strong conflict resolution skills: proven abilities to effectively and expeditiously reach satisfactory resolution among all involved parties
- Strong financial acumen: proven abilities for planning, development and oversight of operating budgets and other resources
- Ability to travel (<20%)

Genentech is an Equal Opportunity Employer.