Genentech
A Member of the Roche Group

Date: 10/18/19

Snr Quality & Compliance Mgr

Job ID: 201910-130161

Job Function
General Regulatory Affairs

Location
South San Francisco
California
United States of America

Company/Division
Pharmaceuticals

Schedule
Full time

Job type
Regular

Job Level
Individual contributor

The Position

Description:

This position serves as an important conduit to the broader organization to ensure a culture of compliance through well-thought out, actionable, aligned and achievable related processes and procedures. Given the nature of the group's work, the incumbent will communicate and interface with a host of internal cross-functional partners, both within gRED and other Roche functions, identifying areas for improvement and ensuring compliance with current regulatory policy, legislation and guidance.

Responsibilities:

- Partner with other departments interacting with Global & Regional functions including, but not limited to: Drug Safety, Quality Assurance/ Risk Management, PD Clinical Operations, Healthcare Law, Corporate Group & Risk Advisory, Medical Affairs to ensure appropriate cross-functional SOPs, Policies or Work Instructions are in place.
- Collaborate with Genentech Early Clinical Development (ECD), Quality and Compliance Office (QCO) on the implementation and maintenance of the Functional Quality Management System (QMS) and its related documents, in alliance with the Quality principles outlined in the Global Roche GCP /GVP Quality Manual.
- Provide expertise and consultative guidance on business initiatives involving systems, processes, procedures, regulations and tools intended for use in clinical trial conduct and/or regulated drug development activities.
- Serve as a key contact for communicating controlled document and policy changes within/across gRED organization.
- Serve as a consultant to management and act as an internal/external spokesperson for the organization on matters pertaining to policies, quality plans, objectives and business goals.

- Proactively research, evaluate and make recommendations associated with evolving laws and regulations. Benchmarks and stays abreast of other industry and marketplace developments and best practices.
- Contributes to annual QCO goals and objectives and contributes to ongoing continuous improvement.
- Effectively integrates compliance risk/context and business knowledge to address unusually complex problems. Keeps current in the area of healthcare compliance, GCP, GVP, company policy and procedures.
- Proactively identifies and addresses compliance issues and risks.
- Recommends and drafts new or amended policies & SOPs in support of regulatory policy, law and regulations while specifying actual or potential implications to existing business operations, procedures and practices.
- Independently leads and/or participates, without appreciable direction, on internal committees as a decision-maker or is lead reviewer in a complex process.
- Acts as a point-of-contact for ECD/gRED policies, SOPs and audits. Responds to inquiries from within and across the organization and may participate as the department's representative in cross-functional committees.
- Prepares regular reports for management and cross functional teams.
- As assigned, assists with other department duties and/or projects.
- Where applicable, manages outside vendors to ensure on-time, on-target and within-budget deliverables

Qualifications:

- 12 - 15 Years with Bachelor's degree of medicine/pharmacy/other healthcare disciplines.
- 10 - 13 Years with Masters experience in pharmaceutical drug development, preferably in regulatory compliance and/or quality responsibilities within a drug development organization.

Skills:

- Has impeccable ethics. Demonstrates, or has proven abilities to demonstrate, Roche Values & Leadership Commitments
- Strong influencing skills: proven track record and experience building and cultivating relationships with key partners and stakeholders across organizational levels
- Strong negotiation skills: can effectively drive discussions and decisions toward desired end-results
- Strong verbal and written business communication skills: highly adept at synthesizing and summarizing complex and/or voluminous content into clear, concise and actionable communications
- Strong process-orientation: has proven effectiveness in identifying, developing and implementing scalable/sustainable process and other continuous improvements to achieve organizational efficiencies and increase effectiveness
- Exercises sound and independent judgment in methods, techniques and evaluation criteria for obtaining results.
- Highly self-motivated, well organized, and able to develop alternative solutions to issues.
- Thinks "outside of the box" for solutions. Applies creative problem-solving and appropriate business solutions to effectively address compliance risk.
- Excellent project management skills: can prioritize multiple tasks and goals to ensure timely, on-target and within-budget accomplishment of such.
- Strong business acumen: understands how the business "works" and demonstrates consistently effective "navigation" across the organization

- Desirable, but not required: Development of Systems/SOPs for an R&D Organization, experience in implementation of new processes, proven success facilitating change within a complex organization.
- Working knowledge of GCP/ICH and QA issues within a global pharmaceutical organization.
- Basic understanding of numerous clinical development functional areas.
- Ability to travel

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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.