

Sr. Clinical QA Specialist

Job ID: 00413584

Job Function

Quality Assurance

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

Summary:

This position serves as an important conduit within the broader organization to ensure a culture of compliance through well-thought out, actionable, aligned and achievable compliance related processes. Given the nature of the group's work, incumbent will communicate and interface with a host of internal cross-functional partners, both within gRED and other Roche functions; identifying key performance indicators, areas for improvement and ensuring compliance with current regulatory policy, legislation and guidance. The Quality Specialist will actively contribute to the development and implementation of Standard Operating Process / Procedures, tools, and templates for application in clinical research and provide and interpretative guidance of such within Clinical Operations and the broader gRED community.

This is achieved through:

- Proactively identify and manage changes in controlled processes and procedures as the organization evolves, industry practices change and/or regulations change to assure high quality standards with applicable laws, regulations, guidelines and Roche

policies.

- Working collaboratively with all internal and external business partners and key stakeholders to assess clinical business systems and processes and provide input on any unique business requirements utilizing strong interpersonal, influencing, and negotiating skills.
- Identifying and anticipating potential problems impacting the ability to meet business goals; developing and implementing methods of improvement and resolution in a pragmatic and effective manner.
- Staying abreast of relevant laws and regulations that affect organizational quality and ability to remain in a state of regulatory compliance
- Proactively communicating and educating others regarding such laws and regulations

Key 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.
- Facilitate SME involvement and partner with global and cross functional teams in the development, review and implementation new/updated controlled documents (Policy/SOP)
- Serve as a key contact for communicating controlled document and policy changes within/across the gRED organization
- Provide direction, and guidance to study teams to address quality issues, concerns and or potential regulatory compliance risks
- Participate in the development and execution of GCP, SOP or Policy related training
- Provide support and guidance during and following internal audits and external regulatory inspections (as required).
- Provide consultative guidance on business initiatives involving new systems, processes, procedures, regulations and innovative tools for use in clinical research activities.
- Facilitate the process of continuous process improvement and support internal and global cross functional initiatives by analyzing “to be” processes; forms, templates and related process documents to ensure alignment, accuracy, and adherence to relevant internal/country/local legal and regulatory requirements.
- Liaise with internal stakeholders and global quality partners to ensure strategic quality risk assessments are completed and provide oversight to gRED management and personnel on contracted service providers to ensure services meet business needs (quality deliverables and alignment to regulatory requirements)
- In partnership PD Quality, identify, interpret, and disseminate quality and compliance related trends, expectations and compliance requirements to leadership and

respective governance bodies.

- Challenge inefficient processes and leverage compliance and maintain highest levels of awareness, expertise in international GxP regulatory requirements, and project-specific procedures applicable to the clinical trial methodology
- Serve as consultant to management and internal/external spokesperson for the organization on matters pertaining to its policies, quality plans, objectives and business goals
- Provide regular updates to senior management functions and participate in the resolution of quality issues by fostering effective interdepartmental and cross-functional relationships

* Perform any other tasks as requested by Management to support quality oversight activities.

Who You Are

Education, Experience, and Other Requirements:

- **Bachelor degree of medicine/pharmacy/other healthcare disciplines with minimum of 8 - 11 Years/6 - 9 Years with Masters in pharmaceutical drug development, preferably in regulatory compliance and/or quality responsibilities within a clinical operations 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. Must be able to work independently majority of the time, ability to prioritize, identify conflicts and meet deadlines.**
- **Requires project management skills including team leadership, consultative facilitation, risk analysis, and project planning; strong interpersonal and communication skills**
- **Ability to influence people at different levels in a matrix organization and assist integration across locations and functions and.**
- **Aptitude to apply advanced theoretical knowledge and contributes to the development of new principles and concepts to independently address unusually complex problems.**
- **Exercises sound and independent judgment in methods, techniques and evaluation criteria for obtaining results**
- **Strong project management skills and computer literacy in MS Word, Excel, Project, Visio and PowerPoint.**
- **Highly self-motivated, well organized, and able to develop alternative solutions**

to issues.

- **Excellent Communication Skills**
- - **Listening, interpreting and summarizing information**
 - **Clear and concise verbal communication**
 - **Professional and concise written communications –exceptional attention to detail required**

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