

Compliance Specialist

Job ID: 00410667

Job Function

Quality

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

Independently lead/participate on GMP compliance audits and identify GMP compliance gaps or risks.

Provide GMP compliance expertise to internal and external customers.

Perform tasks and work to achieve company goals and organizational objectives.

- Follow company policies and procedures.
- Set personal performance goals and provide input to departmental objectives.
- Establish work priorities to meet targets and timelines.
- Manage competing priorities and allocate, adjust, and optimize assigned department

resources.

- Serve as the Quality representative on cross-functional and multi-site teams.
- Identify, design, and implement process and system improvements.
- Manage department and cross-functional initiatives.
- Apply advanced theory, technical principles, expert judgment, and cross-functional expertise to independently address a broad range of complex problems.
- Troubleshoot and direct the resolution of Quality issues by fostering effective interdepartmental and cross-functional partnerships.
- Serve as a technical subject matter expert (SME) in support of department functions.
- Develop and train personnel and internal customers on relevant business processes.
- Mentor junior personnel serving as a subject matter expert (SME) on Quality systems, processes and issues.
- Collaborate and author department policies and procedures.
- Make decisions that impact the goals and objectives of the department.
- Notify Management of potential quality or regulatory issues that may affect product quality or regulatory compliance.
- Sign documents for activities as authorized and described by Genentech policies, procedures and job descriptions.
- Be accountable for behaviors as described in Genentech's Core, Common, and Critical Competencies.
- Perform any other tasks as requested by Management to support Quality oversight activities.
- Participates in audits. Lead audits. Can develop audit findings that address individual gaps and system gaps. Can lead all "low risk" and most "high risk" area audits. Can participate on all high risk audits. Report requires little or no input from manager. May be asked to participate in meetings post audit to discuss unresolved issues with Senior Management.
- Identifies gaps in corporate practices, policies and procedures and prioritizes based on current regulatory environment, guides and regulations. Leads teams to remediate or defend identified risks. Works with customers to develop CAPs and CAs for identified audit findings. Presents information on outcomes to Sr. Management.
- Will be assigned compliance opinions. Needs no guidance from manager on resources / references. Opinion has depth and breadth and requires little or no input from Manager / review team.
- Identifies gaps in corporate practices, policies and procedures. Leads efforts to remediate gaps. Write and or participate in corporate document development.
- Participates in response development to regulatory inspection observations. Author

responses if assigned. Acts as a SME for GMPC.

- Participates in FDA Meetings. Acts as a SME for GMPC.
- Participate as a GMPC representative in team meetings. Is a SME on compliance issues. Independently raises compliance issues with the team. Provides input on issues discussed informing manager of resolution. Communicates issues to manager as necessary.
- Leads mock PAIs
- Attends meetings, conferences and workshops benchmarking industry activities
- Reviews FD-483 observations, EIRs, audit findings to identify corporate issues.
- Independently reviews and comments on regulatory agency draft documents. May lead team to formulate GNE positions.

Who You Are

Sound knowledge of cGMPs or equivalent regulations

Ability to interpret and relate Quality standards for implementation and review

Ability to make sound decisions about scheduling, allocation of resources, and managing priorities

Ability to communicate clearly and professionally both in writing and verbally

Flexibility in problem solving, providing direction and work hours to meet business objectives

Expert knowledge of GMPs/QSRs and other relevant compendia. Able to interpret and apply to GNE operations.

Virtually self-supervised. Manages projects and works with management to obtain resourcing.

Interacts primarily with co-workers, supervisor, internal and external stakeholders and management. Leads interactions with senior management and internal and external customers to negotiate actions and leads teams.

Bachelors/Masters degree or above preferably in a scientific discipline

10+ years working in a regulated GMP/QSR environment

Genentech is an Equal Opportunity Employer.