

Team Leader CSV Auditing

Job ID: 00408820

Job Function

Development

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

Job Purpose:

The Team Lead for CSV auditors in PDQA is responsible for recruitment, management and leadership of department audit staff. Through their leadership and direction, they ensure consistent implementation of PDQA processes and procedures and execution of the audit strategy related to Computer System Validation

Primary Responsibilities and Accountabilities:

- Provide leadership and direction to the PDQA CSV audit team in the execution of the department strategy
 - Recruit, manage, train and develop staff
 - Motivates and manages team members through setting of individual goals, provides on-going feedback and performance evaluations
 - Oversee staff expenditures
 - Collaborate with other Team Leaders to resource and manage the audit program in line with PDQA Strategy
 - Manage resources according to department strategy
 - Review staff deliverables (audit plans, audit reports, quality plans, etc)

- May participate on audits as necessary (staff evaluations)
- Contribute to the development and execution of PDQA goals and initiatives
 - Participate in or lead departmental or cross-functional compliance projects and initiatives as assigned
 - Assists and/or contributes to the development and/or revision of PDQA SOPs, guidelines and tools
- Supports Head of CSV Strategy and TL, Validation Analysts to establish and implement global CSV strategy, goals and objectives for team
 - Participates on IT/CSV projects and task forces to provide quality management oversight
- Ensure consistent execution of PDQA strategy, processes and procedures
 - Oversee execution of department strategy, processes and procedures
 - Provide CSV compliance advice to staff
 - Ensure audits are conducted and reported in compliance with departments procedures
 - Support regulatory authority inspections
 - Escalate compliance issues/risks to PDQA Management
- Maintain knowledge of HR Corporate policies and procedures
- Maintain knowledge of current regulatory, GCP, GLP, CSV and/or PV regulations and guidelines and company policies, SOPs and procedure

Who You Are

Education/Qualifications:

- Bachelor's degree or equivalent in scientific or quality-related field or equivalent combination of education, training and experience.
- Advanced degree in referenced fields preferred.

Minimum:

- Minimum 7 years in pharmaceutical industry and/or quality assurance
- Minimum 5 years in CSV Quality Assurance role (auditing)
- Practical experience of supervisory/management of staff
- Demonstrated knowledge of GCP, GLP, CSV, pharmacovigilance / drug safety and regulatory requirements, as well as analytical, organizational and planning skills.

Desired:

Experience in support regulatory authority inspections

Experience, Skills, Knowledge:

People management

Demonstrated ability to effectively communicate, influence and lead both with and without

authority.

Highly effective teamwork and collaboration skills.

Global team leadership.

Proven demonstration of leadership, strategic and system thinking

- Ability to work effectively in an international multicultural matrix organization.
- Effective communication and customer management skills.
- Fluency in written and spoken English
- Demonstrated knowledge of product development related global regulatory requirements

Other (e.g. Travel):

- Travel: up to 20%

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