

For more than 30 years, Genentech has been at the forefront of the biotechnology industry, using human genetic information to develop novel medicines for serious and life-threatening diseases. Today, Genentech is among the world's leading biotech companies, with multiple therapies on the market for cancer and other serious medical conditions. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset.

The following opportunity exists in our South San Francisco, CA, headquarters:

Senior QA Specialist

Responsibilities:

The candidate will independently participate in cross-functional teams providing GCP/GLP guidance and risk based options during meetings. The incumbent will provide a review of study documents (e.g. protocols, system validation reports, final study reports) and check documents for consistency and acceptable standards and practices. He/she will be a "go to" person and provide technical excellence in all Development QA programs (Procedures, Assessments, Cross functional Teams). The position will independently collaborate and facilitate meetings with specific functional groups providing guidance on SOPs (i.e. content, quality, SOP lifecycle), identifying gaps, addressing any documentation need, conducting process mapping sessions, impacting the process map/flow and suggesting process improvements. He/she will take initiative in completing the improvement. The position independently represents DevQA on Development initiatives (cross-functional teams) applying solid knowledge of internal processes, procedures and regulations.

The incumbent will develop appropriate assessment tools. He/she will plan, schedule and conduct assessments as well as analyze reports, trends and data findings. A key responsibility is to provide support during regulatory inspections and internal functional group audits. He/she will conduct brown bag sessions as well as identify and develop future brown bag topics in consultation with the management team. The position is responsible for effectively coaching junior staff in the areas of regulations and documentation. The candidate will take initiative to identify areas for process improvement and engage in assuming new responsibilities. The incumbent will provide the application of industry guidance and best practices regarding the validation and documentation of computer systems (e.g., GAMP, Computer Systems Used in Clinical Investigations). The position will review SDLC documents used in the validation of GCP/GLP systems (includes IVRS and EDC user acceptance tests). He/she must conduct Good Documentation Practice training for IVRS and EDC User Acceptance testing. The position will perform reviews of SAS data used in Clinical Study Reports and discuss issues found with DevQA review lead or Statistical Programmer analyst. Additionally, the position will perform assessment of computer systems used in Development. The incumbent will identify the impact of intended system use to data integrity and propose procedural controls to mitigate risks. This position will collaborate with functional groups to identify computer systems compliance issues pertaining to regulated systems used within Development as well as systems used at the investigator sites. He/she will provide

risk-based recommendation and be able to influence business process owner to take action for mitigating risks. The incumbent will participate in the selection process for vendor supplied systems used in GxP by attending vendor presentations and providing feedback to the system owner.

Requirements:

This position requires a Bachelor's degree or equivalent in scientific or quality-related field or equivalent combination of education, training and experience or equivalent transferable experience, as well as ten years of GCP/GLP experience in pharmaceutical or biotechnology industry; with at least seven out of ten years in QA arena, or equivalent transferable experience. The applicant must have an advanced understanding and first hand knowledge of drug development, study design, data and trials management systems, procedures and documentation practices. The candidate must possess an expert-level knowledge of GCP/GLP regulations. A solid understanding and application of Development SOPs, departmental controlled documents and GCP and regulations is key to this position.

Genentech is dedicated to fostering an environment that is inclusive and encourages diversity of thought, style, skills and perspective. To learn more about our current opportunities, please visit: <http://careers.gene.com> and reference **Req. # 1000021842**. Please use "Web-XXXX" when a "source" is requested. Genentech is an Equal Opportunity Employer.