

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:

QA Specialist III-GLP Archivist

Responsibilities:

This role provides primary impact through successful contribution, active participation and identification of gaps. He/she will be generally supervised or coached on moderately complex projects. The individual will be responsible for the development of systems to track and manage records and data generated in support of Genentech's non-clinical studies (GLP) as required by FDA regulations, 21 CFR Part 58. The incumbent will manage the Non-Clinical Master Study Schedule. The position will establish and maintain archive systems for GLP study records and materials. He/she will partner with internal functional groups to: identify and track disposition of GLP Study documents and materials with internal groups, CRO Archivists and appropriate service providers; identify and assist in the development of internal QC procedures and tools for the management of records and data generated at Genentech; and independently participate in cross-functional teams providing GCP/GLP guidance and risk based options. The position will review study documents and check documents for consistency and acceptable standards and practices. The incumbent will develop a solid understanding of Development SOPs, departmental controlled documents and GCPs and regulations.

He/she will independently collaborate with specific functional groups providing guidance on SOPs (i.e. content, quality, SOP lifecycle) and address any documentation need. The position will build a solid understanding of Electronic Document Management Systems (EDMS). The incumbent will participate in development of assessment tools. The position will provide support during regulatory inspections and internal functional group audits. He/she will assist in researching, coordinating, delivering and arranging logistics for brown bag participation. The position is required to participate in System Review/Validation activities as needed.

Requirements:

The candidate must have a Bachelor's degree or equivalent in scientific or quality-related fields or equivalent combination of education, training and experience, as well as four years of GCP/GLP experience in pharmaceutical or biotechnology industry with at least

two out of four years in QA arena, or equivalent transferable experience. The applicant must have a solid understanding of and first hand knowledge of drug development, study design, data and trials management systems, procedures and documentation practices. A working knowledge of GCP/GLP regulations is required. The ideal candidate will have knowledge in records management principles (electronic and paper based).

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. # 1000022329**. Please use "Web – XXXX" when a "source" is requested. Genentech is an Equal Opportunity Employer.