Quality Associate I, II, III, Senior

Salary and title commensurate with experience.

Job Site: Zalgen Labs – *In vitro* Diagnostics Division, Aurora, Colorado, USA

Position Summary:

Zalgen Labs is seeking highly motivated applicants with an entrepreneurial spirit for our *in vitro* diagnostics and immune-therapeutics development programs. We are seeking qualified candidates with a degree in the Biological Sciences, Biochemistry, or related field and direct experience with Quality Management Systems in the Medical Device or Pharmaceutical Industry. This is an excellent opportunity to gain valuable experience with an innovative Biotech company and build a career in the biopharmaceutical industry.

Qualifications:

Qualified applicants should have an undergraduate degree (B.Sc.) or higher in the biological sciences, biochemistry or related field and a minimum of 2 years of full-time experience in the areas relevant to this position. Work experience in GLP/GMP/ISO environment is expected. Qualified applicants should possess detailed knowledge (commensurate with years of experience) in Quality Management Systems (QMS), Quality System Regulations (QSR), and product manufacturing following Good Manufacturing Practices (cGMP).

Relevant experience with FDA, EU, and ISO regulations is required (e.g. ISO 13485:2016, IVDD 98/79/EC, and 21CFR820) including Design Control regulations. Technical writing experience of SOP, work instructions and management of document control system is expected. Analysis quality metrics and quality trending is highly desirable. Quality system reviews and auditing including CAPA and vendor audits are desirable. Computer skills include proficiency in MS Office (Word, Excel, PowerPoint), statistical analysis (GraphPad Prizm, JMP, R), and database management (MS Access). Higher level candidates are expected to have experience conducting quality system audits for management and regulatory review. Knowledge of regulatory submission and product licensing procedures in domestic and global markets (US FDA, CE IVDD) is desirable.

Candidates should feel comfortable working in a high risk/potential high reward environment and able to work flexible schedule as project needs are determined. Excellent organization skills, attention to detail, and ability to communicate the quality and regulatory position and requirements to management, regulatory authorities, and authorized representatives are essential. Short term travel may be required occasionally.

Benefits:

Zalgen Labs offers a competitive salary and benefits plan including health insurance (medical, dental & prescription), 401k, Flexible Spending Account, time away from the office based on the Federal Holiday schedule plus two (2) weeks paid vacation per calendar year.