QUALITY ASSURANCE SPECIALIST, LABORATORY SERVICES

Company Description

CTI Clinical Trial and Consulting Services is a global, privately held, full-service contract research organization (CRO), delivering a complete spectrum of clinical trial and consulting services throughout the lifecycle of development, from concept to commercialization. CTI's focused therapeutic approach provides pharmaceutical, biotechnology, and medical device firms with clinical and disease area expertise in rare diseases, regenerative medicine/gene therapy, immunology, transplantation, nephrology, hematology/oncology, neurology, infectious diseases, hepatology, cardiopulmonary, and pediatric populations. CTI also offers a fully integrated multi-specialty clinical research site that conducts phase I-IV trials. CTI has a passion for helping life-changing therapies succeed in chronically and critically ill patient populations. With clinical trial experience across 6 continents, CTI partners with research sites, patients, and sponsors to fulfill unmet medical needs. CTI is headquartered in Cincinnati, OH, with operations across North America, Europe, Latin America, and Asia-Pacific. For more information visit www.ctifacts.com

Information

Deadline: 2022-06-30
Country: Basque Country
Category: Business
City: Bilbao
Province: Bizkaia

Company

CTI - Dynakin

Main functions, requisites & benefits

Main functions

Author, review and maintain Standard Operating Procedures (SOP) for the laboratory. Provide training and guidance regarding quality and regulatory compliance for laboratory staff. Participate and support Risk Assessments within the Quality Management System to continuously improve processes Participate in outside qualification audits for vendors supplying services or products, subcontractors, including contract laboratories; resolve and follow-through on any quality issues Conduct in-study and facility-based audits, including equipment/instrument qualifications, equipment calibration and maintenance, software validation and laboratory processes in compliance with QA SOPs. Conduct reviews of protocols, final reports and contributing scientists reports, when applicable. Effectively report quality issues to supervisor, and CTI Laboratory management, as appropriate. Provide input for process investigations, nonconforming quality events, client concerns and the associated CAPA plans. Support quality-led sponsor audits Support inspections and help ensure laboratory maintains current federal, state, and local licensure and accreditation (as applicable) Support regulatory authority inspections Maintain properly indexed quality assurance records. Assure all QA records are up-to-date and accurate and compile the appropriate records for archiving. Attend pre-initiation, pre-planning, or operational team meetings as needed. Participate in quality projects as assigned Promote strong relationships with CTI sponsors.

Requisites

2 years of related experience in a clinical laboratory in a Quality Assurance role Bachelor's Degree or equivalent combination of education and experience Working knowledge of clinical laboratory regulations (e.g. CAP/CLIA), ISO 15189, and licensing requirements Working knowledge of instrument/equipment qualification, calibration, and software validation Working knowledge of quality assurance GLP GCLP best practices Knowledgeable with electronic data collection systems used in data generation, including proper use, reporting, audit trails, security/Part 11 compliance, data correction, QC, etc. Must possess excellent analytical, critical thinking, oral and written skills Well organized and ability to meet deadlines Ability to work independently and within a team environment High level of attention to detail Proficient in MS Excel, Word, Outlook, and PowerPoint CLIA and/or CAP laboratory inspection experience SQA, CQA or other quality related certification

Benefits

Great work environment Meal allowance Health Insurance Life Insurance