tataabiocenter

Head of Quality Assurance

TATAA is a fast-growing company with two decades of history and is recently backed by a life sciences investment firm. The company is comprised of a team of scientists providing laboratory services, products and education / training services across a broad range of nucleic acid analysis technologies including PCR, NGS and proteomics. The company serves a variety of pharma, biotech and academic customers. This position offers an exciting opportunity to get involved early on in setting up TATAA for its next phase of growth.

Description

TATAA is recruiting a passionate leader to be Head of Quality Assurance. The scope of this role encompasses leading and expanding a group that introduces and maintains GLP and maintains and broadens, as considered strategic, company's current ISO accreditation, which is flexible SS-EN ISO/IEC 17025:2018 with a scope including relative and absolute quantification by qPCR. The QA team interacts close with company's technical management.

Responsibilities

- Act as the primary contact for clients and regulatory inspections and as the site expert for regulatory guidelines, and assist with the preparation and hosting of client audits and/or regulatory inspections.
- Plan and execute protocol, laboratory and supporting data, and final report (interim, draft, final) audits and conduct in-life phase inspections as required for compliance with GLP, SOPs, bioanalytical method validation guidelines (FDA, EMA);
- Lead the GLP implementation effort with tasks including: overseeing hiring of key personnel, writing of SOPs, instrument validation and facilities protocols, implementing raw data storage and retention initiatives, and other duties as needed
- Provide training to technical and professional staff on GLP regulations.
- Lead ongoing process improvements to improve best practices.
- Instill and manage a culture of continuous improvement, quality, and productivity.
- Perform review of raw data against the draft reports of bioanalytical studies to verify that the reports accurately and completely reflect the raw data generated.
- Conduct periodic facility/system and process audits as required for compliance with GLPs and SOPs.
- Report all findings in writing from the audits and inspections to relevant personnel.
- Review audit responses and follow-up with study directors to ensure audit finding impacts are assessed and promptly communicated to test facility management; monitor the progress, appropriateness and correct implementation of corrective measures.
- Prepare, review and improve QA procedures.
- Review and approve procedures of other departments within the organization.
- Collaborate with laboratory technicians, study directors, and test facility management.

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- Act as the contact person for quality questions from the organization
- Maintain current knowledge of standard requirements according to GLP, ISO17025 and other relevant guidelines related to the business process.

Minimum Qualifications

- Bachelor or Master's degree in Life Sciences or a Quality-oriented education
- At least 5 years of experience in a GLP regulated environment with at least 2 years of demonstrated leadership experience.
- Advanced working knowledge of current regulatory guidelines including GLP and ISO 17025
- Experience with LIMS systems
- Excellent communication (in English) and interpersonal skills with the ability to influence others with impact.
- Outstanding experience with client satisfaction and problem solving solutions.
- Experience working in the CRO/Pharma industry highly preferred.

Employment offer
Position: Full time
Placement: Gothenburg, Sweden
Start date: upon agreement

Application
Interviews start: 2021-05-01
Application shall be sent by email and include motivation letter, cv, and contact information to references to jobs@tataa.com. Indicate in email heading "CFO".

Company headquarter address
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Sweden

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