Laboratory Manager

Memphis, TN / On-Site (US)

About MLM Medical Labs

MLM Medical Labs is a leading specialty and central laboratory with comprehensive research services and diagnostic capabilities in Europe and North America. Offering standard and fully customizable analytical and logistics services across a variety of therapeutic areas, we add value at every stage of the drug development process, from nonclinical and preclinical through phase IV clinical trials.

The international team of over 150 highly skilled and experienced persons supports between 190 and 210 clinical trials, phase I–IV, at any given time. With our labs located in and Minneapolis MN, Memphis TN, USA and Mönchengladbach, Germany we work on transcontinental projects, hand in hand with our colleagues worldwide.

This position

We are looking for a Laboratory Manager (full time) to work in our office in Memphis (US). The Laboratory Manager serves as the research functional lead, accountable for the clinical monitoring/site management delivery of assigned study(ies). The position provides leadership, mentoring, and technical support to the lab staff to ensure quality of deliverables and achievement of financial goals. He/she manages, directs, schedules, trains, and organizes the translational laboratory.

Your responsibilities

- Provide day to day management to the laboratory staff in the execution of various tasks to support multiple projects.
- Oversee the scheduling of staff and equipment in coordination with the Project Managers to support the timely completion of tasks and maintain productivity by monitoring workload.
- Ensure adequate training of all staff on testing platforms and manage training records
- Achieve quality results by following SOPs and QA guidelines
- Counsels and disciplines employees as needed to achieve productivity and HR goals
- Implements new programs, tests, methods, and instrumentation
- Oversees assigned site and study team members' conduct and identifies risks to delivery or quality.
- Ensures quality of the clinical monitoring and site management deliverables within a project and maintain proper visibility of its progress using approved systems and / or tracking tools.
- Understands the monitoring strategy required for the study and, where required, participates in the development of the study risk assessment plan. Is accountable for their assigned clinical team members' understanding, ongoing compliance, and delivery according to the stated monitoring strategy, CMP/SMP, and risk plans.
- Interacts with the client and other functional departments related to clinical monitoring and site management activities and deliverables.

- Demonstrates understanding of other functions' roles in achieving site compliance and delivery according to protocol, ICH/GCP and or Good Pharmacoepidemiology Practices (GPP) and country regulations. This may include medical monitoring, Safety, Quality Assurance (QA). Supports Inspection Readiness for Clinical Scope.
- Understands budgeted clinical activities to identify out of scope activities
- Supports study tool and template development. Delivers initial and ongoing training to the study team regarding protocol specificities, Case Report Form (CRF) completion, Sponsor Standard Operating Procedures (SOPs), clinical plans and guidelines, data plans and timelines for the study.
- Oversees assigned clinical staff routinely to assess site processes, perform review of all Source Documents and medical records, and perform Source Data Review (SDR) and/or Source Document Verification (SDV) per the CMP/SMP and reviews identified and newly emerging risks. May develop and support execution of corrective action plans at site and study level, in accordance with the risk-based monitoring strategy outlined in the CMP/SMP. Supports and completes activities to achieve data cut and lock deadlines.
- May evaluate staff's competency to perform visits/site contact. independently via sign-off visits and Performance Assessment Visits (PAVs) according to company standards and process.
- Proactively engages in feedback opportunities that support BU level initiatives.

Required qualifications

- MS/PhD in biology, chemistry or other health and science field or equivalent combination of education, training and experience.
- Demonstrates ability to lead and align teams in the achievement of project milestones, demonstrates capability of working in an international environment.
- Demonstrates learning of basic clinical project financial principles.
- Knowledge of Good Clinical Practice/ICH Guidelines and other applicable regulatory requirements.
- Must demonstrate good computer skills.
- Good communication, presentation, and interpersonal skills among project team and with sites.
- Ability to apply problem solving techniques to resolve complex issues and apply a risk management approach to identifying and mitigating potential threats to the successful conduct of a clinical research project.
- Demonstrates critical thinking to determine the cause and appropriate solution in the identification of issues.
- Expert knowledge of laboratory research and various testing platforms.

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