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Senior/Principal Quality Auditor

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Company: Precision Medicine Group

Location: Poland

Category: life-physical-and-social-science

Precision for Medicine is hiring a Senior/Principal Quality Auditor to join our team, candidates can be based in either UK, Spain, Hungary, Poland, Romania, Serbia or Slovakia.

Position Summary:

The Senior/Principal Quality Auditor supports the audit program and clinical projects to ensure compliance with regulations and Precision procedures.

Essential functions of the job include but are not limited to:

Support the Quality Management System including SOPs, training and CAPA

Process and maintain documentation for controlled documents, as required

Develop and administer training for employees and/or consultants

Host client/sponsor audits and support regulatory inspections

Coordinate and conduct assessments of potential and contracted vendors, including vendor audits as warranted

Coordinate and conduct internal audits of quality systems

Coordinate and conduct investigator site audits

Coordinate and conduct trial master file audits

Participate on computer systems validation projects and systems change control process

Provide QA consultation and support to assigned project teams internally and externally

Support and manage reported quality issues and any associated corrective and preventive actions

Monitor quality systems to provide feedback on compliance risks to QA management and identify opportunities for improvement

Maintains Q&C trackers, databases, metrics, and files

Follow applicable regulations and standards, including but not limited to local regulations (US FDA and EU), ICH, ISO and company policies and procedures

Additional tasks as required

Qualifications:

Minimum Required:

Requires two to five years of applicable experience or equivalent combination of education and experience

Clinical research experience in non-QA role considered (e.g., clinical research associate experience)

Working knowledge of GCP/ICH guidelines and FDA regulations and standards

Hands-on experience leading clinical site audits

Other Required:

Bachelor’s degree in a science, healthcare, or related field of study

Availability to travel up to 50% domestically and/or internationally

Preferred:

CRO, Pharmaceutical and/or Medical device experience

QA certification preferred (e.g., CQA, SQA, etc.)

Experience with electronic clinical trial systems (e.g., EDC, CTMS, IxRS, ePRO, etc.)

Skills:

Excellent interpersonal and problem-solving skills, effective verbal and written communication, computer skills

Competencies:

Strong knowledge of GCP/ICH guidelines and FDA regulations and industry standards

Intermediate proficiency in Microsoft Word, Excel, and PowerPoint, and some knowledge of Access or similar database

Must possess a customer service demeanor; demonstrate collaboration and flexibility, teamwork, and a keen attention to detail

Ability to work independently and in a team environment

Ability to work with cross functional groups and management under challenging situations

Ability to prioritize work and handle multiple and/or competing assignments

Excellent verbal and written communications skills

Must be fluent in the English language

At Precision for Medicine, we believe that the era of one-size-fits-all medication is giving way to a next generation of treatments, medicines that will be more effective because they are prescribed according to the unique biology of an individual patient. Our mission is to help innovative biotech and pharmaceutical companies accelerate the development of these life-changing treatments. Precision does this by developing assays that utilize biomarkers to help identify the right patient for the right drug. We handle every aspect of clinical trials from initial strategy and design to selecting sites and executing quality clinical trials. This is where you come in!

#LI-NC1 #LI-Remote

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