

**Prairie Education and Research Cooperative
Position Description**

POSITION TITLE: Quality Assurance Manager (QA Manager)

REPORTS TO: PERC Director/Chief Operating Officer

APPROVED BY:

President of the Board: _____ Date: _____

Director/Chief Operating Officer: _____ Date: _____

POSITION PURPOSE:

The Manager of Medical Quality Assurance will be an integral member of the Prairie Education & Research Cooperative's (PERC) management team and will function in a high profile, independent role. He/she will be an individual who understands the regulatory requirements and is able to provide expertise to local site and multi-center clinical operational teams to confirm that all requirements are properly adhered to. In addition, the Manager, Medical Quality Assurance will be responsible for monitoring and providing Quality Assurance support for GLP (Good Laboratory Practice Studies).

MAJOR TASKS, DUTIES AND RESPONSIBILITIES:

- 1.) Integrates PERC's mission and vision in the daily tasks through dedication to quality improvement and collaborative working relationships.
- 2.) Full commitment to Quality Assurance, Medicare Compliance, and the Health information Portability and Accountability Act (HIPAA) as defined by PERC policy and the Federal Government.
- 3.) Must be willing and able to incorporate PERC customer service protocols as they relate to interactions with patients, families, physicians and co-workers.
- 4.) Knowledge and compliance with all OSHA guidelines.
- 5.) Maintains strict confidentiality of sensitive material and information.
- 6.) Responsible for performing internal and external clinical vendor audits and clinical investigative site compliance audits and preparing written reports on all audit-related activities.
- 7.) Makes recommendations for corrective actions and the improvement of processes.
- 8.) Performs all necessary follow-up to ensure that PERC employees adhere to applicable GCP standards and applicable federal regulations.
- 9.) Confirm compliance with GCP requirements in clinical trials.
- 10.) Responsible for directing and performing internal GLP activities including review of related method validation audits, vendor audits, development of Quality

- System documents, progress of studies, maintaining a master schedule and overseeing the relevant components of the PERC's Standard Operating procedures.
- 11.) Responsible to revise, update and educate relevant employees on all PERC Standard Operating Procedures.
 - 12.) Assurance that applicable adverse events and protocol deviations are properly reported to the sponsor.
 - 13.) Review of site record accuracy regarding drug/device accountability.
 - 14.) Facilitates communication with Project Manager, Manager of Information Technology and Clinical Trial Supervisor.
 - 15.) Oversees PERC quality assurance program to include regularly scheduled audits of research records for thoroughness, accuracy and timely submission to sponsoring company.
 - 16.) Participates in continuing education of research staff and provides documentation of ongoing education in related field.
 - 17.) Assist in the preparation of FDA submissions including applications, AE's or annual reports.
 - 18.) Assures proper storage and handling of investigational products.
 - 19.) Assist with FDA and/or sponsor inspections

KNOWLEDGE AND SKILL REQUIREMENTS:

- 1.) BS /BA and five (5) years of related industry experience.
- 2.) Thorough knowledge of ICH, GCP, OECD and GLP regulatory requirements.
- 3.) Practical experience in clinical research environment preferred.
- 4.) Demonstrated effective communication skills, both written and verbal.
- 5.) Demonstrated ability to effect change across an organization.
- 6.) Proactive, effective problem solving skills.
- 7.) Possess a positive and diplomatic personality with the ability to function independently as well as in a team member role.
- 8.) Possess keen attention to detail.
- 9.) Possess previous computer experience (preferred).
- 10.) Is able to work under stress (sometimes emergent) and accept constructive criticism.
- 11.) Is able to make objective judgments.
- 12.) Preferred experience in the field of cardiology.
- 9.) Must be Certified Clinical Research Professional Coordinator and/or Associate or working towards certification.

WORK ENVIRONMENT:

- 1.) Each job requires the following demands:
 - A.) Physical Demands
 1. Must possess good physical and mental health.
 2. Must be capable of stooping, bending, stretching and lifting.
 3. Must be able to stand and walk for long periods.

4. Must appear well groomed and poised at all times.
5. Must possess manual dexterity to handle and manipulate equipment and appliances.

B.) Mental Demands

1. Must have the ability to control emotions and maintain composure under stress using tact and good judgment.
2. Must be able to adjust to various personalities and situations.

C.) Special Demands

1. Must be self-confident and maintain a positive attitude.
2. Must be capable of performing in an environment that demands extreme consciousness, emotional stability, attention to the minute details and keen observation.
3. Must have patience and tact in dealing with patients and the public.
4. Must have ability to work effectively in an environment which tends to be tension provoking.
5. Must be able to communicate effectively with patients, doctors, co-workers and other departments.
6. Must work well under supervision, as well as independently and be able to take constructive criticism.