Associate Director, Quality & Compliance

We are looking for an Associate Director, Quality & Compliance to join our team!

Are you someone with background in clinical research quality management and knowledge of regulatory compliance, especially Good Clinical Practice (GCP)? Someone who is able to see the bigger picture and adapt to change easily? Someone who is willing to help build and train a top-notch team? If the answers are yes, keep reading!

In this position you will:

- Help to re-create and manage CPC's Quality Management System (QMS), Quality Manual and regulatory programs/activities.
- In conjunction with the General Counsel & Director of Compliance (GC), identify process gaps and revise policies (POLs), redraft and update all standard operating procedures (SOPs) and work with each functional team to help develop relevant work instructions (WIs) to ensure compliance with applicable regulations and regulatory guidance.
- Implement and oversee a Quality Review Board.
- Help draft or revise all corporate SOPs, policies and work instructions
- Monitor and administer vendor selection, qualification and management
- Serve as a resource for compliance with all applicable regulations for clinical trials.
- Monitor the periodic review, revision, approval, version control, and historical archival of controlled documents within the QMS.
- Serve as an internal resource to address and resolve any questions or issues of a regulatory or quality assurance nature with the assistance of external resources.
- Lead review of any internal audit findings, CPC QMS Review Reports, quality trends, CAPA resolutions, etc.
- Oversee processes relating to misconduct or fraud.
- Oversee all auditing functions utilizing internal and external resources to ensure that CPC is compliant with all applicable local, federal and international regulations, guidelines and standards.
- Oversee external auditing
- Represent CPC in interactions with the FDA and other regulatory bodies.
- Contribute to the achievement of departmental and organizational goals.
- Supervise and train team members to set clear job expectations, access training needs and ensure team members receive training as needed.

Here's what you will need to bring to the table:

- Bachelor's degree.
- Minimum of 6-8 years of experience in a clinical research setting required including regulatory responsibilities.
- Minimum of 3 years of supervisory experience required.
- Experience drafting or helping draft or amend a Quality Manual.

- Experience with computerized systems including: Quality Management (QMS), Learning Management (LMS), Electronic Trial Master (eTMF), Electronic Data Capture (EDC), File Management (e.g. Box with Governance), Clinical Trial Management (CTMS), etc.
- Experience interacting with the FDA and being up to date on trends at FDA on quality matters.
- Experience with QCP.
- Knowledge of applicable regulatory requirements (e.g. 21 CFR Part 11, HIPAA, GDPR, ICH, GCP, GDP, and FDA) for conducting clinical trials.
- Proficiency with Microsoft Office, particularly Word, Excel, and Power Point
- Excellent organizational skills, team skills, and oral and written communication skills.
- Attention to detail and ability to work independently.
- Ability to work as a member of a team, establish a strong team environment for direct reports.
- Good problem-solving skills and ability to prioritize.
- Ability to manage tasks independently.
- Ability and willingness to travel as needed.

Note: Viable applicants will be required to pass a background and education verification check.

Targeted Compensation: $120,000 – $145,000 annually

About CPC:

CPC is an academic research organization that offers full service clinical trial design, oversight, and management with rapid access to Key Opinion Leaders in a variety of therapeutic areas. With over 30 years of experience, CPC has provided services to over 150 clinical trials in a variety of indications, with an emphasis on cardiovascular, wound healing, diabetes and more.

CPC has expertise in managing clinical trials from a variety of funding sources including Industry, NIH, and Investigator Initiated trials.

CPC Community Health focuses on innovative programs that reach into communities to help people find effective ways to become active, empowered and healthy. http://www.cpccommunityhealth.org/

CPC offers:

- Comprehensive benefits package (medical, dental, vision, life, STD, LTD etc.)
- Matching 401(k) plan (dollar for dollar up to 4% of your eligible compensation, fully vested immediately)
- 10 paid holidays
- 15 - 25 vacation days based on years of service
- Paid sick time (2.67 hours accrued bi-weekly up to a maximum of 80 hours)
- In-suite exercise and relaxation room
- Monthly fun events (e.g. team building activities, games, charitable events, potlucks, picnics)
- Flexible and remote work schedules

An Equal Opportunity Employer

CPC provides equal employment opportunities (EEO) to all employees and applicants for employment without regard to race, color, religion, national origin, sex, gender identity, veteran status, marital status, sexual orientation, age forty and over, disability, genetic information or any other status protected by applicable federal, state or local law. It is our intention that all qualified applicants are given equal opportunity and that selection decisions be based on job-related factors.
Applicants with disabilities may be entitled to reasonable accommodation under the Americans with Disabilities Act (ADA) and certain state or local laws. If you need assistance, please email our Human Resources team at careers@cpcmed.org.

Please Apply Online Using The Link Below:

Apply Here!