



Associate Director, Quality Assurance & Compliance

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

Are you someone with background in clinical research quality management and knowledge of regulatory compliance? Someone who is able to see the bigger picture and adapt to change easily? If the answers are yes, keep reading!

In this position you will:

- Manage CPC's Quality Management System (QMS) and regulatory programs/activities.
- In conjunction with the Leadership Committee, identify process gaps and revise policies (POLs), standard operating procedures (SOPs) and work instructions (WIs) to ensure compliance with applicable regulations and regulatory guidance.
- 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. Report all significant or concerning regulatory and/or quality issues to the Executive Director.
- Meet monthly with the Executive Director to review any internal audit findings, CPC QMS Review Reports, quality trends, CAPA resolutions, etc.
- Report all suspected misconduct or fraud to the Executive Director. Oversee internal 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 functions for clinical sites, vendors, subcontractors, partners, third-party CROs and others as appropriate.
- Be involved in representing CPC in interactions with the FDA and other regulatory bodies.
- Serve as a principal contact during external audits of CPC and respond to audit observations or requests, in conjunction with appropriate Leadership Committee members.
- Understand and comply with all applicable regulations for clinical trials and relevant CPC POL, SOPs and WIs.
- Work with the Executive Director, Head(s) of Research Operations, and Department Heads on evaluating departmental, personnel and productivity metrics to assess and implement necessary changes and/or improvements.
- Contribute to the achievement of departmental and organizational goals.
- Supervise team members reporting to this position. Work with each team member to set clear job expectations, assess training needs and ensure team members receive training as needed. Assist all personnel reporting to this position to create improvement and innovation goals annually with biannual reviews. Recommend appropriate promotions for those who are excelling in their job performance. This will also involve individual coaching of members of those functional areas to achieve their individual goals.
- Participate, as assigned, in the QC review of project-related documents including: protocols, CRF's, source documents, monitoring plans, study manuals, data management plans, statistical analysis plans and clinical study reports.

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

- Bachelor's degree preferred, but equivalent experience will be considered.
- Minimum of 15 years of experience in a clinical research setting required including regulatory responsibilities.
- Knowledge of applicable regulatory requirements (e.g. ICH, GCP and FDA) for conducting clinical trials.
- Proficiency with Microsoft Office, particularly Word and Excel.
- Minimum of 2 years of supervisory experience required.
- 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 and to prioritize multiple tasks.
- Ability and willingness to travel up to 15%.

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

Targeted Compensation: \$110,000 – \$140,000 annually

TO APPLY FOR THIS POSITION: <https://cpc.bamboohr.com/jobs/view.php?id=58>

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.