

Recruiter : Steven Karski

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Alchemy Scientific, Inc., 51 JFK Parkway, First Floor West, Short Hills, NJ 07078

Senior Director – Clinical Quality Assurance Compliance 12/7/09

This position will be responsible for the development and oversight of clinical quality programs and policies and will ensure implementation and direction of these programs throughout company's global operations. They will partner with all company sites to harmonize and continuously improve good clinical practice (GCP) quality programs. Coordinate the implementation/revision of procedures and policies to ensure compliance with new regulations, guidelines etc. Assist in preparing company for Regulatory Inspections. Interact with the FDA and other regulatory agencies as required. Build collaborative working relationships with cross functional peers. Prepare and oversee department budget.

Essential Duties & Responsibilities:

1. Recruit staff and build the Clinical QA Compliance and Systems organization responsible for ensuring compliance with applicable regulations, policies and procedures.
2. Directly responsible for the implementation, administration and continuous improvement of clinical GCP quality systems and programs.
3. Review/approve deviations, procedures, protocols, reports etc. as needed.
4. Utilize metrics and other tools to monitor the state of compliance and implement continuous improvements accordingly.
5. Coordinate the initiation/revision of procedures and policies to ensure compliance with new regulations, guidelines etc.
6. Keep Senior Management apprised of compliance risks.
7. Provide leadership, direction, and guidance to address compliance risks.
8. Partner with cross functional organizations to resolve compliance issues and oversee the implementation of corrective and preventative actions.
9. Conduct Clinical-QA sponsored training programs.
10. Plan and administer the department budget. Monitor department spending to remain on track with budget.

Essential Knowledge, Skills, Experience:

1. A strong, seasoned biopharmaceutical Quality professional with substantial experience in GCP Compliance and quality systems.
2. Minimum of 15 years relevant industry experience.
3. B.S degree in the sciences or health-related discipline. Advanced degree preferred.
4. Previous experience working or leading quality functions globally is highly desirable.
5. Strong leader able to achieve agreements through an educational collaborative approach and is decisive on quality and compliance issues.
6. Solid knowledge of FDA and International regulations and industry best practices regarding GCP quality systems, policies and programs.
7. Experienced in leading cross functional teams.
8. Experience with regulatory authority inspections.
9. Excellent communication and interpersonal skills