

Quality Assurance Senior Compliance Specialist

Position Summary: Experienced Quality Assurance Specialist with broad GMP, GCP, and GLP Quality Assurance responsibilities (those internal and for contracted services oversight) for a clinical-stage biopharmaceutical company. Reporting to the Sr. Director of Quality Assurance.

Duties and Responsibilities:

- Controlled Document Management and Training Management e-systems administration.
- GXP training of internal employees and contracted personnel, as necessary. Training curricula and training tools development.
- Quality system (e.g. CAPA, Investigations, Change Controls) administration, record assignment, execution, review and approvals.
- Vendor oversight activities including vendor selection, qualification and monitoring, quality agreement maintenance, batch record review, investigation/CAPA review.
- Internal and External audit program coordination, execution and closure tracking.
- Clinical study deviation and CAPA assessments.
- Quality performance indicator(QPI) tracking, analysis and reporting. Management review coordination.
- SOP development, improvement, process mapping, training and other departmental activities.
- Other duties and responsibilities assigned by the Senior Director.

Education/Skills and Experience Requirements:

- Bachelors of Science degree
- Experience: 5 -8 years of GxP Quality Assurance required.
- Strong knowledge and understanding of GMP regulations required. Exposure to GCP/ICH Guidelines and relevant CFRs for conducting clinical trials desired.
- Effective communication (written and verbal), adaptability and self-motivation are required attributes.
- Strong interpersonal, organizational, and multi-tasking skills.
- Excellent attention to detail and problem-solving skills.
- Ability to work effectively work in a team setting.
- Computer proficiency, including Microsoft Office and electronic enterprise Quality Management System applications (e.g. Trackwise, Compliance Wire)
- Occasional travel (less than 10% of time)

Experience:

- Quality Assurance (GMP and/or GCP): 5 years (Required)

Education:



275 Second Avenue, 4th Floor · Waltham, MA 02451
Tel: 617-498-1070

www.visterrainc.com

- Bachelors of Science (Required) or 7 plus years of relevant experience

Date: June 13, 2018