Senior Program Manager / Program Manager, Clinical Quality Assurance

Job Description:

Are you looking for a patient-focused company that will inspire you and support your career? If so, be empowered to take charge of your future at Takeda. Join us as a Senior Program Manager / Program Manager, Clinical Quality Assurance in our Cambridge office.

Here, everyone matters and you will be a vital contributor to our inspiring, bold mission. As a Senior Program Manager / Program Manager, Clinical Quality Assurance working on the R&D Quality Assurance team, you will be empowered to develop audit programs and represent the team at GCP QA meetings, and a typical day will include:

POSITION OBJECTIVES:

- Provide leadership and influence to the Takeda Clinical Compound Support QA Program Managers and partner with key stakeholders that are integral to clinical development activities.
- Manage Therapeutic Area Programs of a highly complex nature and/or high risk programs including, multiple indications, data safety monitoring boards, endpoint review committees as well as those requiring the coordination of multiple vendors.
- Serve as a strategic GCP quality resource providing GCP technical guidance recommendations to development teams
- Maximize effectiveness and efficiency in the use of available resources in conducting clinical compound support quality assurance activities.

POSITION ACCOUNTABILITIES:

Leadership & Partnership

- Provide GCP QA leadership to drug development teams.
- Act as a quality expert to provide GCP compliance interpretation, consultation, training, and recommendations.
- Coach, educate and collaborate with external sites and cross functional Takeda staff in global regulatory readiness activities and responses in support of successful marketing applications.

Implementation of Audit and Compliance Programs

- Lead domestic and international audits of sites, documents, databases, vendors or internal systems in compliance with the Code of Federal Regulations, local regulations, ICH and Takeda policies and procedures. Assess impact of audit findings on subject safety, data integrity, and business operations. Audits conducted require advanced auditing skills and may include the technically complex assignments, including audits of potentially high risk studies/vendors.
- Ensure that investigator, vendor, facility and system audits are conducted, identified critical compliance risks are mitigated and communicated to Quality Assurance senior management, and that appropriate corrective/preventative action plans implemented.
- Collaborate with Global Clinical Compound Support QA (CCS QA) and all related functional areas to ensure that clinical trial activities are conducted in compliance with Good Clinical Practice (GCP) regulations, the International Conference on Harmonization (ICH) and Takeda Policies and Procedures.
- Develop and implement a strategic quality plan for assigned compounds.
- Supervise and manage investigations into scientific misconducts and/or serious breach of GCP. Analyze findings to identify root/probable cause. Propose, document and track appropriate corrective actions. Assure reporting of potential or confirmed violations to regulatory authorities.
- Assist Takeda R&D during GCP regulatory inspections. Provide GCP compliance technical support during inspections of investigator sites and Takeda facilities. Work with the stakeholders to ensure appropriate and timely response and follow-up.

- Collaborate with QA Global Compound Compliance and Quality Systems to identify and mitigate GCP quality and compliance issues with potential impact across multiple compounds, sites, or functional groups including Takeda EU, Takeda Asia, and JDC (Japan Development Center).
- Rapidly identify, evaluate, and escalate inadequate responses to CCS QA management

Report GCP Compliance status for Therapeutic Teams

- Monitor compliance issues identified across clinical programs. Analyze audit program results, quality issues, and quality investigations in order to optimize global operations and overall global state of compliance.
- Provide appropriate risk analysis for key stakeholders
- Elevate systemic problems with appropriate recommendations/solutions to upper management for immediate and long-term resolution.
- Report metrics for assigned compounds to QA management, clinical staff. Evaluate if CAPA(s) are required and monitor implementation.

Leverage Resources Efficiently and Effectively

- Lead systems monitoring and process improvement initiatives that enhance regulatory compliance and CQA operating efficiency.
- Ensure reports and corrective actions are developed and completed within timelines mandated in internal procedures.
- Leverage global CCS QA Team to drive for on time deliverables and quality service delivery excellence.

EDUCATION, EXPERIENCE, BEHAVIOURAL COMPETENCIES AND SKILLS:

- B.S. in Science, Nursing, or related scientific field.
- 7 years of experience in the pharmaceutical or biotechnology industry with 5 years of GCP-related Quality Assurance experience.
- In Depth knowledge of the applicable global GCP regulations, Good Clinical Practices, ICH Guidelines
- Advanced knowledge in the conduct and reporting of audits and the translation of findings into corrective actions plans that mitigate risks to the company, to safety and data integrity.
- Strong knowledge and experience in key Takeda Key Therapeutic areas.
- Strong written and verbal communication skills. Able to present with influence to Sr Management and Quality Leadership.
- Strong and respectful negotiator and influencer. Demonstrated proficiency in conflict prevention and resolution.
- Able to manage multiple complex projects, and demanding timelines

LICENSES/CERTIFICATIONS:

- ASQ Certified Quality Auditor (CQA), ASQ Certified Manager of Quality/Organizational Excellence, or SQA Registered Quality Assurance Professional – GCP certification preferred, but not required

PHYSICAL DEMANDS:

- Manual dexterity required to operate office equipment (i.e. computers, phones, etc.).
- Carrying, handling and reaching for objects.
- Ability to sit or stand for long periods of time while traveling.

TRAVEL REQUIREMENTS:

- Willingness to travel to various meetings and/or audits, including overnight trips. Some international travel may be required.
- Requires approximately 30% travel.

WHAT TAKEDA CAN OFFER YOU:

- 401(k) with company match and Annual Retirement Contribution Plan
- Tuition reimbursement

- Company match of charitable contributions
- Health & Wellness programs including onsite flu shots and health screenings
- Generous time off for vacation and the option to purchase additional vacation days
- Community Outreach Programs

Empowering Our People to Shine

Apply URL: https://www.takedajobs.com/job/cambridge/senior-program-manager-program-manager-clinical-quality-assurance/1113/6890230

Learn more at **takedajobs.com**.

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No Phone Calls or Recruiters Please.