Belgium Jobs Expertini®

Senior Manager, GCP Auditor

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Company: BeiGene

Location: Belgium

Category: computer-and-mathematical

BeiGene continues to grow at a rapid pace with challenging and exciting opportunities for experienced professionals. When considering candidates, we look for scientific and business professionals who are highly motivated, collaborative, and most importantly, share our passionate interest in fighting cancer.

General Description:

This position within R&D Quality is a senior Auditor role (as Lead or Co-auditor) who is responsible for independently overseeing and conducting GCP audits, to ensure compliance with GCP regulations and industry standards, in accordance with applicable regulatory requirements, guidelines, laws and internally established standards and practices.

The position will play a critical role in safeguarding the integrity, safety, and quality of clinical research processes and data.

Based in Europe, either in Switzerland or UK or Belgium/Netherland/German/France

This position requires:

Extensive knowledge and/or awareness of ICH GCP and applicable global & local regulations and guidance for clinical development.

Strong global mindset and knowledge about regulations (specific expertise regulations/ requirements/ culture awareness)

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.

Extensive experience in managing GCP investigations.

Experience in product/compound lead/consultancy (GCP)

Extensive knowledge and/or awareness of GLP/GCLP and experience in conduct and reporting of GLP/GCLP audits (mainly for China located auditors responsible for GLP/GCLP audits)

Extensive or Direct experience with supporting and involvement in GCP inspections (main inspectorates (FDA, EMA, CFDI etc.,)) and other country specific inspectorates (MFDS, PMDA, TGA etc., based on location of position)

Collaborative team player with a positive attitude and ability to think and act quickly to identify creative solutions to complex problems.

Effective technical writing skills; able to write quality positions, audit reports, and procedures.

Excellent communication skills with ability to negotiate and influence without authority in a matrix environment.

Strong judgment, project management and decision-making skills; able to manage multiple projects and demanding timelines.

Essential Functions of the job:

Audit Planning & Preparation : Operationalize approved audit plans and strategies for R&D GCP audits (External & Internal audits), considering relevant regulations and industry standards; Coordinate audit schedules and necessary resources with relevant stakeholders: Review documentation, procedures, and quality management systems prior to conducting audits.

Conducting Audit : Perform on-site or remote audits (routine, for-cause/directed); Evaluate compliance with GCP regulations, internal quality standards, and relevant guidelines; Document audit findings, deviations, and areas of non-compliance; Interview personnel, review records, and gather evidence during audits.

Reporting & Documentation : Prepare comprehensive audit reports outlining findings, observations, and recommendations for corrective actions; Ensure audit reports and corrective actions are developed and completed within timelines mandated in internal

procedures and ensure effective CAPA are provided by auditee; maintain well-organized and accurate audit documentation for regulatory and internal purposes.

Escalatesystemic, critical and/or major audit findings and recommend appropriate solutions to senior management for immediate and long-term resolution.

Work with leadership to establish processes and standards for excellence in R&D audits, responses, CAPAs and effectiveness checks to optimize effective and consistent performance within R&D Quality and for R&D stakeholders.

Support the process of developing audit programs for clinical studies and oversee the programs on a quarterly basis or as required.

Participate in & support GCP, GVP & GLP authority inspections (FDA, EMA, PMDA, TGA, CFDI etc.,) in assigned roles such as back-room support, inspection hosting support, inspection & pre-inspection preparation support (site and sponsor).

Provide professional expertise and strong leadership in GCP guidance and regulations to internal stakeholder with R&D Quality and other functions within the company.

Supervisory Responsibilities:
This position may include managing staff (junior auditor): coaching and mentoring of junior auditors, with training/orientation/qualification and development plan for new Quality staff, required. Therefore, it may require to have certain leadership experience and mentoring skills. It also includes management of contract auditors.

Mentor and provide support to R&D auditors personnel, as needed.

Qualifications:
BA/BS degree required; advanced degree preferred.

GCP Quality Assurance auditor’s registration/certification preferred.

Minimum of 7 years of experience in GCP-related Quality Assurance function of the pharmaceutical, biotechnology or related health care industry.

Minimum 3 years as GCP auditors (external and internal audits) and relevant clinical trial experience.

Minimum 3 years of direct involvement to support or participation in GCP authority inspections.

High level of understanding of international GCP requirements and standards in the pharmaceutical, medical device and biotech industries.

Excellent English language skills, and additional language depending on locations and need, e.g., /. Spanish for LATAM, German, French, etc., for Europe)

Excellent verbal and written communication skills

Ability to effectively collaborate in a dynamic environment.

Interacts with all levels of BeiGene.

Travel:

Flexible to travel, including international.

May require up to 35% travel, sometimes with short notice time.

Audit travel mostly overnight for on-site audits is required - anticipating min 2 audits/month.

BeiGene Global Competencies

When we exhibit our values of Patients First, Collaborative Spirit, Bold Ingenuity and Driving Excellence, through our twelve global competencies below, we help get more affordable medicines to more patients around the world.

Fosters Teamwork

Provides and Solicits Honest and Actionable Feedback

Self-Awareness

Acts Inclusively

Demonstrates Initiative

Entrepreneurial Mindset

Continuous Learning

Embraces Change

Results-Oriented

Analytical Thinking/Data Analysis

Financial Excellence

Communicates with Clarity

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