Local GCP/PV Auditor

Job ID
REQ-10010458
Jun 10, 2024
China

Summary

About the role: Lead, support and report independent GCP/PV audits and approve follow-up corrective and preventive activities according to the Novartis Quality Systems and Standards, Good Clin-ical Practice(GCP)/Good Pharmacovigilance Practice(GPvP) and the current GCP/PV reg-ulations. Provide GCP/PV related quality guidance and assist in the identification and im-plementation of quality assurance training needs for Global GxP Audit and other business partners. The audits performed on behalf of Global GxP Audit include all audit types across GCP and PV disciplines including internal and external targets.

About the Role

Key Responsibilities
• Plan, lead, conduct, document, report and follow-up of GCP/PV audits according to the requirements specified in the respective Novartis procedures as well as applicable regulations, standards, quality agreements, and guidance documented.
• For this entry-level global auditor role, audits will typically be limited to low risk GCP/PV activities such as Investigator site audits, single service vendors, sys-tems/process, Patient Oriented Programs, etc). Auditor may assist in supporting complex audits (Country Organizations, multiservice vendors, high risk vendors, etc).
• Provide technical guidance and training on audit activities.
• Ensure appropriate escalation to responsible management in case of critical audit findings and support immediate follow-up measures according to the Novartis requirements on Management Escalations and other relevant procedures. Ensure adequate efini-tion and recording of mitigation plans when applicable.
• Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with Follow-up Responsible Person (FURP) and Quality Responsible Person (QARP).
• Maintain current knowledge of regulations, standards, and guidance documents.

Essential Requirements:
• Degree in natural/biological sciences or equivalent (or an equivalent mix of education and experience)
• Chinese (Mandarin, Catonese) fluency at operational and functional level (as first or second language; second language a plus) Proficiency in English is required
• 5 years GCP/GPvP/clinical /industry/health author-ity experience or equivalent; 1-2 years of GCP/PV auditing experience pre-ferred
• Willingness to travel up to 60% of time
• Ability to manage and objectively evaluate com-pliance issues;
• Ability to address a variety of tasks within the same timeframe while maintaining oversight; maintain a moderate degree of independence with respect to decision making and problem solving;
• Good quality and compliance leadership and facilita-tion skills;
• Excellent verbal and written communication, organ-izational and interpersonal skills. Excellent computer

skills, including Excel, Word, etc;

Desirable Requirements:
• Experience with Health Authority inspections and interaction a plus;

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf

Accessibility and Accommodation:
Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Division
Development
Business Unit
Innovative Medicines
Location
China
Site
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type

Shift Work
No
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Local GCP/PV Auditor

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