Senior Global Auditor – Clinical Practice or Pharmacovigilance

Job ID
REQ-10041471
Feb 20, 2025
España

Resumen

As Senior Global Auditor – Clinical Practice or Pharmacovigilance you will lead, support and report independent GCP/PV audits according to the NVS Quality System and the current GCP/PV regulations to assess compliance with applicable regulations, standards, and guidance documents. In this role you will review and approve corrective action plans in support of the audit observations, ensuring alignment with strategic direction of the company and assist in driving imple-mentation of the applicable actions.

About the Role

In this role you will be required to travel up to 60% of time.
This is a full remote job with flexible location (Barcelona or Madrid).

Major accountabilities:

- Support the strategic development of an effective global risk-based audit strategy and programme; collect, collate and incorporate input into audit strategy and plan.
- Lead, plan, conduct, document and follow-up of global quality regulatory compliance audits and assessments of GCP/GPvP according to the requirements specified in the respective Novartis Quality Module as well as applicable regulations, standards, quality agreements, and guidance documents. Perform activities with a high degree of independence.
- Provide technical guidance, leadership, mentoring and training of other auditors on audit related activities.
- Prepare audit reports according to NVS requirements and timelines.
- Ensure appropriate escalation to responsible management in case of critical findings and support immediate follow-up measures according to NVS requirements on Management Escalations and other relevant procedures.
- Assess the adequacy of responses (CAPA plans) to audit findings in cooperation with Follow-up Responsible Person (FURP) and Quality Responsible Person (QARP)..
- Identify and communicate quality and regulatory compliance issues to Quality Management through appropriate channels as well as recommend remediation.
- Lead compliance investigations and initiatives focused on inspection readiness and quality, process and compliance improvement as requested.
- Support Mock Pre-Approval Inspections (PAIs) and Health Authority (HA) inspections as needed.

Minimum Requirements:

- Education: degree in natural/biological sciences or equivalent (or an equivalent mix of education and

experience). Advance degree desirable.
- 7+ years of GCP/PV/Pharmaceutical Industry/Health Authority experience or equivalent up of which 3 years of GCP/PV auditing experience (both GCP and PV auditing is ideal).
- Ability to independently manage and objectively evaluate complex compliance issues with minimal supervision.
- Ability to address a variety of tasks within the same timeframe while maintaining oversight; ability to maintain a high degree of independence with respect to decision making and problem solving.
- Experience with Health Authority inspections and interaction;
- Extensive knowledge of applicable GCP, PV and GxP regulations, guidelines, policies and procedures.
- Good knowledge of computer systems validation and 21CFR Part 11 requirements.

Desirable requirements:

- Auditor certification would be highly valued.

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División
Operations
Business Unit
Innovative Medicines
Ubicación
España
Sitio

Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Madrid Provincial, España
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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