Senior Manager Quality Assurance, Country Development

Job ID
REQ-10051936

5月 28, 2025

Spain

摘要

-Proporcionar garant í a de calidad y supervisi ó n de cumplimiento a las funciones de desarrollo e investigaci ó n. Impulsar la supervisi ó n de los sistemas e iniciativas de gesti ó n de la calidad dentro de la organizaci ó n global, regional y nacional, asegurando el cumplimiento de los requisitos reglamentarios de las autoridades sanitarias aplicables (por ejemplo, GCP, GLP, GMP, PV, IP) y los procedimientos y est á ndares de calidad de Novartis. Modele comportamientos de buena calidad mientras promueve una cultura de calidad (por ejemplo, la primera vez correcta, etc.) para impactar positivamente a las partes interesadas que no son de calidad (por ejemplo, NIBR, GDD). Desarrollar, impulsar y/o apoyar iniciativas de planes de Calidad con el fin de lograr la estrategia, misi ó n y visi ó n organizacional.

About the Role

The RPAC QA is responsible for assuring qualification activities are planned and managed with adequate assurance of quality and compliance as it pertains to the maintenance of the regulatory

landscape. Radiopharmacies may include Site (SRP) and Central Radiopharmacies (CRP); Apheresis and Cryopreservation service providers may include global, regional or country level vendors engaged to provide services for Apheresis and/or Cryopreservation to sites conducting those clinical trials (collectively, SP).

The RPAC QA will operate in direct collaboration with global and local RDQ and GCO colleagues (TRD QA, Study Lead, Study-Start-up Teams, CRAs etc), to ensure the scope of activities being brought in is clearly communicated and understood by receiving functions and actions taken adhere to Novartis requirements and relevant Health Authority (HA) regulations and guidance.

The RPAC QA will also be responsible for supporting HA inspections and audits and leading novel projects (e.g. developing quality risk management strategies, planning and management of resources to support qualification and oversight activities & continuous improvement of the process)

Major Accountabilities

- Service Provider Management: Oversee implementation, maintenance, and monitoring of RPAC service providers (SPs) on a global level and establish/maintain written procedures to ensure GCP, Pharmacovigilance (PV) and good manufacturing practice (GMP) related processes and tasks are compliant with Novartis global requirements and applicable regulations and guidelines.
- SP Qualification: Responsible for the execution of QA activities required for the qualification/requalification of SPs. Ensure the SP selection, QA agreements and oversight processes are properly followed. Drive qualification and oversight of SPs. Support global stakeholders and local teams with the execution of activities required for the qualification/requalification of SPs.
- Risk Identification and Management: Identify any risks relevant to the SP qualification and oversight into Novartis and assure that those risks and any mitigation strategies are communicated to internal and external stakeholders. Assure that risk strategies are working as intended and adjust as needed. Plan and coordinate risk-based audits. Collaborate with business partners to ensure that risks are reviewed for root cause, impact, and recurrence and assure that relevant line function owners put in place mitigation plans to address.
- Audits and Inspections: Support audit and inspection readiness and knowledge transfer to local CDQ associates to assure a successful audit and/or inspection.
- Standard Operating Procedures (SOPs) and Written Processes: Identify/maintain plans for SP qualification and oversight SOPs and Guidelines; contribute to plans for deploying SOP training as needed to CDQ teams and other relevant stakeholders.
- Training and communication: Accountable for providing input to and/or developing and executing plans to communicate information and facilitate training for CDQ teams and other stakeholders, including SOPs and written processes, timelines, expectations for local teams, product information, and disease area as applicable.
- Continuous Improvement: Utilize lessons learned from audits, inspections, Key Quality Indicator (KQI) reviews and day-to-day oversight of quality performance to recommend and initiate continuous improvement efforts.
- Quality Issue Management: Oversee and drive relevant investigation activities of GCP and/or GMP issues at RPs ensuring the implementation of robust Corrective and Preventive Action (CAPA). Take accountability for escalation of GCP/GPvP process non-compliance as needed.

Key Performance indicators

- Service Providers are qualified in time for Study Start-up
- Monitoring/Trending KQIs for SPs
- GCP/PV/GMP risks proactively identified and effectively mitigated.
- The number and severity of GCP/PV/GMP issues identified during internal and external audits is minimized
- No regulatory delays are encountered due to inefficient SP qualification and oversight process

Ideal Background

- Degree in Life Sciences or related fields
- Typically, more than 7 years ' experience in the pharmaceutical industry in a relevant field such as quality assurance, regulatory affairs, pharmacovigilance or a directly related area, preferably
- A minimum of 3 years ' experience in clinical development.
- Blood Bank, Tissue Bank or Nuclear Medicine experience would be advantageous
- Experience in the RLT and/or CGT preferred, GMP, leading projects and Vendor/service provider management
- Internal & external stakeholder management is an advantage.

Why Novartis?
Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Commitment to Diversity and Inclusion:
Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Alternative Location 1
London (The Westworks), United Kingdom

Functional Area
Quality

Job Type
Full time

Employment Type

Regular

Shift Work
No

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