Development Quality Assurance Manager [Radiopharmacy QA]

Job ID
REQ-10051936

9月 26, 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 RP QA is responsible for assuring qualification activities are planned and managed with an adequate assurance of quality and compliance as it pertains to the maintenance of the regulatory

landscape. Radiopharmacies may include Site Radiopharmacies (SRP) and Central Radiopharmacies (CRP) (and intermediate RP). The RP QA will operate in direct collaboration with global and local

Research & Development Quality (RDQ) and G lobal Clinical Operations (GCO) colleagues (Technical Research and Development (TRD) QA, Study Lead, Study-Start-Up Teams, Clinical Research Associates (CRAs) etc.), to ensure the scope of activities being brought in is clearly communicated and understood by receiving functions and actions taken follow Novartis requirements and relevant Health Authority (HA) regulations and guidance. The RP QA will be teamed up with an RP QA colleague from TRD QA to combine Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) knowledge.

The RP QA is responsible for supporting countries in qualifying and oversighting Radiopharmacies, supporting health authority 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, establishing a RP TPM oversight system).

Major Accountabilities

- Radiopharmacy Management - Oversee implementation, maintenance, and monitoring of Radiopharmacies on a global level and written procedures to ensure GCP, Pharmacovigilance (PV) and GMP related processes and tasks are compliant with Novartis global requirements and applicable regulations and guidelines. This includes ensuring adherence to International Council for Harmonization (ICH) GCP, Good PV Practice (GPvP), and GMP guidance documents, Novartis written processes, and acting as the QA subject matter expert (SME) and single point of contact (SPOC) for the maintenance of global procedures and supporting and conducting RP Qualification and Oversight processes.
- ESP/Supplier Management: Responsible for the execution of QA activities required for the qualification/requalification of RPs. Ensure the RP selection, QA agreements and oversight processes are properly followed. Drive Qualification and Oversight of RPs. Support global stakeholders and local teams with the execution of activities required for the qualification/requalification of RPs. Ensure, QA agreements and oversight processes are established and followed to support continuity of activities.
- Risk Identification and Management - Identify any risks relevant to the RP 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 on a risk-based approach audits with the unified quality audit program (UQAP) Audit Group for Central Radiopharmacies or Quality Visits by local CDQ colleagues. Monitor processes and Key Quality Indicators (KQIs) to proactively identify potential quality risk withing the RP Oversight Process. 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. Ensure adequate and timely escalation of issues to relevant functions as needed.
- Audits and Inspections - support audit and inspection readiness and knowledge transfer to local CDQ associates as needed to assure a successful audit and/or inspection. Knowledge transfer can include collating and communicating information on the RP processes, facilitating the development of storyboards in service of explaining processes. May serve as

audit/inspection support as needed in collaboration with local QA teams.

- SOPs and Written Processes - Identify/maintain plans for RP Qualification and Oversight SOPs and Guidelines; contribute to plans for deploying SOP training as needed to CDQ teams and other relevant stakeholders. In addition, may be required to review and input on the content of global SOPs that cover RLT Clinical Trial processes on behalf of the CDQ organization.
- 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. Assure that relevant business areas are maintaining inspection-ready documentation to support reviews of training compliance.
- Continuous Improvement: Utilize lessons learned from audits, inspections, 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 as appropriate and ensure implementation of robust CAPA plans where applicable. Take accountability for escalation of GCP/GPvP process non-compliance as needed.

Key Performance indicators

- Radiopharmacies are qualified in time for Study Start-up
- Monitoring/Trending KQIs for Radiopharmacies
- 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 global RP 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
- A minimum of 3 years ' experience in clinical development
- Experience in the radioligand environment (Blood Bank, Tissue Bank or Nuclear Medicine experience would be advantageous)
- GMP experience
- Experience of leading projects and Vendor/service provider management
- External Service Providers (ESP) management
- Internal & external stakeholder management is an advantage.

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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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