R&D Quality Manager

Job ID
REQ-10060536

9月 05, 2025

Spain

摘要

Step into a pivotal role where your expertise in quality assurance will directly shape the future of radiopharmaceutical innovation. As an R&D Quality Manager, you ’ ll lead global qualification and oversight activities for radiopharmacies within our clinical trial programmes, ensuring compliance with regulatory standards and Novartis quality expectations. Collaborating across global and local teams, you ’ ll drive continuous improvement, risk management, and inspection readiness–making a meaningful impact on patient safety and product excellence.

Location: Barcelona, Spain #LI-Hybrid

This role is based in Barcelona, Spain. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

About the Role

Responsibilities:

- Lead global qualification and oversight of radiopharmacies in clinical trials, ensuring compliance with Novartis and regulatory standards
- Act as the single point of contact for Radiopharmacy QA processes, supporting qualification, requalification, and continuous oversight activities
- Collaborate with global and local teams to ensure seamless communication and execution of Radiopharmacy QA strategies
- Identify and manage risks related to Radiopharmacy qualification and oversight, ensuring mitigation plans are implemented and effective
- Support audit and inspection readiness, including knowledge transfer and documentation preparation for local QA teams
- Maintain and contribute to SOPs and written processes related to Radiopharmacy QA, ensuring alignment with global standards
- Drive continuous improvement initiatives using insights from audits, inspections, and quality performance reviews
- Investigate GMP/GCP issues at radiopharmacies, ensuring robust CAPA plans and timely escalation when needed

Essential for the role:

- Bachelor ' s degree in Pharmacy, Biology, Chemistry or a closely related scientific discipline
- Minimum 5 years of experience in a pharmaceutical Quality Assurance role, ideally within clinical development or radiopharmaceuticals
- In-depth understanding of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and pharmacovigilance regulations and international guidelines
- Proven track record in managing qualification and oversight of radiopharmacies, including supplier selection and compliance monitoring
- Strong interpersonal and communication skills, with the ability to collaborate effectively across global and cross-functional teams
- Demonstrated ability to identify, assess, and mitigate quality risks, including root cause analysis and implementation of corrective actions
- Experience in preparing for and supporting audits and health authority inspections, including documentation and stakeholder coordination
- Fluent in English, with excellent written and verbal communication skills for technical and regulatory contexts

Desirable for the role:

- Familiarity with USP <825> and European guidelines on current good radiopharmacy practices (cGRPP)
- Experience working within radioligand therapy (RLT) programmes or with radiopharmaceuticals in clinical development; GCP experience would be considered a plus.

Commitment to Diversity & Inclusion:

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

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients ' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门
Development

Business Unit
Universal Hierarchy Node

地点
Spain

站点
Barcelona Gran V í a

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

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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

Job ID
REQ-10060536

R&D Quality Manager

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10060536-rd-quality-manager

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Barcelona-Gran-Va/R-D-Quality-ManagerREQ-10060536
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Barcelona-Gran-Va/R-D-Quality-ManagerREQ-10060536