Qualified Person Radiopharmaceuticals

Job ID
REQ-10067977

12月 19, 2025

Germany

摘要

Responsible as a Qualified Person for investigational medicinal products IMPs ((NCEs, Biologics und RLTs) according to §14 AMG (German Drug Law).

About the Role

Major accountabilities:

- Responsible for batch certification / batch release of investigational medicinal products IMPs (NCEs and Biologics)
- Responsible for batch certification / batch release of radiopharmaceutical investigational medicinal products IMPs
- Review and approval of Quality-relevant Documentation to support batch release
- Ensure compliance with local and international regulations, in particular with German Drug Law,

AMWHV
- Continous improvement of QA system and processes
- Systematic improvement of Compliance and operational level
- CAPA Management
- Support in Complaint handling
- Change Control Management
- SOP preparation and review
- self-reliant Project Management
- active collaboration in quality related projects across teams
- Training of interns & student apprentices

Minimum Requirements:

- Pharmacist
- Qualification as a Qualified Person according to AMG §15
- Qualification as a Qualified Person for radiopharmaceuticals according to AMG §15 (3a) 5.

Skills:

- Profound knowledge of pharmaceutical regulations (e.g. Radiopharmaceuticals, German Drug Law, AMWHV)
- Proactive, self-initiated way of work with high sense of responsibility
- Analytical way of thinking, flexible and solution oriented workstyle by maintaining a close collaboration with other teams and country organizations
- Strong organisational and persuasional skills as well as high developed communication competencies across in international teams

Languages :

- German
- English

Novartis is committed to building an outstanding, inclusive work environment and diverse team ' s representative of the patients and communities we serve. Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability. The law provides for severely disabled / equal applicants the opportunity to involve the local representative body for disabled employees (SBV) in the application process. If you would like to request this, please let us know in advance as a note on your CV.

Unterst ü tzungen f ü r BewerberInnen mit Behinderungen:

Das Gesetz sieht f ü r schwerbehinderte/gleichgestellte Bewerber die M ö glichkeit vor, die lokale SBV

in dem Bewerbungsprozess einzubinden. Sollte dies Ihrem Wunsch entsprechen, teilen Sie es uns bitte im Vorfeld als Vermerk in Ihrem Lebenslauf mit.

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

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
Quality

地点
Germany

站点
Nuremberg (Non-Sales Force) (Novartis Pharma GmbH)

Company / Legal Entity
DE14 (FCRS = DE014) Novartis Pharma GmbH

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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