Associate Safety Director (m/f/d)

Temporär Jobregion: Basel Stellenprozente: 100%

Beschreibung

As a first-tier supplier to our renowned business partner F. Hoffmann-La Roche Ltd. in Basel, we are currently looking for a motivated and dedicated **Associate Safety Director** for a temporary assignment of 12 months.

Portfolio Safety Scientists (PCS-Sci) provide safety science and pharmacovigilance support to molecules across the Roche portfolio. As a group, they are responsible for all aspects of safety science/pharmacovigilance, with accountability being held by PCS leadership and experts or SSLs (Safety Strategy Program Leaders) depending on the deliverable/activity.

The Portfolio Safety Scientists (PCS-Sci) supports early and late phase development activities as a member of the safety team, providing essential safety oversight and input into all aspects of study management across the entire development and marketed portfolio. In the post-market setting this may include signal evaluation, safety related activities associated with new drug applications/regulatory filings, benefit-risk assessment and safety risk management. The Associate Safety Director will be expected to work with minimal supervision and apply strong self-leadership. The job holder will be expected to complete the required training.

Tasks & Responsibilities

- Develop and maintain an understanding of the safety profile of their assigned product(s) or therapy areas. Develop and maintain an expert understanding of the safety profile of the assigned product(s) as well as understanding of the relevant strategic context (e.g., disease under study, safety profile of competitors, mechanism of action).

- Responsible for individual and aggregate case reporting activities including ICSR case management (medical review) and aggregate reporting (i.e. DSUR, PBRER).
- Responsible for signal detection and management activities. Contribute to the strategy and review of safety assessments and drug safety reports for signals or issues (incl, product quality) or in response to Regulatory Authority requests.
- Provide expert contribution to the development of the product safety strategy.
- Take independent responsibility for risk management activities including preparation and maintenance of CCDS, labeling document maintenance (including IB), risk communications, RMP.
- Review of clinical protocols, study reports, Investigator's Brochure

BERATER

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Seniority Level
Mitarbeiter

Berufskategorie
Pharma & Chemie & Life Science

Stellenprozent
100%

Jobtyp
Temporär

Referenz-Nr.
AFE-PC-T-53911

Jobregion
Basel

(IB), informed consent form (ICF) and other related documents to ensure alignment with the safety strategy and ensure the appropriateness of risk management strategies and risk communication.
- Take responsibility for safety science contributions to regulatory authority submissions (Investigational New Drug/IND applications, New Drug Applications/NDAs, Marketing Authorization Applications/MAAs, Variations,%u200B Renewals, etc.).
- Responsible for the preparation and maintenance of safety sections of the Company Core Data Sheet and/or Reference Safety Information in the IB.
- Participate in and provide input for Drug Monitoring Committees (iDMC) or internal monitoring committee (IMC) meetings, as applicable.
- In partnership with the SSL, support presentation of important safety issues to the Drug Safety Committee (DSC), Development Review. Committee (DRC) and other internal and external review and governance committees as needed.
- Acts independently to manage safety responsibilities on study teams and in activities supporting clinical safety.
- Take on the responsibility for specialised roles with PCS. These may include, but are not limited to; functional business process owner, subject matter expert.
  May be expected to support non-molecule projects, due diligence evaluations and other projects as needed.
- Perform specialized roles with PCS. These may include, but are not limited to; functional business process owner, subject matter expert, safety committee member.
- Responsible for coordination and collaboration with vendors servicing Safety Science.
  Understanding of GxP and regulated processes and end to end clinical trial lifecycle .
- Strong orientation towards process improvement and cross-functional teamwork.
- Effectively work with remote partners on a global team.
- Excellent communication skills, both written and verbal.
- Apply complex data analysis / statistical methods to evaluate, interpret and present scientific data with clarity.
- Strong presentation skills, effective at summarizing and presenting the key considerations and decision points.

Must Haves

- Qualified healthcare professional or Life Sciences graduate. Preferred Qualifications: A relevant postgraduate qualification (e.g. PHD/MSc in a Life sciences discipline; PharmD or other post-graduate health professional qualifications) would be advantageous.
- Work Experience 4 or more years of drug development experience in the pharmaceutical or related industry.
- At least 3 years in drug safety/PV or a closely related field.
- Minimum level required Associate Safety Director
- IT/Tool Skills good excel/word/powerpoint skills; able to extract data from the Safety Database and apply complex data analysis
- Language Skills: Fluent in English, both written and verba

Benefits

- Become part of one of the most prestigious pharmaceutical companies and actively shape the future of healthcare
- Experience a work culture that promotes diversity and inclusion and where all employees feel valued.
- Work on a state-of-the-art campus featuring green spaces, meeting areas, and an inspiring atmosphere
- Work with modern and up-to-date tools in an innovative work environment
- Start with a professional onboarding process and a thorough introduction to your new role during the Welcome Days
- Benefit from financial support for your professional development plans
- Enjoy a selection of high-quality meals in modern staff restaurants
- As part of a sustainable mobility concept, on-site parking spaces are available to you (subject to eligibility criteria)
- Take advantage of unbeatable, year-round discounts at renowned retailers and over 200 top brands
- Benefit from fleet discounts when purchasing new cars or receive constant fuel discounts with our fuel card

Are you interested? Do not hesitate and submit your complete application documents online today. We look forward to hearing from you!

Wir wertschätzen Vielfalt und begrüssen daher alle Bewerbungen – unabhängig von Geschlecht, sozialer Herkunft, Religion, Alter und Identität. Zur leichteren Lesbarkeit und besseren Verständlichkeit verwenden wir nur eine Gender-Form. Selbstverständlich sind im jeweiligen Kontext alle Genderformen gleichermassen gemeint.

Unser Bewerbungsprozess