Senior Regulatory Affairs Manager m/w/d - Roche Penzberg

(41561)

Standort: Penzberg | Anstellungsart(en): Vollzeit | Gehaltsspektrum: 60000 - 113000 Euro pro Jahr

Über Franz & Wach bieten wir Ihnen im Rahmen einer Arbeitnehmerüberlassung eine Chance zum Einstieg bei **Roche Diagnostics GmbH** in **Penzberg**.

Ihre Vorteile:

- Bestlohn, denn wir holen das Maximum für Sie heraus
- Kontakt auf Augenhöhe - Sie sind uns wichtig! Ihre Zufriedenheit liegt uns am Herzen
- Wir gehen auf Ihre Wünsche ein und planen gemeinsam Ihre Zukunft. Im Fokus steht immer Ihre Übernahme
- Wir sind spezialisiert auf die Pharmabranche und absolvieren dafür Biotechnologische Schulungen
- Wir kennen die Entscheider* durch unsere jahrelange Erfahrung in der Pharmabranche
- Wir leben von hunderten Empfehlungen unserer ehemaligen Mitarbeiter* die mittlerweile direkt bei Roche angestellt sind
- Vom Helfer*, Quereinsteiger* bis hin zum Doktor* - Bei uns sind Sie richtig!

Ihre Aufgaben bei Roche Diagnostics:

Regulatory document and submission compilation:

- Good understanding of complexities and challenges in a global regulatory environment.
- Advanced understanding of internal processes and procedures. Oversees the development of submission/product registration dossiers of more complex products. Uses their broader expertise and experience for more difficult assignments. Mentors more junior team members in this area.

Regulatory knowledge & strategy:

- Deep understanding of healthcare regulatory frameworks and how to maintain compliance while accelerating innovation for customers and patients, Using appropriate knowledge to manage complex issues. Ability to interpret and apply understanding of the regulators’ thinking to projects and apply strategies to the different needs of different regions without significant guidance. Anticipates potential regulatory obstacles, then creates mitigation or influencing strategy.

Manage Stakeholders:

- Effectively communicate and partner with stakeholders to understand and provide best solutions. Take initiative to address problems or opportunities and involves stakeholders for best solutions. Develops relationships that significantly influence the current and future direction for Roche and our products.
- Understands the structure, key roles and responsibilities of external customers/stakeholders. Understands and communicates timely and effectively the needs of external customers/stakeholders. Builds effective and enduring external relationships and applies effective stakeholder management practices. Contributes to audits by supporting preparation, execution and follow up.

VACC Leadership and Influencing:

- Starting to live the spirit of we all lead - identifies opportunities to develop VACC competency, Acts with integrity, courage, passion and honors commitments, Contributes an inclusive environment which supports all dimensions of diversity, Explores the opportunity of leadership and future contribution, Takes initiative when opportunities arise. Fosters an exchange of ideas and support amongst colleagues. Is good at promoting an idea or vision: persuading. Works effectively with other people over whom he or she has no direct authority.

Decision Making and Innovation:

- Ability to work day to day with minimal guidance to no supervision to correctly complete daily scheduled and unscheduled activities. Develop solutions and present both issues and solutions. Drive innovation within their own area of influence. Learn how to apply good decision making principles. Consistently generates new ideas. Leverages the unique talents and viewpoints of others. Seeks new opportunities and tries new approaches. Gathers information necessary to make decisions. Thinks through problems clearly and logically. Self motivated to come up with solutions. Is decisive; doesn’t procrastinate on decisions.

Problem Solving:

- Able to troubleshoot issues as they arise, independently develop and implement cost effective and non-complex actions solutions to ensure that daily work is completed without jeopardizing compliance. Ability to find solution options for highly complex problems and to make decisions to implement.

Agile Mindset and communication:

- Change ambassador for their environment. Actively develops their agile mindsets and behaviors and encourages others to do so as well, identifies and acts on opportunities for improvement within across Q&R, embraces new technologies and other means to simplify and increase productivity. Owns their regulatory data and promotes data stewardship within their RA teams and uses and promotes the usage of all regulatory tools. Contributes to or leads projects with an understanding of how business functions, systems, processes, and data management are connected and essential to achieving digitalization and strategic goals. Makes people feel that they are truly heard. Expresses complex ideas fluently and clearly. Encourages direct and open discussions about important issues. Can be depended on to tell the truth regardless of the circumstances. Recognizes and reflects/articulates multiple points of view on an issue. Provides honest input even in difficult situations. Speaks up and actively participates - creates an environment of recognition and appreciation.

Teamwork and Collaboration:

- Is able to pull people together around a common goal . Seeks to understand and build on different perspectives to enhance outcomes. Addresses and resolves conflict by creating an atmosphere of openness and trust. Brings out the best in people and teams.

Das sollten Sie als Senior Regulatory Affairs Manager m/w/d mitbringen:

- Bachelor’s / Master degree in Life Science, Data Science or related subject or equivalent experience (Completed training as a technician or laboratory technician; or equivalent qualification for the tasks
- At least 5 years experience, 5-7 Years preferred, in Regulatory, R&D, Quality, Operations and/or Clinical Some experience in Healthcare regulatory affairs. Advanced degree is considered an advantage.

- Can manage more complexity work and/or global projects, or equivalent experience.
- English fluent in spoken and written
- Working mostly independently, confident to approach interfaces (e.g. R&D, QC, and the Chinese Regulatory Affairs colleagues)
- Experience from Regulatory Affairs in China would be very desirable.

* Franz & Wach ist Unterzeichner der Charta der Vielfalt. Diese Stellenausschreibung richtet sich grundsätzlich an Menschen jeglichen Geschlechts oder Alters, jeglicher Herkunft, Orientierung oder Identität!

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Impressum