

Regulatory Specialist - Commercial / Post-Marketing & Remediation (CMC) (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 **Regulatory Specialist - Commercial / Post-Marketing & Remediation (CMC)** for a temporary assignment of 12 months.

A healthier future. It's what drives us to innovate. To continuously advance science and ensure everyone has access to the healthcare they need today and for generations to come. Creating a world where we all have more time with the people we love.

That's what makes us Roche.

At Roche, we believe in empowering you to thrive and do your best work. By bringing together our unique strengths in technical regulatory affairs, medicines, and technology, you will collaborate in an environment that nurtures growth, values your unique perspective, and drives sustainable innovation to transform healthcare for patients worldwide.

In the position of Regulatory Specialist (CMC) in Pharma Technical Regulatory (PTR), you will support technical regulatory activities across the lifecycle of commercialized pharmaceutical products.

This position is specifically focused on post-approval regulatory maintenance, change controls, regulatory deviations, system integration and remediation of legacy regulatory data and records.

The role requires strong CMC regulatory expertise, experience working with marketed products and strong proficiency in the Veeva RIM environment.

Tasks & Responsibilities

- Independently manage and execute global technical regulatory submissions for commercial products, ensuring compliance with local and regional registration requirements, internal policies and audit standards
- Manage the regulatory lifecycle of assigned commercial products
- Assess technical change records for regulatory impact and coordinate required post-approval regulatory activities
- Support post-marketing submissions, change controls and regulatory deviations
- Maintain and remediate CMC regulatory documentation and data in Veeva RIM and related document management systems
- Support system integration and clean-up of legacy regulatory information
- Represent Pharma Technical Regulatory on cross-functional project

BERATER



Adnan Ferizi
+41 61 280 50 46

Seniority Level
Mitarbeiter

Berufskategorie
Pharma & Chemie
& Life Science

Stellenprozent
100%

Jobtyp
Temporär

Referenz-Nr.
AFE-PC-T-57658

Jobregion
Basel

teams and provide regulatory advice

- Collaborate with local and global technical teams to ensure continued regulatory compliance
- Support interactions with Health Authorities and external partners on assigned technical topics
- Identify regulatory risks and proactively improve tracking, control systems and workflows
- Monitor changes in global regulatory requirements and assess potential impacts on marketed products and lifecycle strategies

Must Haves

- Minimum Bachelor's degree in a relevant field
- 3-4 years of CMC regulatory / technical regulatory experience
- Experience supporting commercialized pharmaceutical products
- Experience with post-approval / post-marketing regulatory maintenance
- Experience with regulatory change controls
- Experience managing or supporting regulatory deviations
- Working knowledge of legacy / old product data clean-up and remediation
- Strong proficiency in the Veeva RIM environment
- Experience maintaining regulatory submission documentation in Veeva
- Fluent English, written and spoken, minimum C1
- Proactive problem-solving ability and willingness to streamline legacy records and processes

Nice to Haves

- German language skills.
- Previous Roche experience.
- Experience with biologics.

Benefits

- Work with modern and up-to-date tools in an innovative work environment
- Experience a work culture that promotes diversity and inclusion and where all employees feel valued
- Benefit from financial support for your professional development plans
- 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
- Become part of one of the most prestigious pharmaceutical companies and actively shape the future of healthcare
- Work on a state-of-the-art campus featuring green spaces, meeting areas, and an inspiring atmosphere
- Take advantage of attractive fitness and swimming pool facilities or the gaming room as a creative retreat
- 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, provided you meet the relevant qualifications
- Start with a professional onboarding process and a thorough introduction to your new role during the Welcome Days

Are you interested? Don't 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

