Selectchemie Brazil
Work place: Sao Paulo, Brazil

RA & QA Manager (100 %)

About Selectchemie AG

Selectchemie is an independent Swiss company serving the pharmaceutical industry since 1969 as a premier supplier of high quality ingredients and generic finished dosage forms. As a full-service provider we create added value by offering comprehensive technical, scientific, regulatory and commercial support all along the value chain. Worldwide, our 110 experienced professionals with commercial and scientific background, based at the headquarters in Zurich, Switzerland and locations in 18 countries, provide customers, principals and suppliers with solutions tailored to their needs.

Join our Pharma LATAM team

We offer a broad product portfolio of APIs & excipients and are an established hub for customers sourcing high-quality bulk raw material as well as for renowned manufacturers who benefit from our broad customer base in various markets. We are continuously expanding our global network as well as our services. We are seeking a QA & RA Manager to join our Pharma LATAM sales team in achieving their regulatory and quality assurance objectives. This role involves close collaboration with internal teams, suppliers, and customers to ensure compliance with ANVISA and other relevant regulations. The ideal candidate will have a strong regulatory mindset, attention to detail, and excellent communication skills.

Your tasks and responsibilities

1. Regulatory Compliance and Submissions

- Ensure full compliance of customers' product registrations with ANVISA regulations and all applicable Brazilian health authority requirements, as well as the fulfillment of the partner' products to the regulatory guidelines in Mexico.
- Prepare, submit, and manage product registration dossiers and renewals with local regulatory agencies (ANVISA and CADIFA related).
- Continuously monitor regulatory changes and assess their impact on business operations, ensuring timely adaptation, including the regulatory landscape.
- Maintain up-to-date regulatory documentation and ensure prompt communication of updates to relevant stakeholders.
- Oversee the submission of CADIFA applications on behalf of API-manufacturing partners.
- Act as an officially designated authorized user to represent partners before ANVISA, including submission of GMP certification requests and, when applicable, participation in on-site inspections conducted by ANVISA in countries such as India, China, and across Europe.

2. Product Lifecycle Management

- Provide regulatory support throughout the product lifecycle, including coordination of regulatory approvals in line with launch timelines.
- Manage post-approval changes and variations, assessing their potential impact and implementing strategies to mitigate risks to customers.
- Maintain oversight of product registration status and related regulatory filings using internal systems and tools.

3. Sales and Commercial Team Support

- Offer expert regulatory guidance to sales and business development teams (customer) to support strategic decision-making.
- Deliver ongoing training and updates to the commercial team and business partners regarding ANVISA's regulatory requirements, facilitating the successful initiation of new projects.
- Assist in responding to regulatory inquiries, customer documentation requests, and public tenders.
- Work closely with commercial teams to ensure regulatory approvals are available on time for product commercialization.

4. Internal and External Communication

- Act as the primary liaison with Brazilian regulatory authorities, including ANVISA.
- Promote strong and transparent communication with global and regional regulatory affairs teams.
- Support the preparation and execution of customer qualification audits and official inspections conducted by regulatory agencies.
- Provide technical support to customers and partners in the resolution of quality or regulatory deviations, aiming at effective and compliant solutions.
- Training new employees.

5. Data and Systems Management

- Maintain comprehensive and accurate records of all regulatory submissions, approvals, and agency correspondence.
- Ensure that regulatory databases and internal reporting tools are updated regularly and consistently reflect the status of activities.

6. Regulatory Intelligence and Risk Mitigation

- Conduct ongoing surveillance of the Brazilian regulatory environment and provide strategic insights to internal and external stakeholders.
- Evaluate regulatory risks associated with market entry, product modifications, and discontinuations, and propose mitigation plans as needed.
- Participate in official regulatory meetings at ANVISA to discuss and align the most appropriate regulatory pathways, whether related to the issuance of the Good Manufacturing Practices Certificate (CBPF) or the submission and approval of the CADIFA (Active Pharmaceutical Ingredient Dossier).

7. Regulatory Intelligence and Risk Mitigation

- Lead, motivate and mentor high-technical people. This includes setting targets, monitoring performance, training and developing employees, and fostering a positive working culture.

Your profile

– Education: Degree in Pharmacy, Chemistry, Life Sciences, or a related technical field.
– Experience: 3-5 years of previous experience in Regulatory Affairs and Quality Assurance, preferably in the pharmaceutical sector.
– Knowledge: Solid understanding of regulatory requirements from ANVISA and COFEPRIS, GMP requirements, and pharmaceutical regulatory processes.
– Skills: Strong analytical skills, attention to detail, and problem-solving abilities.
– Communication: Ability to effectively interact with internal teams, customers, and suppliers.
– Languages: Proficiency in English and Portuguese; Spanish is a plus.

What's in for you?

– Entrepreneurial position in a dynamic globally acting team
– Your input is key and you're part of creating our future success
– Close cooperation with colleagues across the entire hierarchy within Selectchemie
– Short decision processes
– Attractive compensation package and part or 100% remote working depending on where you will be located

We are pleased to receive your complete application via:
jobs@selectchemie.com