Selectchemie Brazil
Work place: Sao Paolo, Brazil

QA & RA Specialist (100 % workload)

About Selectchemie AG

Selectchemie is an independent Swiss company serving the pharmaceutical and nutrition 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 120 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 Associate to support our Pharma LATAM sales team in achieving their regulatory and quality assurance objectives, with focus on Brazilian and Mexican markets. 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

ANVISA Submissions & API/Excipients Registration

- Prepare, submit, and manage ANVISA dossiers from our partners and of our ownership for API and excipient registrations, renewals, variations, and amendments, in accordance with RDC 359/2022 and RDC 361/2022, which require registration of APIs used in distribution and manufacturing in Brazil.
- Ensure compliance with ANVISA regulatory guidelines, monitor updates to regulatory frameworks, and implement required modifications proactively.
- Be designated as an authorized user in order to act on behalf of the suppliers for CADIFA application.

Life Cycle Management (LCM)

- Carry out lifecycle maintenance activities, including annual renewals, post-approval changes, and variations for APIs registrations – CADIFA under established procedures
- Conduct gap analysis for regulatory documents and gather necessary supporting documentation from suppliers and internal stakeholders.

Regulatory Intelligence & Compliance

- Monitor evolving Brazilian regulatory requirements and advise stakeholders accordingly.

– Support internal teams—such as Quality, Supply Chain, Legal, and Commercial—by providing up-to-date regulatory guidance for API/excipient registration, import, storage, and distribution compliance.

Client & Stakeholder Support

– Provide regulatory support and guidance to internal clients (e.g., sales, procurement) and external clients (e.g., manufacturers or exporters of APIs/excipients) regarding registration strategy, timelines, and documentation requirements.
– Assist during ANVISA inspections, inquiries, or audits, and support resolution of any regulatory issues by preparing requested documentation and supporting senior colleagues.

Documentation & Submission Management

– Assemble submission packages with precision—compiling documentation, certificates (e.g., GMP, certificates of analysis), product specifications, technical data, and translations where necessary.
– Maintain regulatory dossier documentation in tracked systems to ensure completeness and ease of retrieval.

Cross-Functional Collaboration

– Coordinate with commercial, quality assurance, procurement, and legal teams to align on regulatory deliverables and prioritize registration activities.
– Share documentation with regional/global RA teams for alignment. .

Process Enhancement & SOP Development

– Follow existing SOPs related to APIs/excipients registration, dossier submission, product renewal, and regulatory intelligence and provide feedback on potential improvements
– Identify process inefficiencies and propose improvements to optimize submission workflows and compliance robustness.

Training & Regulatory Advocacy

– Educate relevant internal teams (e.g. sales, imports) on regulatory implications—for example, registration deadlines, documentation requirements, handling of restricted substances—to ensure regulatory awareness throughout the organization.
– When relevant, participate in trade associations or regulatory working groups to stay informed and potentially influence ANVISA's regulatory environment.

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: Understanding of ANVISA regulations, GMP, and 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 hybrid working

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