Selectchemie Brazil
Work place: Sao Paulo, Brazil

QA & RA Senior Specialist (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 Senior Specialist to join our Pharma LATAM sales team and act as a senior Quality Assurance reference, supporting the team in achieving its quality, compliance, and regulatory objectives. The role is primarily focused on Quality Assurance activities, including quality compliance, supplier and customer support, audits, quality documentation, and continuous improvement. In addition, the Senior Specialist will provide regulatory support and act as a backup to the RA function, ensuring continuity of key ANVISA-related activities and regulatory requirements when required.

Your tasks and responsibilities

1. Quality Assurance & Compliance

– Act as a senior Quality Assurance reference within the organization, ensuring compliance with applicable quality standards, internal procedures, and regulatory requirements.

Manage and coordinate assigned QA activities, including deviations, CAPAs, change controls, complaints, quality documentation, and other quality-related processes.

Support the maintenance and continuous improvement of the Quality Management System (QMS), including SOPs, work instructions, and quality processes.

– Provide QA guidance to internal stakeholders and support the identification and implementation of appropriate corrective and preventive actions.

2. Audits, Inspections & Supplier Quality

– Coordinate and/or support customer qualification audits, supplier audits, and regulatory inspections, including preparation, follow-up, and management of resulting actions.

– Support the qualification, evaluation, and monitoring of suppliers and manufacturing partners from a QA perspective.

- Review supplier quality documentation, certifications, quality agreements, questionnaires, and other relevant quality information.
- Act as a key QA contact during audits and inspections and ensure appropriate follow-up of observations and commitments.

3. Regulatory Affairs – Backup & Support

Provide regulatory support and act as a backup to the RA function, ensuring business continuity during absences or periods of increased workload.

Support ANVISA activities related to API and excipient registrations, renewals, variations, amendments, and CADIFA applications, in accordance with applicable Brazilian regulations.

Assist with regulatory document reviews, gap assessments, submission preparation, and follow-up with suppliers and internal stakeholders.

- Support responses to ANVISA inquiries, customer requests, audits, and other regulatory matters as required.

4. Regulatory Intelligence & Compliance

Monitor relevant developments in Brazilian quality and regulatory requirements and communicate potential impacts to internal stakeholders.

Support the assessment of regulatory and quality risks related to products, suppliers, manufacturing sites, and business activities.

- Collaborate closely with the RA colleague to ensure alignment between quality and regulatory requirements.

5. Cross-Functional & Stakeholder Support

- Work closely with Commercial, Supply Chain, Procurement, Legal, RA, and other internal teams to provide quality and regulatory guidance.
- Support customers, suppliers, and business partners in resolving quality and compliance-related issues.
- Provide QA input for new suppliers, products, customers, and business opportunities.
- Act as a senior point of contact for assigned QA topics and provide practical, solution-oriented guidance.

6. Documentation, Systems & Process Improvement

- Ensure QA documentation, records, databases, and tracking systems are complete, accurate, up to date, and readily retrievable.
- Identify process gaps and opportunities for improvement and contribute to initiatives aimed at increasing efficiency, compliance, and quality robustness.
- Support the development and revision of SOPs, work instructions, templates, and other quality documentation.

7. Training, Mentoring & Business Continuity

- Provide training and guidance to employees on QA processes, SOPs, quality requirements, and compliance expectations.
- Act as a technical reference and mentor for less experienced QA/RA team members.
- Ensure continuity of critical QA activities during the absence of colleagues or the QA/RA Manager, within the defined scope of responsibility.
- Provide backup support for key RA activities to ensure regulatory deadlines and business-critical activities are maintained.
- Take ownership of complex QA projects and provide senior-level expertise and recommendations to the QA/RA Manager and relevant stakeholders.

Your profile

- Education: Degree in Pharmacy, Chemistry, Life Sciences, or a related technical field.
- Experience: 5+ years of relevant experience in Quality Assurance and/or Regulatory Affairs, preferably within the pharmaceutical industry, with a strong focus on Quality Assurance.
- Knowledge: Solid knowledge of GMP, Quality Management Systems, and applicable ANVISA requirements. Knowledge of CADIFA and Brazilian regulatory requirements for APIs and excipients is an advantage.
- kills: Strong analytical and problem-solving skills, attention to detail, sound judgment, and the ability to work independently on complex topics.
- Communication: Excellent communication and stakeholder management skills, with the ability to interact effectively with internal teams, customers, suppliers, and regulatory authorities.
- Languages: Fluent English and Portuguese; Spanish is a plus.
- Seniority: Proactive, reliable, and able to take ownership of assigned activities, mentor colleagues, and provide backup support to the RA function when required.

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

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