

	<b>JOB DESCRIPTION</b> Regulatory Affairs I	CÓDIGO: F-622-SGC-007
		REV: B
		FECHA: Febrero 2022
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<b>JOB TITLE:</b> Regulatory Affairs	<b>REVISION:</b> September 2021
<b>CLASSIFICATION:</b> Exempt	<b>REPORTS TO:</b> Division Supervisor

## Overview of the role of Regulatory Affairs Specialist at Rebexa Group

Coordinate and document internal regulatory processes, such as document inspections, license renewals, or registrations. May compile and prepare materials for submission to customers or regulatory agencies. Work on document preparation, information management, file maintenance, and coordination of tasks across multiple departments, as well as data analysis to create final product submission dossiers for different authorities in order to obtain the licensing and/or & the registration of the product at different countries. *On this role the incumbent will start to establish direct contact with customers.* Tasks must be performed in compliance with established Quality System.

### Essential job tasks:

1. Compile and maintain regulatory documentation databases or systems.
2. Coordinate efforts associated with the preparation of regulatory documents or submissions.
3. Coordinate, prepare, or review regulatory submissions for domestic or international projects.
4. Interpret regulatory regulations or regulation changes and ensure that they are communicated to internal and external customers.
5. Provide technical review of data or reports that will be incorporated into regulatory submissions to assure scientific rigor, accuracy, and clarity of presentation.
6. Review product labeling, packaging, specification sheets, or test methods for compliance with applicable regulations and policies.
7. Advise customers teams on subjects such as premarket regulatory requirements, export and labeling requirements, or clinical study compliance issues.
8. Determine the types of regulatory submissions or internal documentation that are required in situations such as proposed product or device changes or labeling changes.
9. Obtain and distribute updated information regarding domestic or international laws, guidelines, or standards.
10. Participate in internal or external audits.
11. *Start developing project leader skills by the preparation of additional information or responses as requested by customers or regulatory agencies.*
12. *Will start to be introduced on a personal and direct contact with customer, it has guidance until customer service training is complete an execution is efficient.*
13. *Start on personal direct contact conferences and phone meetings participation, with direct supervision.*

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14. Recommend changes to customer procedures in response to changes in regulations or standards.
15. Prepare written responses to customer requests for information, such as product data, written regulatory affairs statements, surveys, questionnaires and any other customer specific concerns. *Some of the responses will be reviewed by colleague or supervisor.*
16. Suggest changes and/or updates to internal standard operating procedures, work instructions, or policies.

### Other work activities

1. **Evaluating information to determine compliance with standards** -- Using relevant information and individual judgment to determine whether events or processes comply with laws, regulations, or standards.
2. **Getting information** -- Observing, receiving, and otherwise obtaining information from all relevant sources.
3. **Updating and using relevant knowledge** -- Keeping up-to-date technically and applying new knowledge to your job.
4. **Interacting with computers** -- Using computers and computer systems to write, set up excel functions, enter data, or process information.
5. **Communicating with supervisors, peers, customers, and regulatory agencies** -- Providing information by telephone, by phone texting, written forms, e-mail, or in person.
6. **Organizing, planning, and prioritizing work** -- Developing own specific goals and plans to prioritize, organize, and accomplish your work.
7. **Processing information** -- Compiling, coding, categorizing, calculating, tabulating, auditing, or verifying information or data.
8. **Making decisions and solving problems** -- Analyzing information and evaluating results *propose* the best solution to solve problems. *Low decision-making level.*
9. **Establishing and maintaining interpersonal relationships** -- Developing constructive and cooperative working relationships with others and maintaining them over time.
10. **Interpreting the meaning of information for others** -- Translating or explaining what information means and how it can be used.
11. **Diversity Mindset** -- Understanding that each individual is unique and recognizing our individual differences. These can be along the dimensions of race, ethnicity, gender, sexual orientation, socio-economic status, age, physical abilities, religious beliefs, political beliefs, or other ideologies.
12. **Communicating with persons outside organization** -- Communicating with people outside the organization, representing the organization to customers, the public, government, and other external sources. This information can be exchanged in person, in writing, or by telephone or e-mail and could be in Spanish or English.
13. **Documenting/Recording Information** -- Entering, transcribing, recording, storing, or maintaining information in written or electronic form.
14. **Identifying Objects, Actions, and Events** -- Identifying information by categorizing, estimating, recognizing differences or similarities, and detecting changes in circumstances or events.

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15. **Analyzing Data or Information** -- Identifying the underlying principles, reasons, or facts of information by breaking down information or data into separate parts.
16. **Performing administrative activities** -- Performing day-to-day administrative tasks such as maintaining information files and processing paperwork.
17. **Support team's environment** -- Encouraging and building mutual trust, respect, and cooperation among team members.
18. **Monitor processes, materials, or surroundings** -- Monitoring and reviewing information from materials, events, or the environment, to detect or assess problems.
19. **Resolving conflicts and negotiating with others** -- Handling customer or regulatory agencies complaints, settling disputes, and resolving conflicts, or otherwise negotiating with others, *with direct supervision*.
20. **Training and teaching others** -- Identifying own educational needs, as well as share with other knowledge obtained.

## REGULATORY AFFAIRS COMPETENCIES

1. **Strategy** – Ability to assess information and by using an analytical thought process to achieve a defensible conclusion.
1. **Communication** – Communicating with diverse populations through verbal, written and non-verbal means. Including questioning to obtain better understanding.
2. **Business and Organizational Awareness** – Understanding of what the role of regulatory agency and their authority, structure means and represents. Awareness on the expectations on ethical behavior of working with regulatory agencies. Respect confidentiality of employer as well as the customers. Recognize the meaning of conflict of interest.
3. **Technical** – Competencies related to the regulatory oversight of healthcare/veterinary products development and commercialization.
4. **Influence** Ability to have a positive impact on others, to persuade or convince them to gain their support. Being persuasive and engaging to build buy-in from key people.
5. **Results oriented** – Recognize what results are important, and what steps need to be taken to achieve them. Being proactive and results-driven and will always take the necessary steps to achieve set goals or targets.

## Expected behaviors.

1. Attention to detail — Work requires careful detail and in-depth care to complete work tasks.
2. Integrity — Work requires being honest and ethical.
3. Cooperation — Ability to work cooperatively within diverse teams, work groups and across the organization to achieve group and organizational goals. It includes the desire and ability to understand and respond effectively to other people from diverse backgrounds with diverse views.
4. Reliability — Demonstrates a **medium level** of dependability in all aspects of the job. Behavioral Indicators: Shows commitment/dedication and accountability in one's work, and follows through on all projects, goals, aspects of one's work. Completes all assigned tasks on time and with **medium level of supervision**.
5. Self-control and tolerance — Demonstrates awareness, accurate assessment and control of one's own emotional state, attitudes, beliefs system, image, and strengths in a way to maintain momentum, personal effectiveness, and emotional stability, even in the face of adversity, provocation, stress and/or high workload.

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## POSITION REQUIREMENTS

### A. Technology skills required.

1. Software; Microsoft Office tools; Excel, Power Point, Word, Adobe Acrobat and/or Nitro
2. Communication tools as per Teams, Zoom and emails.

### B. Basic knowledge requirements needed to hold the position.

1. **Customer service approach** — The act of taking care of customer needs by providing and delivering professional, helpful, high quality service and assistance before, during and after the customer's requirements are met.
2. **Project Management** — *Some knowledge* on project management **basics** including the initiation, planning, executing, controlling, and closing of a project.
3. **Psychology** — General knowledge of human behavior and performance; individual differences in capacity, personality, and interests; learning and motivation and emotional intelligence to promote collaborative working styles.
4. **Security and Public Safety** — Knowledge of relevant equipment, policies, procedures, and strategies to promote effective security of operations for the protection of persons, data, and property.

### C. Skills Required

1. **Listen to the active mind** — Pay full attention to what other people are saying, take time to understand the points being made, ask questions accordingly, and not interrupt at inappropriate times.
2. **Understanding Technical Reading** — Understand written sentences and paragraphs in technical work-related documents in Spanish and English.
3. **Time management** — Efficiently manage your time and that of others.
4. **Coordinate** — Adjust your actions in relation to the actions of others.
5. **Oral Understanding expression, speech clarity** — The ability to listen and to understand the information and ideas presented through words and sentences spoken. As well as to transmit information and ideas effectively, when speaking to and for others. (Spanish and English)
6. **Written Understanding** — The ability to read and understand written information and ideas in Spanish and English.
7. **Monitoring/Evaluation** — The performance of different activities performs by yourself, to make continuous improvements or take corrective action.
8. **Problem sensitivity** — The ability to know when something is wrong or likely to go wrong, without falling into constant pessimism.
9. **Basic Troubleshooting** — Identifies issues and reviews related information to develop and evaluate options and implement solutions.

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10. **Judgment and decision-making** — Considering the relative costs and benefits of potential actions to choose the most appropriate step or action.
11. **Learning Strategies** — Select and use appropriate training/instructional methods and procedures for the situation when learning or teaching new things.
12. **Persuasion** — Persuading others to change their minds or behaviors.
13. **Timeshare** — The ability to switch back and forth between two or more activities or sources of information (such as speaking, sounds, touching, or other sources).
14. **Self-starter** — Sufficiently motivated or ambitious to start a new actions or initiatives or to pursue further projects without the help of others.
15. **Strong passion** — Intense enthusiasm and excitement for what you do.
16. **Multitask** — Handling several tasks, priorities, and projects with different customers at once and work well in a high pace environment.
17. Ability to work with **medium supervision** while working as part of a high-quality team.

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#### D. Education and Experiences Required

1. BS in biology and/or science related field preferred.
2. Two (2+) or more years' experience in a pharmaceutical or medical device environment, preferred. Or at least 1 year of experience as a Document Control at Rebexa Group, Inc.
3. Three (3+) or more years of experience on similar position at a pharmaceutical or medical device environment, would be accepted only if the candidate does not have appropriate educational background.

#### Physical Requirements and Work Environment

1. **Perform general physical activities** — Perform physical activities that require considerable use of your arms and legs and move your entire body, such as walking, bending, and manipulating materials.
2. **Handling and moving objects** — Use of hands and arms in handling, installing, positioning, and moving materials, and handling things.
3. **Contacts required at work** — The extent to which the position requires the ability to gain cooperation, persuade and influence others.

<i>Contacts</i>	<i>Frequency</i> (N) Never, (O)Occasionally (C)Constantly
Immediate pairs	C
Colleagues in other departments.	O
Immediate Manager	C
Customers	O
Other (specify)	

4.

<b>Physical Activities</b> <i>Check all that apply</i>	<b>Frequency</b> <i>(N) Never, (O) Occasionally            (C) Constantly</i>
Up or downstairs	N
Move-in different positions to perform tasks in various environments, including tight spaces.	O
Staying in a stationary position, often standing, or sitting for extended periods of time.	C
Move to perform tasks or move from one workplace to another, walking.	O
Adjust or move objects up to 20 pounds in all directions.	N
Communicate with others to exchange information.	C
Repeat movements that may include wrists, hands and/or fingers.	C
Operating machinery and/or power tools.	N
Operating motor vehicles or heavy equipment.	N
Evaluate the accuracy, neatness, and thoroughness of the assigned work.	C

5.

Position	% time in position
Walk	Low
Standing in a static position	Low
Lifting	None
Pushing	None
Narrow or confined space	Low
Sitting	High

6.

<b>Environmental conditions</b> <i>(Check all that apply)</i>	<b>Frequency</b> <i>(N) Never, (O) Occasionally            (C) Constantly</i>
Low temperatures.	N
High temperatures.	N
Exterior elements such as precipitation and wind.	N
Noisy environments.	N
Dangerous conditions.	N
Poor ventilation.	N
Small and/or enclosed spaces.	N

1. **Working conditions:** Degree of exposure to adverse conditions

There are no adverse working conditions.

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**EMPLOYEE CERTIFICATION**

I certify that I received a copy of this Job Description. I have read it (or read it to me) and fully understand all my duties and job responsibilities. I certify that I can perform the functions described with or if I provide reasonable accommodation. I understand that my work may change temporarily or regularly according to the needs of Rebexa Group, without being specifically included in the job description.

If you have any additional questions about the work tasks specified or not in this Job Description, I must discuss them with my immediate supervisor. In addition, I understand that future evaluations, performance bonuses, pay increases, and job retention areas are based on my ability to perform the duties and responsibilities described in this job description to the satisfaction of my supervisors, while meeting the business metrics and standards.

Employee's Name \_\_\_\_\_

Employee's Signature \_\_\_\_\_

Date \_\_\_\_\_