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Sr. Regulatory Affairs Specialist.

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Company: Philips

Location: Buenos Aires

Category: computer-and-mathematical

Job Title

Sr. Regulatory Affairs Specialist.

Job Description

Sr. Regulatory Affairs Specialist.

Responsible to execute the regulatory strategies of new product introduction and lifecycle product (renewals, modifications, etc.) by coordinating, compiling, and submitting applications to the regulatory agencies in accordance with regulatory compliance and business strategy for Argentina, Bolivia, Chile, Paraguay and Uruguay countries.

The role is critical in interaction with commercial and regulatory partners in the region to expedite submissions and approvals of application. The role includes but is not limited to collaboration with management personnel and cross-functional partners to establish and implement regulatory strategies and generation agility and compliance practices for the regulatory activities, leading projects of small and medium scope, such as regional projects.

Your role:

- Conduct and coordinate regulatory activities in Argentina, Bolivia, Chile, Paraguay and Uruguay countries.
- Execute strategies for new and existing products, based on business priorities, and global regulatory strategies to ensure timely commercialization of new or modified

products in compliance with current and appropriate regulations.

Support the supervision and positively influence the regulatory environment by representing the company in regulatory industry associations and anticipating the impact of new and changing regulations on the company’s portfolio.

To expedite approvals and to resolve post-submission queries and issues, communicate and conduct negotiations with Regulatory Agencies and/or commercial and regulatory partners, as needed.

Support the evaluation of proposed product modifications for Regulatory impact, completing Regulatory Assessments as needed.

Maintain the appropriate regulatory framework (processes, procedures, standards, etc.) to facilitate efficiency and compliance.

You're the right fit if:

You hold a **bachelor’s degree in biomedical engineering or similar.**

You have acquired a **minimum 5 years of regulatory experience** in highly regulated medical devices industry, including experience in regulation in **Argentina, Bolivia, Chile Paraguay and Uruguay.**

Your skills included strong interpersonal and communications skills, proactive, accurate, independent worker with initiative, ability to work cross functionally in a multinational organization, solution and detailed-oriented; well organized and self-motivated, ability to prioritize multiple tasks and projects, problem-solving skills being able to accurately analyze situations and propose solutions.

Excellent written and oral communication skills in Spanish and English.

About Philips

We are a health technology company. We built our entire company around the belief that every human matters, and we won't stop until everybody everywhere has access to the quality healthcare that we all deserve. Do the work of your life to help the lives of others.

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If you’re interested in this role and have many, but not all, of the experiences needed, we encourage you to apply. You may still be the right candidate for this or other opportunities at Philips. Learn more about our commitment to diversity and inclusion .

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