

# Colombia Jobs Expertini®

## Regulatory Affairs Consultant

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Company: Parexel

Location: Medellin

Category: business-and-financial-operations

**When our values align, there's no limit to what we can achieve.**

We are looking for a Regulatory Affairs Senior Associate or Consultant to join our team located in Colombia. The candidate must understand the organization's basic consulting models and methodologies, as well as elementary knowledge of what services PC provides. A Senior Associate or Consultant may act in a client facing role with support from line management. Interested candidates must have 3 or 4 years of experience working with clinical trial regulation in Colombi, including submitting regulatory dossiers and responding to Health Authority's queries during the whole cycle of the project.

### **Accountability / Scope**

As the professional in the Regulatory Affairs function, the individual will assist teams in the registration of products by preparing documentation needed for registration.

Individual shall develop partnership with other regulatory functions, affiliates & other stakeholder to define plan & strategy for submissions and any deficiencies and develop approach to solutions.

### **Major Responsibilities:**

Possess well developed skills in supporting development of product registration dossiers, submission, progress reports, deficiencies, and amendments.

Support teams to develop regulatory submissions strategy and update strategy based upon regulatory changes.

Partnership with affiliates to support regulatory agency interactions to expedite approval of pending registration.

Participates/ Awareness on project plans, regulatory submission strategy, any risks management.

Partner with other regulatory functions for smooth project transition and launch.

Support review of change controls to determine the level of modifications and consequent submission requirements.

Support pulling reports, metrics related to submissions and approvals.

Offers country specific regulatory support (INVIVA).

**Requirements Include:**

Prior experience (3-4yrs) and bachelor's degree in health care or science.

Good English skills.

Experience with Veeva Vault, not mandatory.

Good understanding and working experience in different regulatory environment in Colombia.

Decision Making/ Exercises judgment in selecting innovative, practical methods to achieve problem resolution. Influence stakeholders on technical solutions.

Adaptable in cultural and political diversity.

Capacity to learn and challenge status quo.

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