

Argentina Jobs Expertini®

Regulatory Affairs Associate - Publisher

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Company: Parexel

Location: Argentina

Category: other-general

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

An Associate must have a knowledge of the organization's basic consulting models and methodologies as well as basic knowledge of what services the department provides. An Associate must be technically competent and continually developing the skills as defined in the department, under general direction of his/her Line Manager and Supervisor, taking responsibility for ensuring that client work is performed and delivered on time, meeting the quality expectations based on Processes of the department and client preferences.

The publisher:

The publisher assists in the production of submissions and delivery of regulatory services in accordance with defined agency guidelines (ICH) while balancing the quality and timeliness of customer deliverables. A Publisher must be technically competent and continually developing the skills as defined in the responsibilities section of this document. Publisher, under the general direction of a Line Manager and Supervisor takes responsibility for ensuring that client work is performed, and delivered on time, meeting the quality expectations of the department and the client. The guidance of more senior staff may be needed to accomplish more complex tasks.

Essential Function

The Publisher of the Lifecycle team is responsible for the following items during her/his shift:
Works effectively within a team environment, reporting to his/her LM and Supervisor.

Works within broad project guidelines as directed by Line Manager.

With the guidance of the Supervisor and Manager, demonstrates the ability to prioritize work to achieve specified project outcomes.

Under supervision provides electronic publishing services, including preparation of submission packages, bookmarking, hyperlinking, compilation among others.

Under supervisor performs basic document management task including file transfer, storage, tracking and archival.

Capitalizes on opportunities to improve one's own performance and seeks feedback from Manager,

Supervisor, and colleagues. Applies information provided by Manager or supervisor to complete assigned project activities.

Produces quality work that meets the expectations of the department based on process and client needs.

May serve as client facing role for publishing submissions.

Identify and escalate issues to upper management for a quick resolution based on process and client needs.

Ensures that the tasks received are done with quality.

Work and prepare in trainings of New Regulations that will help to the global team.

Prepares planners, forms, and covers for specific projects.

Understands ICH Regulations and Health Authorities regulations that impact in his / her daily work.

Skills:

Autonomy and proactivity organized knowing how to prioritize and plan.

Interpersonal communication.

Client focus, results orientated,

Flexibility to work in different scenario.

Minimum Work Experience:

Initial years of experience in an industry-related environment.

Preference Regulatory knowledge, ICH Guidance.

Education:

Scientific (Pharmaceutical, Biochemistry, Biotechnology, others) or Technical Discipline (Translator, IT)

Language Skills:

Fluent verbal and written English.

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