

Argentina Jobs Expertini®

GRA-Int Alliance Regulatory Senior Analyst - SPECC

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Company: Lilly

Location: Buenos Aires

Category: computer-and-mathematical

We're looking for people who are determined to make life better for people around the world.

Partner Collaboration and Oversight

Collaborate on maintaining strong working relationships with assigned Partners.

Keep track and Document submission plans and follow-up on progress of submission/timelines with assigned Partners.

Conduct routine oversight and keep track of performance metrics, via regular interactions with the Partner(s).

Serve as regulatory point person for any queries from Partner when the Alliance Regulatory Manager is not available.

Serve as affiliate regulatory point person for queries from the business or global functions (GRA, Quality, Supply Chain, Manufacturing and Legal)

Archive External Party Management documentation

Regulatory Planning

Collaborate with Partners to ensure timely and clear dossier requirements are provided to Lilly support groups during submission planning

Collaborate with the Alliance Regulatory Manager to liaise cross-functionally with Lilly and the External Partners to agree submission strategy for new products, new indications, renewals and source changes/adds

Maintain submission plans are created and maintained in RIM based on information from Partner

Support implementation of the Regulatory Plan in alignment with Lilly and Partner business plans.

Dossier Management

Work with global Lilly functions to obtain all required submission documents and ensure timely responses to Regulatory Authority requests received from the Partner

Coordinate feedback to ensure documents are as required by Partner and use regulatory expertise to provide creative solutions/alternatives in cases where Lilly is unable to meet requirements.

Provide submission documents to Partner as per agreed timelines

Archive electronic copies of applications.

Regulatory Compliance

Maintain data integrity of internal Regulatory IT tools with defined compliance metrics.

Support implementation of local quality system in line with the global quality system and local regulations.

Support internal and external audits / assessments / self-inspections in collaboration with Regulatory Quality personnel.

Raise awareness to leadership and relevant functions on compliance issues and initiatives.

Labelling

Perform the function of Alternate or Delegate Affiliate Labelling Responsible Person (ALRP), ensuring that Product Information complies with Lilly Core Data Sheet.

Follow global labelling procedures to review Proposed Labelling for exceptions to Core Labelling and ensure all such exceptions are documented

Create and/or support creation of labelling projects in BLUE and liaise with Supply Chain and PPD to ensure new/revised labelling available in line with Partner's timelines

Process Improvement

Support alignment and implementation of internal regulatory initiatives.

Personal and Professional Development

Knowledge and understanding of local and regional regulations and local, regional, and global regulatory procedures.

Develop Country/Subject Matter Expertise in one or more countries and/or key areas of Regulatory Affairs (CMC, Labelling, etc.)

If needed, attend appropriate external regulatory trainings to develop technical expertise

Lilly does not discriminate on the basis of age, race, color, religion, gender, sexual orientation, gender identity, gender expression, national origin, protected veteran status, disability or any other legally protected status.

#WeAreLilly

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