Job Description: **EMEA Regulatory Professional** **Requisition ID: 00001DPJ**

Please send your application to Ivelina Guneva IGuneva@its.jnj.com

You will be responsible for supporting the Regulatory Liaison (RL) for a broad range of regulatory activities in the Established Products area in the Europe/Middle East/Africa (EMEA) region.

Main duties and responsibilities:
You are responsible to provide regulatory input on submission documents to ensure compliance with regulatory requirements. You may also provide regulatory support for and appropriate follow-up to inspections, audits and issue management. You act as the regulatory representative on specific multi-disciplinary teams as well as provide support in portfolio optimization activities. A more detailed description of the role requirements follows:

1. Strategic and tactical input in Post-approval and Life cycle management including Portfolio optimization and issue management

- Support the RL to advise the Project Team and/or Regional Therapeutic Area Leader on applicable regulatory issues, project-specific regulatory issues, and issues related to regional regulatory climates
- Participate in global regulatory team meetings, cross functional life cycle management and issue management teams as appropriate.
- Work to understand the competitive landscape, e.g., views of HA, regulatory precedents, labelling differences and therapeutic area issues.
- Keep abreast of current and pending approvals and issues in specific therapeutic areas and be knowledgeable of laws, guidances and requirements related to those areas.

2. Liaison with Regulatory Agencies and Local Operating Companies, in support of the Regulatory Liaison to:

- Act as RL-back-up contact with Regulatory Agencies as needed.
- Ensure that issues raised by Regulatory Agencies are promptly and adequately addressed
- Prepare team, manage, conduct and facilitate contacts/meetings with Regulatory Agencies as appropriate
- Negotiate labelling with Regulatory Agencies, going through each of the back-up strategies if necessary
- Act as contact with the EMEA RA functional network and ensure appropriate involvement with LOC regulatory affairs personnel. Ensure responses to queries are made in a timely manner and content is consistent with regulatory strategy

3. Input in document and process development

- Advise teams on required documents and processes to support Regulatory Agency contacts and submission
- Provide input to and review submission documents to ensure that they are fit for purpose and support labelling statements as appropriate
- Coordinate submission of appropriate data-driven (regional/local) responses to Regulatory Agency questions
- Ensure necessary regulatory activities are planned and adequately tracked in company systems
- Provides input to Standard Operating Procedure documents to ensure accuracy and compliance.

4. Clinical Trial Applications (CTA) and Post approval commitments

- Review clinical trial plans and protocols and ensure alignment with regulatory requirements

5. Health Authority Submissions and communications

- Provide regulatory support throughout life-cycle management
- Advise team in required documents and submission strategies (in collaboration with LOCs as appropriate)
- Assist with timely availability of submission documents and ensure that all document components are in place on time
- Draft and review some document content
- Understand submission details and liaise with Submission management, review and approve submission plans
- Review of submission documents to ensure compliance with regulatory requirements
- Ensure country-specific submission packages are made available to the LOCs in accordance with agreed plans
- Enable appropriate & timely communications to HAs in case of issues

Qualifications
Education and Experience:

- University degree - medical or paramedical (pharmacy, biology, veterinary etc.), or equivalent by experience
- Regulatory experience in drug development and commercialization. As this function is responsible for a broad portfolio of established products additional experience with late life cycle management & issue management will be an advantage.
- Experience with EU regulatory procedures (CP, DCP/MRP, referrals & national)
- Experience in working in project teams and/or a matrix organization
- Excellent oral and written communication skills.
- The ability to work successfully within a collaborative team environment and as an individual contributor and decision maker within a cross-functional organization.

Primary Location: Europe/Middle East/Africa, United Kingdom-High Wycombe or Belgium-Beerse

Primary Location	**Other Locations**	
Belgium-Antwerp-Beerse	Europe/Middle East/Africa-United Kingdom-England-High Wycombe	
Organization	**Job Function**	**Requisition ID**
Janssen Pharmaceutica N.V. (7555)	R&D	00001DPJ

Please note this post can be offered at Sr. Associate/Manager level dependent upon experience