EMEA Regulatory Affairs Liaison Established Products
Associate Director/Director-00001C3P (Janssen Pharmaceutica NV)

Position Summary
You will be the Regulatory Liaison (RL) for a broad range of regulatory activities in the Established Products area in the European/Middle East/African (EMEA) region.

Job description
Janssen's EMEA Regulatory Affairs group is looking for a talented, ambitious and experienced Regulatory Affairs Liaison to join the EMEA team for Established Products. The successful candidate will lead the EMEA Regulatory Affairs Strategy for a portfolio of diverse products, in close cooperation with the global and regional project teams and direct reports. The ideal candidate will bring to this role a high-level awareness of the EU and broader EMEA regional regulatory environment, including Central/MRP/national procedures, issue management and portfolio optimization.

The candidate will require regulatory expertise and problem-solving capabilities that will enable successful development of regulatory strategies and technical solutions to support the business. The candidate will have excellent interpersonal, negotiation and communication skills. The successful candidate will have the ability to work across different businesses and cultures on a worldwide basis to ensure alignment and compliance with key stakeholders. This position is open at Associate Director or Director level. Depending on the profile of the final candidate, the appropriate level will be applicable.

Key responsibilities
- Strategic regulatory input in Post-approval and Life cycle management including Portfolio optimization and Issue management
- Liaising and negotiating with Regulatory Agencies, external partners and Local Operating Companies
- Advise teams on required documents and processes to support Regulatory Agency contacts, submission and maintenance activities
- Understand the competitive landscape, e.g., views of HA, regulatory precedents, labelling differences and therapeutic area issues.
- Ensure compliance and alignment with regulatory requirements and company processes

Qualifications
- University degree - medical or paramedical (pharmacy, biology, veterinary etc.), or equivalent by experience
- Broad 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
- Significant experience with people management will be a plus
- 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 remote organization.

Primary Location: Europe/Middle East/Africa-Belgium-Antwerp-Beerse
Other Locations: Europe/Middle East/Africa-United Kingdom, Europe/Middle East/Africa
Job Function: Regulatory Affairs

--- If you're interested in this position, please apply through our career site www.careers.jnj.com and search for requisition number 00001C3P. ---