Job Description

Please fill in this form and save it as described in SOP 000151.

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Background information			
Name of employee (John Doe)		**LEO-id**	
Revised (date and version)	1 Mar2021, v9		
Title (E.g. Specialist, coordinator, project manager, Head of Department etc.)	Principal Regulatory Affairs Executive UK/IE (with GDP)		
Department name (e.g. Patient Solutions Thrombosis)	Regulatory Affairs Department		
Org. Unit ID (optional) (e.g. 30030281)	GB30000071		
Location (Country/State/Provence/Region or City)	Hurley, United Kingdom		
Job type (e.g. Business Administration & Support, see Pulse for more info, here)	Senior Professional		
Job Level (e.g. P3, see Pulse for more info, here)	P5		
Immediate manager title (Reports to e.g. Vice President Sourcing)	Head of Regulatory Affairs UK/IE		
Business responsibility (if applicable)			
No. of direct reports	None.		
Financial magnitude (Budget owner, P/L, Sales and/or Cost)	None.		
Authority (Areas where the position holder is accountable)	Areas where the position holder is accountable – see below.		
Objectives and tasks			
Overall objective (Short description of the overall objective of the position - the purpose of the role)	To positively contribute towards increasing the company's financial results and the appropriate use of LEO Pharma products by: • Obtaining and maintaining clinical and/or marketing authorisation approval for the Company's products. • Providing strategic regulatory input from local market to drug development, e.g. biologics,		

	innovation, rare. Secure essential interface with EU Regional Leads. • Maintaining strong and positive working relationships with the Health Authorities in the UK and Ireland, Global Regulatory Affairs (GRA) and other key Global Departments.
Role and responsibilities (Short description of the tasks and responsibilities which are key to the role. List in prioritised order)	**Roles and responsibilities** • Responsible for executing highly complex or specialised projects or activities essential to the achievement of overall functional objectives. • Input into the preparation of applications to the UK Health Authority, the Medicines and Healthcare products Regulatory Agency (MHRA) and the Irish Health Authority, the Irish Healthcare Products Regulatory Authority (HPRA), for Clinical Trial and Marketing Authorisation approval. • Maintenance of existing Clinical Trial and Marketing Authorisations. • Preparation and maintenance of text for product packaging, patient leaflets, SmPCs, etc. • Update and verify eRIMS records, as applicable, for products registered in the UK and IE for which LEO Pharma UK/IE is Marketing Authorisation Holder. For products registered under MRP/DCP/CP, LEO Pharma UK/IE is responsible for provision of local specific details, eg MA, SmPC, PIL, labelling, marketing dates, etc. • Creation of local regulatory documents in eDOC LEO, as applicable. • Regulatory check of company promotional material to ensure consistency with the Marketing Authorisation. • Uploading and circulating regulatory documents in the LEO Pharma electronic Copy Approval system, as applicable. • Maintain current awareness of legislation affecting pharmaceuticals in UK, IE and Europe. • Maintain good working relationships with the Regulatory Authorities (MHRA, HPRA, EMA) and trade associations. • Maintain good working relationships with personnel in GRA to ensure all necessary data for submissions are available in a timely manner. • Deputise for the Head of Regulatory Affairs, or other team members, on an *ad hoc* basis, including representing UK/IE RA at global and external meetings. • Effectively communicate, both internally and externally, to key stakeholders, on matters of varying complexity. • Regulatory intelligence and networking: Contact with Regulatory Authorities, Trade Associations

	and other pharmaceutical companies, including attendance at external meetings. Reading of journals and other published articles. Review of new legislation when issued, and sharing information with key stakeholders, as applicable. • RA Project Management, with minimal supervision. • Active participation in RA Working Groups, as applicable. • Coaching and mentoring of other GRA team members. • Development of proposals to enhance existing processes and practices. • Good Distribution Practice (GDP) deputy, in the absence of the Head of Regulatory Affairs. • Support for the Annual Product Quality Review (APQR) for relevant product responsibilities. • Travel: Attendance at overseas meetings, including Head Office and other EU+ affiliates, as required.
Key working relationships (Interface and cooperation with e.g. internal functions or external partners)	• **Internal:** All departments in the UK/IE, including senior management. Regulatory Affairs colleagues in Region EU+. Global Regulatory Affairs, Global Safety, Global Quality Assurance, Clinical and Internal Market Access (IMA) departments, including Senior Management. Other EU+ affiliates. • **External:** Regulatory Authorities, Trade Associations.
Job specific competencies	
Requirements to e.g. • **Professional competencies** (education, training, experiences) • **Business insights** (knowledge of the business and industry) • **Behavioural competencies** (demonstrated behaviours - see Pulse for more info, *here*)	**Functional/Technical Skills:** • Degree in Life Sciences or Pharmacy or equivalent experience. • A high level of experience within Regulatory Affairs is essential for this role, as is knowledge and understanding of the pharmaceutical industry, particularly the Medical, Commercial, Market Access, Research and Information functions. • Ideally familiar with MHRA Portal and CESP, electronic document and information management systems (eg Veeva, eRIMS, eDOC and MyDoc) and IT systems (eg MS Word, Excel, Powerpoint, Lotus Notes, Visio and Outlook). **Behavioural competencies:** • Ensures accountability [1] • Collaborates [6] • Communicates effectively [7]

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	• Manages complexity [8] • Decision quality [12] • Being resilient [26]
Job description hereby understood and agreed: Date: _____ Employee's signature	**The correctness of the job description is hereby confirmed:** Date: _____ Manager's signature

Acknowledgement

LEO Pharma reserves the right to make modifications to this job description as deemed necessary by changing position and business requirements.

The job description is a requirement under LEO Pharma's Quality Management System. It does not form part of the employment agreement between the employee and LEO Pharma and cannot be relied on in this respect.