— we help people achieve healthy skin

Job Description

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

Background information			
Name of employee: *(John Doe)*	TBC	**LEO-id:**	TBC
Revised: *(date and version)*	RA_001_V8_Nov_2017		
Title: (*E.g. Specialist, coordinator, project manager, Head of Department etc.)*	Head of Regulatory Affairs UK/IE		
Department name: (*e.g. Patient Solutions Thrombosis)*	Regulatory Affairs UK/IE		
Org. Unit ID (optional): (*e.g. 30030281)*	GB30000071		
Location: *(Country/State/Provence/Region or City)*	Hurley, UK/IE		
Job type: *(e.g. Business Administration & Support, see Pulse for more info, here)*	Manager		
Job Level: *(e.g. P3, see Pulse for more info, here)*	M3		
Immediate manager title: *(Reports to e.g. Vice President Sourcing)*	Senior Director, Regulatory Affairs, EUROPE+		
Business responsibility (if applicable)			
No. of direct reports:	4		
Financial magnitude: *(Budget owner, P/L, Sales and/or Cost)*	Budget approximately £400,000 Responsible for UK and IE RA budgets		
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 products by: • Engaging and liaising with the UK and IE Health Authorities, the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Health Product Regulatory Agency (HPRA). • Supporting the RA team to obtain and maintain clinical trial and/or marketing approval for the Company's pharmaceutical products. • Managing, leading and co-ordinating the work of Regulatory Affairs staff by example and active participation in order to meet business targets. • Being the company technical expert on Regulatory Affairs.		

	• Maintaining strong and positive working relationships with the Health Authorities and our parent company in Denmark. • Managing the RA budgets for UK and IE.
Role and responsibilities: *(Short description of the tasks and responsibilities which are key to the role. List in prioritised order)*	**Role tasks** • Day to day management of Regulatory Affairs department. Manage and develop departmental employees/team. • Oversight of: — Maintenance of existing Clinical Trial and Marketing Authorisations. — Preparation and submission of applications to the UK Health Authorities (MHRA) and Healthcare Products Regulatory Authority (HPRA) for Clinical Trial and Marketing Approval for pharmaceutical products. — Regulatory check of Company promotional material to ensure consistency with Marketing Authorisations. • Liaise with the Senior Quality Manager to ensure all GDP requirements, SOPs and training are covered and in place. With regard to all activities relating to GDP, the Principal Regulatory Affairs Executive (with GDP) is responsible for deputising for the Head of Regulatory Affairs, when required. • Deputy contact for Health Authorities for product quality complaints (the Senior Quality Manager is the Primary contact). • Maintain current awareness of legislation affecting pharmaceuticals in UK and Europe and ensure company complies with all relevant legislation and actively volunteering information to stakeholders. • Maintain good working relationships with Regulatory Authorities (MHRA, HPRA, EMA) and trade associations. • Maintain good working relationship with Regulatory Affairs & Pharmacovigilance Department in Denmark to ensure all necessary data for submissions are available in a timely manner. Provide support for Group activities where requested. • Recommend and manage overhead and support budget. **Job Tasks** • Monitor workload and review progress of projects with each member of staff. Departmental meetings to share information and experience. Provide advice and guidance when required. Ensure staff are adequately trained by coaching or attendance at appropriate meetings. • Preparation, submission and follow-up of licence renewals, variations, etc. Preparation and maintenance of text for product packaging, patient leaflets, SmPCs, etc. • Preparation of appropriate documentation for submission. Liaison with personnel in HQ and Region to ensure appropriate data is available. Review

	and assess data prior to submission. Follow-up with Health Authorities to ensure successful outcome of applications. • Review and comment on Company promotional material to ensure any statements made are consistent with the Marketing Authorisations. • Liaise with the Senior Quality Manager to ensure all GDP requirements, SOPs and training are covered and in place. With regard to all activities relating to GDP, the Principal Regulatory Affairs Executive (with GDP) is responsible for deputising for the Head of Regulatory Affairs, when required. • Regulatory Intelligence: Contact with Regulatory Authorities, Trade Associations and other pharmaceutical companies. 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. • Build and maintain the knowledge base within the RA Department. • Advise senior management in UK/IE and HQRA and Region on regulatory issues, strategy and developments and the impact of these on the company. • Regular telephone and written contact with Health Authorities. Attendance at appropriate meetings. Actively participate in Trade Association working groups. • Regular telephone and written contact with Regulatory Department in HQ and Region. Visits to Head Office and other EU affiliates on regular basis. Advise on changes in data requirements, new legislation, etc. Actively participate in working groups on LEO Group projects and prepare and submit European applications where requested. • Preparation of budget forecast according to company plans. Monitor and review costs on on-going basis.
Key working relationships: *(Interface and cooperation with e.g. internal functions or external partners)*	• *Internal:* All departments in the UK/IE. Regulatory and Pharmacovigilance, Clinical and IMA departments in HQRA and Region. Other LEO affiliates. • *External:* Regulatory Authorities, Trade Associations. Other companies handling products through licensing agreements.
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, Pharmacy or equivalent experience. • Extensive experience in Medical Affairs including several years' senior management experience. It is important in this role to have a wide experience and understanding of the pharmaceutical industry particularly marketing, research and information functions.

	• Familiar with MHRA Portal and CESP, electronic document management systems, electronic Review Systems (eg Veeva PromoMats) and IT systems such as Word, Excel, PowerPoint, Visio, Lotus Notes and MS Outlook. • It is essential to keep up to date with scientific and regulatory changes on an ongoing basis. Frequent changes to the legislation make this a demanding aspect of the job. • Imperative to gain co-operation and influence of senior managers in Denmark and UK/IE. • Regulatory dossiers consist of large volume of complex data which must be reviewed and assessed prior to submission to the Health Authorities. **Behavioural competencies:** • Business insights [5] • Drives engagement [16] • Interpersonal savvy [20] • Persuades [24] • Plans and aligns [25] • Situational adaptability [31] • Strategic mindset [33]

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.