Job Description

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

Dermatology beyond the skin

Background information			
Name of employee (John Doe)		**LEO-id**	
Revised (date and version)			
Title (E.g. Specialist, coordinator, project manager, Head of Department etc.)	Head of Compliance & Medical Governance		
Department name (e.g. Patient Solutions Thrombosis)	MEDICAL DIVISION		
Org. Unit ID (optional) (e.g. 30030281)			
Location (Country/State/Provence/Region or City)	United Kingdom		
Job type (e.g. Business Administration & Support, see Pulse for more info, here)			
Job Level (e.g. P3, see Pulse for more info, here)	TBC		
Immediate manager title (Reports to e.g. Vice President Sourcing)	Medical Director UK/IE		
Business responsibility (if applicable)			
No. of direct reports	Two		
Financial magnitude (Budget owner, P/L, Sales and/or Cost)	Budget Owner, ~ £300K		
Authority (Areas where the position holder is accountable)	ABPI, IPHA, MHRA, HPRA		
Objectives and tasks			
Overall objective (Short description of the overall objective of the position - the purpose of the role)	▪ Under the direction of the Medical Director, acting as the interface between Global Compliance and the UK, to strategically partner with respective stakeholder groups internally, to identify opportunities and proactively offer solutions within the boundaries of Pharmaceutical compliance requirements. ▪ To be responsible for an operational framework of systems and processes, that enable employees to be accountable for the delivery of high quality, ethical initiatives across the lifecycle of POM products to		

	health care providers ensuring safe and appropriate use of LEO prescription medicines. ▪ Working alongside the medical director as the Compliance Ambassador - responsible for continuous improvement of compliance process / implementation and gaining positive support for the Compliance function throughout UK/IE and also in the field.
Role and responsibilities (Short description of the tasks and responsibilities which are key to the role. List in prioritised order)	• Business advisor, ensure compliance with all LEO company processes. This must be done in accordance with all relevant legislation and guidelines including Global Compliance, EU directives, UK Medicines Law, the ABPI Code of Practice, IPHA Code, MHRA guidelines for the advertising and promotion of medicines in the UK, HPRA for Ireland, and other agencies such as the Advertising Standards Authority and company standard operating procedures; • Manage an office and field based compliance executive team, who can also act as AQPs where appropriate • To lead on audit and CAPA management, for example global auditing teams, the Prescription Medicines Code of Practice Authority (PMCPA), external consultants and medical governance, of all activities associated with the promotion and advertising of medicines; • Provide support for Local SOP Responsible Person ▪ Deliver regular Medical Governance/Compliance updates to the Cluster Leadership team; ▪ Help deliver training on Compliance related topics and updates to the organisation; ▪ UK Code Compliance Officer interfacing with global and local Legal & Compliance and Governance functions; ▪ Lead creation, maintenance and execution of a Medical Governance plan incorporating strategic business involvement, regulatory activities, global and local policy and process review, audit and training activities; ▪ To contribute in a cross functional team environment, PMCPA case ruling expertise to add value to response content for complaints received from regulatory bodies ▪ To provide a source of expert guidance to Managers and ABPI/IPHA signatories on governance of commercial and medical activities, product support in accordance with all relevant legislation and guidelines including EU directives, UK Medicines Law, Irish medicines law, the ABPI Code of Practice, IPHA Code, MHRA guidelines for the advertising and promotion of medicines in the UK, HPRA for Ireland, and other agencies such as the Advertising Standards Authority;

	▪ To ensure that all changes to EU Directives, Medicines Law, ABPI Code of Practice, PMCPA case rulings, IPHA Code and case rulings, LEO SOPs and corporate compliance policies, other agency standards and guidelines are monitored and reflected in local compliance procedures; ▪ To ensure tracking and archive of LEO PMCPA & IPHA complaints repository is maintained. ▪ To collate, and coordinate annual HCP disclosures/TOV submission in accordance with UK/IE and European regulations ▪ Forecast and manage Medical Governance budget
Key working relationships (Interface and cooperation with e.g. internal functions or external partners)	**a) Subordinates –** Senior Compliance Executive, Field Compliance Executive **b) Superior(s) -** Medical Director, MD&VP UK/IE **c) Other Contacts** i) Within the Company LEO General Counsel, Finance and Controlling, Corporate Communications, Business Unit Directors, Heads of Market Access & Commercial Excellence, Medical Managers, and Platform Functional Heads ii) Outside the Company Prescription Medicines Code of Practice Authority (administers ABPI Code of Practice), IPHA, Advertising Standards Unit of the MHRA, HPRA, other agencies such as the Advertising Standards Authority and Faculty of Pharmaceutical Medicine of the Royal College of Physicians when required, Pharmaceutical Compliance Specialists. iii) Global Legal & Compliance, Quality Assurance team, Risk Management
Job specific competencies	
• **Professional competencies** (education, training, experiences) • **Business insights** (knowledge of the business and industry)	▪ Life science degree or equivalent ▪ Commercial role experience beneficial ▪ Knowledge of EU Directives, UK and Ireland Medicines Law, International and European Pharmaceutical Codes of Practice (EFPIA). ▪ Detailed knowledge of the ABPI Code of Practice, Regulatory Authority (EMEA, MHRA) requirements, MHRA guidelines for promotion of medicines, Advertising Standards Authority and other Agency requirements. IPHA and HPRA knowledge desirable but not essential. ▪ Good commercial awareness essential ▪ Good experience in people management
• **Behavioural competencies** (demonstrated behaviours - see Pulse for more info, *here*)	▪ Understanding the business – business insight and customer focus ▪ Building collaborative relationships – interpersonal savvy and builds networks ▪ Being authentic – has courage and instills trust ▪ Making complex decisions – manages complexity ▪ Influencing people – persuasive and communicates effectively ▪ Being flexible and adaptable – manages ambiguity with situational adaptability

Job description hereby understood and agreed: Date: _____ Employee's signature	**The correctness of the job description is hereby confirmed:** Date: _____ Manager's signature

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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.