— 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)*		**LEO-id:**	
Revision Date: *(dd-mmm-yyyy)*	18-Oct-2018		
Title: (*E.g. Specialist, coordinator, project manager, Head of Department etc.) (Outline internal vs. external, if applicable)*	Quality Assurance Manager		
Department name: (*e.g. Patient Solutions Thrombosis)*	Scientific Affairs		
Org. Unit ID (optional): (*e.g. 30030281 or N/A)*	Ca3130003966		
Location: *(Country/State/Province/Region or City, as applicable)*	Canada		
Job type: *(e.g. Business Administration & Support, see Pulse for more info, here)*	Generic Professionals		
Job Band & Job Level: *(e.g. P3, see Pulse for more info, here)*	P3		
Immediate manager title: *(Reports to e.g. Vice President Sourcing)*	Vice President, Scientific Affairs (Direct) Director, Regulatory Affairs and Quality Assurance (Dotted)		
Business responsibility (if applicable)			
No. of direct reports:	0		
No. of reports in total:	0		
Financial magnitude: *(Budget owner, P/L, Sales and/or Cost)*	N/A		
Authority: *(Areas where the position holder is accountable)*	N/A		
Objectives and tasks			
Overall objective: *(Short description of the overall objective of the position - the purpose of the role)*	The Quality Specialist's key role is to ensure the integrity of LEO products. The QA Specialist ensures that the manufacturing and distribution of LEO products are done according to Canadian Food and Drugs regulations. This function maintains quality compliance with Good Manufacturing Practices (GMP) and LEO Standard Operating Procedures (SOPs). The quality function also ensures the timely release of incoming product batches into the marketplace for sale; assisting LEO Pharma Inc. in meeting financial sales targets and ensuring that quality product is available to patients.		
Responsibilities: *(Short description of the tasks and responsibilities which are key to the role. List in prioritised order)*	Manage the Quality Control/Quality Assurance including but not limited to: lot management, stability review, temperature monitoring, maintenance of quality agreements, release of products for sale, product inspection (audits) and preparation and development of Standard Operating Procedures. This role is also responsible for document management, archiving of QA/QC records and		

	responding to any Compliance related issues such as Canadian Environmental Protection Act (CEPA) registry notices. **Quality Assurance** • Maintain LEO product list • Assist Regulatory projects that involve QA oversight including stability changes, updates to labelling etc. • Coordinating new launch shipments • Manage and evaluate (trending) product complaints, deviations, Corrective Actions and Preventative Actions (CAPAs) • Development, review, revision and implementation of SOPs as required • Annual product reviews and review of stability reports for compliance with Canadian registration • Together with Compliance and RAQA Specialist manage maintenance of quality agreements with manufacturers, wholesalers and distributors • Conduct inspections of distributors and wholesalers as necessary as per GMP requirements • Act as primary quality contact person with Third Party Logistics (3PL) and as qualified person for internal quality compliance matters • Implement recall procedures if necessary and perform mock recall yearly to ensure our recall procedures are adequate. • Monitor QA aspects of warehousing and shipping practices for compliance with warehouse procedure manuals (Third Party Logistics-3PL). • Liaise with customers and regulatory authorities regarding quality matters, including hosting inspections and responding to observations. **Quality Control** • Timely approval of incoming batches, batch inspection and perform release according to LEO SOPs • Maintain appropriate documentation (i.e., C of A's) and ensure document compliance according to GMPs. • Manage deviation reports. • Manage returns • Manage/check/follow-up on the monitoring the distribution and product handling of physician samples for compliance with labeled storage conditions • Managing off site retained samples according to GMP • Maintain QC master documents for all registered products **General** • Ensure compliance with appropriate SOP's, policies and guidelines. • Complete mandatory training in assigned timelines upon hire as well as when new policies, SOP's, guidances are issued. • Participate in personal development and training sessions as required for the position. • Work in a safe manner that does not endanger yourself or co-workers. Report any health or safety concerns (internal and external) in compliance with LEO policy and standard procedures. • Strive to consistently uphold LEO Pharma's core values. • Execute other duties as may be required by Executive team members and other members of LEO Pharma's Management team as training and experience allow.
Key working relationships: *(Interface and cooperation with e.g. internal functions or external partners)*	Internally this position interacts with all departments at LEO Pharma, in particular Compliance, Logistics, Medical Information, and LEO Corporate Quality Assurance. Externally this position interacts with Health Canada (Inspectorate),

	third-party logistics providers, wholesalers and distributors, industry organizations, consultants, vendors, and health care professionals.

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)*	• B.Sc. in Science, with analytical chemistry • Background in manufacturing and analytical techniques • 5 + years relevant experience in the regulated pharmaceutical industry, specifically including Quality Assurance/Quality Control and/or Regulatory Affairs • Experience with Health Canada GMP inspections and third party audits • Detail oriented • Solid decision making skills • Excellent communication skills • Solid computer skills (MS Office, MS Word, Lotus Notes, excel etc.) **Behavioural Competencies** • Customer Focus • Manages Ambiguity • Plans and Aligns • Courage • Communicates Effectively • Decision Quality • Adaptability • Builds Networks • Collaborates • Drives Results • Instils Trust • Strategic Mindsets
Working Conditions:	Normal business working conditions

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

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 documents the general nature and level of work but is not intended to be a comprehensive list of activities, duties and responsibilities required of job incumbents. Therefore, job incumbents are expected to perform all other duties as assigned or required, as training and experience allow.

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.