FORM – Job Description

Job Title:	**Regulatory Affairs Officer**

Job Purpose:	To support the Scientific Affairs Department in activities associated with the registration of EirGen's/OPKO's products in Worldwide markets including US, EU and Japan, as well as Regulatory compliance liaison with QA for registered products. The role includes regulatory activities associated with both human and veterinary new drug developments as well as generics. To support activities for running Bioequivalence and Clinical safety and efficacy studies.

Responsibilities:	• Licence maintenance support to customers, EirGen's Regulatory agents and internal departments within EirGen • Regulatory Compliance liaison with QA • Support licensing activities for existing Marketing Authorisation applications in Europe, US, Japan, Canada and various markets in South America, Asia and the Middle East • Dossier preparation for submission to all EirGen target markets, including liaison with R&D, QC, and Production as well as external experts where required • Strategic planning of regulatory activities in target markets for EirGen's products (human and veterinary; solid oral dosage forms, fill finish and inhalations) • Support activities in the areas of Bioequivalence and Clinical safety and efficacy study management

Minimum Qualifications & Experience	• Minimum B.Sc. or a third level qualification required, preferably in Chemistry, Pharmacy or Pharmacology. • Previous pharmaceutical experience required; 1-2 years regulatory affairs experience desirable.

Other Information	Reports to Senior Regulatory Affairs Officer or Manager as appropriate. **Skills & Behavioural Competencies:** **Skills** 1. Familiarity with cGMP and cGCP in pharmaceutical manufacturing. 2. Familiarity with EU and US Clinical trials legislation. 3. Familiarity with concepts of Regulatory Approval process for both new drug developments (human and veterinary), and human generic pharmaceutical products. 4. Technical knowledge of analytical/formulation development of pharmaceutical products including solid oral dosage forms (tablets, hard capsules, soft gel capsules), fill finish (biologics and small molecules) and inhalations. 5. Ability to understand complex clinical terminology and to learn new clinical research skills though working with internal and external experts. 6. Ability to assist in design and management of PK/bioequivalence and efficacy studies. 7. Working knowledge of EDMS (Electronic Document Management System). 8. Competent in the use of Microsoft Office.

	Competencies 9. Planning and organising – effectively develop and implement plans to accomplish project objectives. 10. Communication – write, speak and present information effectively across communication settings. 11. Adaptability – maintain effectiveness in varying environments and with different tasks, responsibilities and people. 12. Problem Solving/Analysis – secure relevant information and identify key issues and relationships from a base of information; relate and compare data from different sources, identifying cause-effect relationships. 13. Teamwork and Collaboration - working effectively with team / work group or those outside the formal line of authority (e.g. peers, senior managers) to accomplish organisational goals; taking actions that respect the needs and contributions of others, contributing to and accepting the consensus; subordinating own objectives to the objectives of the organisation. 14. Customer Service Orientation - making efforts to listen and understand the customer (both internal and external); anticipating and providing solutions to customers needs; giving high priority to customer satisfaction. 15. Initiative - making attempts to influence events to achieve goals; self starting rather than accepting passively; taking action to achieve goals beyond what is required; being proactive.

Signatures:	**Job Holder:**	*Print Name:*	
		Signature:	*Date:*
	Manager:	*Print Name:*	
		Signature:	*Date:*