Job Title: Regulatory Manager	Reporting to: Head of Regulatory	
Revision Date: November 2016	Department: Regulatory	
Signed: (manager) Date:	Signed: (employee) Date:	Signed: (QP) Date:

Position Overview

Reporting to the Head of Regulatory, this role will be based in our UK Head Office and will be involved in the day to day management of regulatory activity for existing and new products.

Essential main job functions:

- Manage the schedule of regulatory submissions including Marketing authorisation applications for innovative regulatory pathways (Centralised Procedure, Mutual Recognized Procedure or National requirements), variations and renewals
- Prepare and submit Marketing Authorisation dossiers in Europe and Rest of the World
- Responsible for the regulatory management of medical devices (Europe and Rest of the World) either for manufacturer or distributor
- Establish key contacts within the various Health Authorities
- Responsible for creating, updating, reviewing and approving product information (leaflets, labels, boxes, SPCs etc) and promotional materials
- Manage the regulatory activities with EUSA Pharma's local partner representatives in order to register and maintain the relevant marketing authorisations/licences.
- Participate in the preparation and management of the regulatory budget process

Additional Requirements:

- Management of the CMC activities with in line with pharmaceutical development, maintenance and strategy
- Maintain a strong working relationship with the medical/pharmacovigilance and marketing/ commercial teams
- Contribute to the implementation of the regulatory strategies for new product
- Manage regulatory intelligence
- Involvement with reimbursement/pricing dossiers

General Administration:

- Completion of regulatory documentation
- Maintain an understanding of company SOPs, Working Practices and Policies as required under GDP and related to the role.

Experience/qualifications required:

- Excellent communication skills
- Ability to build relationships with key stakeholders both internally and externally in order to obtain quick approvals

- Able to work independently, with moderate supervision on multiple projects and within multi-disciplinary teams
- Previous experience of regulatory requirements for launching a new product
- Second European language ideal but not essential
- Educated to degree level or equivalent

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the on-going needs of the organisation.