Job title:	*Regulatory Affairs Manager*
Department:	Regulatory Affairs
Reports to:	Chief Regulatory Officer

Purpose of the job:	*Prepare, obtain and maintain regulatory approvals for Minoryx' products*

Major accountabilities

- Manage and lead assigned regulatory projects including management of budget, timelines and submission planning and in accordance with internal procedures and legislative requirements
    - Coordinate centralized marketing applications in Europe, CTD and application process. Leads dossier planning activities and liaison with contributing groups and external experts and review of components
- Manage the different regulatory procedures in compliance with related regulatory timetables and requirements, pre and post-authorization (i.e. CTA, scientific advices, orphan applications, expedited pathways, FUMs, variations, PSUR, product renewals etc.)
- Prepare regulatory submissions documentation with input from subject matters experts. Will coordinate with various technical professionals to gather, organize and compile information including amongst others IMPDs, INDs, MAAs, NDAs, variations, briefing documents, Q&A for meeting requests etc.
- Preparation for meetings with regulatory authorities, including preparation of background materials, logistical organization and preparation of meeting minutes
- RMP elaboration and review (supported by RMP team)
- Act as liaison between RA and manufacturing / QA to ensure alignment with the regulatory dossiers. Evaluation of regulatory impact in change control and definitions of actions accordingly
- Set up and maintain contacts with regulatory authorities
- Stay current with changes in regulatory requirements, assess and inform the internal organization on relevant regulatory legislation
- Identification, compilation and approval of Regulatory SOP's

Skills, experiences and qualifications required for the job:

- Demonstrated knowledge of relevant regulatory processes in Europe and US (demonstrated contribution to centralized submissions and approvals in EU and life-cycle maintenance activities). Knowledge and experience in other territories i.e. Middle East and Asia is an asset
- Excellent writing skills in English
- Proficiency in the required software and computer skills
- Publishing software is a plus
- Demonstrated ability to manage multiple tasks/projects/priorities and complex issues
- Independently manages complex technical documents and procedures
- Demonstrated attitude of reliability and attention to detail
- Demonstrated professional attitude towards external and internal contacts
- Demonstrated direct interaction with regulatory authorities
- Demonstrated coordination of regulatory processes
- University degree in health sciences, a biological science, chemistry or related field
- Accumulated experience of minimum 8 years in Regulatory Affairs positions

Contact : careers@minoryx.com