

## Mundipharma Research

### Job Description

JOB TITLE: Senior Regulatory Affairs Officer - Labelling	LOCATION: Cambridge
DEPARTMENT: European Regulatory Affairs	COMPANY: MRL
RESPONSIBLE TO: Head of Labelling	DATE: August 2009

**A: BROAD PURPOSE OF JOB:**

- Take responsibility for Regulatory activities associated with the creation and management of Labelling across Europe including Summary of Product Characteristics (SPCs), Patient Information Leaflet (PIL) text and Company Core Data Sheets (CCDs).
- Provide regulatory support for the production and submission of Global Periodic Safety Update Reports (GPSURs).

**B: SPECIFIC DUTIES & RESPONSIBILITIES:**

**Labelling:**

- Write and update PIL text for products authorised through the Mutual Recognition, Decentralised or Centralised Procedure.
- Schedule the user testing programme for PILs.
- Act as primary contact for user testing service providers. Place user testing projects with contract organisations, ensure compliance with agreed timelines, monitor budget and track payments.
- Provide guidance and support to others involved in PIL user testing activities.
- Provide regulatory advice for the preparation of SPCs for new products in association with the relevant project team members and functional experts.
- Liaise with Independent Associated Drug Safety Centres (IADSCs) and relevant project teams regarding the preparation, revision, review and issue of CCDs.
- Maintain CCDs in the Regulatory Affairs document management system.
- Monitor compliance of local labelling to CCDs across the associated companies and 3<sup>rd</sup> parties in Europe.
- Co-ordinate activities related to the translation of labelling as required during regulatory procedures

**Pharmacovigilance Support:**

- Record GPSUR requirements and safety submission activities in the GPSUR tracking system.
- Collect and collate Regulatory data for provision to IADSCs for inclusion in GPSURs.
- Ensure timely despatch of GPSURs to the relevant associated companies and European Regulatory Authorities.

**General:**

- Participate in project teams and provide guidance on behalf of the Labelling Group on the issues and requirements for both research and marketed products.
- Provide guidance and support to other team members.
- Advise junior staff on data requirements for their activities.
- Raise issues related to Labelling and Pharmacovigilance activities with the appropriate Regulatory Affairs team members. Perform actions to address these issues, as agreed.
- Ensure where appropriate that the electronic regulatory document management systems are used to record regulatory activities.
- Maintain records of tasks and registered product information in the internal regulatory databases.
- Be aware of and keep up to date with current legislation appropriate to Labelling Compliance and Pharmacovigilance, providing expert advice on items or issues which will affect Regulatory and R&D project teams.
- Work as a team player and perform all reasonable tasks related to regulatory activities in accordance with the priorities of the department.
- Plan and execute tasks according to the agreed schedule and priority.
- Ensure that the appropriate standards of good regulatory practice are employed.
- Ensure that department procedures are followed. Develop and document new working practices as appropriate.
- Displays wide range of leadership attributes and works by Company values.
- Take responsibility for personal training and development in order to reach and maintain the required skills, knowledge and experience to perform the role.

**C: KNOWLEDGE & EXPERIENCE**

- Science degree or equivalent qualified: e.g. chemical and physical sciences, pharmacy, biochemistry, medical chemistry, biomedical science; or HND or equivalent qualified with some applied industry experience.
- Positive work style, with an approachable, flexible manner.
- Strong analytical and problem-solving skills.
- Ability to negotiate and influence internal and external bodies.
- Has experience of leading tasks.
- Good written and oral communication, including presentation skills.
- Has an in-depth knowledge of relevant Regulatory Guidelines and can assess their impact on the business.
- High attention to accuracy and detail.
- IT literate particularly in relation to using databases and document management systems
- Ability to work to strict deadlines and manage own time.
- Is results focussed.
- Actively works as a team member.
- Ability to get on with others and willingness to proactively network.
- Has demonstrable experience in the regulatory field.
- Ability to work unsupervised.
- Ability to build effective working relations internally and externally.