

## Mundipharma Research

### Job Description

JOB TITLE:	Regulatory Oncology Specialist (m/f)	LOCATION:	Cambridge, UK/ Limburg, Germany
DEPARTMENT:	European Regulatory Affairs	COMPANY:	MRL/MRG
RESPONSIBLE TO:	Executive Director, European Regulatory Affairs	STATUS:	Live

#### A. BROAD PURPOSE OF JOB:

Provide input into the regulatory strategy for Oncology products and regulatory advice on potential Oncology projects for both internal projects and in-licensed products.

Liaise with MINT / 3<sup>rd</sup> party companies during all phases of development for Oncology products.

Provide advice on EU and international regulatory requirements.

#### B. SPECIFIC DUTIES AND RESPONSIBILITIES:

1. Advise on strategy for Marketing Authorisation Application submissions for Oncology products *via* National or European Procedures in EU/EEA markets in the appropriate format.
2. Provide input into responses to questions from Regulatory Agencies, and the subsequent maintenance of Marketing Authorisations (MA's) via renewals and variations.
3. Coordinate the provision of pharmaceutical, clinical and other technical information to our Associated Companies and Licensees to assist with the registration and maintenance activities of MAs for Oncology products.
4. Provide responses to a wide range of regulatory questions relating to the group of independent associated companies Oncology products – registered or undergoing registration.
5. Represent the European RA department on R&D project teams as required, providing European regulatory advice (e.g. for new and existing product developments).
6. Raise items or issues related to Regulatory Affairs activities with the appropriate Regulatory Affairs project team members. Perform actions to address these items or issues, as agreed by the Regulatory Affairs project team.
7. Ensure that the regulatory management systems are employed to record day to day regulatory activities.
8. Have in-depth knowledge of the current legislation and guidelines and provide expert advice on items or issues which will affect Regulatory and R&D project teams.

9. Perform all reasonable tasks related to regulatory activities in accordance with the priorities of the department.
10. Ensure that the highest standards of Good Regulatory Practice are employed throughout Europe.
11. Provide regulatory guidance and support to department members.

**C. QUALIFICATIONS / EXPERIENCE:**

Positive work style, approachable and flexible, adopter of company core values; negotiation & influencing skills; project management & strategic/problem solving skills; good organisational, presentation and communication skills; willing and active team member and ability to lead, train and mentor others; accurate; efficient in time management; results focused; work unsupervised.

Demonstrate an in-depth knowledge of relevant EU Guidelines and their impact on the business and disseminate information to the department and R&D project teams.

Proficient in the use of MS Word, PowerPoint, MS Project, Excel, electronic document management systems; knowledgeable in RA & IT tools.

This position is also suitable for severely disabled applicants who possess all the qualifications outlined above.