

Mundipharma Research

Job Description

JOB TITLE:	Functional Director, Regulatory CMC & Manufacturing Compliance (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:

- Lead and manage the Regulatory CMC & Manufacturing Compliance function for EU and all additional International countries within scope.
- Ensure CMC regulatory strategies and implementation plans are in place to support the business needs for portfolio across the lifecycle.
- Ensure CMC/manufacturing regulatory obligations are met for the marketed product portfolio.
- Ensure that effective support is given to development project teams.
- Ensure performance management and people development plans in place for all staff.
- Ensure that all CMC regulatory and compliance activities are delivered to agreed time, cost and quality standards.
- Provide pharmaceutical data and reports, including expert reports, as required to support regulatory submissions.
- Liaise with data generators and ensure networking with other regulatory groups and departments takes place on a regular basis with a view to sharing information and professional experience.
- Ensure that in respect of Pharmaceutical particulars, an efficient process of change control operates.
- Ensure that MRL comply with all relevant Home Office licensing requirements in respect of activities related to controlled drugs.

B. SPECIFIC DUTIES AND RESPONSIBILITIES:

- Accountable for ensuring CMC regulatory contributions achieve the objectives, agreed standards and minimise resource demands, whilst maximising overall project delivery time, probability of success and facilitating post filing activities.
- Build and maintain a highly motivated and high performing regulatory function, identify and implement appropriate change management, recruitment and retention strategies to maintain a viable organisation.
- Ensure pharmaceutical data generated or compiled is of the highest scientific standard, meets the relevant regulatory requirements and is in compliance with the departmental SOPs.

- Provide expert advice and opinions on pharmaceutical matters and support development project teams.
- Maintain knowledge of pharmaceutical regulations and guidelines relevant to the project portfolio ensuring that any new requirements are advised to the affected departments and are implemented.
- Provide suitably trained regulatory professionals to participate in the cross functional project teams set up, both within Research & Development and with other Bard/Napp /Mundipharma companies, to develop new products or in support of existing products.
- Maintain an effective liaison between the Home Office and MRL departments using controlled drugs ensuring all activities at the Cambridge site are conducted in accordance with the licences held by MRL. This includes annual returns, record keeping, product manufacturing and all import and export activities.
- Ensure that all staff members are trained to use the relevant IT systems (e.g. MIDAS, DELTA, eDoc) and continue to use such systems in accordance with the relevant SOPs or working practices.
- Appoint and liaise with regulatory consultants to ensure any work conducted by such individuals meets the required regulatory standards in accordance with the relevant agreements.
- Liaise with external suppliers as necessary to allow access to all necessary data in support of regulatory submissions.
- Provide expertise for in licensing activities as requested.
- Deputise as required for the Executive Director of European Regulatory Affairs.

C. QUALIFICATIONS / EXPERIENCE:

- Scientific Degree.
- Demonstrable CMC regulatory experience across the Research & Development and commercialisation lifecycle.
- EU and other regional regulatory experience including knowledge of CTA & MAA submission processes.
- Previous line management experience.
- Proven ability to manage complex regulatory issues.

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