JOB DESCRIPTION

ROLE: Regulatory and Specials Project Manager
SALARY AND BENEFITS: Negotiate
REPORTS TO: Regulatory Manager
LOCATION: Ruislip

PRIMARY RESPONSIBILITIES
To manage a Regulatory Team in India and UK on Module 2.

SECONDARY RESPONSIBILITIES
- Prepare and review submission packages to the MHRA and IMB in a timely manner
- Write and prepare responses to a high quality
- To raise and action appropriate change control, maintaining compliance
- To prepare and submit high quality submission for post approval activity to strict dead lines
- Liaise with the Regulatory Authorities to ensure product approvals are received in a timely manner
- Review artwork for national phase submission and prior to launch
- Review health authority website for product safety updates and new requirements

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES
MSc or BSc Pharmaceutical Science,
Previous experience 6-10 years
Clinical Regulatory Organisation experience is preferable
Module 2 sign off ideal
Must have high attention to detail and proactive
Ability to prepare high quality regulatory applications and the ability to communicate effectively
Demonstrate excellent verbal and written English
Ability to handle multiple tasks in a fast-paced and constantly changing environment
Good knowledge of Microsoft word and excel
Ideally some knowledge of drug development
Ideally some knowledge of Decentralised procedures