JOB DESCRIPTION

ROLE: Regulatory Executive

SALARY AND BENEFITS: Negotiable

REPORTS TO: Assistant Regulatory Manager

LOCATION: Vadodara

PRIMARY RESPONSIBILITIES

- To write and review high quality documents for submission to EU Regulatory Health Authorities.
- Write and review responses to the Health Authority.
- Liaise and co-ordinate with the UK office for preparation of submission.
- Pro-actively work with various departments to ensure submission dates are met.

SECONDARY RESPONSIBILITIES

- Handling Parallel imports licensing work for MHRA, IMB and EMA.
- To prepare documents for applications, renewals and variations from start to end.
- Responding to the queries received from the regulatory bodies (MHRA, IMB and EMA) in a timely manner.
- Performing monthly in-house tasks for licence updation and audit.
- Ad hoc duties as and when required.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

- Good understanding of CMC.
- Must have some understanding on EU Regulatory Requirements.
- Sound knowledge on pharmacological front will be an added advantage.
- Experience with EU Regulatory would be ideal.
- Proactive attitude.
- Good written and oral communication in English.
- High attention for detail.
- Capability to take initiative and work as a team.
- Working knowledge of MS Office.