JOB DESCRIPTION

ROLE: Asst. Manager – RA (CMC)
SALARY AND BENEFITS: Negotiable
REPORTS TO: Head - Regulatory Affairs
LOCATION: Baroda, India
JOB TIMING: 12.00 P.M to 9.00 P.M.

PRIMARY RESPONSIBILITIES

Responsible for submission and monitoring of successful pharmaceutical licence applications by liaising with Europe regulatory agencies to obtain granted licences in timely manner.

SECONDARY RESPONSIBILITIES

❖ ***OPERATIONAL EXCELLENCE***

➢ **Responsible for all the regulatory submissions and deficiency response:**

- Responsible for submission and monitoring of new product dossier for submission.
- Responsible for handling and review all the regulatory documents required for the dossier and deficiency submission in timely manner.
- Responsible for handling of variations/supplement filings/ life cycle management of products and all the regulatory status updates.

➢ **Regulatory strategy:**

- Proposal for regulatory strategies to file dossier and deficiency.
- Provide regulatory clearance for formulation and analytical development.

➢ **Regulatory audits:**

- Handling of regulatory audits and filing of audit response in timely manner.
- Support the self Inspection programme from regulatory point of view.

❖ **STAKE HOLDERS:**

- Liaising with Europe regulatory agencies to obtain granted licences in timely manner.
- Co-ordination with all stake holders for smooth regulatory submissions.
- Review and approval of master and GMP documents.
- Keeping up to date with regulatory issues in drug development processes and working to eliminate or minimize regulatory barriers.

❖ **MANAGERIAL CAPABILITY:**

- Keeping up to date with regulatory issues in drug development processes and working to eliminate or minimize regulatory barriers.
- Organize team and inter departmental meetings and conferences.
- Time and manpower management with quality output.
- Ensure all precise updation of status.

❖ **INNOVATION AND TRAINING:**

- Keeping up to date with regulatory guidelines and expectations.
- Training of junior colleagues.
- To help any of the R&D department to resolve issues related to development of product with respect to regulatory strategies.

ESSENTIAL EXPERIENCE, SKILLS AND ABILITIES

❖ **EXPERIENCE**

- 7 - 10 years of experience in the Regulatory affairs, especially for Europe market.
- Able to manage team for equal work distribution with quality output
- Able to manage submission of new products dossier/Deficiency Response, Post-Approvals and renewals.
- Able to resolve issues during development for regulatory concerns (i.e. Prototype development trials and bio-waiver).
- Able to resolve any issue of API/Excipient manufacturer for regulatory concerns.
- Able to maintain all the regulatory status updates.

❖ **SKILLS AND ABILITIES**

- Sound knowledge of Regulatory guidelines & eCTD software.
- Good communication skill.
- Can give quality output in any circumstances.
- Previous experience in a similar role is required
- Knowledge of completing a dossier for EU countries through DCP, MRP, National procedures
- Knowledge of completing a dossier in Nees or eCTD submission

- Clear communication skills both written and verbal
- Can demonstrate excellent analytical skills and openness to change
- High attention to detail
- A conscientious and innovative individual who shows attention to detail
- Ability to keep up-to date with pharmaceutical trends and developments within the industry

Cab services available for Female candidates (Pickup & Drop).