Inviting candidates for the post of Deputy Manager / Manager for Biopharmaceutics and Clinical Development (Formulation R&D) for Pharmaceutical Technology Centre, Ahmedabad

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Biopharmaceutics and Clinical Development (Formulation R&D)

Deputy Manager / Manager : M.Pharm / PhD / M. Sc. in Pharmacology and Toxicology with 5-10 years of experience in clinical and preclinical development for Formulation R&D.

Candidates would be responsible for the following tasks -

Clinical and preclinical development of 505(b)(2) products:

- Literature search focusing on preclinical and clinical development programmes.
- Understanding and defining the rationale of unmet needs for identified product.
- Thorough understanding of disease physiology and preclinical safety pharmacology.
- Identifying appropriate CRO for conducting non-clinical POC, Toxicity, safety pharmacology studies, PK / PD studies in human and bioequivalence / bioavailability studies.
- Budgeting of preclinical and clinical studies.
- Authoring and reviewing of study plan, protocol, scientific justification and publication for non-clinical studies.

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Candidates would also be responsible for the following tasks -

Clinical and preclinical development of 505(b)(2) products:

- Reviewing the data of preclinical POC, bioavailability and bioequivalence studies and leading the discussion with different cross functional teams and CROs.
- Authoring and reviewing of clinical, non-clinical sections in IND, briefing package, investigator's brochure and NDA for regulatory submission.
- Monitoring preclinical and clinical studies in India and overseas CROs.
- Oversee local regulatory application submission and approvals.

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Candidates would also be responsible for the following tasks –

Genotoxicity / Toxicity studies:

- Outsourcing and overseeing all technical and regulatory aspects of AMES test (invitro, invivo tissue distribution studies) and toxicity studies.
- Reviewing of study data, study report and defining the strategy for the assessment of genotoxicity/toxicity study as per USFDA, ICH and OECD guidance.
- Managing the budget and financial aspects of CROs.

To apply,
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