

**Title: Principal Investigator, DMPK**

**Job Summary:**

Reporting to the Vice President, DMPK, Pharmacology and Bioanalysis, the Principal Investigator, DMPK will design and execute DMPK experiments while interacting with Discovery, Toxicology and Clinical Scientists. This role will also write and edit sections of new drug applications (NDA). The Principal Investigator will mentor junior staff and assist in their professional development while providing scientific excellence and leading by example. In addition, the Principal Investigator will interact with regulatory representatives to develop a coherent and efficient development strategy for drug candidates.

**Responsibilities:**

- Responsible for non-clinical pharmacokinetic/toxicokinetic and related ADME studies on small molecules to advance early and late stage programs
- Understanding & keeping abreast of current FDA guidelines as they pertain to DMPK
- Writing & proof-reading sections of new drug applications (NDA)
- Mentor junior DMPK staff
- Propose novel approaches and experiments
- Independently design DMPK studies
- Performing *in vitro* incubations
- Design (as needed) new techniques to apply in the laboratory
- Independently troubleshooting lab experiments
- Assist junior staff troubleshooting experiments
- Overseeing CRO studies
- Analyzing and reporting data
- Writing relevant reports and regulatory documents

**Qualifications:**

- PhD training in Pharmacokinetics/Pharmacodynamics or related sciences with 12+ years of experience in a relevant industry
- Excellent knowledge of standard PK software (Phoenix etc)
- Understanding of standard DMPK modeling tools
- Thorough understanding and current knowledge of ADME principles and interspecies scaling
- Ability to incorporate in-vitro ADME studies information with in-vivo pharmacokinetic data
- Experience with regulatory submissions
- Ability to effectively manage multiple projects
- Good understanding of drug development processes
- Excellent oral and written communication and interpersonal skills are essential
- Previous writing or editing of NDAs is highly desired

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If you would like to be considered for a job on the Concert team, send your resume to: [careers@concertpharma.com](mailto:careers@concertpharma.com).

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