HERON THERAPEUTICS

Position: Scientist II, Toxicology

JOB DESCRIPTION:

The successful candidate will provide support for the non-clinical components for clinical development programs and participate in the preparation of regulatory submissions including Investigator Brochures, INDs, and NDAs. Although the major function of this position will be toxicology the individual will perform cross-functional activities within the department including pharmacology, bioanalytical and PK roles.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Assists in the planning, designs, analyzes, interpretation and reporting of data from non-clinical pharmacology, PK and toxicology studies.
- Prepare necessary documentation and report study results for IND/NDA submissions.
- Coordinate activities and provide support across the Translational Sciences group (Toxicology, PK, bioanalytical sciences), and with other groups such as pharmaceutical sciences and the rest of the organization (clinical operations).
- Coordinates with CRO regarding shipping of test article and study related samples
- Receive study updates, data and documents, track and maintain study specific milestones
- Ensure proper following of FDA guidelines and internal SOPs for all studies.
- Creation of various data tables (e.g., CTD) and documents for regulatory submissions (e.g. IND, IB) and perform QC review of regulatory documents
- Other duties as may be necessary.

REQUIREMENTS:

- Bachelor Degree (B.S.) in Biological Sciences or equivalent, with a minimum of 5 years' experience in pharmaceutical research environment.
- Experience working with GLP regulations is a requirement.
- Experience in the conduct of nonclinical studies to support both drug discovery and drug development activities.
- Strong written and verbal communication skills are a must.
- Experience working with animals in a scientific setting.
- Team-oriented with excellent communication and interpersonal skills.
- Flexibility to work in a fast-paced environment. Ability to manage multiple and diverse issues.
- Ability to "roll up your sleeves" and individually contribute results in a team-based environment.
- Experience authoring of documents, reports and presentations.
- Basic knowledge of FDA and ICH nonclinical guidelines and the ability to interpret and apply applicable regulations.