

**JOB DESCRIPTION**

<b>Job Title</b>	<b>Pharmacokinetic (PK) Scientist</b>
<b>Department</b>	Pharmacokinetic Department
<b>Specific Tasks</b>	<ul style="list-style-type: none"> <li>• Write protocols and Informed Consents, prepare and submit documents for ethical approval , preparation and review of study-related documentation, preparation of final report</li> <li>• Perform literature search on drug substances to determine their pharmacokinetic characteristics, identify reference products, determine sampling profiles</li> <li>• Update previous literature reviews in electronic database and paper-based files as required</li> <li>• Incorporate research findings into protocols</li> <li>• Ensure protocol designs meet the appropriate regulatory requirements (i.e., TPD, ICH, FDA, EU, etc.)</li> <li>• Consult with Sponsors on clinical trial designs (BA/BE, Phase I-IV)</li> <li>• Participate in the PK and statistical analysis of drug trials when needed</li> <li>• Write appropriate sections of the Final Study Report and Comprehensive Summary: Bioequivalence (CS-BE)</li> <li>• Participate in tracking meetings</li> <li>• Assist in the development, revision and/or implementation of Standard Operating Procedures (SOP's) for the Pharmacokinetic department ensuring consistency with GCP and regulatory guidelines</li> <li>• Participate in Sponsor meetings as required</li> <li>• Execute other duties as may be required by the President</li> </ul>
<b>Reports to</b>	President
<b>Communications</b>	•
<b>Requirements</b>	<ul style="list-style-type: none"> <li>• Masters of Science (M.Sc.) degree specializing in pharmacokinetics or biopharmaceutics or equivalent</li> <li>• Proven experience in pharmacokinetics or biopharmaceutics in the clinical research industry</li> <li>• Working knowledge of SAS</li> <li>• Strong analytical and problem solving skills</li> <li>• Excellent organizational skills, efficient and able to multi-task and prioritize effectively</li> <li>• Excellent interpersonal skills; strong verbal and written communication skills</li> <li>• Decisive, good trouble-shooting and decision making skills, able to escalate response to situations when relevant</li> <li>• Solid project coordination/management and project planning skills</li> <li>• Detail-oriented</li> <li>• Proficient in MS Office Suite (Word, Excel)</li> </ul>

This job description should not be constructed to imply that these requirements are the only duties, responsibilities and qualifications for this position. Employee may be required to follow any additional related instructions, acquire job skills and perform other related work if deemed necessary.