Job Description

Department	Biostatistics
Designation	Manager - Biostatistician
Location	Mississauga, Ontario, Canada
Basic qualification required	1. A master's degree in statistics or mathematics and 2-3 years of relevant experience, or an equivalent combination of education and experience 2. Good Knowledge of statistical techniques and experimental design 3. Proficient in SAS programming, preferably SAS certified 4. Solid understanding of the clinical drug development process 5. Good knowledge of Health Canada and FDA regulatory requirements, as well as ICH/GCP guidelines is preferred 6. Ability to coordinate statistical activities for a clinical study 7. Experience in CDISC standards 8. Strong analytical and problem solving skills 9. Excellent organizational skills, detail-oriented, efficient and able to multi-task and prioritize effectively 10. Excellent interpersonal skills 11. Strong written and verbal communication skills
Experience	2-3 Years
Brief JD	1. Lead all statistical services for a clinical study project and act as Study Biostatistician for the project 2. Attend all internal and external meetings for a clinical trial project and communicate with the sponsors, if necessary 3. Review or contribute in study protocol's statistical section 4. Review and provide feedback on Case Report Forms (CRFs) and Data Management Plans (DMPs) 5. Write or review Statistical Analysis Plans and mock Tables, Listings and Graphs (TLGs) 6. Create or validate CDISC Analysis Data Model (ADaM) datasets and associated documentations (Specification, Define.xml and Reviewer's Guide) for applicable studies 7. Generate or validate statistical analysis output Tables, Listings and Graphs (TLGs) as detailed in the Statistical Analysis Plan (SAP) 8. Perform exploratory statistical analyses 9. Assist in planning, developing and monitoring timelines for statistical and programming tasks, based on resources and needs 10. Review and provide input on SOPs and internal guidelines related to biostatistics and programming activities 11. Provide statistical and programming support to Research & Development, Pharmacokinetics, and Data Management groups 12. Perform analyses and generate outputs as per external requests from regulatory and sponsors.