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# Example of Manager, Biostatistics Job Description

Our company is growing rapidly and is looking to fill the role of manager, biostatistics. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

## Responsibilities for manager, biostatistics

* Develops systematic documentation of methods, results and statistical programming
* Assists in the design and testing of clinical databases and will consult with product development teams providing statistical expertise on new design features
* Participates in meetings with regulatory authorities and external advisors to coordinate the transfer of and review of data (CROs, central laboratories)
* Develops SOPs, dept procedure documents as required for functions within the role, ensuring consistency in statistical methodology, programming standards, and data specifications with all studies
* Collaborates with Science, Engineering to develop statistically based verification and validation acceptance criteria and analyzing field data to provide insight into trends, and Regulatory in defining strategic approach and with Clinical in producing Clinical Investigation Plans and Case Report Forms
* Provides statistical methodology for study protocols including sample size estimation, power calculation, and study design/conduct
* Plans all aspects of data analysis
* Coordinate and ensure quality-controlled production of all tables, listings, and graphs for the clinical documents (study reports, publications, regulatory submissions, etc) and work closely with programmers to provide specifications for report tables and listings
* Reviews edit checks and Data Management Plans
* Provides Randomization schema for treatment assignment

## Qualifications for manager, biostatistics

* Ability to interact across different cultures, builds global relationships
* Accurate and keen eye for detail
* Collaborative teamwork and interpersonal skills that demonstrate initiative and motivation
* Experience in pharmaceutical clinical development in at least one therapeutic area
* Basic to advanced pharmacokinetic knowledge regarding applicable variables, calculation methods, and statistical analyses/programming of these variables
* Experienced in reporting databases and ADaM datasets