Job Position: Regulatory Affairs Specialist

Job Description:

Compile, review and submit original submissions, Supplements and Amendments for ANDAs. Validate analytical test methods for assay, related compounds, dissolution, particle size distribution, and residual substances. Prepare and submit controlled correspondences to USFDA. Submit annual reports and periodic adverse drug experience reports. Write method validation protocols, technical reports to document Analytical methods, transferring documented analytical methods to the QC department and Updating SOP. Review change controls and submit documents to FDA through eCTD publishing software and MS Excel.

Mail Resumes to:
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