

**Assistant Manager - Regulatory Affairs (Durham, NC)** Prepare, review and compile high quality Abbreviated New Drug Applications (ANDA). Analyze, interpret and summarize technical information related to submission and approval of Chemistry, Manufacturing and Controls sections of product dossier. Scientific reports which are prepared, reviewed and compiled are as follows: Manufacturing of active pharmaceutical ingredient (Drug substance) by the drug substance manufacturer and the drug product manufacturer according to relevant directions and guidelines; Analytical method validation for the determination of assay, related substances and residual solvents of drug substance by High Pressure Liquid Chromatography (HPLC); Description, composition and pharmaceutical development report of drug product; Manufacturing, primary and secondary packaging, quality control testing and stability testing of the drug product. Use of excipients in the manufacturing of drug product; Validation of assay, dissolution and related substances of drug product by HPLC; Quality overall summary which includes technical information related to raw material, formulae, finished product, clinical overview and non-clinical summary, QbR (Question Based Review) for drug substance and drug product; Prescribing information of the drug product; and Documents related to Patent and Exclusivity certifications. Maintain primary contact with the FDA on all issues related to regulatory submission and prepare responses to their queries in a timely manner. Keep abreast of the FDA regulations, and ICH guidelines. Work in accordance with relevant laws and policies governing drug development and approval. Interact closely with other departments and coordinating with groups internally and externally towards the completion and submission of the product dossier. Provide regulatory support and feedback to R&D department in development methods, techniques and evaluation criteria for obtaining results. Ensure effectiveness of regulatory compliance by monitoring and reporting the company's compliance to regulations. Requirement: Masters Degree in Pharmaceutical Sciences with Graduate/Undergraduate level courses in the following: Pharmaceutics and Industrial Pharmacy, Pharmaceutical Analysis and Pharmacology. Resumes to: HR, Intas Pharmaceuticals, 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703. Please refer to Job Code: RA0901