Example of Lab Specialist Job Description

Our company is searching for experienced candidates for the position of lab specialist. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

Responsibilities for lab specialist

- Supports raw material activities such as sample and reagent management
- Participates in the drafting of new standard operating procedures (SOPs), Technical bulletins and the maintenance of existing SOPs related to the departmental activities on both a regional or global basis
- Participates in audits/inspections from regulatory agencies and pharmaceutical sponsors
- Actively communicate with technical counterparts located at other facilities throughout the organization to ensure harmonization
- Provides troubleshooting techniques for difficult methods or methods which have developed some analytical imprecision which may adversely affect the assay performance
- Leads in the design, performance and evaluation of sample stability studies as required
- Provides statistical analysis of data from all laboratory sites, certification studies, and other tasks as needed
- Develops and maintains an accurate Task List and provide Metrics related to assay validations, stability studies, QC, Proficiency surveys, and/or laboratory performance indicators
- Provides training on instrument validationss, assay validations, quality control, handling of proficiency surveys and/or accreditation scheme samples
- Develops and maintains a comprehensive validation program for all new instruments and new assays in accordance with regulatory guidelines

- Typically a minimum of 1-3 years of experience in a cGMP Quality Control department in a FDA regulated industry
- Experience with laboratory raw material testing and release required
- Limited use of laboratory equipment, chemicals and biological materials
- Develops and maintains the development of schedules and completes data analysis for performing linearity and comparison studies, or other studies as required by regulatory agencies or as requested by sponsors
- Ensures all Technical Bulletins received in the laboratory are distributed in a timely manner for review by lab management and the global harmonization team
- Develops and maintains comprehensive proficiency testing survey and accreditation program for all active assays in accordance with regulatory guidelines