

REVA Medical, LLC
JOB DESCRIPTION

Job Title: Analytical Development Chemist
Function: Development
Date: N/A

Summary of Essential Duties and Responsibilities

Develop and validate methods for testing of drug, polymer and monomer samples by HPLC, GPC, IR, GC/MS and NMR. Sample systems will also include extended release drug product formulations.

Develop knowledge of requirements (commercial, Regulatory, cGMP, GDP, GLP, ISO-, etc.) specific for REVA processes and products and adapt to the quality control and development programs as appropriate for FDA and other agency filings.

Coordinate as needed with external contract laboratories for test method development and method qualification.

Co-manage internal and external analytical testing and data analysis in accordance with established test methods and validation/qualification protocols.

Execute and coordinate stability testing of polymer devices and combination drug products.

Prepare documentation for test article traceability, and for product release.

Provide support to Quality Assurance and Manufacturing by analyzing various polymer and drug products, the test information will be incorporated into a Certificate of Analysis.

Manage the calibration, preventative maintenance, and qualification activities related to analytical equipment.

Responsible for written technical summaries and reports.

Basic laboratory coordination (order supplies, lab housekeeping, organize and maintain equipment).

Perform other duties as assigned to meet company goals.

Education and/or Experience

The ideal candidate will possess an MS or PhD in Chemistry with 3 to 5 years of pharmaceutical/medical device industry experience, or BS in Chemistry or equivalent with 6 to 8 years industry experience. Equivalent combination of education and experience is acceptable. Knowledge of pharmaceutical analytical procedures and ISO 13485 or cGMP documentation is highly desirable. Experience with polymer analysis or production in a medical device context a plus.

Required Knowledge/Skills

Must have experience in operation of chromatography and spectroscopy lab equipment.

Good written and oral communication skills.

Operate manual and computerized equipment following specified safety measures.

Careful experimental techniques and attention to detail are needed.

Ability to work in a team environment.

Physical Demands/Working Environment

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is frequently required to sit or stand for prolonged periods of time. The employee must occasionally lift and/or move up to 25 pounds. Specific vision abilities required by this job include close vision, and microscope work.

Approvals

**REVA Medical, LLC
JOB DESCRIPTION**

Employee/Date: _____

Manager/Date: _____