

Job Description	
Title: Formulation Scientist 1, 2, or 3	Salary: 65K – 120K depending on Experience
Department: R&D	Shift/Hours: 1st/40 hours per week
Reports To: Director of Technical Services	

**Job Summary:**

We seek talented Formulation Scientists at various levels to join our expanding R&D team who will be responsible for developing the final product formulation and process procedures of sterile injectable products.

**Essential Functions:**

- Develop and formulate laboratory homogenous parenteral batches which are scalable for exhibit and commercial production.
- Reverse engineering of commercially available drug products to assure the generic form is equivalent or better than the innovator. This includes upstream and downstream controls such as evaluation of API's and excipients, identification of appropriate container closure systems, Identification and controls for CPP's, recommendation of CQA's from raw materials through product shelf life
- Literature searching and review, patent searching and interpretation, performing risk assessment for formulation/process development which include the correlation of material and process attributes to critical quality attributes.
- Authoring of product development reports and summaries included as part of the application.
- Collaboration with internal and external resources such as contract laboratories, CMO's to resolve technical issues related manufacture of the drug product.
- Selection and sourcing of API's, excipients, containers and closures.
- Writes Chemistry, Manufacturing and Control (CMC) documents for Regulatory submission
- Determine potential impurity and degradation profiles for the API, excipients, and the drug product.
- May write and review SOPs, Validation Protocols, Quality Protocols, Test Methods, and Specifications.
- Designs multivariate experiments to assist with product and process knowledge
- Working knowledge of aseptic processing and terminal sterilization of parenteral products

**Additional Responsibilities:**

- Deadlines are met with no errors.
- Shows ability to train new employee chemists.

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- Performs pre-formulation laboratory experiments and studies.

**Qualifications:**

Motivated, independent and team worker, with effective communication, documentation, writing and problem solving skills. Ability to perform assigned tasks in mutli-disciplinary environment – process, manufacturing, analytical, and R&D. Strong computer skills including Microsoft Word and Excel.

**Education and Experience:**

- BS or MS in chemistry or related field with a minimum of 20 hours of chemistry coursework.
- Must have a minimum\* of two years of laboratory experience with a demonstrated proficiency in injectable formulation.
- Must have experience or demonstrated ability working with little supervision.
- Background check required.

\*If the candidate has an advanced degree in chemistry, the experience requirement may be waived.

**Physical Demands and Work Environment:**

Regular (50% - 69%) exertion including standing/walking for extended periods of time, lifting/carrying more than 15 and up to 25 pounds, works with chemicals and wears basic personal protective equipment (PPE) (glasses, gloves, ear protection), and restrictive PPE (tyvek suits, respirators), operates lab instruments. At times low physical effort includes sitting, and operating computers or other small equipment.

***DISCLAIMER:*** *The lists under Essential Functions and Additional Responsibilities are not exhaustive, but are merely the most accurate lists for the current job. Management reserves the right to revise the job description and to require that other tasks be performed when the circumstances of the job change.*