

<b>KVK Tech</b>	<b>Employee Job Description</b>
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**1. Employee details:**

First Name		Middle Initial		Last Name	
Hire Date		Department	F R&D		
Location	110 Terry 100 Campus	Job Title	Formulation Scientist	FLSA Status:	Exempt
Role	N/A				
Sub role (If any)	N/A				

**2. Role Purpose:**

Design and development of formulations and processes by QbD, manufacturing of exhibit batches, preparation of product development reports, support of all necessary documentation for ODR and regulatory submissions.

**3. Key Duties & Responsibilities:**

- Formulation Development of solid dose pharmaceutical products that include Sustained / Extended / Delayed Release dosage forms.
- Design and conduct pre-formulation and formulation studies, process development and optimization of prescription dosage designs
- Utilize DOE, QbD, QbR and SOPs under cGMP conditions
- Perform Labeling and Process Validation
- Develop bio-equivalent products using pilot Bio batch and Master Formula cards.
- Prepare and review CMA, CQA, control strategy, BMR and FMEA documents
- Create and write manufacturing batch records, packaging records, scale-up batch records, protocols and complete Product Development reports for FDA and ANDA submissions
- Research various product ingredients and determine which are suitable for use in the product under development
- Write product development experimental batch records which include amount and type of ingredients express instructions for their processing and blending and instructions for the final tableting/filling of the dosage form.
- Submit samples to the laboratory including instructions for their testing
- Research equipment for use in the laboratory
- Analyze lab data and makes changes to subsequent experiments accordingly
- Interact with manufacturing and laboratory departments to facilitate completion of work
- Handle all new and developing products

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- Handle small scale batches
- Finish product sampling for Quality Control and Quality Assurance
- Calibrations and Maintenance of all machines such as fluid bed dryers, tablet presses
- Research and gather information in a timely manner
- Handle and complete special projects as required
- Other duties as assigned

**4. Typical Supervisory Responsibility:**

N/A

**5. Education/Technical Competencies/ Certifications/ Licenses:**

Technical competencies	<ul style="list-style-type: none"> <li>• Previous Pharmaceutical Industry experience with 1-3 years developing various dosage forms</li> <li>• Experience with Solid/Liquid Oral Dosage forms is a must</li> <li>• Manage tight timelines, multiple projects, duties and assignments.</li> <li>• Advanced knowledge of theories, practices and principles of physical pharmacy, pharmaceuticals, pharmacokinetics, bio-pharmaceuticals and statistical designs</li> <li>• Ability to efficiently handle pharmaceutical unit operations, such as fluid bed coater, compression, roller compaction, high shear granulation, particle and tablet coating, encapsulation and packaging.</li> <li>• Current knowledge of product formulations, product stability, packaging, and FDA submission methods, practices and regulatory requirements.</li> <li>• Product design of controlled release dosage forms, working knowledge of multi-particulate systems, matrix systems, diffusion controlled and osmotically engineered pharmaceutical</li> </ul>
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	<p>dosage forms. Experience with other dosage forms is a plus.</p> <ul style="list-style-type: none"> <li>• Ability to perform mathematical calculations, operations and basic statistics.</li> <li>• Capability to research and utilize current and new technology.</li> <li>• Experience with multiple bench top, pilot and manufacturing equipment.</li> <li>• Excellent interpersonal and communication skills</li> </ul>
Education/Certifications/Licenses/Other	<ul style="list-style-type: none"> <li>• Degree in Pharmacy, Pharmaceutical Technology or Pharmaceutical Chemistry, ideally an M.S. or Ph.D.</li> </ul>

**6. Physical Demand and Work Environment:**

a. Physical demands:

While performing the duties of this job, the employee is required to walk, sit, and use hands to finger, handle or feel tools or controls, reach with hands and arms, balance, stoop, crouch, bend, talk and hear. The employee must lift and/or move up to 20 pounds. Specific vision abilities required by the job include close vision, distance vision, color vision, peripheral vision, and depth perception.

b. Work environment:

N/A