

KVK Tech	Employee Job Description
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1. Employee details:

First Name		Middle Initial		Last Name	
Hire Date		Department	Operations		
Location	110 Terry, 100 Campus	Job Title	General Manager	FLSA Status:	Exempt
Role	General Manager				
Sub role (If any)	N/A				

2. Role Purpose:

The General Manager of oral solid dose Operations will fulfill a critical role in ensuring successful manufacturing readiness, site licensure, and ultimately cGMP supply through strong leadership. This position requires tactical and strategic leadership to influence, establish, and implement short and long-range goals, plans and policies related to oral solid dose operations. The position will have executive leadership and plant management production responsibilities in oral solid dose pharmaceuticals. Upon FDA licensure the position will be responsible for assuring the successful development, transfer, and qualification of manufacturing processes for the company’s commercial oral solid dose processing product pipeline. Interacting closely with Product Development, Quality, Regulatory, and other appropriate groups, the candidate will be responsible for development/transfer of manufacturing processes (e.g. drug substance, drug product, finish packaging, ANDA/NDA, etc.), technical management of existing processes, and continuous cGMP compliant supply of oral solid processed commercial products. The Vice President/GM will also manage the company’s external manufacturing contract suppliers (e.g. raw materials, packaging components, labeling, etc.) as related to the supply of oral solid dose commercial products.

3. Key Duties & Responsibilities:

- Production**
- Develops, recruits, and maintains a manufacturing staff that will enable the continuous and compliant supply of oral solid dose manufactured products
 - Provides leadership to the team that will develop and implement high quality, robust, and scalable manufacturing processes that meet the needs of the company’s product pipeline
 - Codevelops and maintains manufacturing quality standards that exceed industry expectations
 - Manages contract suppliers, supply agreements, compliance to standards, resources, and budgets

- Directly supports regulatory ANDA/NDA submissions with data, reports, and filing content
- Motivates, inspires, and leads a high-performance technical team providing coaching/mentoring as necessary
- Develops and leads training activities to ensure staff are appropriately qualified, developed, and retained
- Directs the efforts of personnel responsible for the day-to-day production/product delivery requirements

Compliance

- Establishes and maintains robust manufacturing procedures that exceed industry/CFR/FDA expectations
- Promotes and enforces a culture of compliance and quality excellence
- Works closely with Regulatory to ensure successful NDA/ANDA submissions and regulatory responses
- Leads/collaborates on critical quality technical reports required for product development, validation, stability, comparability, and manufacturing investigations
- Establishes and maintains highly credible relationships with regulatory, state, and local agencies
- Prepares and readies manufacturing team for PAI, biennial, and new product FDA site inspections
- Refines and further develops the operational related policies and procedures to continually increase quality, compliance, and cost effectiveness

Safety

- Builds and maintains a culture of individual and product safety that exceeds industry standards
- Develops operational safety practices, procedures, and policies that eliminate and/or minimize exposure to personnel/staff injury
- Develops and integrates investigational standard documentation practices upon incident identification
- Develops and maintains steadfast compliance in response to potential product complaints per FDA/regulatory standards

Strategy

- Leads the specification, identification, recruitment, training, and daily production leadership of a comprehensive technical team of manufacturing supervisors, technicians, operators, and specialists that will commission and maintain oral solid drug product commercial operations.
- Cross functionally collaborates with Engineering, Quality, Regulatory, Development, and Marketing to commissioning (PAI), licensing, and staffing.
- Develops comprehensive production expansion strategies to further business objectives, generate competitive advantage, support long-range goals, and optimize capital deployment
- Collaborates with production planning to align production with market demand

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- Develops an adaptable organization that readily accommodates current technologies yielding the highest quality and compliance standards when producing commercial finished goods
- Defines, establishes, and drives high standards of training, teamwork, morale, and work performance
- Coordinates with senior management to develop delivery budgets (e.g. contract services, materials, training, capital expenditures) and track/report on this budget throughout the year
- Maintains sound effective relationships with executive, regulatory (agency), and site leaders

4. Typical Supervisory Responsibility:

Oversee all plant and operational processes.

5. Education/Technical Competencies/ Certifications/ Licenses:

Technical competencies	<ul style="list-style-type: none"> • A minimum of 20+ years of supervisory and/or manufacturing management experience in biopharmaceutical operations with 10+ years in oral solid dose processing manufacturing and 10+ years in technical leadership roles in an biopharmaceutical industry environment. • Industry experience as a technical professional supporting the development, launch, and/or production of commercial products • Direct experience with regulatory requirements for drug product and drug product manufacturing including NDA/ANDA submissions, correspondence, process validation, post approval inspections, and technology transfer. • In-depth knowledge of cGMP and process requirements in early, late- stage, and commercial manufacturing • Successful track record of collaborating with Quality, Development, and supplier/contract organizations • Strong proven leadership and management skills with a
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	<p style="text-align: center;">commitment to operational excellence</p> <ul style="list-style-type: none"> • Excellent verbal and written communication skills, detail-orientation, and ability to work productively • Experience in developing supply chain strategy and meeting company, performance objectives, and regulatory expectations • Established interpersonal skills complemented with strong cross functional manufacturing competencies • Ability to motivate teams and bring together diverse organizations in achieving common goals • Ability to effectively collaborate and be decisive with highly developed ability to listen, acknowledge, and expand on other inputs and priorities • Excellent oral and written communications with the ability to balance all business considerations • High energy leadership skills that get results in partnership with team members • Ability to be creative and innovative in addressing areas and challenges impacting the business • Displays original thinking and creativity; meets challenges with resourcefulness; generates suggestions for improving work: develops innovative approaches and ideas; presents ideas and information in a manner that gets others attention • Takes independent actions and calculated risks; looks for and takes advantage of opportunities; consults with subject matter industry experts when appropriate. • Quality oriented with strong attention to detail and driven by exceeding standards
Education/Certifications/Licenses/Other	<ul style="list-style-type: none"> • BS in Engineering or Science related discipline. Additional degree or applicable certifications desirable (e.g. Project Management, Six Sigma)

6. Physical Demand and Work Environment:

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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: