



TITLE: SR. DIRECTOR, PRODUCT DEVELOPMENT (FORMULATION)	LOCATION: EXTON, PA
TO APPLY: SEND RESUME TO: GVERDI-FRANCESCO@FRONTAGELAB.COM & REFERENCE JOB TITLE IN SUBJECT LINE	
VISIT US AT: WWW.FRONTAGELAB.COM FOR A LIST OF ALL JOB OPENINGS	
EEO	

DUTIES:

The ideal candidate will have a minimum of eight (8) years experience in the pharmaceutical industry, excellent understanding of cGMP and GLP regulations and relevant FDA guidelines, and strong written, verbal, and managerial skills.

QUALIFICATIONS:

- PhD in Pharmaceutical Sciences or related discipline with eight (8) or more years or MS with ten (10) or more years or BS with fifteen (15) or more years of relevant experience in pharmaceutical/biotech industry
- 3-5 years of managerial experience
- Solid experience and records for product development in oral solids, liquid formulation, and/or sterile products
- Strong knowledge in GLP/GMP regulatory requirements for pharmaceutical product development
- Excellent communication skills
- CRO experience a plus

RESPONSIBILITIES:

- Direct the overall planning, execution, and quality of assigned product development projects in oral solids, liquid formulation, and/or sterile products, process development and the manufacturing of clinical trial materials
- Responsible for the department Profit and Loss for Product Development operations
- Assist Business Development and Project Management in quote generation, follow up, and approval process
- Estimate resource requirements and project priorities and assign project responsibilities to ensure agreed timelines
- Prepare, review, and approve protocols, product development reports, SOP's, SOP deviations, and change control documentation when applicable
- Provide technical guidance to lab staff and train staff on new equipment and technologies
- Manage and train staff in providing services that comply with cGMP regulations and internal SOPs
- Manage a group of scientists including department daily operations, task assignment, material handling, and instrument qualification
- Support client regulatory submission, such as IND, NDA, or ANDA filings
- Coordinate communications and interact with project management, QA, and clients to solve any project issues
- Minimum travel to visit clients