

Director, Regulatory Affairs Cover Letter

6605 Kris GlensLeanport, LA 33494

Dear Lennon Bosco,

I submit this application to express my sincere interest in the director, regulatory affairs position.

In my previous role, I was responsible for regulatory and scientific expertise to develop regulatory CMC strategies for biologics product development and commercialization.

Please consider my experience and qualifications for this position:

- Develop and implement strategy for early and late stage products to achieve regulatory approvals
- Collaborate closely with multiple departments in the company and also manage and provide guidance to staff as needed to support regulatory activities
- Relevant regulatory requirements
- Skilled within primary functions of legislative development, research, manufacturing and quality assurance
- Knowledge of systems for electronic storage and submission
- Knowledge of pharmaceutical generic industry regulatory affairs discipline throughout the product lifecycle, including Development, Promotion and Advertising, Labeling, CMC, Commercialization, and Operations
- Knowledge of domestic laws, regulations, and guidance that affect generic prescription products
- Pharmaceutical generic experience (ANDA) in establishing regulatory strategy highly preferred

Thank you for taking your time to review my application.

Sincerely,

Indigo Blanda