

Director, Regulatory Affairs Cover Letter

2542 Willian UnionPort Gregoriofurt, CO 07039

Dear Lennon Parisian,

In response to your job posting for director, regulatory affairs, I am including this letter and my resume for your review.

In the previous role, I was responsible for regulatory guidance to the CMC department (e.g., stability protocols, specifications, report reviews, C of A's, product labels, and CMC development plans).

Please consider my experience and qualifications for this position:

- Assist Development teams and Regulatory Senior Management in developing Regulatory strategies that are EU appropriate and take advantage of EU regulatory systems and processes, in particular the application of innovative regulatory pathways, to expedite development
- Lead interactions with EU regulatory agencies at both national and central level, and assist internal teams in navigating such interactions
- Proven track record of supporting EU regulatory applications
- Utilize knowledge and past experience to review submissions to Regional HA to ensure regulatory compliance
- Basic knowledge of local Health Authority (HA) regulations (FDA or EMA) to support filings
- Basic understanding of drug development (PK, PD, statistical concepts, data collection, endpoints)
- Knowledge of company policies and procedures in drug development and product maintenance requirements
- Demonstrated problem solving skills as applied to local regulatory issues

Thank you for taking your time to review my application.

Sincerely,

Drew O'Reilly