

Director, Regulatory Affairs Cover Letter

708 Pacocha Square North Georgetown, MD 23330-6476

Dear Riley Pfannerstill,

I would like to submit my application for the director, regulatory affairs opening. Please accept this letter and the attached resume.

In the previous role, I was responsible for specific regulatory environment intelligence, anticipate regulatory hurdles and strategic guidance to both Commercial Operations and Global Regulatory Affairs.

I reviewed the requirements of the job opening and I believe my candidacy is an excellent fit for this position. Some of the key requirements that I have extensive experience with include:

- Demonstrated record of successful product commercialization using creativity in devising regulatory submission strategies
- Solid understanding of regulatory requirements interfacing with the FDA and working within an IVD company
- Understanding of CLIA regulations, laboratory practices/requirements
- RAC certification
- Experience developing and implementing successful global regulatory strategies
- Experience working with Health Authority
- Negotiate and obtain agreements on behalf of the company at meetings with regulatory agency officials at director levels or above
- Interact with and advise U.S. Product Supply Quality Assurance senior management in all matters concerning the FDA's oversight of the local manufacturing facilities

Thank you in advance for taking the time to read my cover letter and to review my resume.

Sincerely,