

# Regulatory Affairs Cover Letter

982 Jess Roads Lake Foster, NJ 00429-7288

**Dear Marion Yundt,**

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

In my previous role, I was responsible for guidance to business unit on global compliance, such as CE Marking and product registrations, clinical evaluations in accordance with MDD Annex X, EU MDR (moving forward), ISO 13485, Canadian CMDCAS, US FDA's and China CFDA's guidance documents & etc.

Please consider my experience and qualifications for this position:

- Advise the Director of Quality Assurance FDA officials and investigators concerning company NADA (new animal drug application) records and procedures
- Review written responses to FDA inspection findings and provide the Director of Quality Assurance with recommendations that ensure FDA acceptance of company responses
- Work with the Manager of Administration in R&D in the development of regulatory affairs budgets and project schedules
- Approve department expenditures and ensure all administrative commitments are met
- Provide the department staff with coaching, training and career development opportunities to maximize the potential of each individual, build teamwork and problem solving skills and stimulate innovation in the workplace
- Ph.D., D.V.M., or M.S
- Should have a thorough knowledge of the pharmaceutical industry and regulated government regulations with extensive experience in dealing with consultants and clinical investigators
- Displayed experiences and career achievements to be assessed as capable in the competencies of Building Effective Teams, Driving Vision and Purpose, Attracting and Developing Talent, , Collaboration

Sincerely,

Drew Wuckert