

Regulatory Affairs Coordinator Cover Letter

54080 Brigette Forks East Hildegardview, IN 53785-0549

Dear Story McClure,

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

In my previous role, I was responsible for regulatory support for ongoing and planned clinical trials including the review of essential regulatory document, protocols, SAP etc.

Please consider my experience and qualifications for this position:

- Fluent English, additional language skills will be an asset
- Passion about Regulatory Affairs for state-of-the-art implantable medical devices and energy for the dynamic area of European medical device regulations
- Be eager to build internal and external relationships to optimize business results
- In-depth knowledge of the clinical research regulatory environment including experience with the FDA's Good Clinical Practice (GCP) guidelines, Office for Human Research Protections (OHRP) guidelines, and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines
- Certification as a research professional preferred (ACRP, SOCRA)
- Experience with document/data management systems
- Experience in healthcare (e.g., medical device, biotech, or pharma)
- Comprehensive knowledge and operational expertise of the EU regulations

Thank you for taking your time to review my application.

Sincerely,

River Durgan