



Chelsea Miller

MA, BA

PROFESSIONAL SUMMARY

A regulatory affairs professional with over more than five years of experience, including the preparation, submission, and negotiation of product submissions with the FDA, EPA, and Health Canada

PROFESSIONAL EXPERIENCE

Feb 2021 – Present

The Bracken Group

Senior Regulatory Consultant

- Perform, coordinate, compile, submit, and maintain submissions, including INDs and NDAs for the FDA and other global health authorities
- Prepare and submit Orphan Drug Designation Application and Annual Reports
- Serve as US Agent and/or FDA Point of Contact for sponsors
- Prepare and review FDA written correspondence and IND/NDA components
- Prepare and file FDA Meeting Requests and Briefing Packages, prepare clients for FDA Meetings
- Support clients by integrating into their regulatory affairs departments to provide day to day regulatory input and support
- Register studies with and provide necessary Clinical updates to ClinicalTrials.gov

Jul 2019 – Jan 2021

Tender Corporation

Regulatory Manager

- Managed and ensured product compliance for OTCs, Class I/Class II medical devices, and pesticides.
- Reviewed and approved product labeling, marketing copy, and advertisements to ensure regulatory compliance.
- Prepared, submitted, and negotiated product submissions with the EPA, FDA, and Health Canada.
- Maintained and renewed company registrations and licenses.

Sept 2015 – Jul 2019

Tender Corporation

Regulatory Manager

- Ensured compliance with EPA, FDA, State, DOT, PMRA, and Health Canada regulations related to OTC drugs, medical devices, and pesticides
- Audited and implemented new and changing regulations as they apply to company products.

CONTACT

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[LinkedIn Profile](#)

www.thebrackengroup.com

EDUCATION

Bachelor of Arts 2012
University of New Hampshire

Master of Arts 2014
University of New Hampshire

RECENT ACCOMPLISHMENTS

Successful filing of 2 Orphan Drug Designation Applications

IND filings with the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) and the Division of Psychiatry