Chelsea Miller, MA, BA

CONTACT

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EDUCATION

- **Bachelor of Arts;** 2012
  University of New Hampshire
- **Master of Arts; 2014**
  University of New Hampshire

PROFESSIONAL SUMMARY

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

PROFESSIONAL EXPERIENCE

Jan 2021– Present — **The Bracken Group**
Regulatory Consultant

- Coordinate, compile, submit, and maintain submissions, including ODDs, INDs, and NDAs for the FDA and other global health authorities
- Prepare and submit Orphan Drug Application and Annual Reports
- Serve as US Agent and 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; and prepare clients for FDA Meetings
- Integrate into sponsor regulatory affairs departments to provide day to day regulatory 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 Specialist

- 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