

## KAREN ZHOU, J.D.

### EXPERIENCE

- **Assistant Teaching Professor /Regulatory Advisor/Regional Faculty Lead**, Northeastern University College of Professional Studies, since 2021
  - Serve as a subject matter expert on global regulatory affairs and compliance
  - Serve as the regional faculty lead for the graduate degree program in pharmaceutical and medical device regulatory affairs
- **Senior Regulatory Affairs Professional**, Fresenius Kabi 2021 – 2022
  - Regulatory Lead for the entire device portfolio in infusion and transfusion technologies
  - Regulatory Project Management
  - Revamped domestic procedures in alignment with domestic and global requirements
  - Reviewed and provided guidance on QMS procedures per ISO 13485 and MDSAP guidelines
- **Compliance Officer**, Health Canada 2015
  - Advised the pharmaceutical industry on compliance with establishment licensing requirements per Health Canada guidelines

### CREDENTIALS

- ISO 13485:2016 Internal Auditor Certification (BSI)
- Regulatory Affairs Certification (Devices RAC)
- Regulatory Affairs Certification (Global RAC)
- Regulatory Affairs Professionals Society (RAPS) Ontario, Co-Founder and Program Manager (2020-Present)
- Canadian Association for Professionals in Regulatory Affairs (CAPRA), Member
- **Juris Doctor (JD)**, University of Maryland School of Law
- **M.Sc. in Molecular Biology and Genetics**, University of Toronto
- Honours **B.Sc.** with Distinction in **Biochemistry**, University of Toronto – Trinity College