SOFTWARECPR®

CRISIS PREVENTION AND RECOVERY, LLC

GINNY KWAN GATTINGER

CREDENTIALS

- IEC 62304 and Emerging Standards Impacting Medical Device and Digital Health Software
  Training Course, SoftwareCPR, 2020
- Regulatory Requirements for Software Validation
  Training Course, AAMI, 2019
- Regulatory Affairs Certificate
- Multilingual: English, French, Chinese
- MS, Regulatory Science
  John Hopkins University
  Baltimore, MD USA
- BSc, Biochemistry
  Concordia University
  Montreal, Canada

EXPERIENCE

- Over 10 years in regulated industry including medical devices, pharmaceuticals and biotechnology. RA Specialist, Senior RA Specialist, and RA Manager.
- Expert with regulatory strategies for SiMD and SaMD, AI/ML-based technologies
- Practical knowledge of ISO 13485, IEC 62304, IEC 82304, ISO 14971 and IEC 62366
- Experienced with 510(k), PMA, Q-subs submissions and global submissions
- Expertise in design controls and DHF documentation
- Track record of building regulatory processes and SOPs including product change assessments
- Experience with new product developments and sustaining projects
- Ability to understand and capture product concepts into regulatory submissions
- Trained and coached cross-functional team members, served as software regulations subject matter expert to regulatory teams
- Experience with FDA inspections, notified body audits and technical file audits, remediation activities
- Experience in both start-up environments and global enterprises
- Experience with Agile / Lean methodologies