



CRISIS PREVENTION AND RECOVERY, LLC

DR. PETER RECH

EXPERIENCE

- Systems and safety engineering professional with 20+ years in regulated industries in individual contributor and management roles
- Class II and III medical devices including implantable pacemakers, infusion pumps, and remote monitoring devices and apps
- Pre-market development, post-market maintenance, and FDA deficiency response for risk management files per ISO 14971
- Cohesive system risk analysis with in depth understanding of reliability, human factors, software, and cybersecurity risk analysis
- Safety assurance case development per AAMI TIR38:2019
- Product safety certification per IEC 60601 series standards using equivalent safety
- Functional safety for programmable electronic systems
- Model Based Systems Engineering (MBSE) and integrated risk analysis
- FDA compliant design control and risk management process development
- In depth technical trouble shooting
- Co-chair AAMI infusion device working group
- Convenor IEC infusion device working group

CREDENTIALS

- INCOSE Certified Systems Engineering Professional (CSEP) #972 (exp.)
- TUV Rheinland Certified Functional Safety Engineer Hardware and Software #2060/09 (exp.)
- DFSS Green Belt
- Advanced Cardiac Physiology and Anatomy, UoMinnesota Medical School
- Doctor of Philosophy (PhD), Physical Chemistry, Free University Berlin
- Physics and Electrical Engineering, 5 year degree in Physics, University of Saarland
- Medtronic CVG Star of Excellence
- Medtronic Quality at the Roots
- Multilingual: English, German, French