

### EXPERIENCE

- 18+ years of software validation experience including 13+ for Medical Devices, IVDs, Laboratory Information Management Systems (LIMS), Clinical Trials Data Systems and QC laboratory instruments
- Compliance and quality audits of Medical Device software development, including EN 62304 conformance, and of computer systems and applications used for regulated quality systems activities including compliance with 21 CFR Part 11
- Performed FDA Consent Decree mandated independent Computer System Validation Assessments
- Software Compliance to FDA regulations for Medical Devices, LIMS and other products; performed gap analyses and developed plans for compliance
- Validation Planning and oversight for production and quality system software including Off-the-Shelf Software
- Developed SOPs for Software Development Life Cycles and Validation
- Preparation of FDA premarket510(k) software information sections
- Test Planning and Test Management – including data migration, client/server systems, automated testing
- Test Protocol Development and Execution—18+ years hands-on experience in both manual and automated testing
- Requirements Development – defined requirements working with both customers and development teams and for small medical device startups
- Software Risk Analysis for medical devices following IEC TIR80002-1

### CREDENTIALS

- Trainer for the public AAMI/FDA Software Validation Course
- Lead Software Quality Assurance Engineer for several Medical Device and Clinical Data Management Companies
- Member American Society for Quality
- Bachelor of Science degree, Virginia Polytechnic Institute and State University

#### Formal on-going education including:

- Safety Assurance Cases for Medical Devices – AAMI
- Efficient Use of Medical Devices Software Standards for Safety and Regulatory Compliance – SoftwareCPR<sup>®</sup>
- Software Validation Requirements and Industry Practice – AAMI
- Quality System Requirements and Industry Practice – AAMI
- Certified Quality Auditor class - ASQ
- Rational Robot training - Winmill Software.
- Oracle Clinical Training – Oracle Educational Services
- Seminar on Computer and Software Validation: Beyond the Obvious: Advanced Solutions for the Pharmaceutical Industry
- Seminar on Hazard Analysis - FMEA and FTA, Noblitt and Rueland.
- CASE Methodology and Tools (Software through Pictures), Interactive Development Environments.