Frank Clay, CSQE

Medical device software quality, risk & cybersecurity, design controls & regulatory

Principal Consultant, Software Quality Guru LLC · Chester, Virginia · Remote-first
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SUMMARY

Medical device software quality and compliance consultant working across regulated product development, quality systems and post-market. Specializes in IEC 62304 and IEC 82304-1 lifecycle governance, ISO 14971:2019 risk management, and IEC 62366-1 / HE-75 human factors and usability engineering.

Cybersecurity subject-matter expert for FDA submissions and audits: SBOM governance, threat modeling (TARA, STRIDE), security risk analysis, and security controls traced through requirements, verification and the risk file.

Experienced in design assurance, CAPA leadership and GAMP 5 validation for GxP quality systems.

CORE COMPETENCIES

- IEC 62304 software lifecycle: plans, traceability, verification, SOUP, maintenance
- IEC 82304-1 health software product safety and security
- ISO 14971:2019 risk management: RMF, dFMEA/uFMEA/pFMEA alignment, benefit-risk, post-market feedback
- Medical device cybersecurity: SBOM, TARA/STRIDE threat modeling, security risk controls, vulnerability management
- Human factors: IEC 62366-1, HE-75, formative and summative planning, usability engineering file
- GAMP 5 computer system validation: MasterControl and PLM tool validation, change control
- CAPA and NCMR investigations, root cause analysis, audit readiness, supplier and software quality
- 2nd- and 3rd-party auditing to ISO 13485, ISO 9001 and AS9100D
- Tools: Python, Git, Jira, Confluence, Minitab, Excel

EXPERIENCE

Software Quality Guru LLC · **Chester, VA (remote)**

Principal Consultant / Lead Auditor

- Plan and lead 2nd- and 3rd-party audits; classify findings and manage them through closure.
- Perform GAMP 5 validation of quality management platforms (e.g., MasterControl deployments) that govern regulated QMS processes.
- Remediate Design History Files and Risk Management Files to current expectations, including ISO 14971:2019 alignment and post-market linkage.
- Design risk assessment and governance for non-product software; statistical complaint trending for management review.

Cybersecurity and software quality SME, AI-enabled medical device startup

- Authored the SBOM template and governance approach to meet FDA cybersecurity expectations and supplier transparency.
- Ran the cybersecurity risk analysis and threat modeling (TARA, STRIDE) and produced an assessed security risk package with traceable mitigations.
- Drafted and coordinated the cybersecurity content of the response to an FDA request for additional information on a new device submission.
- Integrated security risk controls into system requirements, verification evidence and risk management records for end-to-end traceability.

Curonix · **neuromodulation devices**

Principal Software Quality Engineer

- Owned software and firmware quality across release planning, design controls, V&V and post-release surveillance, including review and approval of protocols and reports.
- Managed risk activities under ISO 14971:2019, including hazard analysis updates, FMEA alignment and traceability from risk controls to verification evidence.

- Supported EU MDR readiness and software compliance documentation, including IEC 62304 test report forms and DHF evidence organization.
- Led investigations of software and firmware anomalies, complaints and NCMRs, driving CAPA containment, correction and effectiveness checks.
- Drafted submission content for software, firmware and cybersecurity (SBOM, security risk) and maintained TIR57-aligned QMS procedures.

Philips · Colorado Springs, CO and Cleveland, OH

Principal Design Assurance Engineer · Software Design Assurance Engineer · CAPA Program Manager · SME CAPA Consultant / Investigator

- Led design assurance for Class II products: design controls, DHF governance and cross-functional risk management.
- Site lead for human factors and usability engineering under IEC 62366-1 and HE-75, including formative and summative planning and usability file review.
- Developed, reviewed and approved ISO 14971:2019 risk management files using dFMEA, pFMEA, uFMEA and FTA.
- Represented the organization in AAMI, IEC and ISO standards work in software, statistics and human factors; supported audits and regulatory interactions.
- Managed CAPA in TrackWise and closed legacy CAPAs through DMAIC investigations; built a cause-mapping tool adopted across multiple business units.

Jabil · St. Petersburg, FL

Global Quality Engineer

- Owned the customer satisfaction process; supported NPI and verification and validation of complex electro-mechanical devices.
- Quality consultant for DO-254-aligned processes in aerospace program development.

Baxter · Thousand Oaks, CA and McGaw Park, IL

Senior Principal Software Quality Engineer

- Software quality engineering for a recombinant Factor VIII (rFVIII) hemophilia A therapy, then for a renal therapy (nephrology) system.

Boston Scientific · Minneapolis, MN and corporate headquarters

Senior Software Quality Engineer

- Started in product software quality in Minneapolis before moving to corporate headquarters.
- Led GAMP-based validation of non-product software, from off-the-shelf tools to custom-built systems; supported EtO sterilization work.

Independent consulting · multiple clients

Quality / Validation Consultant

- Verification, validation and quality assurance with an emphasis on software and design controls.
- CAPA leadership and process design for medical device and pharmaceutical development clients.

STANDARDS WORK

- IEC 62304:2006/AMD1:2015: development team
- ANSI/AAMI SW91:2018: development team
- AAMI/ISO/IEC 82304-1:2016: SME reviewer
- AAMI/IEC TIR80002-3:2016 (IEC 62304 process reference model): SME reviewer
- ANSI Associate; IEC subject-matter expert

CERTIFICATIONS

- ASQ Certified Software Quality Engineer (CSQE)
- Certified Lead Auditor: ISO 13485, ISO 9001, AS9100D
- Lean Six Sigma Black Belt
- Certified ScrumMaster
- Kepner-Tregoe Problem Solving & Decision Making

LEADERSHIP

- Past Vice Chair, Technology, ASQ Software Division
- Past Chair, IEEE Computer Society Chicago Chapter
- Member: ASQ, IEEE, INCOSE (work group participant)

EDUCATION

- M.S., IT (Information Security), Capella University
- B.S., Software Systems Engineering, Colorado Technical University