Michael Phenner
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SUMMARY

Senior Quality Engineer with management and hands-on experience in electronic medical device development and validation in secured laboratories. Motivated team player with excellent organization, communication, & technical problem solving skills. Proved track record of consistently handling multiple tasks to high levels of competence and integrity, while also meeting critical deadlines in minimally supervised environments. My areas of expertise include:

- Quality Systems Management of: Supply Chain, Inspection, NCR, CAPA, Training, Doc. Control, Calibration
- Medical device test development, risk assessment, verification, validation, and reliability tests (R&D & MFG)
- Author DCNs, ECOs, FMEAs, IQ/OQ/PQ, test procedures, test cases per GMP, FDA QSR and ISO 9001/13485
- Medical device assessment & testing per ISO 14971, ISO 13485, FDA QSR, IEC 60601-1, EN 61326, IEC 62304
- Qualify electronic laboratory test equipment & SW per ISO 17025, ISO 14971 and FDA QSR (21CFR:820)
- Troubleshoot and repair complex electronic SMD/Through-hole circuitry and systems to the component level

EQUIPMENT: O-Scopes, Logic/Spectrum Analyzers, Emulators, DMMs, Vibrometers, Height Gage, Verniers
OS/SW/APPS: MiniTab (for statistics), Win(all), C, Unix, LabVIEW, Oracle, PTC Integrity, JAVA, MS Office(all)

PROFESSIONAL EXPERIENCE

Sr. Quality Engineer (4/11 – Present) at: **ProTom International Holding Corp. -** Wakefield, MA

►Leading developer & manufacturer of accelerated proton beam cancer therapy systems for hospitals

- Author: SOPs, WIs, Assembly & Test Procedures, Verification & Validations (IOPQ) and service manuals
- Perform risk analysis/magement for all phases of product life cycle (concept, design, process, post-market).
- Audit suppliers and their quality system/purchasing processes using FDA QSR and ISO 13485 requirements
- Manage: NCR, CAPA, Calibration, Document Control (Oracle Arena/PTC Integrity), Supply Chain, Int. Audits
- Generates graphs & charts to trend/evaluate effectiveness of the quality system for management reviews.

Sr. Quality Engineer (11/09 – 3/11) at: Covaris, Inc. - Woburn, MA

►Developer of ultrasonic instruments for molecular-level CSI sample prep. & DNA splicers

- Create, maintain, and execute PCB and system level testing of new and existing ultrasonic products
- Author engineering design change orders for medical device products and controlled documentation
- Develop PCA and system level calibration and setup procedures for engineering and manufacturing
- Carry out investigatory testing, inspections, and vendor qualifications as QA MRB committee member
- Risk assessment, troubleshooting, & root cause analysis on electronic systems, PCBs, & components

Quality Engineer (4/08-7/09) at: **ESA Biosciences** (now Magellan Biosciences), Chelmsford, MA

►Developer of blood-lead analyzers and High Precision Liquid Chromatography [HPLC] systems

- Assisted new product designs incl. risk assessment, design verification & validation testing (R&D & Mfg)
- Authored/ managed ECOs, calibration, training, complaints, CAPA systems, & database tracking S.W.
- Mitigated vendor defects through supplier corrective action processes as QA MRB committee member
- Maintained Quality System in accordance with ISO13485, ISO9001, ISO17025, FDA QSR (21CFR:820)
- Performed internal/external supplier audits to assess Quality System compliance & improvement areas

Sr. Quality Engineer/Manager (2/05 -11/07) at: OmniSonics Medical Technolgies,Wilmington, MA

►Developer of catheter-based ultrasonic technology to treat Peripheral Vascular Occlusive disease

- Created DFM test fixtures, procedures, & reports for electromechanical intravascular ultrasound devices
- Performed Class III medical device prototyping, EN60601-2 compliance testing, Life tests, & validations
- Performed design verification, validation, risk analysis, and EMC testing for QA, R&D and manufacturing
- Managed engineering lab personnel & authored/performed medical equipment qualifications (IQ/OQ/PQ)
- Reduced open issues by 75% as Manager of the Corrective And Preventative Action (CAPA) committee

Quality Engineer (10/04 - 7/05) at: RSA Security (Division of EMC), Bedford, MA

►Leading provider of cryptography systems and data security devices

- Wrote & Performed QA test cases for embedded SW security tokens on Windows & Linux platforms
- Performed hardware and software based security identity token testing, verifications, and validations
- Created & qualified testing fixtures and equipment for use in controlled test laboratory environments
- Pre-screened & agency lab tested security tokens for EMC, Safety, Shock, Drop, HALT/HASS testing

R&D Test Engineer/Lab Manager (3/98-10/04) at: **Abbott Diabetes Care** (MediSense) - Bedford, MA

►Developer and manufacturer of blood-glucose test meters and management systems

- Developed medical device testing fixtures, procedures and V&Vs for R&D, QA, & MFG per ISO 13485
- Pre-screened SW embedded medical device prototypes and DFMs for IEC 60601-1, FCC, FDA, and UL
- Hired and supervised senior electrical / mechanical R&D laboratory engineering Technicians, and aids
- Managed R&D E.E. & M.E. (Model shop) Labs & environmental chamber labs (& its test equipment).
- Maintained > 350 pieces of calibrated laboratory measurement equipment per ISO 17025 & FDA QSR

Electromagnetic Compatibility Systems Test Engineer (12/95-3/98) at: **Parker Chomerics -** Woburn, MA

►Provider of military and medical device harmonized EMC and safety agency certified testing services

- Led U.S./ European EMC testing on electronic devices/ systems per FDA, EN60601, EN50081/82 QSRs
- Calibrated/qualified laboratory test equipment, test fixtures via federal agency test protocol interpretation
- Interfaced with customers & equipment in EMC and environmentally controlled laboratory test chambers
- Held "**SECRET**" Dept. of Defense security clearance for testing military devices and their control systems

Sr. R&D Technician (3/94 - 12/95) at: Zoll Medical Corporation - Chelmsford MA

►Developer and manufactures external and internal cardiac pacemaker and defibrillator systems

- Constructed and tested prototype circuitry and qualification of test equipment for defibrillator designs
- Documented test results using MS WORD/EXCEL for engineering change & product design reviews
- Performed PCB and system-level bench testing on prototype and production defibrillator instruments
- Accompanied defibrillator prototypes & finished products for 60601 agency testing to 3rd party test sites

Sr. R&D Technician (6/90-3/94) at: CR Bard (now BaxterHealthcare)-Tewksbury/N Reading,MA

►International developer of hospital and home medical devices ...and other innovative biotechnologies

- Created test circuitry and fixtures for in fiber-optic catheter-based blood-gas monitoring devices
- Developed prototype circuitry and testing fixtures used for hospital room IV drug infusion pumps
- Interfaced with test equipment (via RS232, IEEE488) and other PC based data acquisition boards
- Pre-screen tested and accompanied prototypes/final products at EMC (CE Mark) testing facilities

EDUCATION AND TRAINING

►**Bachelor of Science in Computer Science:** Franklin Pierce College, Rindge/Portsmouth, NH [GPA: 3.5]
►**Diploma Sylvania Technical School** (now Wentworth Tech) : Computer Electronics - [GPA: 3.5]
►**A.A.M.I. Certificate: Quality System Requirements and Industry Practice**" training certificate
►**American Society for Quality (ASQ) Member:** Full membership since 2004
►**National Instruments (LabWindows [CVI]) certificate:** Virtual Instrumentation training
►**National Instruments (LabView & CVI) Certificate:** Virtual Instrumentation application training
►**Kimmel-Gerke Associate Certificate:** ESD/EMI training seminar for design engineering

EXTERNAL LINKS

--- View my profile on LinkedIn ► http://www.linkedin.com/in/mphenner

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