Global Director of Design Quality

AREAS OF EXPERTISE

- **Proven Device Software and Design Controls Remediation expert**
- **Device Software & Product Safety Risk Analysis expert**
- **Substantive Medical Device Quality & Design Management experience**
- **Substantive Successful Product Remediation Leadership experience**
- **Third Party Consent Decree assessment, Warning Letter & QSR audit expertise**
- **Compliant Quality System implementation expertise**
- **Senior Design Management backfill while client site was under extreme FDA scrutiny**
- **Substantial Device Software V&V and Product Test expertise**
- **Process Validation Remediation expertise**
- **Process Software and Quality System Software Validation expertise**
- **Expert Quality Record reviewer**

INTRODUCTION

As an experienced medical device industry consultant, Consultant has more than 30 years of industry experience in Medical Device Design, Quality and Regulatory up through Executive Director of Engineering and Global Director of Design Quality at multi-billion dollar companies with prior experience in the nuclear power industry and as a Naval Officer. In addition, this consultant holds a Regulatory Affairs Certification (RAC).

EXPERIENCE

2008 – Present
Principal Consultant
Duties:

- Provided expert FDA and MDD device compliance advice and remediation leadership for US and EU clients especially in the areas of device design controls, risk management, device software and process validation.
- Complex leadership roles such as the device software and design controls remediation SME for consent decrees as well as warning letters, thirteen month role as acting executive director of heart lung engineering to correct existent device product issues under extreme FDA scrutiny, third party consent decree and warning letter quality system assessments for design controls and software, design history reconstruction to current US requirements, design corrective action effectiveness assessments, device safety risk assessments for complex devices including software and systemic risks (e.g. medication delivery systems, auto-injectors, defibrillators, CT, interventional X-ray equipment, heart-lung equipment, proton therapy equipment, endo-surgery equipment, nebulizers, cell phone and information technology based software medical devices).
- Software and device safety standards guidance, 510K submission advice, creation of technical documentation for software 510K submissions, device software validation, process software validation, CAPA root cause analysis, plus Nonconforming record, Device History Record, Device Master Record and Design History File review for remediation.

1988 – 2008
Medical Device Technical and Quality Management
Duties:

- Managed design and quality assurance teams consisting of 20 to 75 personnel with direct responsibility for medical equipment design assurance, device software QA, system engineering, software technical standard compliance, regulatory compliance, reliability engineering and product V&V in medium to large companies up to the Global Director Level. Also, provided quality systems gap assessments and redesign leadership to drive changes regarding discipline based design practices such as design controls, V&V, software validation, design sourcing, product reliability, product safety risk management and software hazards analysis.
- Gained invaluable FDA inspection experience that includes several large comprehensive post remediation inspections of Design Controls and Process Controls by FDA experts. Also, attained FDA 483 free compliance within several major product design organizations that previous obtained multiple FDA Warning letters, and generally had a poor regulatory compliance track record.
- Provided technical and quality expertise for a wide range of products including: single use catheters, stents, endoscopy equipment, ablation devices, infusion pumps, automatic needle injectors, imaging workstations, nurse stations, medical beds, incubators, medical gas delivery, CT and ultrasound.
- Standing member of the Product Safety Committee at two medical device companies, and adjunct member at a third company. Active member of several medical device standards committees for software including IEC 62304, AAMI SW 68 and AAMI TIR32. In addition, hold membership with several professional societies such as the Reliability Society, AAMI and RAPS. In addition, attained the Regulatory Affairs Certification (RAC).

1982 – 1988
Civilian Nuclear Power
Duties:

- Responsible for design changes, technical support and preoperational testing of the neutron monitoring and rod control systems during the nuclear reactor startup programs at two nuclear plants for General Electric. This included design modifications to electronic, electromechanical and microprocessor based equipment, test procedure development and execution, NRC site inspections, answering NRC regulator questions, as well as the investigation of reported problems. Once my assigned systems completed operational qualification, tasked by the utility to manage the evening shift pre-operational test program.
- Gained valuable international experience through a multiyear residency in Switzerland. Promoted twice from engineer (L9) to senior engineer II (L11).

1977 – 1981
Naval Officer, US Navy
Duties:

- Commissioned Officer (O-1 to O-3) responsible to ensure the safe and effective operation of a Nuclear Powered Submarine, and watch officer of submarine operations. Managed technically diverse divisions including Electrical, Reactor Controls, Radiologic Controls and Machinery divisions, as well as department head roles as the Operations and Weapons officer over more junior officers.
- Consistently attained top 1% performance reviews as well as several personal commendations from superiors as a leader and naval officer who could be counted on to get the job done right in tough situations.

EDUCATION

University of North Carolina at Chapel Hill, December 1976
Bachelor Degree: Physics and Chemistry

Naval Officers Nuclear Power School
Completed graduate level curriculum in top 10% of the class

TRAINING & BACKGROUND

- AAMI committee member for IEC 62304:2006, Medical Device Software- software lifecycle processes
- AAMI committee member for AAMI TIR32:2004, Medical Device Software- risk management
- AAMI committee member for AAMI SW68:2001, Medical Device Software- software lifecycle processes
- Member of the Regulatory Affairs Professional Society with RAPS Certification (RAC)
- Member of the Association for the Advancement of Medical Instrumentation (AAMI)
- Basic German language and technical documentation reading skills gained through work in Switzerland.